Konelab Reference Manual

www.thermo.com/konelab

Thermo
ELECTRON CORPORATION

KONELAB REFERENCE MANUAL

Program version: 6.0

Manual version: E

Date: 5.4.2004

Code: 895250-4301

Information in this manual is subject to change without prior notice.

ISO 9001 QUALITY ASSURED FIRM

Thermo Electron Oy
Clinical Diagnostics
Clinical Chemistry &
Automation Systems

Ratastie 2, P.O.Box 100
FIN-01621 VANTAA
Tel: +358 9 329 100
Fax: +358 9 3291 0500
www.thermo.com/konelab

NOTICES, APPROVALS AND SYMBOLS

CE The CE mark attached on Konelab indicates the conformity with the IVD (in vitro diagnostic medical devices) directive 98/79/EC.

FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Symbols


Consult operating instructions

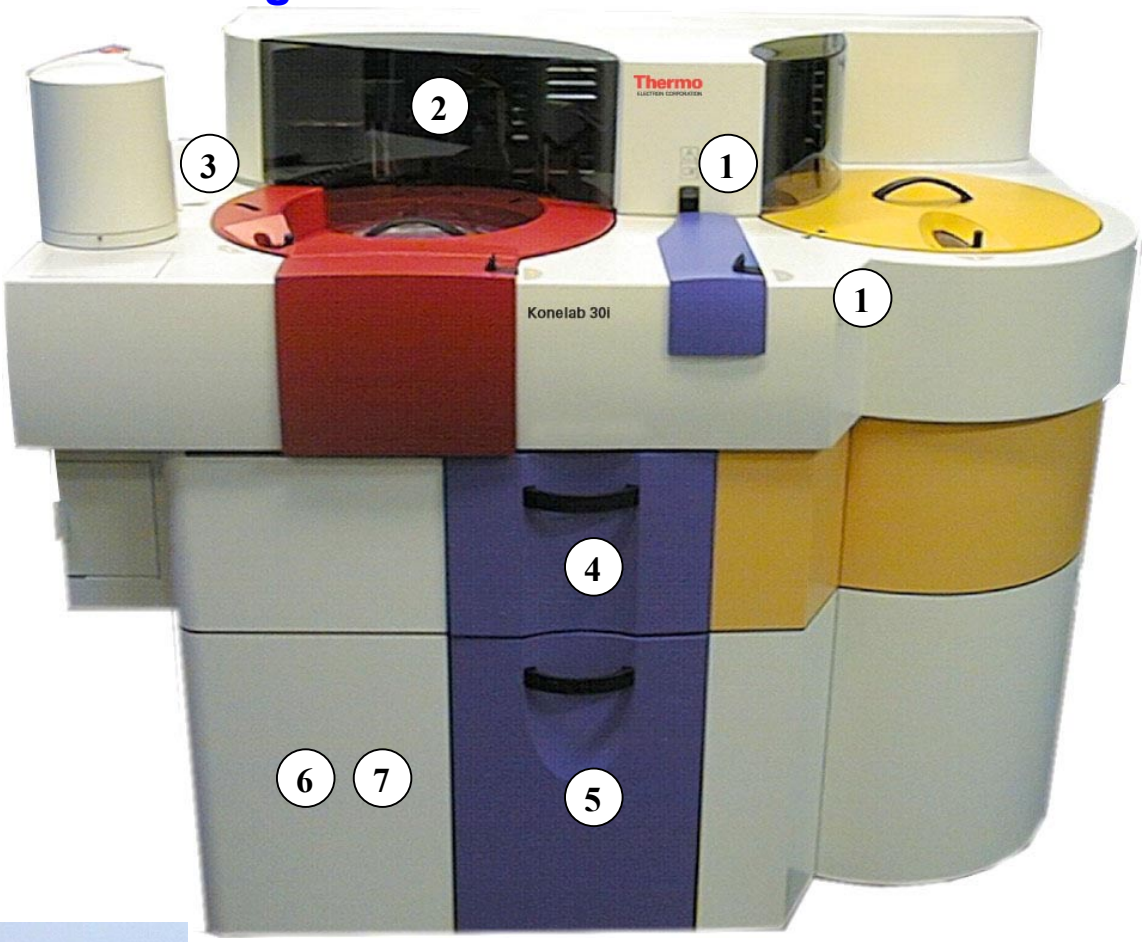
For in vitro diagnostic use

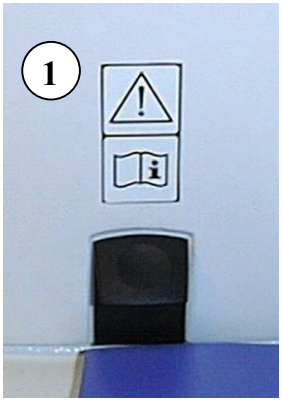

Biological risk


Manufacturer

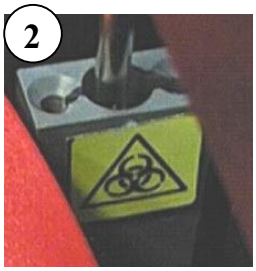
APPENDIX A: WARNINGS AND RECOMMENDATIONS

Warnings in the instrument

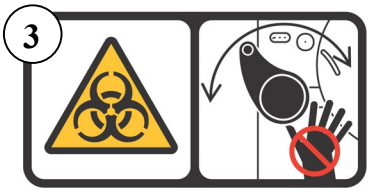




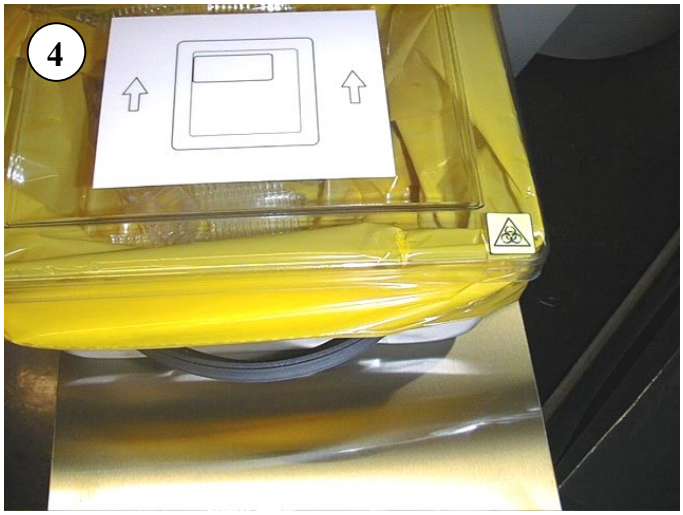
WARNING: Follow the instructions to ensure correct and safe operation. Do not open the cover when analysing is going on, because moving dispensers and mixer cause biohazard if hitting you by accident.



BIOHAZARD:
All dispensers, mixers and washing stations are potential sources of infectious agents. Do not put your hand inside the analyser when dispensers and mixers are moving. When cleaning them, be cautious and always use gloves.



BIOHAZARD: The Kusti dispenser is a potential source of infectious agents. Do not put your hand to the area where Kusti dispenser is moving.



BIOHAZARD: The cuvette waste box is a potential source of infectious agents. Be cautious and always use gloves and protective clothes when handling it.

Place the cover of cuvette waste box so that arrows show away from you.

BIOHAZARD: The wastewater canister is a potential source of infectious agents. Be cautious and always use gloves and protective clothes when handling it.

WARNING: The low current switch, found in Konelab 60 and KUSTI models, does not turn power totally off.

The low current switch has two settings.
1) The analyser has power on, when the low current switch is ON (I), and at the same time the main power switch, in the back of the analyser, is on. Refer to section 2.6.2.

2) When the low current switch is in the stand by setting , only the boards of analyser and the internal PC are powered off. To turn the power totally off, turn the main power switch, in the back of the analyser, off. If you cannot reach the main power switch, unplug the mains cable.
– If you take the mains cable off when the low current switch is on, the back-up batteries of the instrument are turned on.

You can boot the internal PC by turning the low current switch in the stand by setting and waiting at least one minute before turning it on.

WARNING: The lamp house can be hot.

Recommendations for the instrument

It is highly recommended that the workstation PC is equipped with UPS (= uninterrupted power supply) to avoid problems after power failure between PC's XP operating system and database management software.

APPENDIX B: BARCODE SPECIFICATION

Supported barcode types

Konelab analyzers are supporting only the following barcodes:

- Code 128
- Code 39 with check digit
- USS Codabar with check digit
- Interleaved 2 of 5 with check digit

Code 128 is recommended, all other barcode types should be replaced with Code 128 before December 31, 2003 according to NCCLS AUTO2-A.

The following barcodes, Code 39, USS Codabar or Interleaved 2 of 5 without check digits can be used, but correct reading cannot be guaranteed.

Thermo Electron Oy shall have no liability to any person whatsoever nature with respect to any claim, action, suit, loss, cost, damage or expenses arising out of, as a result of, or in connection with product if barcodes without check digits are used.

Placement Zone

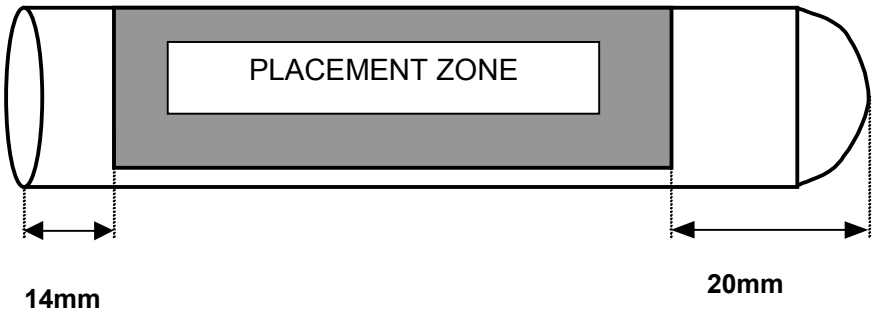


Figure 1. Placement zone

The center of the label should be placed in the center of the placement zone. The label should be applied below the top 14 mm of the tube and above the bottom 20 mm of the tube according to NCCLS AUTO2-A. The label width must be 5 mm less than circumference of the tube according to NCCLS AUTO2-A.

The label skew shall be ±5° according to ASTM E1466-92 and less than ±7% according to NCCLS AUTO2-A with respect to the axis of the sample container.

Read Zone

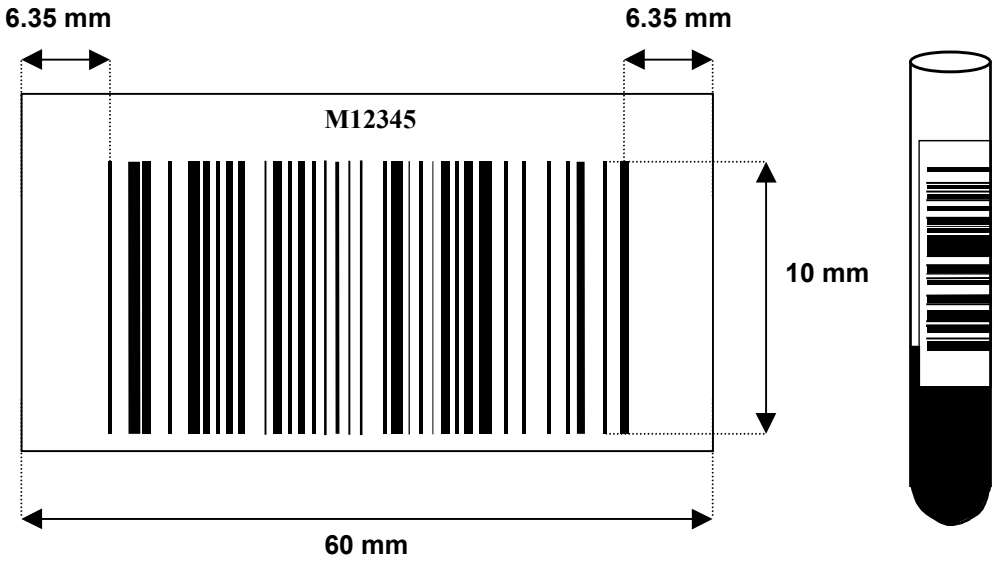


Figure 2. Read zone

The maximum length of the barcode is 60 mm and minimum width 10 mm according to ASTM E1466-92. The quiet zone must be at least ten times the minimum width of the narrow bar (10 x 0.191 mm or greater) according to NCCLS AUTO2-A. According to the manufacturer of the barcode reader, the quiet zone with the Konelab barcodes must be 6.35 mm (0.25 inch) in the barcode label on both sides of the barcode.

Other Requirements

- The minimum width of a narrow bar must be equal to or greater than 0.191 mm (NCCLS AUTO2-A).

- The thickness of the label and its associated adhesive shall be less than 0.090 mm (NCCLS AUTO2-A).

- No more than four labels, including the manufacturers label, should be affixed to a tube. The total thickness of all labels must be less than 0.36 mm. (NCCLS AUTO2-A)

- The bar code print quality shall be at least of quality C according to ANSI X3.182-1990.

- Label opacity must be sufficient to prevent the read of any barcode printed on an underlying label. The recommended label opacity is 90% or greater.(NCCLS AUTO2-A)

References

1. NCCLS AUTO2_P – Laboratory Automation: Bar Codes for Specimen Container Identification; Accepted Standard, NCCLS 1998

2. ASTM E1466-92 – Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory, American Society for Testing and Materials 1999

3. ANSI Standard X3.182-1990 – Bar Code Print Quality Guideline, American National Standards Institute 1990.

4. Scanteam 3600 Technical Manual, Welch Allyn, Rev. C, p.3-7.

CONTENTS

4. TESTS

5. PRINCIPLES OF THE OPERATION AND THE ANALYSIS

6. MAINTENANCE

7. INTERFERENCES OF SAMPLES

8. ERROR MESSAGES & TROUBLESHOOTING

9. INSTALLATION INSTRUCTIONS

10. WORKSTATION SOFTWARE

11. ACCESSORIES AND CONSUMABLES

12. TECHNICAL SPECIFICATIONS

Copyright

Trademark

Konelab is a registered trademark of Thermo Electron Oy.

No liability for consequential damages

Thermo Electron Oy shall not be liable for any damages whatsoever arising out of use or inability to use this product.

1. GENERAL

Konelab, the selective chemistry analyser for in vitro diagnostic purposes is an integrated system solution for convenient and automatic testing of routine clinical chemistry tests, electrolytes and special chemistries, such as specific proteins, therapeutic drug monitoring and drugs of abuse tests.

The Konelab family consists of four basic models and four models with the ISE unit:
- Konelab 60 and 60i with a workload dependent throughput up to 600 tests per hour in typical routine use.
- Konelab 30 and 30i with a workload dependent throughput up to 300 tests per hour in typical routine use.
- Konelab 20XT and 20XTi with a workload dependent throughput up to 250 tests per hour in typical routine use.
- Konelab 20 and 20i with a workload dependent throughput up to 200 tests per hour in typical routine use.

The ISE unit combines the direct measurement of Na^+, K^+ and Cl^- electrolytes with a sample volume as low as 50 µl. Li^+, Ca^{2+} and pH are offered as option for Konelab 60i and 30i, Li^+ for Konelab 20XTi and 20i.

Konelab 60 and 30 can be connected to the laboratory automation for direct sample dispensing from the conveyor to the analyzer.

The instrument workstation has fully graphical user-interface software. The software provides reliable control over the analysing process and gives easy access to advanced functions.

1.1 MAIN PARTS OF THE ANALYSER

Figure 1-1a: Konelab, the selective chemistry analyser for in vitro diagnostic purposes

A. Segment loader
B. Sample disk
C. Cuvette loader
D. Reagent disk
E. Cuvette waste compartment
F. Wastewater and distilled water containers
G. Optional interface for the automated sample transport line, so called KUSTI module

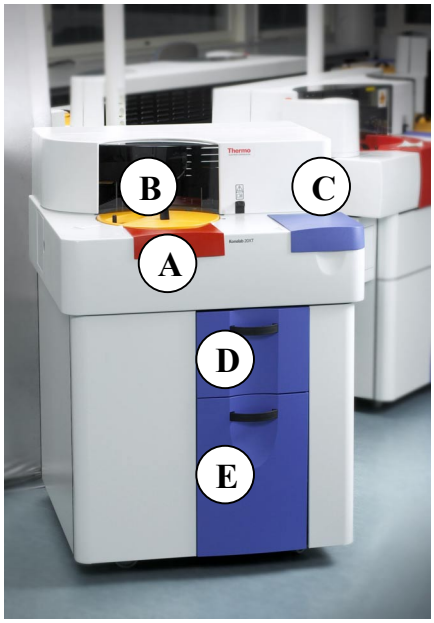


Figure 1-1b: Konelab 20XT, the selective chemistry analyser for in vitro diagnostic purposes

A. Segment/ STAT sample loader
B. Reagent disk
C. Cuvette loader
D. Cuvette waste compartment
E. Wastewater and distilled water containers

SAMPLES

Samples are inserted in a 14 positions sample segment. Continuous processing is made possible by the use of independent bar-coded sample segments, which the user can insert or remove during analysis to enable loading and unloading of samples. After loading the segment, samples are immediately identified by direct barcode reading and cup/tube recognition. Six segments can be in the sample disk at the same time. For the STAT samples there are dedicated positions between the segments, 5 positions in Konelab 20 and 20XT and 6 positions in Konelab 30 and 60.

Standard segment holds 5 and 7 ml primary tubes as well as 0.5 and 2 ml sample cups. A special segment for 10 ml tubes is available. The data can be given and results reported according to a patient or according to a sample. In addition the data can be entered during analysis.

Figure 1-2: A sample segment

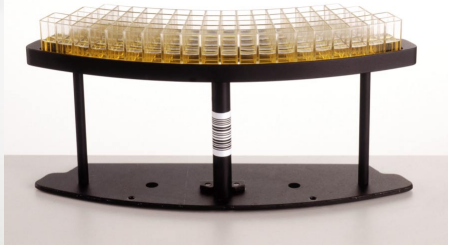


Figure 1-3: A KUSTI segment available to Konelab 30 and 60

Konelab 20XT and 20

Calibrators and controls are introduced as normal samples into a segment or into STAT positions. One STAT sample position is reserved for the ISE prime sample.

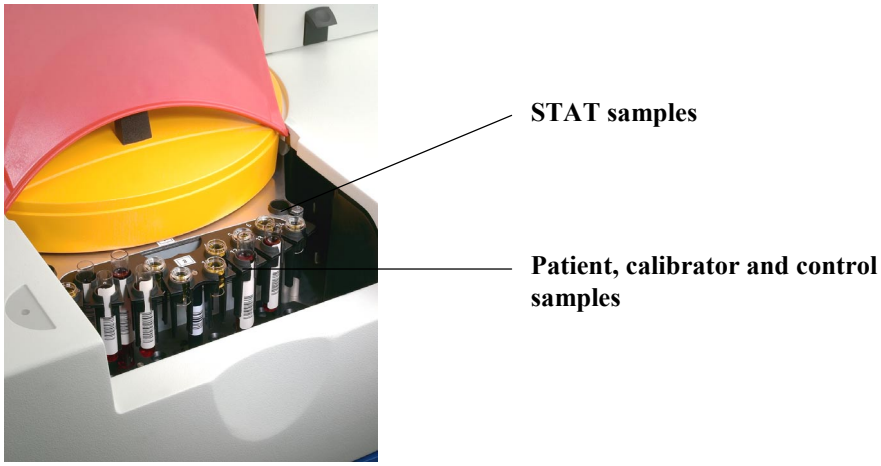


Figure 1-4a: The sample disk of Konelab 20 and 20XT

Konelab 30 and 60

Calibrator, control and ISE prime samples have 40 fixed cooled positions in the middle of the sample disk. The positions are marked from S0 to S19, from C1 to C19 and ISE PRIME. Calibrators and controls can also be without fixed positions. In that case they are introduced as normal samples into a segment or into STAT positions.

In case automated sample transport is used, the analyser is equipped with the optional KUSTI module and samples are dispensed to a disposable 92 positions segment. Further analysis of the sample from the KUSTI segment continues in a normal manner according to the analysis requested. Simultaneous manual sample operation, e.g. for STAT and special samples, is possible.

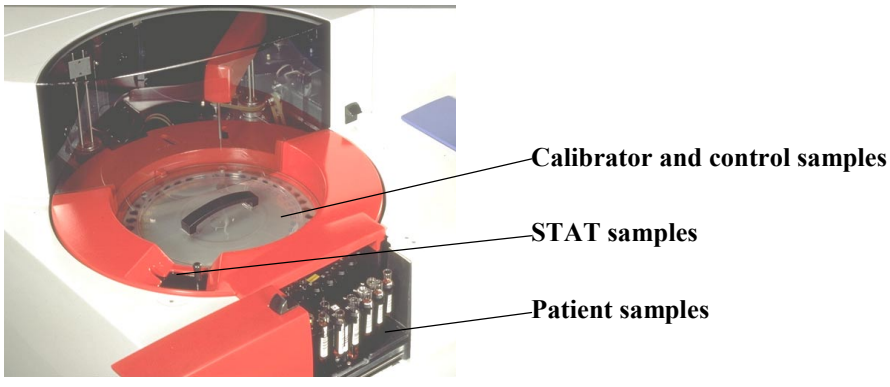


Figure 1-4b: The sample disk of Konelab 30 and 60

REAGENTS

The analyser has a cooled reagent disk for 60 ml vessels, 20 ml and 10 ml bottles. The reagent disk of Konelab 30 and 60 includes integrated barcode reader, in Konelab 20 and 20XT the barcode reader for reagents is external. The data for the reagents without barcode has to be entered in the REAGENT DEFINITION window. Dilution as well as buffer solutions are placed in the reagent disk.

Figure 1-5a: Reagent vials and the 35-position reagent disk in the Konelab 20 and 20XT

Figure 1-5b: Reagent vials and the 45-position reagent disk in the Konelab 30 and 60

CUVETTES

Samples and reagents are dispensed into a cell of multicell cuvette. One multicell cuvette has 12 cells.

! WARNING: The quality of results is guaranteed only with new cuvettes.
Do not reuse the cuvettes.

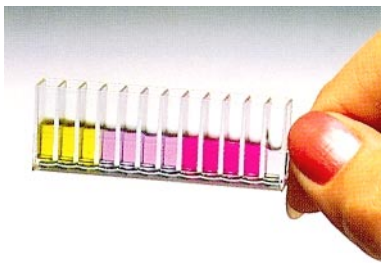


Figure 1-6: A multicell cuvette

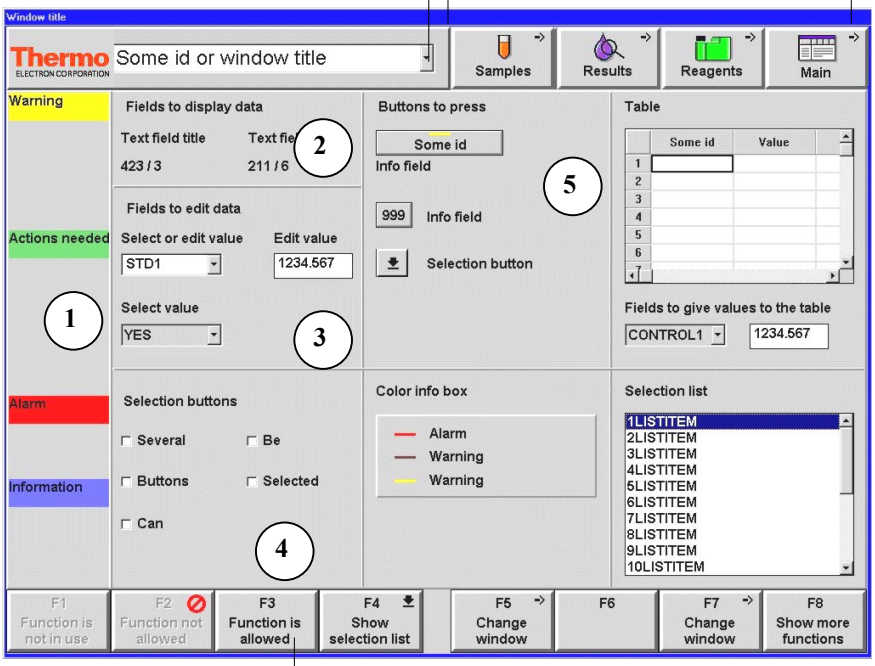
1.2 BEFORE YOU START TO WORK WITH YOUR INSTRUMENT

1.2.1 GENERAL FEATURES

Note! This window is only for instructions, you cannot find it in the software.

Open the list of the window items, e.g. tests, samples, reagents, by clicking the down arrow or press F4.

These 4 buttons are in every window.



All active functions have black text. Activate the function by clicking the button in the window with the left mouse button or by pressing the function key (F1 - F12) on the keyboard.
Functions, which cannot be used, are grey.

(1) Coloured labels:

Yellow:	Warning, e.g., the volume of reagent is below the alarm limit.
Green:	User actions are needed, e.g., results are waiting for acceptance.
Red:	Alarm, e.g., the cuvette loader is empty.
Blue:	Information, e.g., the analyser's status.

(2) Fields to display data: This data cannot be edited.

(3) Fields to edit data: Type the value to the field or select the value from the list.

(4) Group of buttons: Select several items.

(5) Buttons to press: Click the button to open the window for further actions. The coloured line gives an additional information, e.g., segment button with a green line means that the segment has been analysed. Clicking the button opens the Sample segment window.

Moving in the window from one field to another:

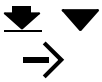
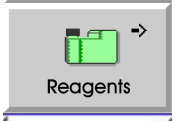
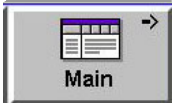
To move from one field to another click the left mouse button or press enter ↵ or tabulator keys on the keyboard.

To move backwards, press shift ⇧ and tabulator keys at the same time.

Selection from the list and from the table:

Clicking the left mouse button or moving the cursor with the arrow keys on the keyboard and pressing Space bar selects an item from the list and from the table.

When you select the same list/ table item again, the item becomes unselected.

Symbol in the window:	Symbol on the keyboard:	Meaning/ Function:
		Function, e.g. Saving, is not allowed.
		Activating the analyser.
		Selection list. Changing the window.
!		STAT sample.
*		Undefined value, e.g. a limit in test parameters marked with * is not checked.
	**F9**	Sample/ patient data and test requests.
	**F10**	Tests results.
	**F11**	The status of all reagents in the reagent disk.
	**F12**	The analyser's status.

1.2.2 SPECIAL KEYS ON THE KEYBOARD

- *Start*	Press START to begin analysis. Note that you must be on the Main window to get it working.
- *Stop*	Press STOP to stop all analysing. To restart analysing, press START.

1.2.3 COVERS AND LEDS IN THE ANALYSER

1.2.3.1 Konelab 60 and Konelab 30

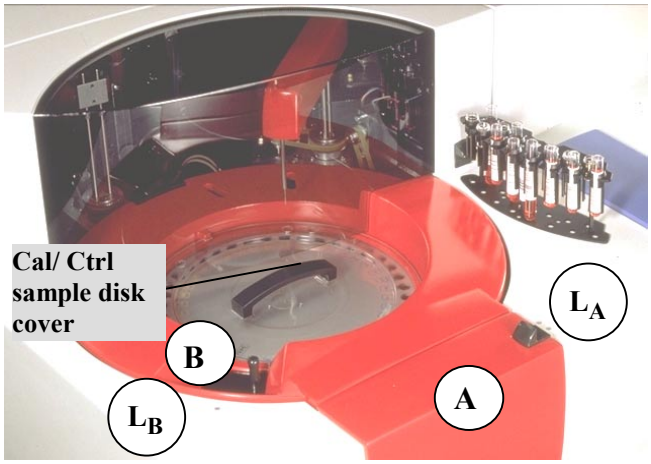
A. The segment insert cover:

- When the green LED (L_A) is on, the user is allowed to open the cover.

- When the red LED is on, the user must NOT open the cover because all six segment positions are occupied or the analyser is transporting the segment between the segment loader and the sample disk.

B. The STAT insert cover:

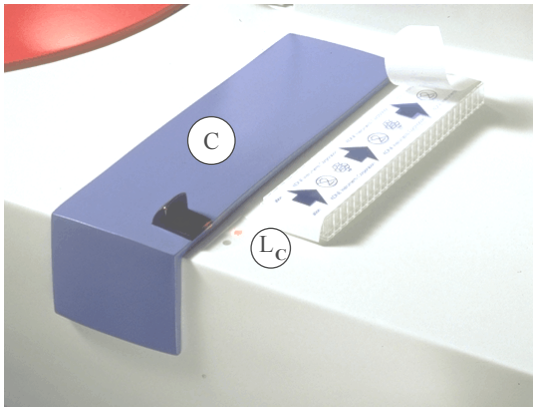
- The LED (L_B) starts to blink red when the user opens the STAT insert cover. The analyser turns to a free STAT insert position.
AFTER the LED stops blinking and remains green, the user can insert the STAT sample.



C. The cuvette loader:

- When the green LED (L_C) is on, the user is allowed to open the cuvette loader cover.

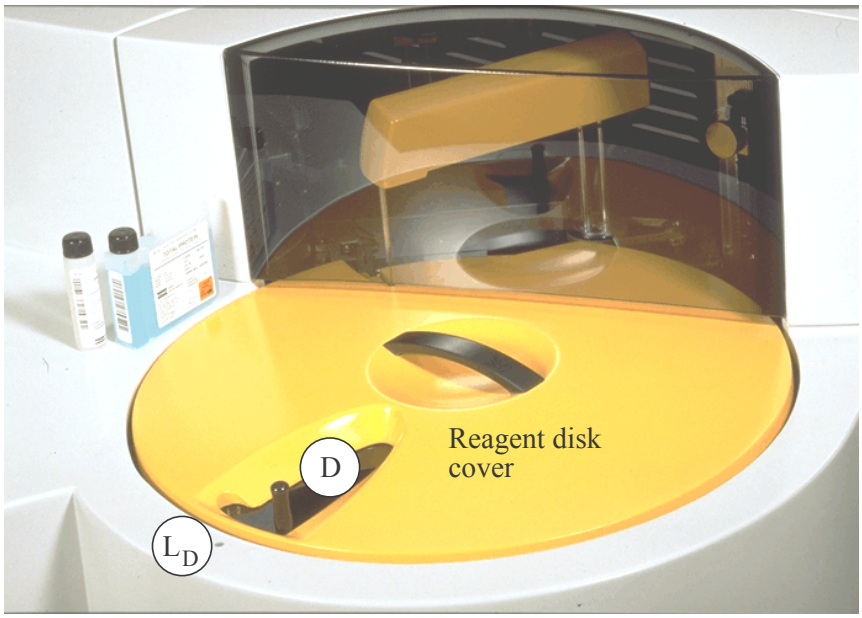
- When the red LED is on, the user must NOT open the cover because the analyser is transporting the cuvettes between the cuvette loader and the cuvette storage or the cuvette storage is full.



D. The reagent insert cover:

- The LED (L_D) starts to blink red when the user opens the reagent insert cover.

The analyser turns to a free reagent position.
AFTER the LED stops blinking and remains green, the user can insert the reagent.

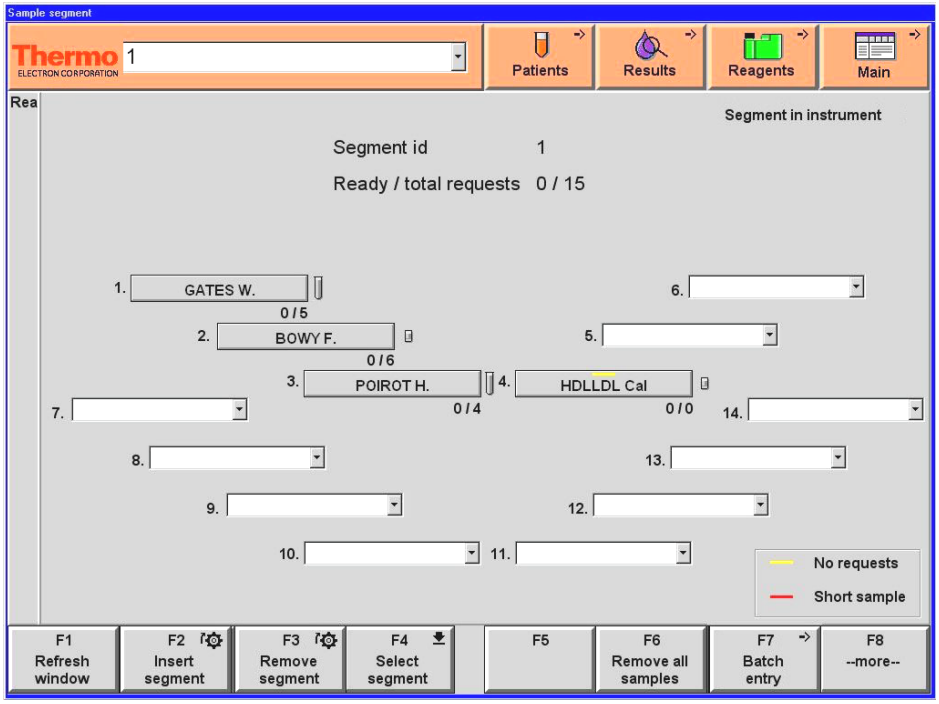


1.2.3.2 Konelab 20XT and Konelab 20

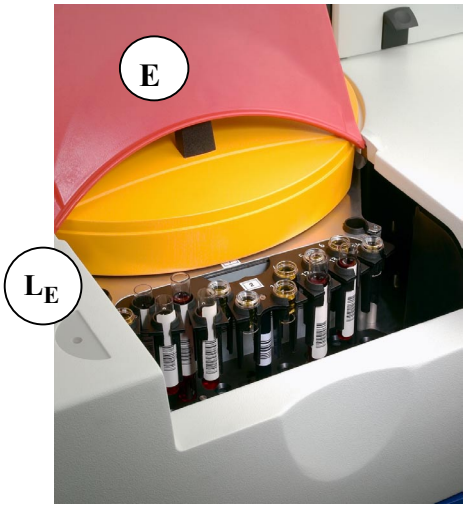
E. The segment/ Stat insert cover:

Inserting the segment

☞ The procedure to insert segment into Konelab 20XT or 20 must be started from the workstation, select F2 either in the Sample/Patient entry window or in the Segment window.

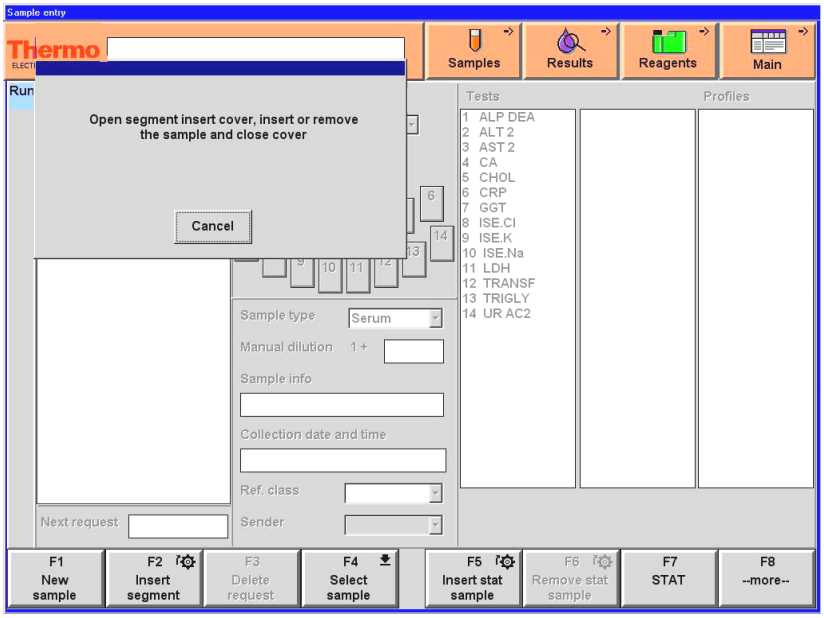


The LED (L_E) red light starts to blink. The analyser turns to a free segment/ STAT insert position. After the LED stops blinking and remains green the user can open the cover and insert the segment. When the cover is closed the LED goes out.



Inserting the STAT sample

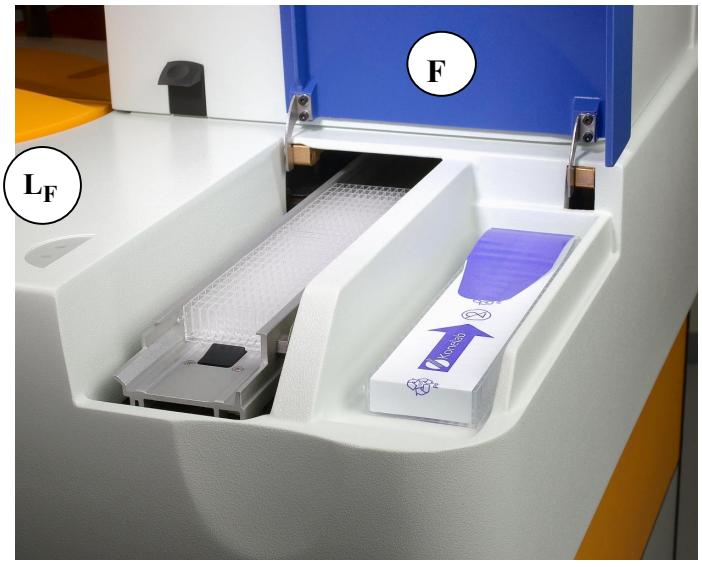
Select F5, Insert stat sample in the Sample/Patient entry window.



The LED (L_E) starts to blink red. The analyser turns to a free segment/ STAT insert position. After the LED stops blinking and remains green the user can open the cover and insert the STAT sample. When the cover is closed the LED goes out.

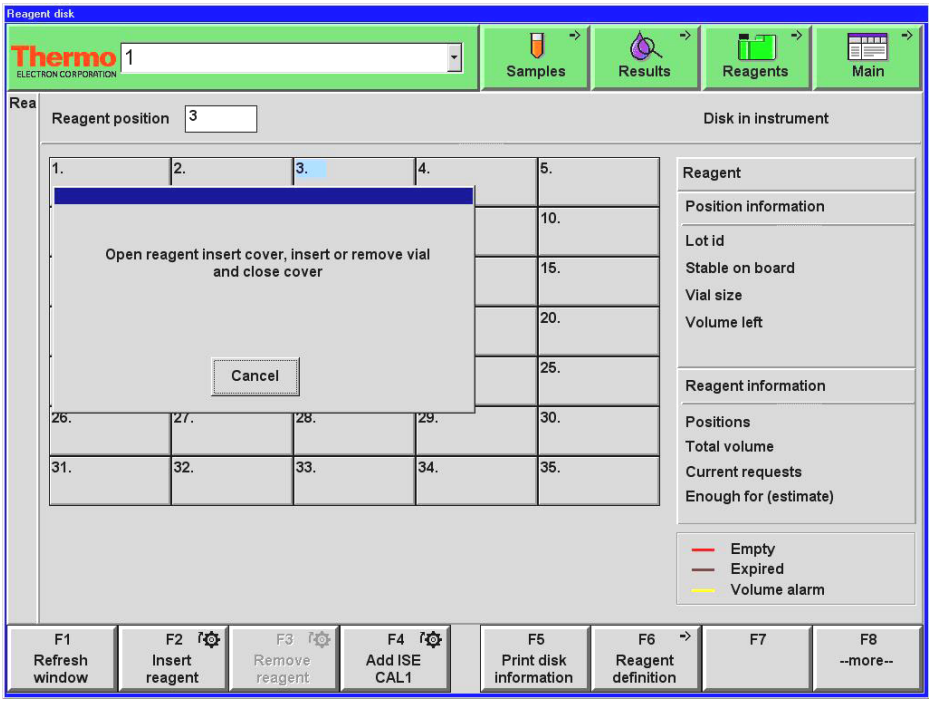
F. The cuvette loader:

- When the green LED (L_F) is on the user is allowed to open the cuvette loader cover.
- When the red LED is on the user must NOT open the cover because the analyser is transporting the cuvettes between the cuvette loader and the cuvette storage or the cuvette storage is full.

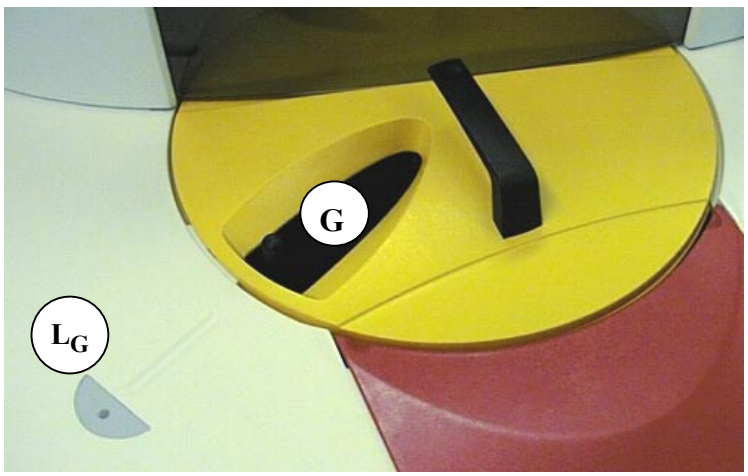


G. The reagent insert cover:

☞ The procedure to insert reagent into Konelab 20XT or 20 must be started from workstation. Select F2 in the Reagent disk window.



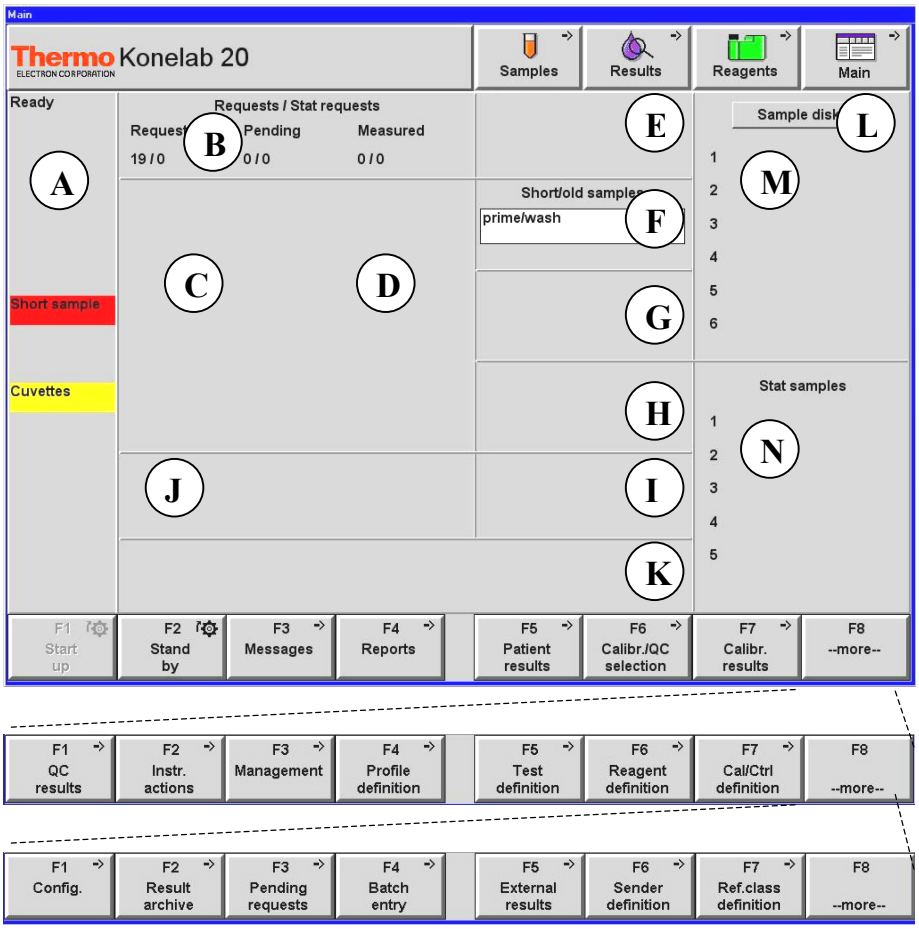
The LED (L_G) starts to blink red. The analyser turns to a free reagent insert position. After the LED stops blinking and remains green the user can open the cover (G) and insert the reagent vial. When the cover is closed the LED goes out.



1.3 MAIN WINDOW

If user levels have been set on (refer to section 3.7) the password is required to login the instrument.

Old calibrations and reagent vials are seen in Start up. The user must insert new vials and request new calibrations or accept the old ones before continuing.
To look at Maintenance actions is reminded if the workstation has not been booted during a week. Booting makes the system work faster.



A STATUS: The analyser's status (e.g. start up needed, analysing etc.) is seen and if e.g. cuvettes are missing *Cuvettes* highlighted in red appears. For further information refer to section 1.3.1.

B STATISTICS: The number of all unanalysed requests, the number of unanalysed requests in the sample disk, and the number of analysed requests are seen.

C TESTS TO ACCEPT: Calibrations and tests, which have unaccepted results, are seen. Refer to sections 3.4.2. and 3.3.1.

D SAMPLES/ PATIENTS TO ACCEPT: Samples/ Patients, who have analysed, unaccepted results are seen. Samples/ Patients with STAT requests are listed first. Refer to section 3.3.2.

E OPEN COVERS: The name of the open cover is listed. When the cover is closed, the name disappears. The covers are reagent insert cover, segment insert cover, STAT insert cover, cuvette loader, reagent disk cover, and sample disk cover.

F SHORT SAMPLES: List of short and old samples is seen. Refer to section 3.2.2.

G REAGENTS BELOW ALARM: List of reagents with volume below the defined alarm limit is seen. Refer to section 3.1.2.

H SHORT REAGENTS: List of short reagents is seen. Refer to section 3.1.2.

I SHORT CALIBRATORS AND CONTROLS: List of short and old calibrators and controls is seen. Refer to section 3.4.1.

J INVALID TESTS: Invalid tests are listed; e.g., calibration, reagent or antigen excess sample is missing or the analyser is unable to do the test because the checking of test's parameters is needed.

K MESSAGES, All messages are seen in the MESSAGES window with an explanation, an identification number, and time. Refer to section 8.2.

L SAMPLE DISK, The status of all segments and patient samples is seen. Refer to section 3.2.8.

M SEGMENTS: Segments on board are seen. Segment identification is on a button. Refer to section 3.2.7.

The segment's status is seen beside the button:
- *In process*: The segment is under analysis.
- *Ready* (the green line in the button): The segment has been analysed.
- *Not started* (a yellow line in the button): The segment is in the sample disk but the barcode has not been read.
- *In loader*: The segment is in the loader and can be removed.
- *Check data* (a red line in the button): There is unrecognised sample in the segment. Refer to section 3.2.7.1.1.
- *Discarded segment* (a red line in the button): The analyser has been unable to read segment's barcode. Click the button or press F9 and further F8/F5 keys on the keyboard; with F3, remove the segment and check the barcode.

N STAT SAMPLES: Samples on the STAT positions are seen. Sample identification is on a button. The green line in the sample button means that the sample is ready to accept or report. The red line means short sample. Refer to section 3.2.4.

To open a window for further actions:

Click the name on the list (C, D, F, G, H, I and K).
Click the button (L, M and N).

- or -

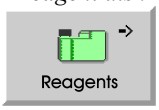
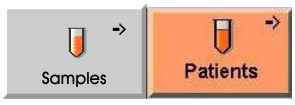
Select the name from the list (C, D, F, G, H, I and K) and press the appropriate key on the keyboard, e.g. F10 to open the TEST RESULTS window. Press the appropriate keys on the keyboard (L, M and N), e.g. F9 and further F8/F6 keys to open the SAMPLE SEGMENT window.

1.3.1 STATUS INFORMATION IN THE MAIN WINDOW - DISPLAYED ONLY WHEN NECESSARY

- *Connecting/ Connected/ Start up needed/ Ready/ Analysing/ Running/ Closing/ Not in use*	The whole instrument's status, the photometric unit's status and the ISE unit's status are informed separately beneath one another. *Connecting:* Instrument's connecting under process. *Connected:* The instrument has been connected but it is not in use yet. *Start up needed*: The Start up is needed. *Ready:* The instrument is waiting for orders. *Analysing:* The instrument is analysing. *Running:* The instrument is performing other functions than analysing, e.g., moving cuvettes, pumps. *Closing*: The STOP key has been pressed. *Not in use*: An error situation, needs correcting. The ISE unit can have the situation: *ISE cal* with a red label: The bag of ISE Calibrator sol. 1 is empty.
- *KUSTI* with a blue label	The KUSTI module is dispensing.
- *KUSTI not in use* with a red label	An error situation, needs correcting. After resolving the problem to get KUSTI in use, Perform water wash (F6) in the Instrument actions window.
- *Reports/ Stat reports* with a green label	Ready patient or sample results. See the list *Samples/ Patients to accept*.
- *Calibrations* with a green label	Unaccepted calibration. See the list *Tests to accept.*
- *Calibrations* with a red label	Calibration is missing.
- *Results/ Stat results* with a green label	Unaccepted results. See the lists *Tests to accept* and *Samples/ Patients to accept*.
- *Covers* with a yellow label	Open cover. See the list *Open covers.*
- *Short sample/ Short Stat* with a red label	Short or old patient, calibrator or control sample on board. See the lists *Short samples* and *Short cal & ctrls*.
- *Reagents* with a yellow label	The volume of the reagent is below the alarm limit. See the list *Reagents below the alarm*.
- *Reagents* with a red label	Short reagent. See the list *Short reagents*.
- *Invalid test* with a red label	The test cannot be done there is, e.g., missing calibration or short reagent. See the list *Invalid tests*.
- *Cuvettes* with a yellow label	One cuvette packet is left.
- *Cuvettes* with a red label	The cuvette loader is empty.
- *Temperature* with a yellow label	Is seen when instrument has been connected, turns off when temperatures are stable.
- *Temperature* with a red label	Temperature of some unit is out of limits. See Instrument actions, Check temperatures.
- *Water* with a red label	The distilled water canister is empty.
- *Waste* with a red label	The wastewater canister is full.
- *Messages* with a red label	General messages existing. See the list *Messages*.

- *Printing* with a blue label	Printing is in progress.
- *Online* with a blue label	The online data transmission is in progress.

1.4 BRIEF DESCRIPTION OF WINDOWS

- *Batch entry*	Functions to give test requests for a batch of samples. Refer to section 3.2.2.3.
- *Configuration*	In the Configuration window, the user can see e.g., the usable wavelengths. In addition the user can e.g., define the criterion for data entering: sample or patient, change the default sample type used in Sample/ Patient entry, define the printing type: manual or automatic and connect the ISE unit on and off. Refer to section 3.8.
- *LIMS configuration*	The used laboratory information management protocol is defined. Refer to section 3.8.1.
- *Management*	Functions to stop the instrument immediately and to clear the daily files and simultaneously to save accepted QC results to the cumulative data. Refer to section 3.6.
- *User management*	Functions to set user levels on and change passwords. Refer to section 3.7.
- *Restrictions*	Functions to determine different user levels. Refer to section 4.10.
- *Messages*	Detailed information from the messages is seen. Refer to section 8.2.
- *Profile definition*	Functions to define the profiles. Refer to section 4.7.
- *Reagent definition*	Functions to give the reagent data. Refer to section 3.1.3.
- *Reagent disk*	The status of all reagents in the reagent disk is seen in this window.
	The user has access to the REAGENT DISK window from every window. Refer to section 3.1.1.
- *Reference class definition*	Functions to define reference classes. Refer to section 4.8.
- *Reports*	Functions to report the results manually. Refer to section 3.5.
- *LIMS connection*	Functions to manually ask requests or send results online. Refer to section 3.5.1.
- *Sample disk*	The status of all segments and patient samples on board is seen in this window. Refer to section 3.2.8.
- *Sample/ Patient entry*	Functions to give sample/patient data and test requests. The criterion for the data entering (sample or patient) is defined in the Configuration window.
	The user has access to the SAMPLE/ PATIENT ENTRY window from every window. Refer to section 3.2.2.

- *Sample list*	A brief preview of all samples is seen in this window. Refer to section 3.2.9.
- *Sample/ Patient results*	Functions to see the results of samples/ patients. The unaccepted results can be accepted, rejected, or rerun. Refer to section 3.3.2.
- *Sample segment*	The status of sample segment with all 14 positions is seen. Refer to section 3.2.7.
- *Pending requests*	Pending requests and the time estimation for analysing them are seen in this window. Refer to section 3.2.10.
- *Sender definition*	Functions to define the sender data, which is seen in Sample/ Patient entry and in reports. Refer to section 4.9.
- *Calibrator & Control definition*	Functions to define calibrators and controls and to give the test values. Refer to section 4.6.
- *Calibration parameters*	Functions to define the test calibration parameters. Refer to section 4.4.
- *Calibration results*	The status of the test calibration is seen. Calibration can be accepted and compared to the previous one. Every calibration request can be rejected and rerun. Refer to section 3.4.2.
- *Calibration/ QC selection*	The list of tests in the order of the calibration status and the status of calibrators is seen. The user can calibrate the test and ask the Manual QC for the test. The status of controls is seen. Refer to section 3.4.1.
- *Quality control results*	Cumulative data and quality control results are seen on the lists or graphically. Refer to section 3.4.3.
- *Results by controls*	Daily quality control results by controls are seen. Refer to section 3.4.4.
- *Quality control parameters*	Functions to define tests' quality control parameters for manual qc and routine qc. Refer to section 4.5.
- *Test definition*	Functions to define tests. Tests' general parameters are given in this window. Refer to section 4.1.
- *Test flow*	Functions to define the test flow i.e. the parameters for reagent and sample dispensings, for dilution, incubation and measurement. Additional mixing can also be defined. Refer to section 4.2.
- *Electrodes*	Function to define which electrodes is used. Refer to section 4.3.
- *Test results*	Functions to see the results of the tests. Unaccepted results can be accepted, rejected or rerun.
	The user has access to the TEST RESULTS window from every window. Refer to section 3.3.1.
- *External results*	Functions to enter results for tests analysed by other instruments to provide fully collated patient reports. Refer to section 3.2.6.1.
- *Result archive*	Result archive includes sample and control results. Refer to section 3.9.

- *Calibration archive*	Calibration archive includes old, accepted calibrations. Refer to section 3.9.1.
- *Reagent lot archive*	Reagent lot archive includes information of used reagent lots. Refer to section 3.9.2.
- *Statistics*	Both daily and cumulative number of accepted and rejected requests of samples, calibrators and controls are seen test by test. Refer to section 3.10.
- *Report formats*	Functions to format the patient, sample, or test report. Refer to section 3.11.
- *Instrument actions*	Functions for the user service actions, e.g. to order water blank and ISE prime and to remove cuvettes. Adjustment and test programs for Service Engineers. Refer to section 3.12.
- *Water blank*	Functions to check water blank measurements wavelength by wavelength. Refer to section 3.13.
- *Maintenance*	Maintenance checking table. The user is reminded to perform tasks after the given time period. Refer to section 6.1.
- *Accuracy results*	After the preventive maintenance done once per year, it is recommended to perform accuracy measurements to check the condition of instrument. Results of these measurements are seen in this window. Refer to section 6.4.
- *Accuracy factors*	Accuracy measurements are done with the accuracy solution kit. Authority measures values of these solutions. Lot dependant factors, affecting accuracy result calculations, are given in this window. Refer to section 6.4.1.

I.5 FUNCTIONS IN THE WINDOWS

	F1	F2	F3	F4	F5	F6	F7	F8
MAIN	Start up	Stand by	Messages→	Reports→	Sample results→	Calibr./QC select.→	Calibr. results→	--more--
	QC results→	Instr.actions→	Management→	Profile → definition	Test definition→	Reagent → definition	Cal/ Ctrl definition→	--more--
	Config. →	Result archive→	Pending requests→	Batch entry→	External → results	Sender definition→	Ref.class def.→	--more--
CONFIGUR.		Save changes	Cancel changes			Report formats→	LIMS configur.→	
LIMS CONFIG.		Save changes	Cancel changes				Config. →	
INSTR.ACTIONS	Perform water blank	Prime ISE	Exit cuvettes	Check temperatures	Check needles	Perform water wash	Manual cuvette exit	--more--
	Check → water blank	Accuracy → results		Clean needles	Adjustment program		Maintenance→	--more--
MANAGEMENT	Stop instrument	Logoff		About	Save DB	Save DB to CD	Clear daily files	--more--
			EXIT	Statistics→	User manager→	Save to diskette	Maintenance→	--more--
MESSAGES	Message details on/ off	Accept selected		Accept page	Print messages	Next page	Previous page	--more--
	Show all messages/ Show notaccepted		Delete all msgs in DB (=database)		Print last page			--more--
PROFILE DEFINITION	New profile	Save changes	Cancel changes	Select profile	Remove request	Delete profile	STAT	--more--
				Batch entry →	Test definition→			--more--
REAG. DEFINITION	New reagent	Save changes	Cancel changes	Select reagent	Print reagent data		Remove lot	--more--
		Change name	Delete reagent		Reagent lot archive			--more--
REAG. DISK	Refresh window	Insert reagent	Remove reagent	Add ISE CAL1	Print disk information	Reagent → definition		--more--
	Check reagent disk	Change disk	Clear disk data	Select disk	Clear short list			--more--

	F1	F2	F3	F4	F5	F6	F7	F8
REF. CLASS DEFINITION	New ref.class	Save changes	Cancel changes	Select ref. class	Test definition→		Remove test	--more--
		Change name	Delete ref.class					--more--
REPORTS	Stop reporting	Report selected	Report all	Daily report	LIMS connection	Report formats→	Pending req.→	--more--
				Results to file				--more--
SAMPLE DISK	Print disk information	Clear short list	Check sample disk		Remove segments	Remove STAT samples	Batch entry→	--more--
				Pending requests→	Sample → segment		Sample list→	--more--
SAMPLE ENTRY	New sample	Insert request/ Insert segment (=K20 & K20XT)	Delete request	Select sample	Insert STAT sample	Remove STAT sample	STAT	--more--
		Change name	Delete sample	Batch entry→	Sample → segment	Sample disk→	Sample list→	--more--
	Change dilution		Pending requests→	Profile → definition	Clear short list			--more--
PATIENT ENTRY	New patient	Insert request/ Insert segment (=K20 & K20XT)	Delete request	Select patient	Insert STAT sample	Remove stat sample	STAT	--more--
	New sample	Change name	Delete sample	Batch entry→	Sample → segment	Sample disk→	Sample list→	--more--
	Change dilution	Change sample id	Pending requests→	Profile → definition	Clear short list			--more--
BATCH ENTRY	Set sample mode on/ Set segment mode on	Save changes	Cancel changes		Insert request	Delete request	STAT	--more--
		Change name		Profile → definition	Sample → segment	Sample disk→	Sample list→	--more--
SAMPLE LIST	Next page	Previous page		Pending requests→	Sample → segment	Sample disk→	Batch entry→	

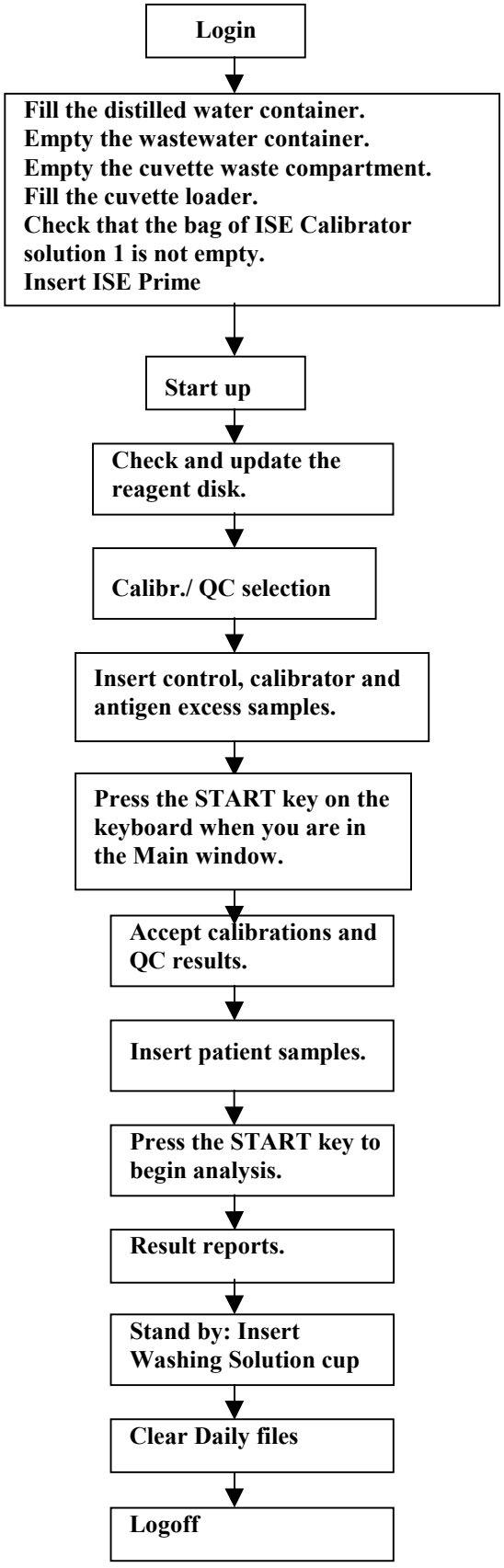
	F1	F2	F3	F4	F5	F6	F7	F8
SAMPLE RESULTS	Request details on/ off	Accept selected	Accept page	Select sample	Print results	Next page	Previous page	--more--
	Print details	Reject selected	Rerun selected	Rerun with dilution	External results→	QC results→	Result archive→	--more--
PATIENT RESULTS	Request details on/ off	Accept selected	Accept page	Select patient	Print results	Next page	Previous page	--more--
	Print details	Reject selected	Rerun selected	Rerun with dilution	External results→	QC results→		--more--
SAMPLE SEGMENT	Refresh window	Insert segment (=K20 & K20XT)	Remove segment	Select segment	(Clear errors)	Remove all samples	Batch entry→	--more--
	Print segment			Pending requests→	Delete segment	Sample disk→	Sample list→	--more--
PENDING REQUESTS	Refresh window	Print requests		Reports→	Sample → segment	Sample disk→	Sample list→	
CAL/ CTRL DEFINITION	New cal or ctrl	Save changes	Cancel changes	Select cal or ctrl	Print cal or ctrl		Remove test	--more--
	Delete cum. of tests	Change name	Delete cal or ctrl		Calibr.params.→	QC params.→	Results by controls→	--more--
TEST DEFINITION	New test	Save changes	Cancel changes	Select test	Calibr.params.→	QC params.→	Test flow→/ Electrodes	--more--
	Display more params	Change name	Delete test	Profile definition→	Ref. class → definition	Calibr./QC → selection	Print parameters	--more--
TEST FLOW		Save changes	Cancel changes	Select test	Test definition→		Delete last item	
ELECTRODES		Save changes	Cancel changes		Test definition→			
CAL. PARAM.		Save changes	Cancel changes	Select test	Test definition→	Calibr./QC → selection	Cal/Ctrl definition→	--more--
			Remove list item					--more--

	F1	F2	F3	F4	F5	F6	F7	F8
CAL. RESULTS	Request details on /off	Accept calibration	Compare cal. on/ off	Select test	Use old calibration/ Delete calibration	Recalibrate	Print calibration	--more--
	Print details	Reject selected	Rerun selected	Calibr./QC selection→	Calibration archive→	Accept bias corr.	Reject bias corr.	--more--
CALIBR./QC SELECTION	Calibrate	Perform manual QC	Cals/ Ctrls needed	Add cal or ctrl/ Add prime/ wash (=K20 & K20XT)	Man QC for all tests	QC results→	Calibration results→	--more--
					Calibr. params. →	QC params.→		--more--
QC RESULTS	Display cumulatives/ Display results	Accept selected	Reject selected	Select test	Print results/ Print cumulatives	Change ctrl values	Display graph/ Display numbers	--more--
	Delete cum. of tests		Delete cumulatives	Sample results→	Test definition →	Calibr./QC → selection	Results by controls→	--more--
RESULTS BY CONTROLS				Select control	Print all	Cal/Ctrl definition→	QC results→	
QC PARAM.		Save changes	Cancel changes	Select test	Test definition→	Calibr./QC → selection	Cal/Ctrl definition→	--more--
			Remove list item					--more--
TEST RESULTS	Request details on /off	Accept selected	Accept page	Select test	Print results	Next page	Previous page	--more--
	Print details	Reject selected	Rerun selected	Display all on/ off	Test definition→	Rerun with dilution	Calibration results→	-more--
	Calculate statistics		Pause/ Resume test run		External results→	QC results→		-more--
EXTERNAL RESULTS		Save changes	Cancel changes	Select test	Test definition→	Sample results→	Print list	
SENDER DEFINITION	New sender	Save changes	Cancel changes	Select sender		Delete sender		

	F1	F2	F3	F4	F5	F6	F7	F8
RESULT ARCHIVE	Request details on/ off	Retrieve results			Sample results→	Delete results	Print results	--more--
	Print details	Display reagent lots			Reagent lot → archive	Recreate archive	Calibration → archive	--more--
CALIBRATION ARCHIVE	Request details on/ off		Select calibration	Select test			Print calibration	--more--
	Print details	Display reagent lots			Calibr. results →		Result archive→	--more--
REAGENT LOT ARCHIVE				Select reagent	Print reagent data	Reagent definition	Result archive→	
STATISTICS	Display cumulatives/ daily data		Management→		Print statistics		Delete cumulatives	
USER MANAGEMENT	New user	Change password	Delete user	Print users	Restrictions→	Set login on		--more--
		Logoff	Management→					--more--
RESTRICTIONS	New level	Save changes	Cancel changes	Select level	User manager→	Print restrictions	Delete restriction	--more--
		Change level name	Delete level					--more--
REPORT FORMATS	Set all to default	Save changes	Cancel changes	Select format	Print report	Reports→	Remove last component	--more--
							Configuration→	--more--
CHECK WATER BLANK	Instr.actions→		Select water blank	Select wavelength	Show all/ separately	Print summary	Print details	

	F1	F2	F3	F4	F5	F6	F7	F8
MAINTENANCE	Mark performed	Save changes	Cancel changes	Change interval	Print operations	Instr.actions→	Management→	
ACCURACY RESULTS	Previous results	Save results			Accuracy → factors	Instr.actions→	Print results	
ACCURACY FACTORS		Save changes	Cancel changes		Accuracy→ results			
LIMS connection	Set send/ query mode on	Query for requests	Send results	Reports →	Reset connection			

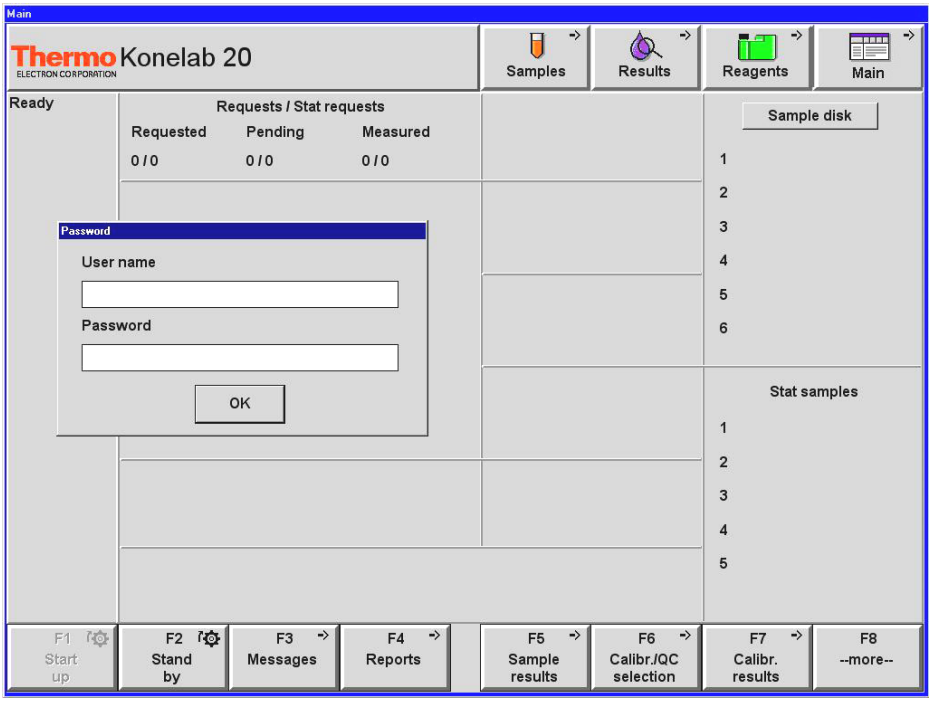
2. ROUTINE OPERATION



It is recommended to run QC daily.

Temperatures in different channels are seen if they are not stabilized when START is pressed. Before continuing, the user must either wait stabilization or accept the situation. In case the reagent register is too warm, run Manual QC and change reagents.

2.1 LOGIN



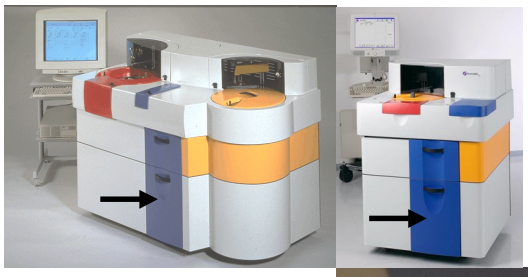
If user levels have been set on:

☞ Give your user name and password.

The password can be changed in the User manager window. Refer to section 3.7.

2.2 CHECKS PRIOR TO ANALYSIS

2.2.1 CHECK DISTILLED AND WASTEWATER CONTAINERS



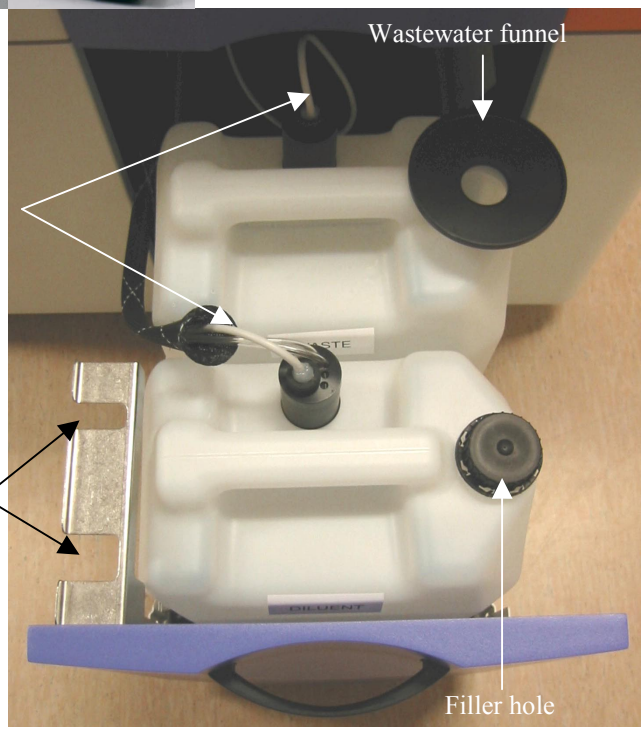


Figure 2-1: The distilled and the wastewater containers are located in the lower drawer of the stand.

Purified water (water type 1) is preferred. Refer to section 9.3 for the requirements of type 1 water.

It is recommended to change distilled water at least two times a week and fill the container one day before the use to get air bubbles away before analysis.

The operator is warned if the distilled water container needs refilling and if the wastewater container needs emptying.

Prior to starting analysis:

- Fill the distilled water container. The container may be refilled through the filler hole also during operation. There should be at least 2 litres in canister when water is added.
- Empty the wastewater container. The container can be emptied during operation since there is above a wastewater collector coming automatically when the waste-water container is removed. Add one spoon of chloramine into the empty wastewater container to prevent a bacteria growth.

The 10-litre volume of the containers is usually enough for one day's operation. The containers are equipped with liquid level sensors.

2.2.2 CHECK THE CUVETTE WASTE COMPARTMENT

Figure 2-2: The cuvette waste compartment is located in the upper drawer of the analyser stand. Place the cover of cuvette waste box so that arrows show away from you.

☞ Discard the bag prior to starting analysis. The bag is big enough for one day's operation.

Wipe the cuvette output area once a week to remove all splashes.

2.2.3 CHECK THE BAG OF ISE CALIBRATOR SOLUTION 1

If ISE Calibrator solution 1 is added during analysis it must be done in the REAGENT DISK window with the function F4, Add ISE CAL 1. Refer to section 3.1.1.

Figure 2-3: The bag of ISE Calibrator solution 1 locates behind the door in the left side of the analyser.

The ISE Calibrator solution 1 is in foil bag, which minimises the evaporation.

☞ Check that the bag of ISE Calibrator solution 1 is not empty - replace if required.

2.2.4 FILL THE CUVETTE LOADER

The cuvette loader has a capacity for six cuvette packets in Konelab 60 and two packets in Konelab 30, 20XT and 20. When the message *Cuvettes* with a yellow background appears in the Main window, there is only one cuvette packet left.

☞ The cuvettes can be added only when the green LED is on. Open the cuvette loader cover. Push the cuvette packet to the loader and remove the tape over the packet. Close the cover.

When the red LED is on, do not open the cuvette loader cover because either the analyser is transporting the cuvettes between the cuvette loader and the cuvette storage or the cuvette storage is full.

Figure 2-4a: The cuvette loader and a cuvette packet in Konelab 60/30.

Figure 2-4b: The cuvette loader and a cuvette packet in Konelab 20XT/ 20.

WARNING: Do not touch the optical surfaces of the cuvette. The measurement signal goes through the long side of the cuvette.

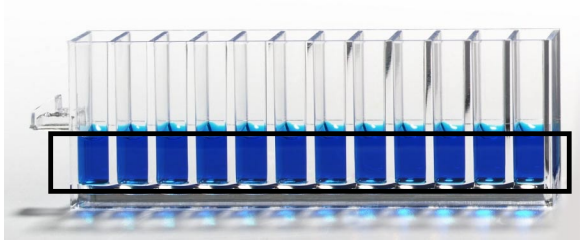


Figure 2-4c: The optical surface of the cuvette.

2.2.5 INSERT CALIBRATOR, CONTROL, ISE PRIME, AND ANTIGEN EXCESS SAMPLES

In Konelab 20XT and 20 calibrators and controls are loaded as normal samples into segments or into STAT positions. ISE prime sample is always inserted into the sixth STAT position. If an ISE prime sample or a Washing solution sample is added during analysis it must be done in the Calibr./QC selection window with the function F4, Add prime/wash. Refer to section 3.4.1.

When Konelab 60 or 30 is used, it is recommended to insert calibrators and controls into the cal/ctrl sample disk before starting analysis. Inserting them during analysis interrupts dispensing.

In Konelab 60 and 30 calibrator and control samples with no fixed positions are loaded as normal samples into segments or into STAT positions. Furthermore, they can be loaded into their dedicated positions in the cal/ctrl sample disk. In this case, use 0.5 or 2 ml sample cups for calibrator, control, ISE prime, and antigen excess samples. If a calibrator or a control sample is added into the cal/ctrl sample disk during analysis it must be done in the Calibr./QC selection window with the function F4, Add cal or ctrl. Refer to section 3.4.1.

In the Cal/ctrl definition window values and positions for calibrators and controls are seen and can be edited. Furthermore, an antigen excess sample is specified as a control sample in the same window. Refer to section 4.6.

The test's automatic result acceptance is changed to manual if a control sample is short.

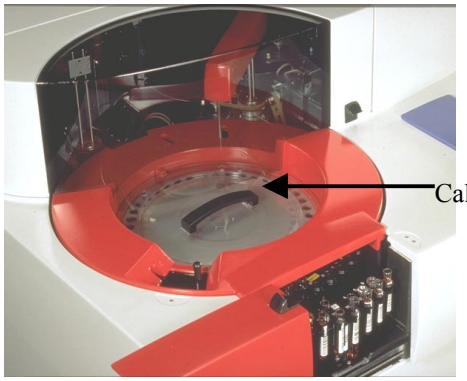
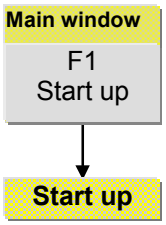


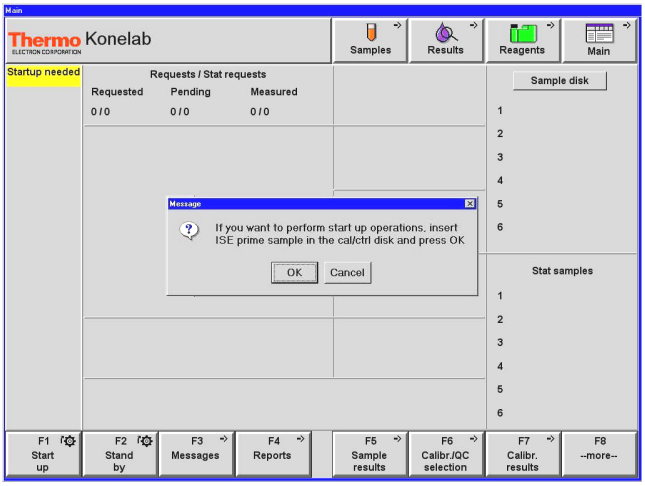
Figure 2-5a:In Konelab 60 and 30 calibrator, control, ISE prime, and antigen excess samples have their dedicated cooled positions in the sample disk.

Figure 2-5b: In Konelab 20XT and 20 calibrator, control and antigen excess samples are loaded into segments as normal samples. ISE prime sample is always inserted into the sixth STAT position.

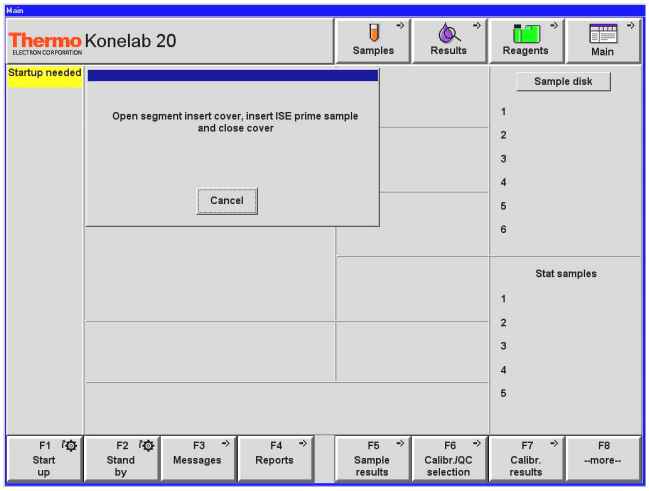
2.3 START UP



You cannot start analysis before Start up has been done.
The *'Start up needed'* message informs you of this situation.
The user is warned if the workstation has not been booted once a week. After a boot the system works faster.



In Konelab 20XT and 20 the ISE Prime sample is inserted in the sixth STAT position.



Old calibrations and reagent vials are seen in Start up. The user must insert new vials and request new calibrations or accept the old ones before continuing.

During the START UP function, the instrument is not available for other actions.

The START UP function must be done:

☞ Once a day prior to starting the analysis.

☞ When analysis is continued after the STAND BY function.

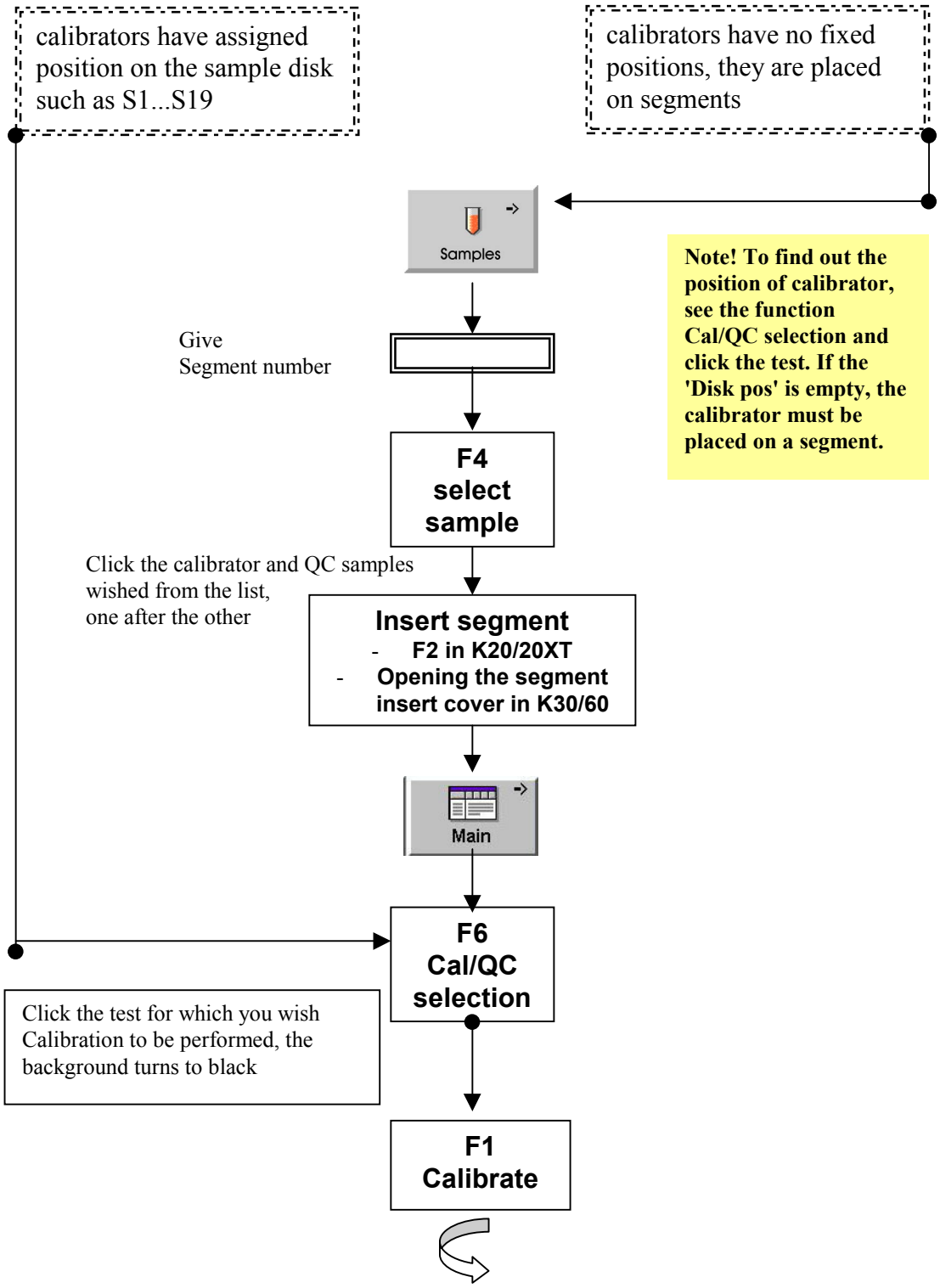
☞ Always after switching on the analyser.

The START UP function causes the following automatic operations:

- Performs all necessary initialisation procedures.
- Rinses and washes tubes.
- Fetches ISE Calibrator solution 1 for ISE measurements.
- Primes serum through the ISE block if a prime sample has been inserted in the position of ISE Prime.
- Measures water blank.

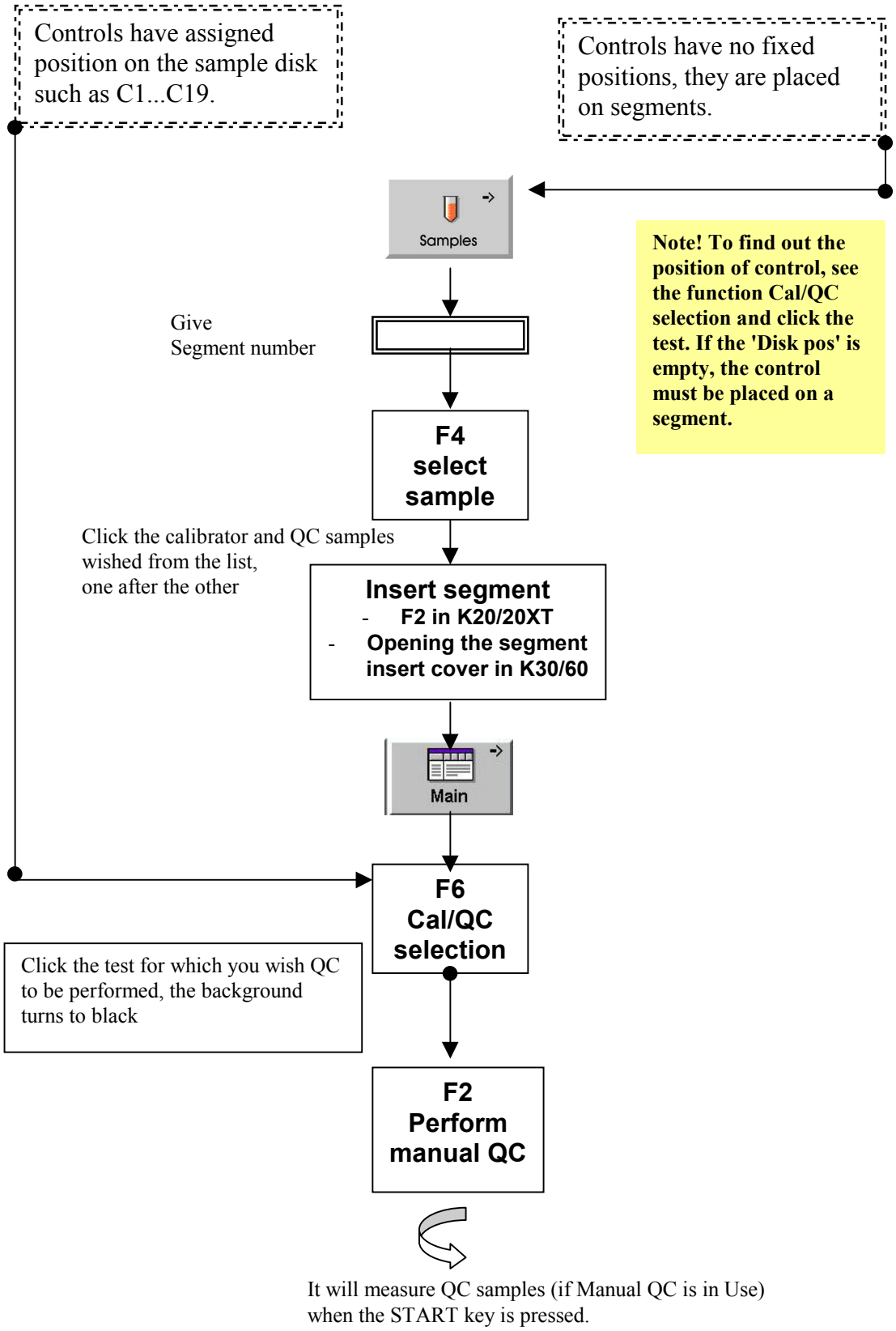
2.4 HOW TO REQUEST CALIBRATION/QC

2.4.1 CALIBRATION SELECTION

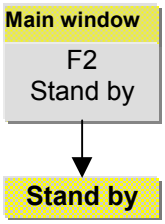


It will measure calibrators and QC samples (if Manual QC is in Use) when the START key is pressed.

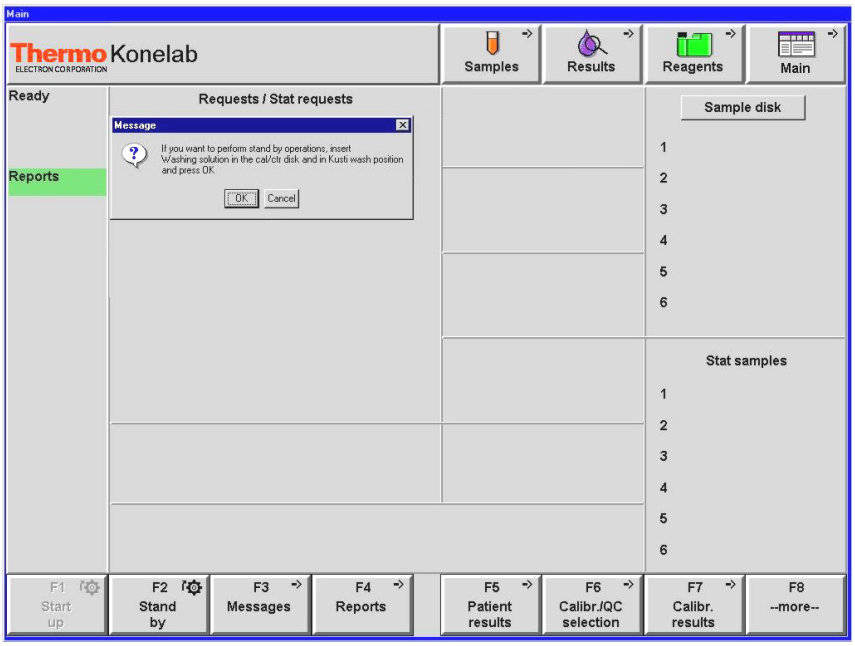
2.4.2 QC SELECTION



2.5 STAND BY

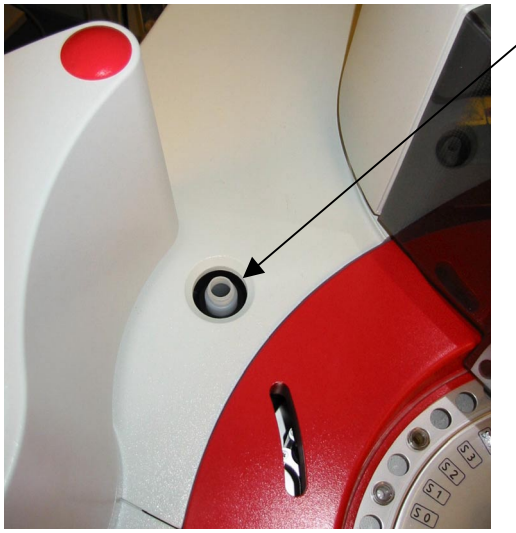


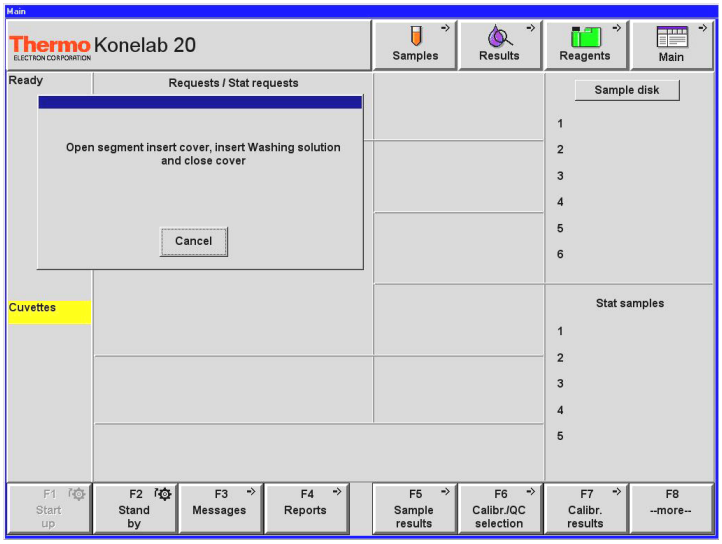
Stand by should be carried out once a day after the daily workload.



Insert a cup of Washing solution in the position of ISE Prime in the cal/ctrl sample disk in Konelab 60 and 30.

Insert a bottle of Washing Solution in KUSTI wash position beside the sample disk when the KUSTI module exists.





Insert a cup of Washing solution in the sixth STAT position in Konelab 20XT and 20.

Selecting STAND BY causes the following:

- Electrodes, the ISE dispensing needle, the KUSTI dispensing needle and mixing paddle(s) are washed with Washing solution.
- Cuvettes are moved to the waste compartment.
- Stepping motors are powered off.

2.6 SWITCHING THE ANALYSER OFF AND ON

2.6.1 SWITCHING OFF

IMPORTANT! Switch the PC off and on at least once a week to get the system work faster.

Exit from the Konelab program in the Management window with F8/F3.

Shut down the computer (the button Start: Shut down in the left corner of the window). Switch off the mains of monitor.

☞ Switch off the mains of Konelab by turning the mains key to the OFF position at the rear of the analyser.

Konelab 60 or KUSTI equipped with the low current switch

In case you have Konelab 60 or KUSTI and you cannot reach the main power switch at rear of the analyser, open the left front door and locate the low current switch, turn it in the stand by setting ⏻ and unplug the mains cable to turn the power totally off.

When the low current switch is in the stand by setting, only the boards of analyser and the internal PC are powered off.

– If you take the mains cable off when the low current switch is on, the back-up batteries of the instrument are turned on.

WARNING: The low current switch does not turn power totally off.

You can boot the internal PC by turning the low current switch in the stand by setting and waiting at least one minute before turning it on.

2.6.2 SWITCHING ON

☞ Switch on the mains of the PC and monitor.

When switching on Konelab 20XT/20, switch first Konelab 20XT/20 on, and after that the PC!

☞ Login: Check that the domain name is Konelab and enter password Konelab. Konelab program starts automatically.

☞ Switch on the mains of Konelab by turning the mains key to the ON position at the rear of the analyser and wait until the Konelab main window is seen.

Konelab 60 or KUSTI equipped with the low current switch

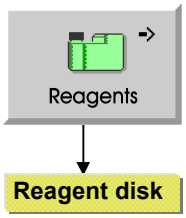
In case you have Konelab 60 or KUSTI, open the left front door, locate the low current switch, and turn it ON (I). To get the analyser working, both the low current switch and the main power switch at the rear of the analyser must be on.

3. FUNCTIONS

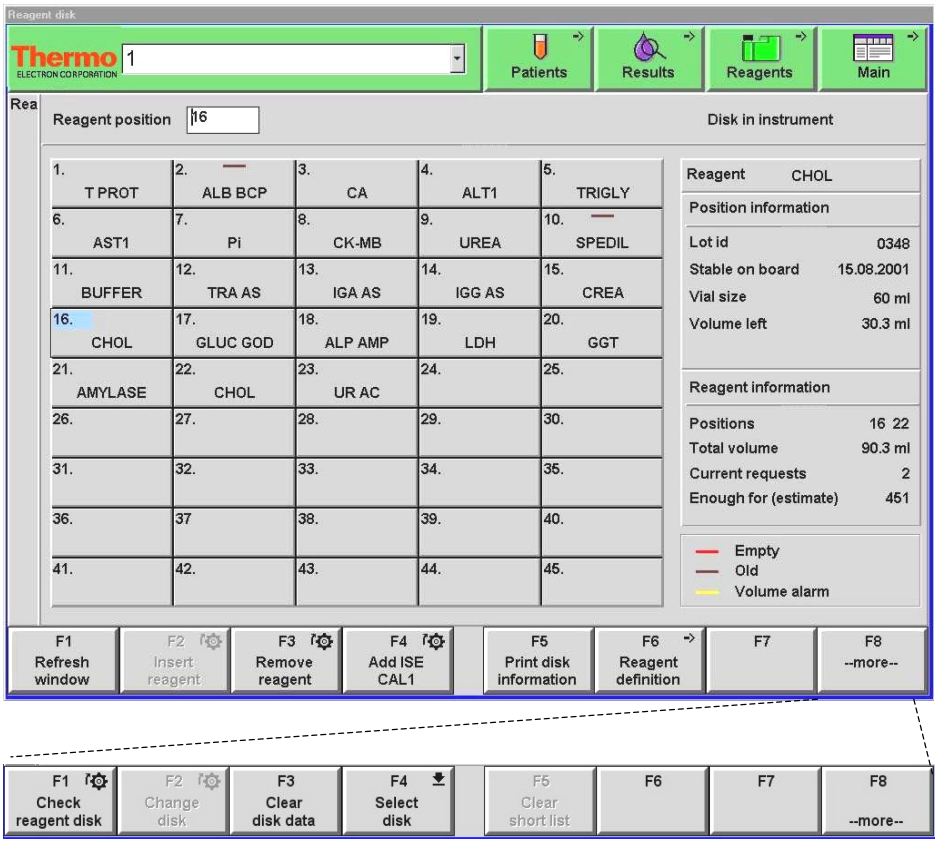
3.1 REAGENTS

This chapter describes how:
- to check the reagent's status,
- to insert a reagent with and without barcode,
- to remove the reagent,
- to change the reagent disk,
- to edit the reagent data.

3.1.1 CHECKING REAGENTS

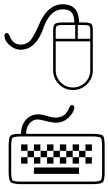


In case the reagent register is too warm, run Manual QC and change reagents. Temperature of the reagent register is seen by F4, Check temperatures in the Instrument actions window.



Check the reagent's status. In Konelab 60 and 30, activating F8/F1 means that the barcodes and volume of vials are read automatically. With F1 you can update the window.

If the colour line on the reagent position is:
- red the reagent is short,
- yellow the reagent is below the alarm limit,
- brown the reagent lot is old or the reagent's on-board stability has expired or will expire on that day.



Click the disk position button to display the position and reagent information to the right side of the window.

Typing the position number in the *Reagent position* field and pressing ↵ performs the same function.

In order that the reagent lot follow up is functioning in a proper way in every situation, there should not be two different lots for the same reagent in the reagent disk at the same time.

Reagent information relating to the selected position:

- *Reagent*	The reagent's name.
- *Lot id*	The manufacturing identification of the reagent.
- *Expiry date*	The last day the reagent is usable.
- *Vial size*	The size of the reagent vial in the position.
- *Volume left*	The remaining reagent volume in the vial is seen after a first dispensing. At first is seen * when a new bottle is introduced.
- *Reagent status*	The reagent's status is shown with a colour and explanation: if the reagent is short (red), below the alarm limit (yellow) or the reagent lot is old or the reagent's on-board stability is over or will be over on that day (brown).

Reagent information relating to the selected reagent:

- *Positions*	All positions in the disk where the reagent exists.
- *Total volume*	The total volume of the reagent in the disk is seen after a first dispensing. At first is seen * when a new bottle is introduced.
- *Current requests*	The number of unanalysed requests using the reagent.
- *Enough for (estimate)*	The estimate of the number of requests that can be done with the remaining reagent volume. At first is seen * when a new bottle is introduced. The estimation is seen after a first dispensing. If the sign * stays, it means that the reagent is not used in any test.
- *Reagent status*	The yellow status means that there is not enough reagent to all requests.

3.1.2 INSERTING REAGENTS

3.1.2.1 Konelab 60 and Konelab 30

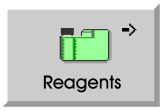
Do not put your fingers or reagent vial through the reagent insert cover whilst the LED is blinking.

Insert the bar-coded reagent vial without cap in the reagent disk. Check that there is no foam in the vial. If there is, pipette foam carefully away.

☞ Open the reagent insert cover on the analyser. The LED starts to blink, the analyser turns a free position to the reagent insert place. Wait until the LED stops blinking.

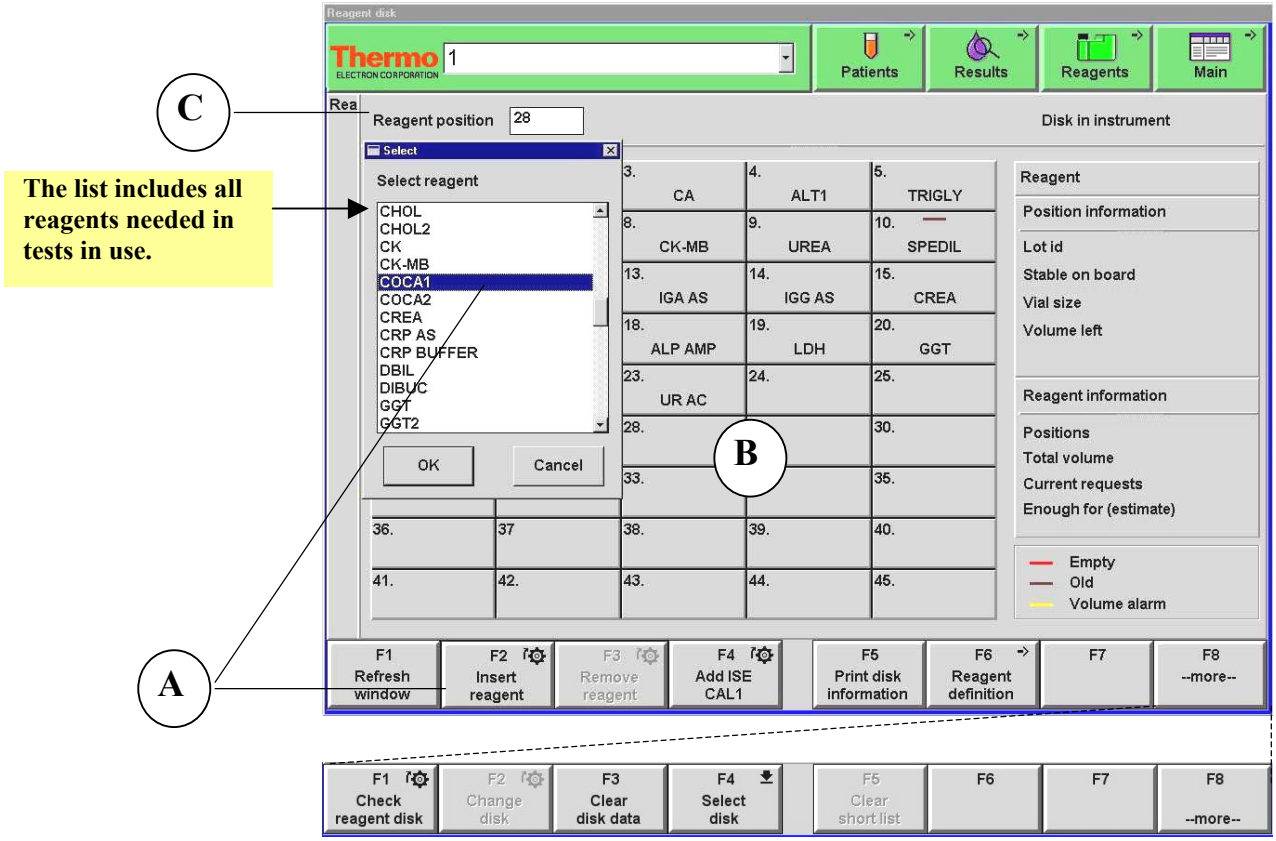
☞ Insert the reagent so that barcodes are towards the reagent LED. Close the cover. The barcode reader inside the reagent disk reads the reagent information before analysis starts.

It is recommended to have 'Additional condition' in use in the QC parameters window (see section 4.5) so that routine qc is performed every time when reagent vial is changed. In case reagent vial is inserted and old ones are taken away during the ready state, the user must ask manual qc to be done. If the old reagent vials are not taken away at the same time then the routine qc is run also in this case when the analyser starts the new reagent.

In case the reagent is not bar-coded, activate 

(F11).

You get the REAGENT DISK window with all 45 positions. A blank space shows a free position for the reagent.



A Activate F2 and select the reagent from the list. The position is given automatically.

-or-

B Click a blank button on the window to select the position for the reagent. Activate F2 and select the reagent from the list.

-or-

C Type the number (1-45) in the *Reagent position* field and press ↵. Activate F2 and select the reagent from the list.

Insert the reagent vial without cap in the disk. Check that there is no foam in the vial. If there is, pipette foam carefully away.

Open the reagent insert cover on the analyser. The LED starts to blink, the analyser turns to the selected position. Wait until the LED stops blinking.

Insert the reagent. Close the cover.

To remove the reagent

Click on the position of the reagent.

-or-

Type the reagent's position number in the *Reagent position* field and press ↵.

Activate F3.

☞ Open the reagent cover on the analyser. LED starts to blink, analyser turns to the selected reagent position. Wait until the LED stops blinking.

☞ Remove the reagent. Close the cover.

To check the reagent disk

☞ Activate F8/F1 when you want to check the contents of the reagent disk, i.e. the barcodes and volume of vials are read automatically.

NOTE: It is recommended to run manual QC after changing the reagent disk.

To change the reagent disk

☞ Activate F8/F2 when analysis is not in progress. Remove the reagent disk and insert a new one into the analyser.

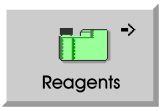
To clear the old reagent disk data

☞ Activate F8/F3 when you want to clear all data relating to the reagent disk. To free all positions of reagent disk is useful in case reagents are removed from the analyser, e.g. for the night. With F8/F3 the disk is cleared and there is no need to place reagents on the same positions next time.

To clear short list

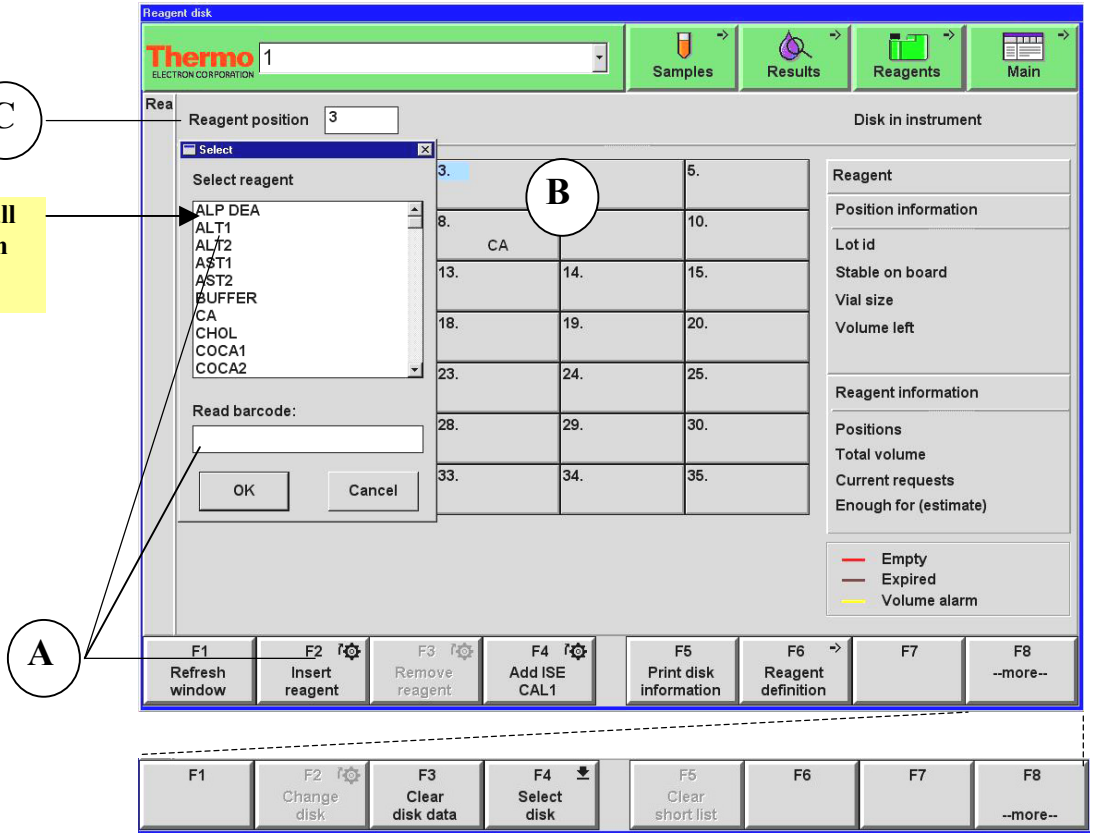
☞ Activate F8/F5 when you want to clear the reagent short list seen in the Main window, e.g. in case you don't need the short reagent for the tests measured on that day.

3.1.2.2 Konelab 20XT and Konelab 20

Activate 

(F11).

You get the REAGENT DISK window with all 35 positions. A blank space indicates a free position for the reagent.



The list includes all reagents needed in tests in use.

A Activate F2 and select the reagent from the list or read the barcode of the reagent vial with the external barcode reader. The position is given automatically.

-or-

Note that when reading barcode labels of reagents, Caps Lock in the keyboard must be off otherwise the bars become letters.

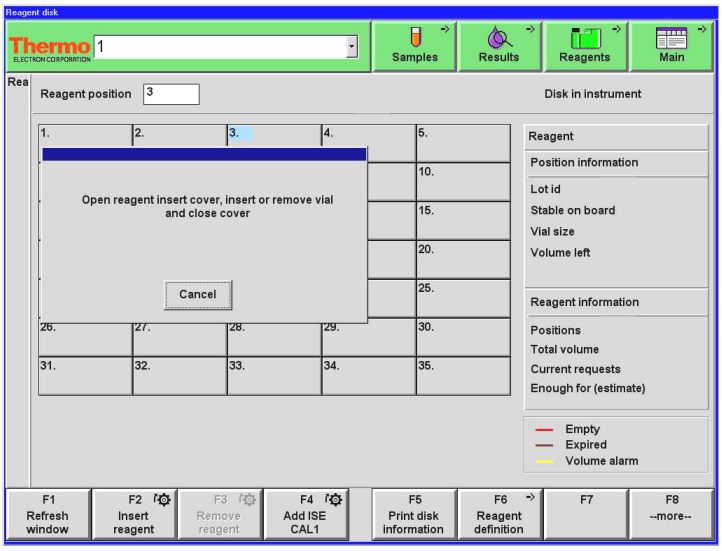
B Click a blank button on the window to select the position for the reagent. Activate F2 and select the reagent from the list or read the barcode on the reagent vial with the external barcode reader.

-or-

C Type the number (1-35) in the Reagent position field and press ↵. Activate F2 and select the reagent from the list or read the barcode on the reagent vial with the external barcode reader.

Insert the reagent vial without cap in the disk. Check that there is no foam in the vial. If there is, pipette foam carefully away.

Reagents should be cooled in the refrigerator before inserting them into the reagent disk. The disk maintains reagents cool but cannot cool them.



The LED starts to blink red, the analyser turns to the selected position. Wait until the LED stops blinking and remains green.

☞ Open the reagent insert cover, insert the reagent so that barcodes are towards the reagent LED and close the cover.

It is recommended to have 'Additional condition' in use in the QC parameters window (see section 4.5) so that routine qc is performed every time when reagent vial is changed. In case reagent vial is inserted and old ones are taken away during the ready state, the user must ask manual qc to be done. If the old reagent vials are not taken away at the same time then the routine qc is run also in this case when the analyser starts the new reagent.

To remove the reagent

Click on the position of the reagent.

-or-

Type the reagent's position number in the Reagent position field and press ↵.

☞ Activate F3. LED starts to blink red, analyser turns to the selected reagent. Wait until the LED stops blinking and remains green.

☞ Open the reagent insert cover, remove the reagent and close the cover.

NOTE: It is recommended to run manual QC after changing the reagent disk.

To change the reagent disk

Activate F8/F2 when analysis is not in progress. Remove the reagent disk and insert a new one into the analyser.

To clear the old reagent disk data

Activate F8/F3 when you want to clear all data of the reagent disk. To free all positions of reagent disk is useful in case reagents are removed from the analyser, e.g. for the night. With F8/F3 the disk is cleared and there is no need to place reagents on the same positions next time.

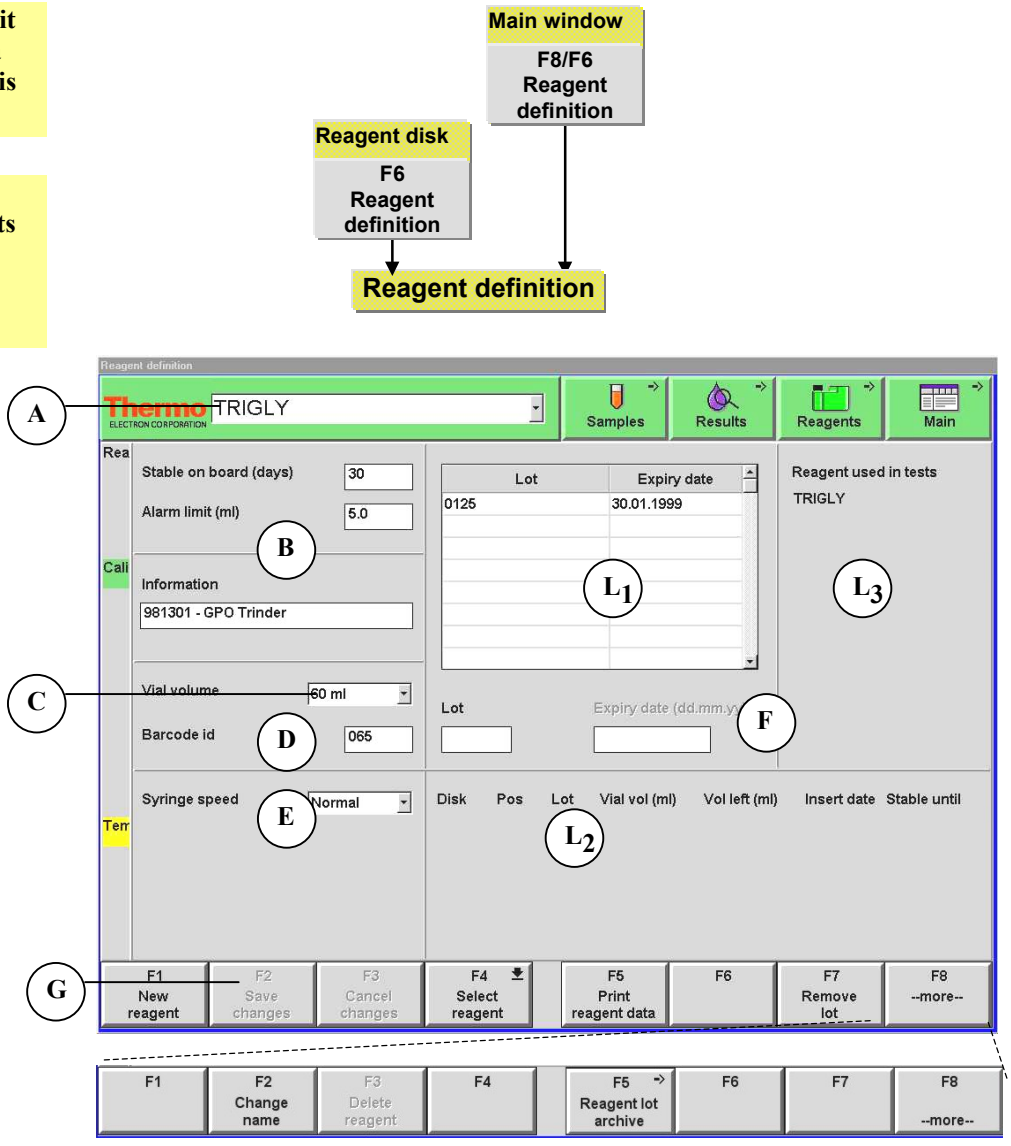
To clear short list

Activate F8/F5 when you want to clear the reagent short list seen in the Main window, e.g. in case you don't need the short reagent for the tests measured on that day.

3.1.3 EDITING THE REAGENT DATA

You can only edit the reagent data when analysing is not in progress.

When you use Konelab reagents the barcode includes all necessary data.



(A) Type the name of the reagent (max. 10 characters, cannot start with a number, the symbol & cannot be used) and press ↵.

(B) Give the other reagent's data:

- *Stable on board*	The reagent's stability on board in days.	(3 numbers)
- *Alarm limit*	The alarm limit in volume (ml).	(4 numbers)
- *Information*	General information.	(30 characters)

(C) Select the volume of the reagent vial from the pull down menu: 10, 20 or 60 ml.

The barcode index has always three numbers.

(D) Give the barcode index to the *Barcode id* field (3 numbers).

Slow syringe speed should not be used if reagent volume is over 130 µl.

(E) Select the normal or slow syringe speed when dispensing reagent. Slow syringe speed can be useful e.g. with very viscous reagents.

(F) When the reagent does not have a barcode give the lot number and the expiry date (in the form: dd.mm.yyyy, e.g. 05.12.1997) in the *Lot* and *Expiry date* fields.

(G) SAVE the selections with F2. With F3 you can CANCEL the changes made after the last SAVE.

Lists in the REAGENT DEFINITION window:

(L_1) The lot numbers and expiry dates of the reagent. Old reagent lots are cleaned when Clear files is done in the Management window. Old lots are seen in the Reagent lot archive window if archiving is in use. See section 3.9.2.

(L_2) The disk positions of the reagent:
- the reagent disk identification (*Disk*),
- the reagent position in the disk (*Pos*),
- the lot identification (*Lot*),
- the vial size in ml (*Vial vol*),
- the remaining reagent volume in the vial in ml (*Vol left*),
- the date when the reagent has been inserted in the disk (*Insert date*),
- the date of expiration (*Expiry date*).

(L_3) All tests where the reagent is used.

You can only remove the lot if it is not being used in any reagent disk and analysing is not in progress.

To remove the reagent lot

Select the reagent lot from the list (L_1) and activate F7 to remove it.

If the user first activates F7 without selecting the lot the cursor goes automatically to the first lot without removing it. Activating F7 again removes the lot.

You can only delete the reagent if it is not defined for any test, it is not in any reagent disk and analysing is not in progress.

To delete the reagent data

Activate F8/F3 to delete the reagent data.

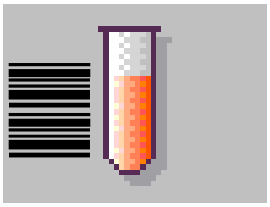
Only name is changed, not the values.

To change the reagent name

Activate F8/F2 to change the reagent name when analysis is not in progress. The analyser accepts both small and big letters, e.g. if you type Trigly, the other reagent can be named trigly. So for the same reagent, type the name exactly the same way.

3.2 SAMPLES

This chapter describes:
- how to insert a sample with and without barcode,
- the sample data in detail,
- how to handle the sample coming through the automated sample transport line,
- how to insert a STAT sample,
- how to request a calculated test,
- how to request an external test and how to give a result for it manually,
- the SAMPLE SEGMENT, DISK and LIST windows.



3.2.1 INSERTING BAR-CODED SAMPLES

☞ Insert sample cups/ tubes in the sample segment.

Insert primary tubes so deep that there is only abt. 10 mm above the segment. Insert cups as far as possible. Check that the barcode can be read from the segment's slot.

Figure 3-1: The sample segment

Do not use reflecting paper for barcodes.

3.2.1.1 Konelab 60 and Konelab 30

☞ Open the segment insert cover when the green LED is on.

☞ Remove another, analysed segment if the loader contains one.

☞ Insert a new segment in the loader so that the two positioning pins align with the segment holes. Close the cover.

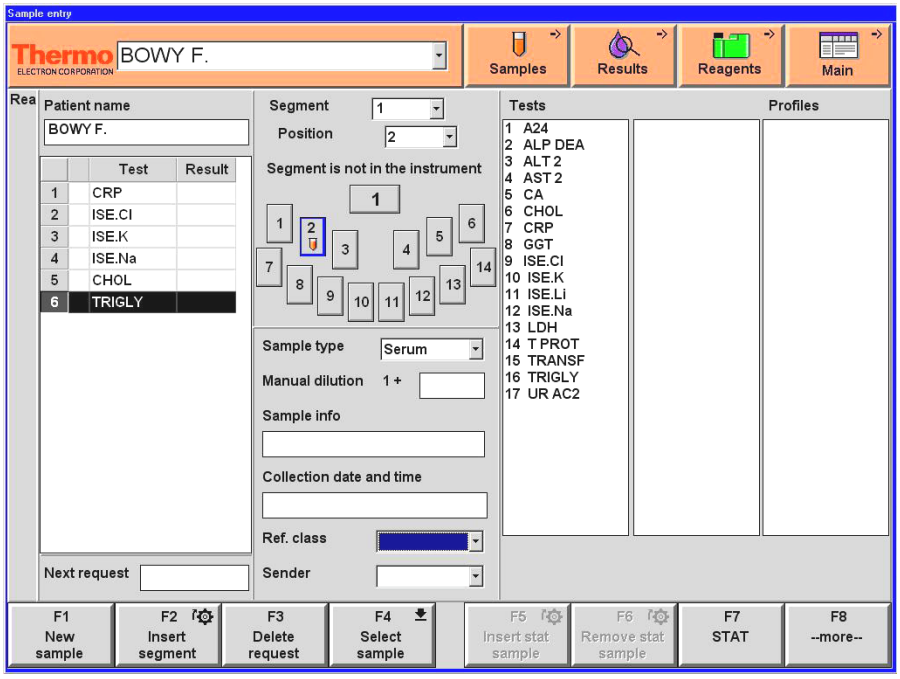
To insert requests refer to next section 3.2.2.1 items C and E or 3.2.2.2 items D and F.

☞ Activate 

(F9) and give requests.

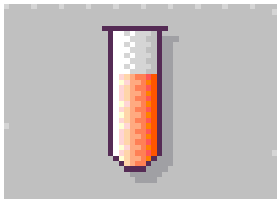
3.2.1.2 Konelab 20XT and Konelab 20

Select F2, Insert segment either in the Sample/Patient entry window or in the Segment window. The LED starts to blink red. The analyser turns to a free position. Wait until the LED stops blinking and remains green.



To insert requests refer to next section 3.2.2.1 items C and E or 3.2.2.2 items D and F.

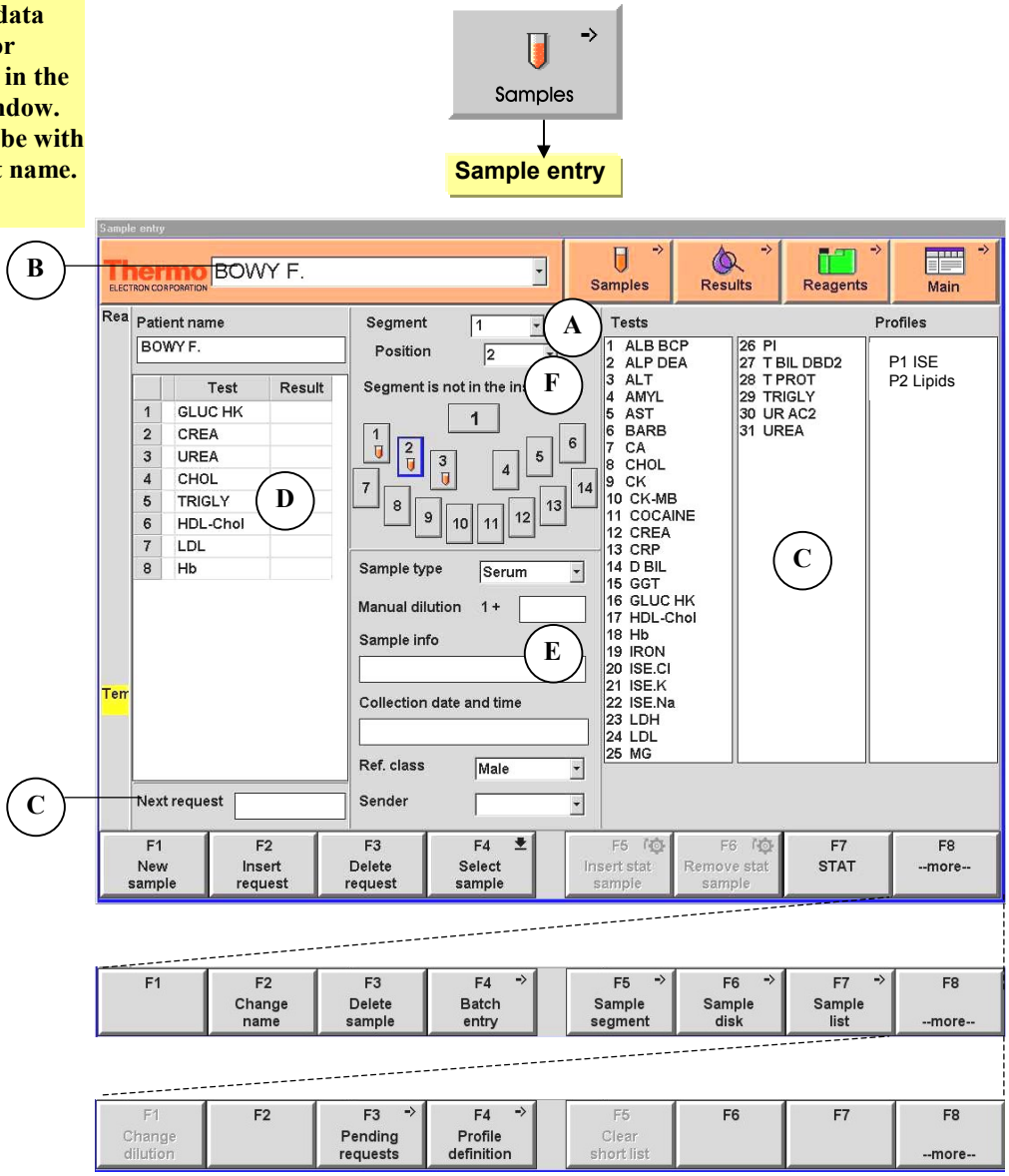
Open the segment insert cover, insert a new segment and close the cover. Give requests.



3.2.2 INSERTING SAMPLES WITHOUT BARCODE

3.2.2.1 SAMPLE ENTRY

The criterion for data entering, sample or patient, is defined in the Configuration window. Sample entry can be with or without patient name.



A Click the number of the segment where you are inserting the sample from the selection list.

-or-

Type the number in the *Segment* field and press ↵ .

A position is given automatically.

B Type the sample identification (max. 16 characters) and press ↵.
With F8/F2 you can change the sample name.

If the given sample is a calibrator or control, no other information is given in this window. In this case the identification must be exactly the same as given in the Cal/Ctrl definition window. When Konelab 60 or 30 is used the calibrator or control sample given here must be with no fixed position. Refer to section 4.6. Calibration or manual QC are requested in the Calibration/ QC selection window. Refer to section 3.4.1.

C Test selection:

Click the desired tests from the test or profile lists seen on the right of the window to enter the requests.

-or-

Type the test or profile name or number in the *Next request* field and press ↵.

The tests are numbered in alphabetical order. The profile has the letter P before the number.

If Konelab is connected to the laboratory information system with ASTM protocol as defined in the Configuration window (section 3.8) requests can be asked for from the host computer. In this case the user has to wait before going on.

D The selected requests are seen as a list with the order number and the test name. An accepted result is shown later.

The normal request waiting for the analysis can be changed to a STAT request. Click the test and press F7, STAT. The request is marked with the sign !.

If the requested test is screened with another test, then the request seen in the list is the screening test (not the original test) with the mark S. For example you request U-Alb but screening test for it is U/CSF Prot, so in the list you see U/CSF Prot with S. When result of screening test is accepted, request of original test is created automatically with the mark R (as Reflex test). Result of screening test is used to determine the right dilution ratio for the original test.

E Give the sample information:

- *Sample type* — Select the sample type from the pull down menu. The alternatives are: *Serum*, *Plasma*, *Urine*, *Csf* and *Other*.
- *Manual dilution* — Give the manual dilution if you insert a diluted sample in the segment. Type the part of a diluent versus one part of a sample, e.g. 1 + 4 corresponds to 1:5. This information is needed for the calculation of the sample result.
- *Sample info* — Type the additional sample information, e.g. a lipemic or icteric sample.
- *Collection date and time* — Type the sample collection time.
- *Ref class* — Select the reference class from the pull down menu.
- *Sender* — Select the sender information from the pull down menu.

The user is warned if the selected sample type differs from that given in Test definition. Refer to sections 4.1.2. and 4.1.3.

F You can change the sample position (1-14) by clicking a new position number from the list or by clicking a free sample position button.

Reserved positions are marked with a sample tube, e.g. 

You can also change the position by typing a new number in the *Position* field and pressing ↵.

Clicking the reserved sample position button gives the sample data for that position to the window.

Clicking the segment button gives the segment data in the Sample segment window.

Insert primary tubes so deep that there is only abt. 10 mm above the segment. Insert cups as far as possible. Check that the barcode can be read from the segment's slot.

☞ Insert the sample cup/tube in the right segment position.

Activate F1 to give a new sample.

When you insert the segment into the analyser in Konelab 60 or Konelab 30:

☞ Open the segment insert cover when the green LED is on.

☞ Remove another, analysed segment if the loader contains one.

☞ Insert the new segment in the loader so that the two positioning pins align with the segment holes. Close the cover.

When you insert the segment into the analyser in Konelab 20XT or Konelab 20:

☞ Select F2, Insert segment. The LED starts to blink red. The analyser turns to a free position. Wait until the LED stops blinking and remains green.

☞ Open the cover, insert the segment and close the cover.

In case of a short sample

☞ Give another segment number to the sample and insert a new sample cup/ tube into another segment.

- or -

☞ Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. The segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

To remove the sample from the segment

☞ Select *Remove* from the Segment selection list or empty the Segment field or type 0 and press ↵. Remove also the sample cup/ tube from the segment.

To delete the request

Select the request on the list and activate F3 to remove it.

If the user activates F3 without selecting any request the cursor goes automatically to the request list without deleting anything. In this case activate F3 again to delete the request.

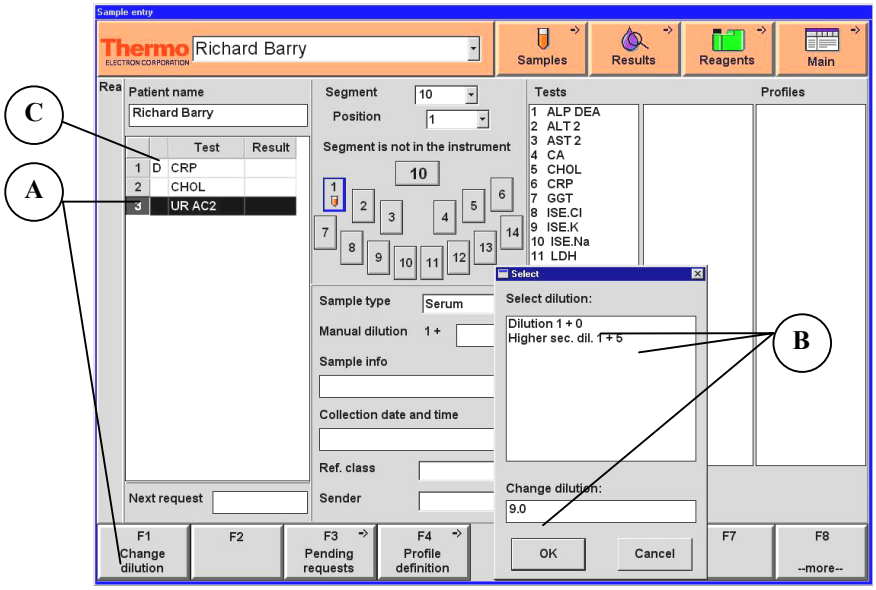
To delete the sample

Select F8/F3 to delete sample data.

To clear short list

Activate F8/F8/F5 to clear the sample short list seen in the Main window, e.g. in case you can't measure the sample on that day.

To change dilution



A Select the request and activate F8/F8/F1 when you want that the sample is automatically diluted for that particular test.

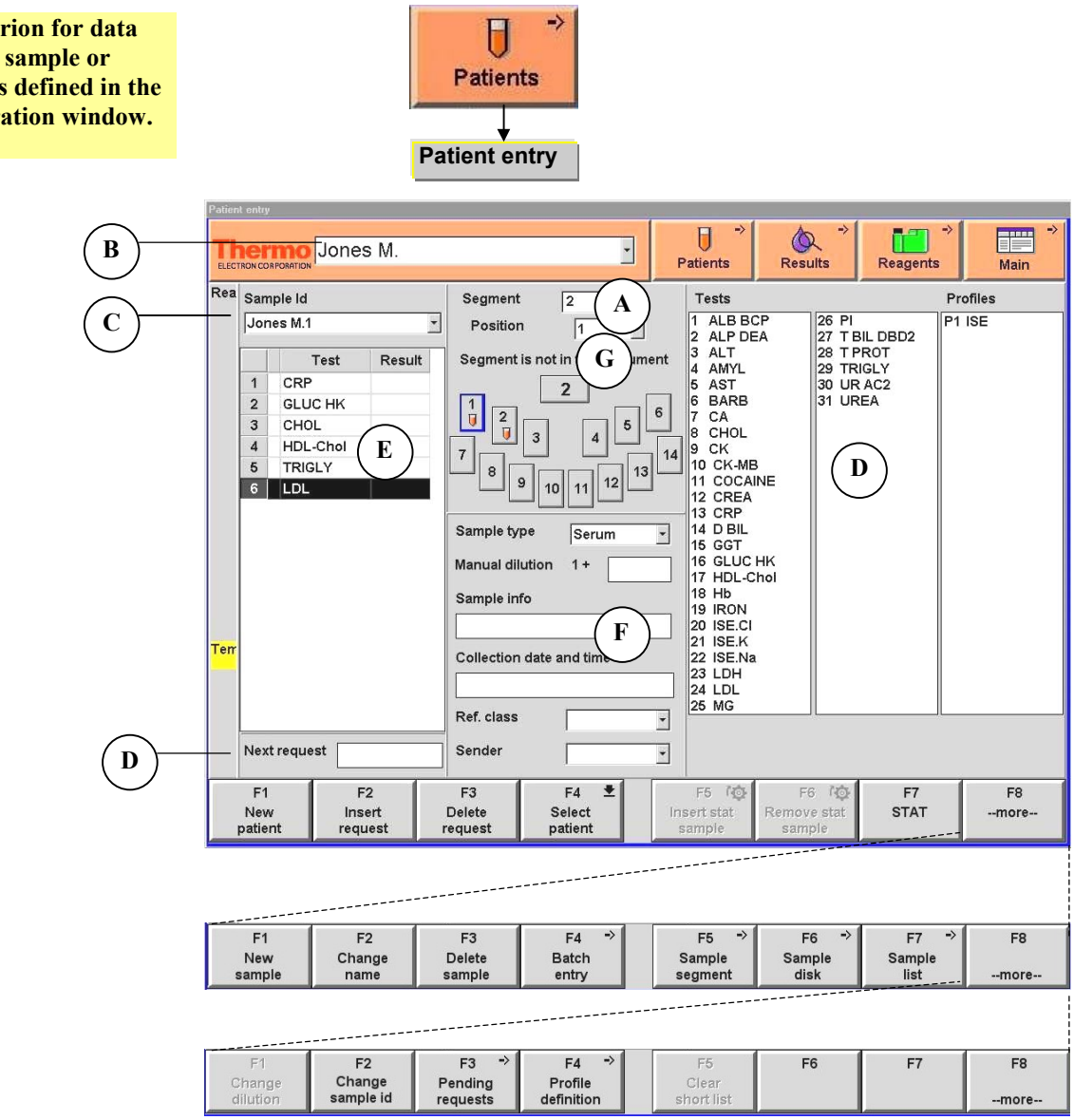
If you have been already in another window than Sample entry, you have to first delete the request and select it immediately again to be able to change dilution.

B Select the dilution according to ratios given in parameters or give a new ratio. It can vary between 1 and 120 with 0.5 decimal. Note that e.g. 9.0 means that the sample is diluted 1+ 9 corresponding to 1:10.

C The letter D informs that the sample is diluted for that test.

3.2.2.2 PATIENT ENTRY

The criterion for data entering, sample or patient, is defined in the Configuration window.



A Click the number of the segment where you are inserting the sample from the selection list.

-or-

Type the number in the *Segment* field and press ↵ .

A position is given automatically.

B Type the patient identification (max. 16 characters) and press ↵.
With F8/F2 you can change the patient name.

If the given sample is a calibrator or control, no other information is given in this window. In this case the identification must be exactly the same as given in the Cal/Ctrl definition window. When Konelab 60 or 30 is used the calibrator or control sample given here must be with no fixed position. Refer to section 4.6. Calibration or manual QC are requested in the Calibration/ QC selection window. Refer to section 3.4.1.

C The sample id is given automatically. The default is the patient name.
With F8/F8/F2 you can change the sample identification.

D Test selection:

Click the desired tests from the test or profile lists seen on the right of the window to enter the requests.

-or-

Type the test or profile name or number in the *Next request* field and press ↵.

The tests are numbered in alphabetical order. The profile has the letter P before the number.

If Konelab is connected to the laboratory information system with ASTM protocol as defined in the Configuration window (section 3.8) requests can be asked for from the host computer. In this case the user has to wait before going on.

E The selected requests are seen as a list with the order number and the test name. An accepted result is shown later.

The normal request waiting for the analysis can be changed to a STAT request. Click the test and press F7, STAT. The request is marked with the sign !.

If the requested test is screened with another test, then the request seen is the screening test (not the original test) with the mark S. For example you request U-Alb but screening test for it is U/CSF Prot, so in the list you see U/CSF Prot with S. When result of screening test is accepted, request of original test is created automatically with the mark R (as Reflex test). Result of screening test is used to determine the right dilution ratio for the original test.

F Give the sample information:

- *Sample type* — Select the sample type from the pull down menu. The alternatives are: *Serum*, *Plasma*, *Urine*, *Csf* and *Other*.
- *Manual dilution* — Give the manual dilution if you insert a diluted sample in the segment. Type the part of a diluent versus one part of a sample, e.g. 1 + 4 corresponds to 1:5. This information is needed for the calculation of the sample result.
- *Sample info* — Type the additional sample information, e.g. a lipemic or icteric sample.
- *Collection date and time* — Type the sample collection time.
- *Ref class* — Select the reference class from the pull down menu.
- *Sender* — Select the sender information from the pull down menu.

The user is warned if the selected sample type differs from that given in Test definition. Refer to sections 4.1.2. and 4.1.3.

G You can change the sample position (1-14) by clicking a new position number from the list or by clicking a free sample position button.

Reserved positions are marked with a sample tube, e.g. 

You can also change the position by typing a new number in the *Position* field and pressing ↵.

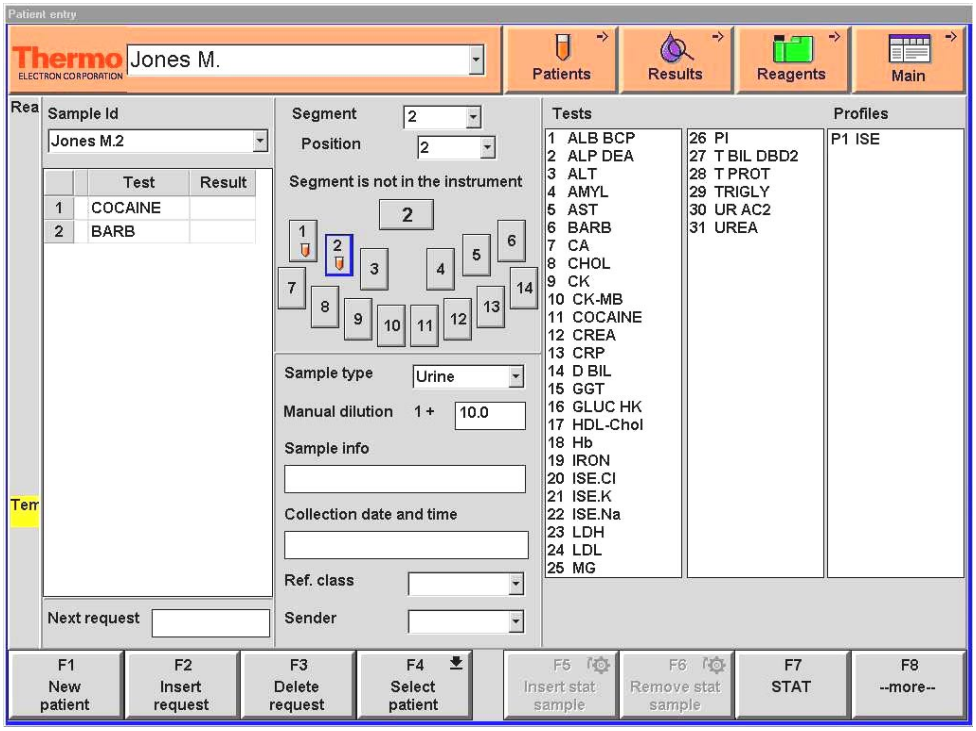
Clicking the reserved sample position button gives the sample data for that position to the window.

Clicking the segment button gives the segment data in the Sample segment window.

Insert primary tubes so deep that there is only abt. 10 mm above the segment. Insert cups as far as possible. Check that the barcode can be read from the segment's slot.

☞ Insert the sample cup/tube in the right segment position.

☞ Activate F8/F1 to give a new sample to the same patient. Give the sample ID.



Activate F1 to give a new patient.

When you insert the segment into the analyser in Konelab 60 or Konelab 30:

☞ Open the segment insert cover when the green LED is on.

☞ Remove another, analysed segment if the loader contains one.

☞ Insert the new segment in the loader so that the two positioning pins align with the segment holes. Close the cover.

When you insert the segment into the analyser in Konelab 20XT or Konelab 20:

☞ Select F2, Insert segment. The LED starts to blink red. The analyser turns to a free position. Wait until the LED stops blinking and remains green.

☞ Open the cover, insert the segment and close the cover.

In case of a short sample

☞ Give another segment number to the sample and insert a new sample cup/ tube into another segment.

- or -

☞ Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. The segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

To remove the sample from the segment

☞ Select *Remove* from the Segment selection list or empty the Segment field or type 0 and press ↵. Remove also the sample cup/ tube from the segment.

To delete the request

Select the request on the list and activate F3 to remove it.

If the user activates F3 without selecting any request the cursor goes automatically to the request list without deleting anything. In this case activate F3 again to delete the request.

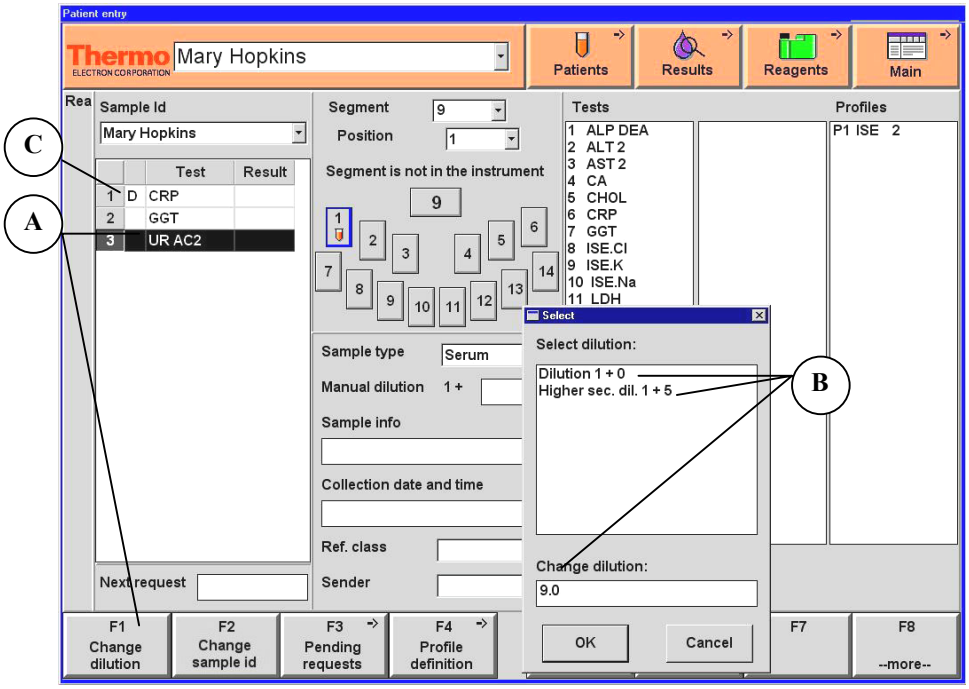
To delete the sample

Select F8/F3 to delete sample data.

To clear short list

Activate F8/F8/F5 to clear the sample short list seen in the Main window, e.g. in case you can't measure the sample on that day.

To change dilution



A Select the request and activate F8/F8/F1 when you want that the sample is automatically diluted for that particular test.

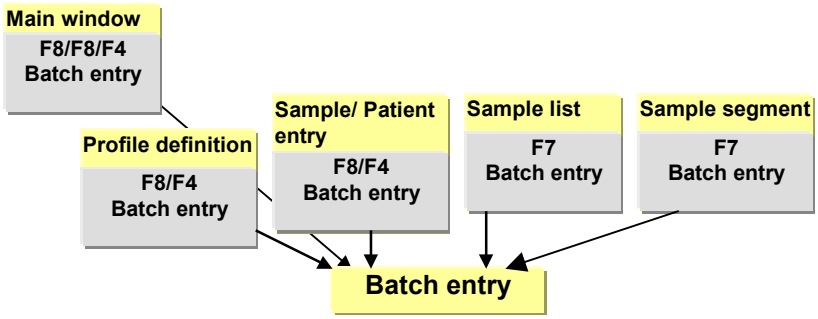
If you have been already in another window than Patient entry, you have to first delete the request and select it immediately again to be able to change dilution.

B Select the dilution according to ratios given in parameters or give a new ratio. The ratio can vary between 1 and 120 with 0.5 decimal. Note that e.g. 9.0 means that the sample is diluted 1+ 9 corresponding to 1:10.

C The letter D informs that the sample is diluted for that test.

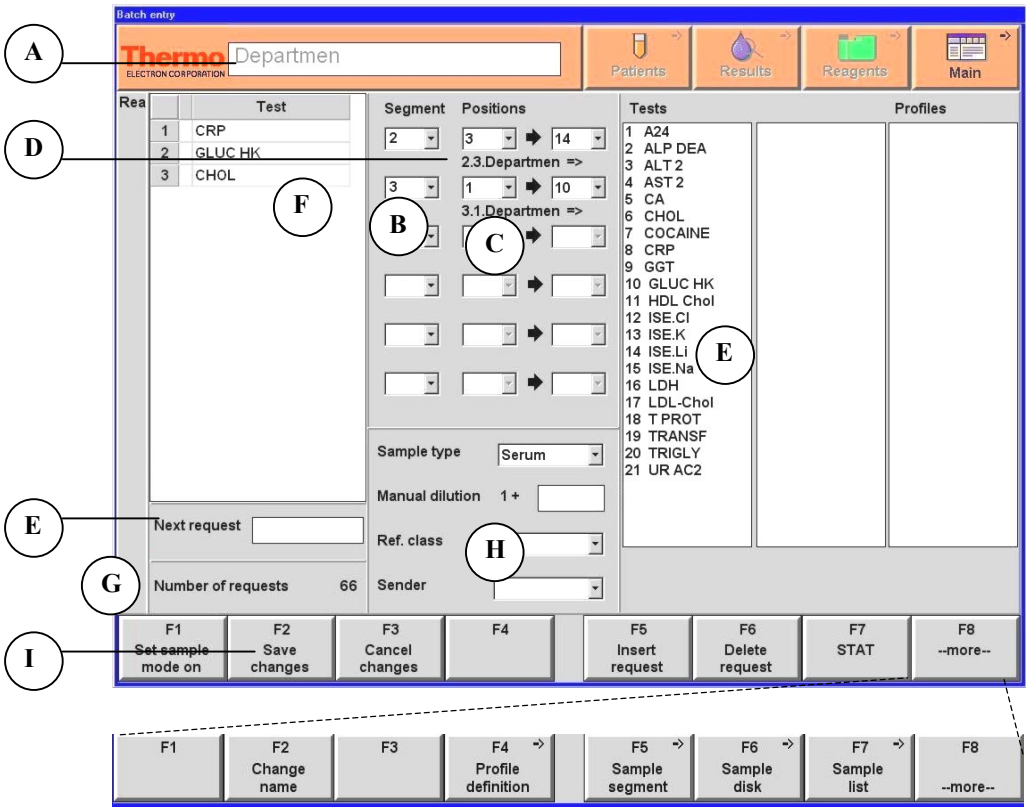
3.2.2.3 BATCH ENTRY

Batch entry is convenient to use when you have lot of samples without barcodes to insert with the same test requests.



With F1 button you can select either segment mode or sample mode on. In segment mode you put sample cups immediately into their positions in the segment. In sample mode you can later insert samples and pick up positions, e.g., in the sample segment window.

3.2.2.3.1 Segment mode



A Type the batch identification (max. 9 characters) and press ↵.
With F8/F2 you can change the batch name.

B Click the number of the segment, where you are inserting the batch of samples, from the selection list.

-or-

Type the number in the *Segment* field and press ↵.

C All free positions of a segment are given automatically. You can change the first and the last position by clicking a new position number from the list or by typing a new number in the *Position* field and pressing ↵. **Batch samples must be in the sequential order in the segment.**

D The sample identification is given automatically. It is formed as segment id.position id.batch id, e.g. in the segment 2 position 9 being sample is named as 2.9.Departmen.

E Test selection:

Click the desired tests from the test or profile lists seen on the right of the window to enter the requests.

-or-

Press F5 and type the test or profile name or number in the *Next request* field and press ↵. The tests are numbered in alphabetical order. The profile has the letter P before the number.

If Konelab is connected to the laboratory information system with ASTM protocol as defined in the Configuration window (section 3.8) requests can be asked for from the host computer. In this case the user has to wait before going on.

F The selected requests are seen as a list with the order number and the test name.

G The total number of requests is seen automatically. In this example, 22 samples with 3 requests are together 66 requests.

H Give the batch information for the samples:

The user is warned if the selected sample type differs from that given in Test definition. Refer to sections 4.1.2. and 4.1.3.

- *Sample type* — Select the sample type from the pull down menu. The alternatives are: *Serum*, *Plasma*, *Urine*, *Csf* and *Other*.
- *Manual dilution* — Give the manual dilution if you insert diluted samples in the segment. Type the part of a diluent versus one part of a sample, e.g. 1 + 4 corresponds to 1:5. This information is needed for the calculation of the sample result.
- *Ref class* — Select the reference class from the pull down menu.
- *Sender* — Select the sender information from the pull down menu.

Insert primary tubes so deep that there is only abt. 10 mm above the segment. Insert cups as far as possible.

I Save the selections with F2 before you insert the segment into the analyser. With F3 you can cancel the changes made after the last save.

☞ Insert sample cups/tubes in the right segment positions.

When you insert the segment into the analyser in Konelab 60 or Konelab 30:

☞ Open the segment insert cover when the green LED is on.

☞ Remove analysed segment if the loader contains one.

☞ Insert the new segment in the loader so that the two positioning pins align with the segment holes. Close the cover.

When you insert the segment into the analyser in Konelab 20XT or Konelab 20:

☞ Select F2, Insert segment in the Sample segment window. The LED starts to blink red. The analyser turns to a free position. Wait until the LED stops blinking and remains green.

☞ Open the cover, insert the segment and close the cover.

In case of a short sample

☞ Give another segment number to the sample and insert a new sample cup/ tube into another segment.

- or -

☞ Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. The segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

To remove the batch data from the segment

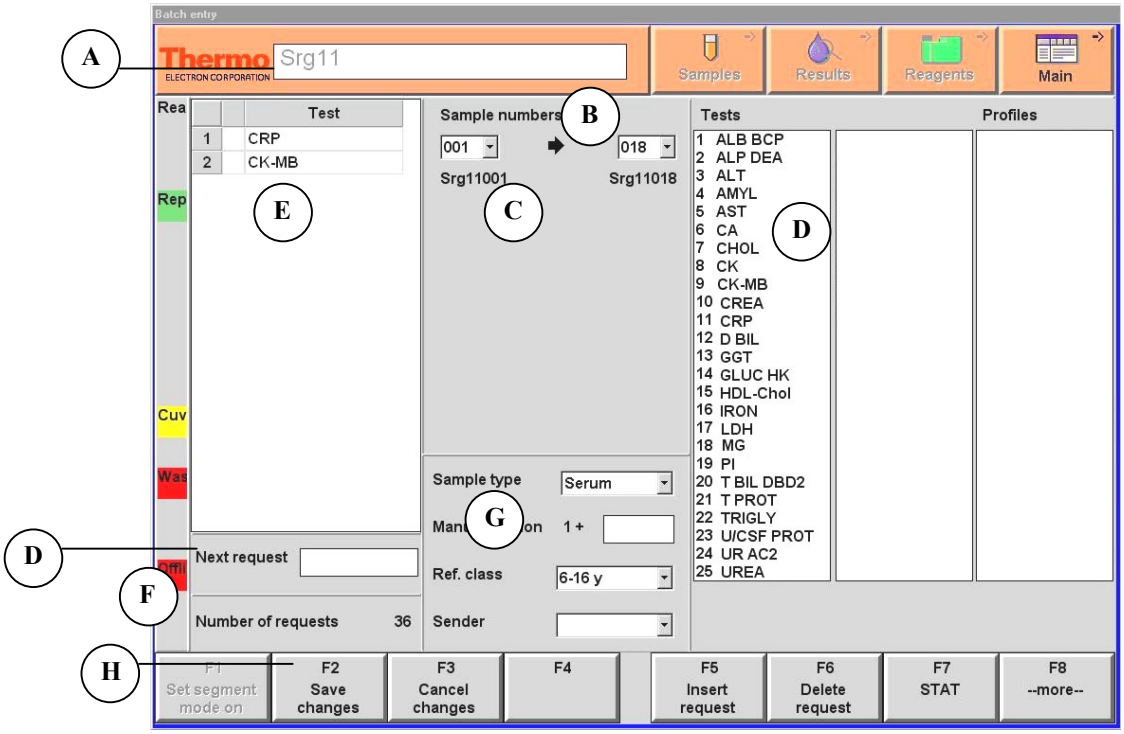
Empty the *Segment* field or type 0. Remove also the sample cups/ tubes from the segment.

To delete the request

Select the request on the list and activate F6 to remove it.

If the user activates F6 without selecting any request the cursor goes automatically to the request list without deleting anything. In this case activate F6 again to delete the request.

3.2.2.3.2 Sample mode



A Type the batch identification (max. 13 characters) and press ↵. With F8/F2 you can change the batch name.

B You can give the first and the last sample number by clicking a new number from the list or by typing a new number in the *Sample numbers* field and pressing ↵. **Batch samples must be in the sequential order in the segment**. The max number of batch is 1000 samples.

C The sample identification is given automatically. It is formed as batch idsample number, e.g. in the batch Srg11 sample number 12 is named as Srg11012.

D Test selection:

Click the desired tests from the test or profile lists seen on the right of the window to enter the requests.

-or-

Press F5 and type the test or profile name or number in the *Next request* field and press ↵. The tests are numbered in alphabetical order. The profile has the letter P before the number.

If Konelab is connected to the laboratory information system with ASTM protocol as defined in the Configuration window (section 3.8) requests can be asked for from the host computer. In this case the user has to wait before going on.

E The selected requests are seen as a list with the order number and the test name.

F The total number of requests is seen automatically. In this example 18 samples with 2 requests makes totally 36 requests.

The user is warned if the selected sample type differs from that given in Test definition. Refer to sections 4.1.2. and 4.1.3.

G Give the batch information for the samples:

- *Sample type* — Select the sample type from the pull down menu. The alternatives are: *Serum*, *Plasma*, *Urine*, *Csf* and *Other*.
- *Manual dilution* — Give the manual dilution if you insert diluted samples in the segment. Type the part of a diluent versus one part of a sample, e.g. 1 + 4 corresponds to 1:5. This information is needed for the calculation of the sample result.
- *Ref class* — Select the reference class from the pull down menu.
- *Sender* — Select the sender information from the pull down menu.

H Save the selections with F2. With F3 you can cancel the changes made after the last save.

To delete the request

Select the request on the list and activate F6 to remove it.

If the user activates F6 without selecting any request the cursor goes automatically to the request list without deleting anything. In this case activate F6 again to delete the request.

3.2.3 SAMPLES COMING THROUGH AUTOMATED SAMPLE TRANSPORT LINE

When Konelab is equipped with the KUSTI option and samples are loaded through the automation system, they are directed to the bypass module. Tubes are stopped and fixed on the dispensing position and from there the sample is dispensed to the disposable KUSTI segment in Konelab.

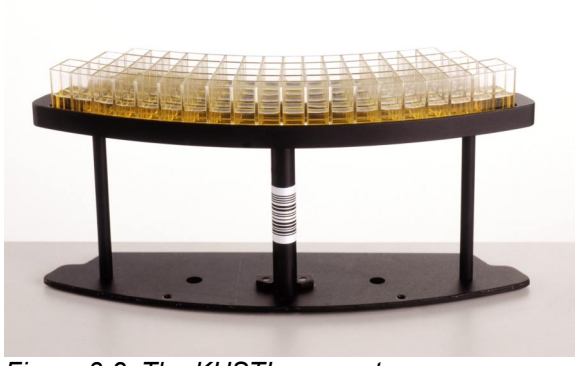


Figure 3-2: The KUSTI segment

Inserting KUSTI segment into the analyzer

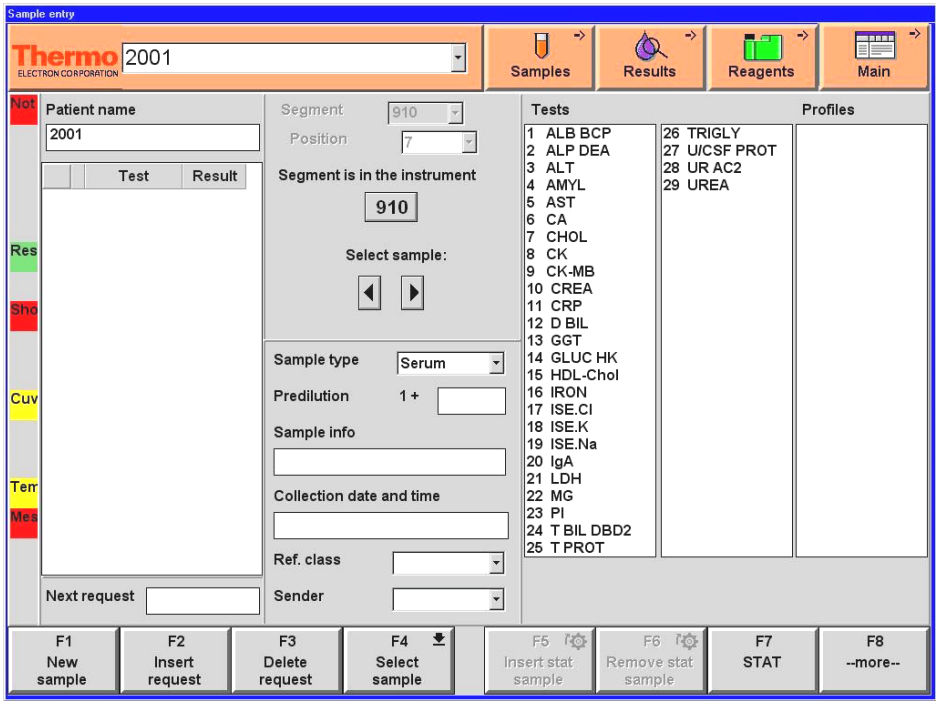
☞ Open the segment insert cover when the green LED is on.

☞ Remove analysed segment if the loader contains one.

☞ Insert a new segment in the loader so that the two positioning pins align with the segment holes. Close the cover.

If necessary, requests can be given in the Sample/Patient entry window.

To insert requests refer to 3.2.2.1 items C and E or 3.2.2.2 items D and F.

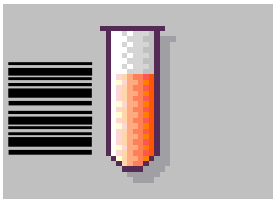


Refer to section 3.2.7.2. for more information about KUSTI segment window.

3.2.4 STAT SAMPLES

3.2.4.1 INSERTING BAR-CODED STAT SAMPLES

Konelab 60 and Konelab 30



Open the STAT insert cover on the analyser to insert a bar-coded STAT sample. The LED starts to blink. The analyser turns to a free STAT position. Wait until the LED stops blinking and remains green.

Insert the sample so that the barcode is in the middle of the slot. Close the cover.

Activate 

(F9), give requests in the same way as for normal samples. Refer to the section 3.2.2.1 items C and E or 3.2.2.2. items D and F.

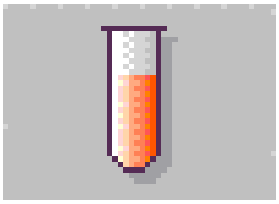
Konelab 20XT and Konelab 20

Activate Samples (F9), select F5, *Insert stat sample.* The LED starts to blink. The analyser turns to a free STAT position. Wait until the LED stops blinking and remains green.

Open then cover, insert the STAT sample so that the barcode is in the middle of the slot. Close the cover.

Give the requests in the same way as for normal samples in the Sample/Patient entry window. Refer to the section 3.2.2.1 items C and E or 3.2.2.2. items D and F.

3.2.4.2 INSERTING STAT SAMPLES WITHOUT BARCODE



Activate Samples (F9), give the sample/patient/calibrator/control identification, requests and other sample information. Refer to the section 3.2.2.1 items B, C and E or 3.2.2.2 items B, D and F.

Activate F5, *Insert stat sample.*

In Konelab 60 and 30 open the STAT insert cover. The LED starts to blink. The analyser turns to a free STAT position. Wait until the LED stops blinking and remains green. In Konelab 20XT and 20 open the STAT insert cover now.

Insert the STAT sample and close the cover.

3.2.4.3 REMOVING STAT SAMPLES

A STAT sample can be removed when analysis is not in progress or when the STAT sample is analysed or when it is short.

Activate Samples (F9) and select the STAT sample to be removed.

Activate F6, *Remove STAT sample.*

Open the STAT insert cover in Konelab 60 and 30. The LED starts to blink. The analyser turns to the selected STAT sample position. Wait until the LED stops blinking and remains green. In Konelab 20XT and 20 open the STAT insert cover now. Take the sample and close the cover.

3.2.4.4 INSERTING A SAMPLE WITH STAT REQUESTS IN A SEGMENT

STAT positions will be prioritised during analysis. First introduced STAT samples are handled first.

Samples can also be introduced with STAT requests into segments as routine samples. Refer to the sections 3.2.1. and 3.2.2.

☞ In the SAMPLE/ PATIENT/ BATCH ENTRY window activate F7, *STAT*, to define requests as STAT requests. Over the button is the text *!Stat ON* and the requests are marked with the sign !

To return to the normal mode activate F7 (with the text *STAT off*) again. Editing a new sample also turns the STAT mode to the normal mode.

3.2.5 CALCULATED TEST

A result can be calculated from the measured and entered data, and the desired result will be included in the result report.

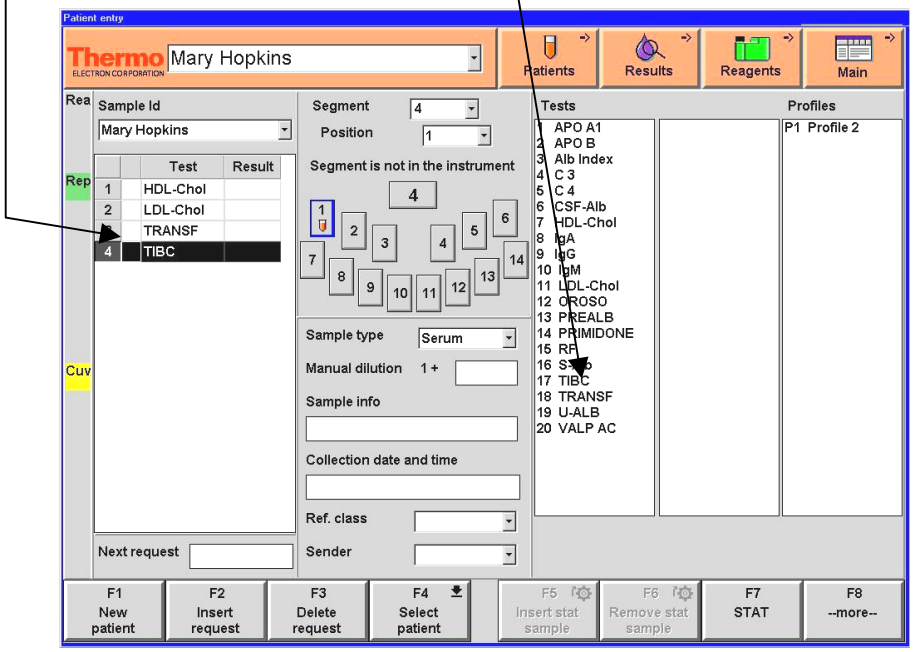
Two types of calculated tests exist:

1) Calculated (sample)

A result can be calculated from a single sample. For example total iron binding capacity (TIBC) is calculated as follows:

TIBC (mg/l) = Transferrin (g/l) x 1.25

When a calculated (sample) test has been defined in the test parameters (refer to section 4.1.4) it can be requested as a normal test. It generates the needed test requests automatically. So, do not ask those test requests separately.



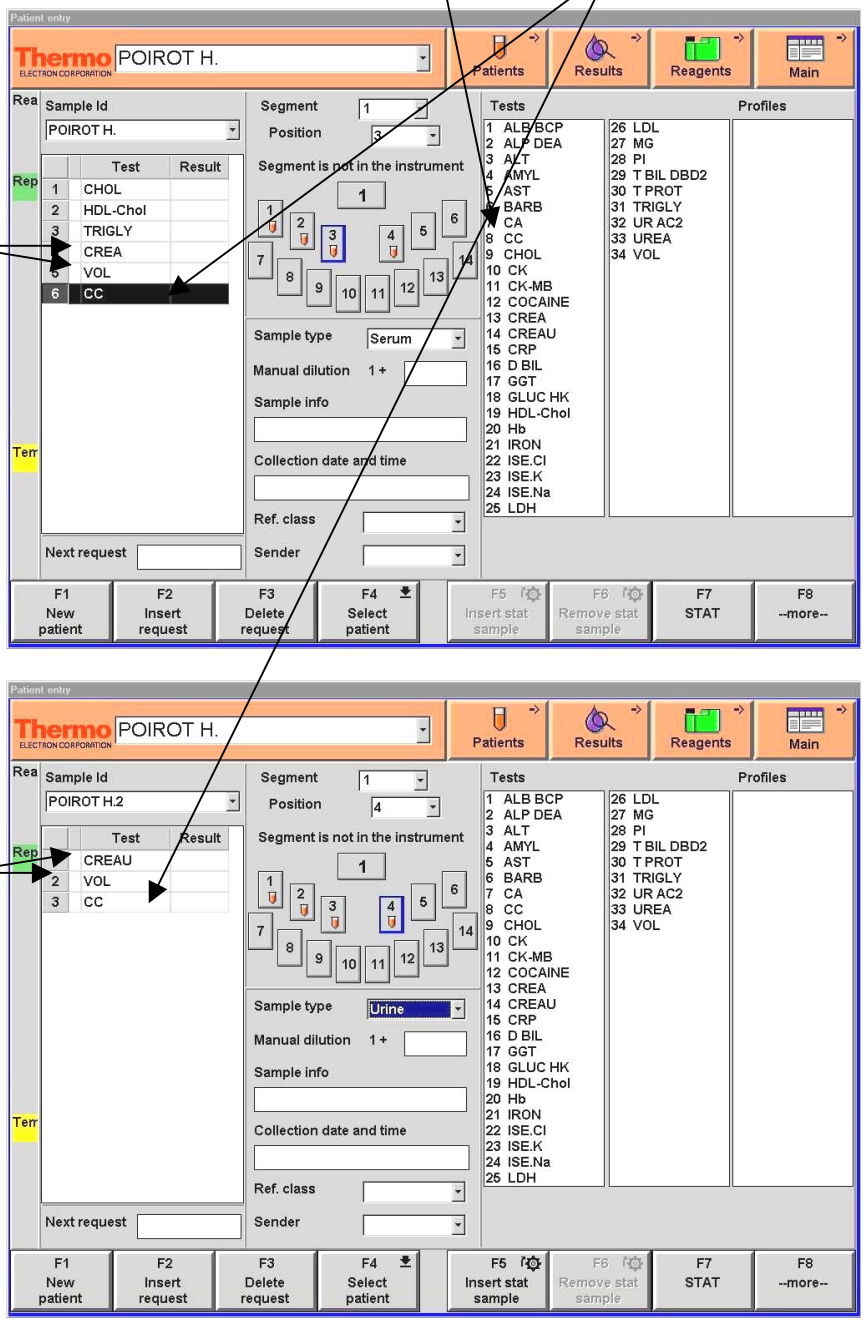
2) Calculated (patient)

A result calculation uses at least two samples of the same patient. For example the creatinine clearance (CC) is defined as following:

CC = (CREAU * VOL) / CREA

Where CREAU is the creatinine result from the urine sample,
CREA is the creatinine result from the serum sample and
VOL is the volume of 24 hours' urine collection (VOL has to be defined as an external test, refer to section 4.1.1. Result for the urine volume is given manually in the External results window, refer to section 3.2.6.1)

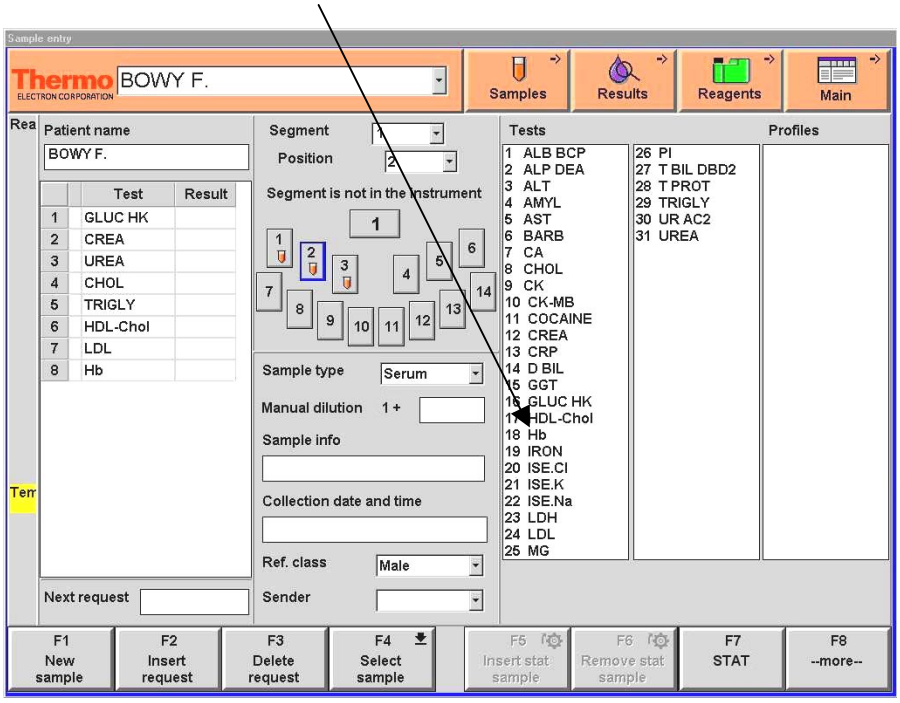
When a calculated (patient) test has been defined in the test parameters (refer to section 4.1.4) it can be requested from the test list. **First introduce all test requests belonging to the calculated (patient) test and last the calculated test itself.**



3.2.6 EXTERNAL TEST

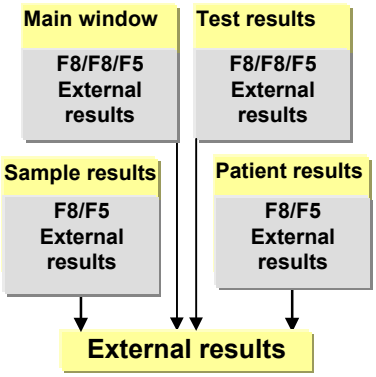
Results, which have been analysed by other analysers, can be entered manually to provide fully collated result reports.

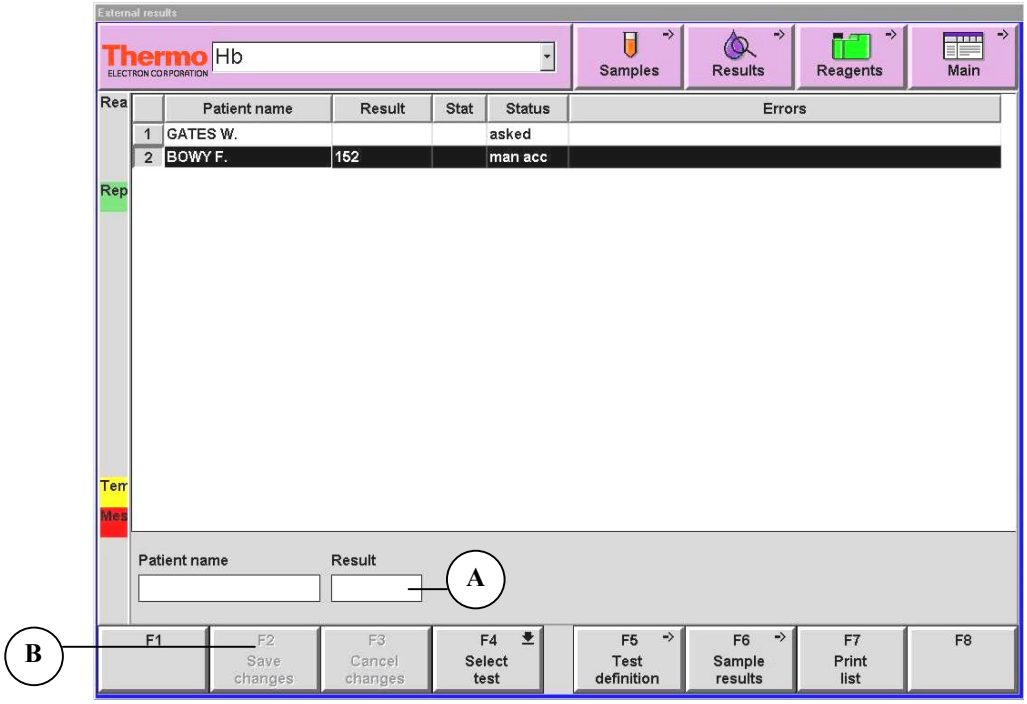
When an external test has been defined in the test parameters (refer to section 4.1.1) it can be requested as a normal test.



Result for the external test is given manually in the External results window. Refer to next page.

3.2.6.1 EXTERNAL RESULTS





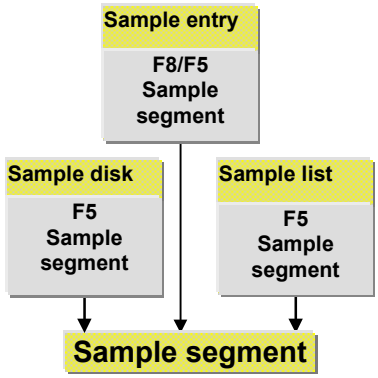
All the given requests for the external test is seen automatically in the External results window.

A Give the result for the external test's request.

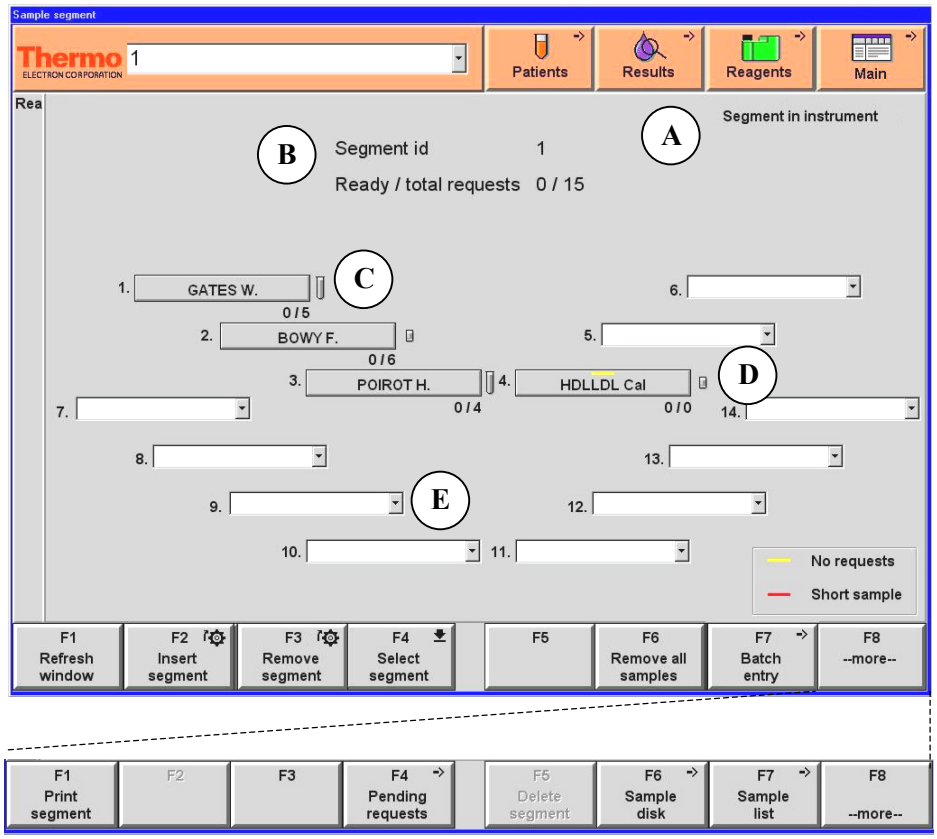
B Save the data with F2. With F3 you can cancel the changes made after the last save.

To print the list, activate F7.

3.2.7 SEGMENTS



3.2.7.1 SAMPLE SEGMENT



A Segment's status is seen up right:
- *Segment in instrument*
- *Please remove segment when green led is on*
- *Segment NOT in instrument*

B Segment's identification, the number of ready, accepted requests and the number of total requests are seen.

C Sample's identification, the number of ready, accepted requests and the number of total requests are seen. You can click the button to see the sample data in the Sample/Patient entry window.

D The inserted sample vial type, cup or tube, is seen.

E A free sample position is seen as a blank field in the window.

- You can give a new sample by typing identification in a blank field and pressing ↵. The field, now with sample ID, if pressed displays the Sample/Patient entry window (also accessed by pressing F9). Give requests and all necessary information for the sample.
- You can select a position for the sample, which has no position assigned as yet, e.g. the sample data has been given on-line. Click the sample identification from the list attached with every free position or type the sample identification exactly as it has been given previously.
- You can change the sample position inside the segment or between the segments (not between the segments, which are already in the analyser except in the case of a short sample).

To insert the segment

Activate F2 when you use Konelab 20 and 20XT. Wait until the LED remains green, open the cover and insert segment.

In Konelab 30 and 60 you can open the segment insert cover always when the green LED is on.

To remove the segment

☞ Activate F3.

Segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

It is recommended to remove the segment:
- when the segment is ready (= analysed and requests are accepted or rejected),
- when the instrument is not analysing,
- when all segment data is not correct. In this case the data which was not correct disappears.

No requests (a yellow line on the sample id button)

- Click the sample identification button or press F9 and give requests for the sample in the Sample/Patient entry window. Refer to section 3.2.2.
- If the sample is a calibrator or a control, request calibration or manual QC in the Calibration/QC selection window. Refer to section 3.4.1.

Short sample (a red line on the sample id button)

- Click the sample button, give another segment number and insert a new sample cup/ tube into another segment.

- or -

- Remove the segment by F3 and add fresh sample to the cup/ tube in the segment.

F6 is not needed with the bar-coded samples because the information read from the barcode labels displaces the old data.

To clear the old sample data

After analysing activate F6 to clear the old sample data when the segment is no longer in the analyser.

To delete the segment

Activate F8/F5 to delete the segment id, e.g. if the segment has been damaged or when the instrument has been unable to read the segment's barcode.

3.2.7.1.1 DISCARDED SEGMENT OR SEGMENT DATA NOT OK

The user is alerted if the segment is in the instrument and there is something wrong with the segment's data. In the Main window is seen 'Discarded segment' in case the segment's barcode cannot be read. When the segment's data is not ok, the segment's button has a red line with beside it the text: *Check data*.

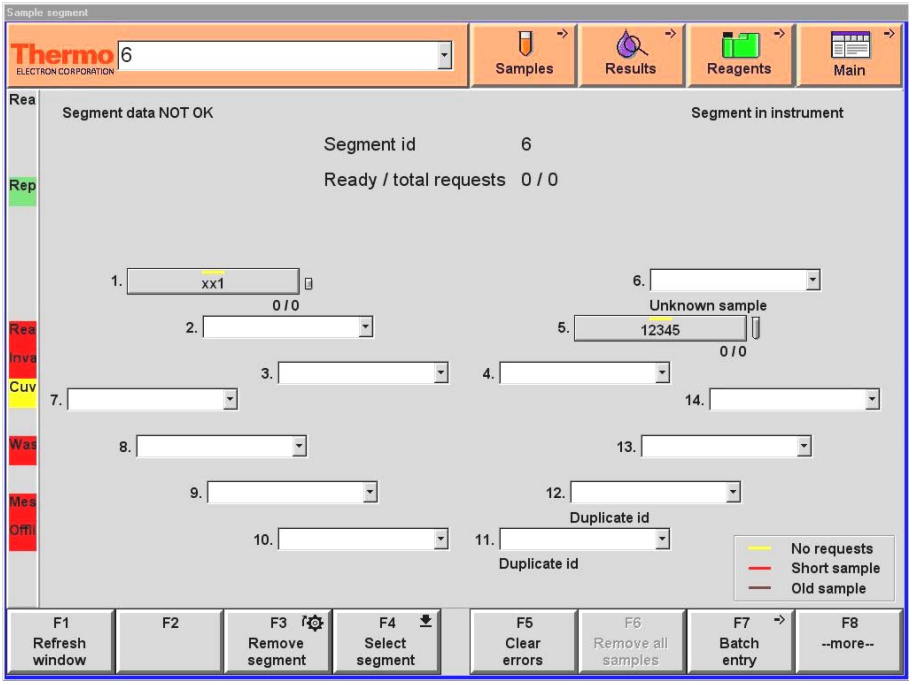
Discarded segment

In Konelab 30 and 60, the discarded segment is in the segment loader. Open the segment insert cover, and remove segment. Replace the proper barcode to it.

In Konelab 20 and 20XT, select F2, Insert segment in the Sample/patient entry or Segment window. After that you can remove the discarded segment. Replace the proper barcode to it.

Segment data not OK

F5, Clear errors empties the sample data of ALL positions where there is either Unknown sample or Duplicate id. Samples with problems will not be analysed but the analysis of other samples in that segment will continue.



In the SAMPLE SEGMENT window the message *'Segment data NOT OK.'* is seen up left. Under the sample position button is either the text *Unknown sample* or *Duplicate id*.

UNKNOWN SAMPLE:

A) A sample tube without barcode is in the segment and the user has not given the data for the sample.

- Type the sample identification in the field and press ↵. There appears a button. Click on it or press F9 to open the Sample/Patient entry window. Give requests and all necessary information for the sample.

Note that the analyser cannot recognise if the segment has a sample cup without the data.

B) The instrument has been unable to read the barcode.

- Remove the segment from the instrument activating F3. When the LED is green open the segment insert cover and turn the sample tube so that the barcode is seen from the segment's slot. Close the segment insert cover.

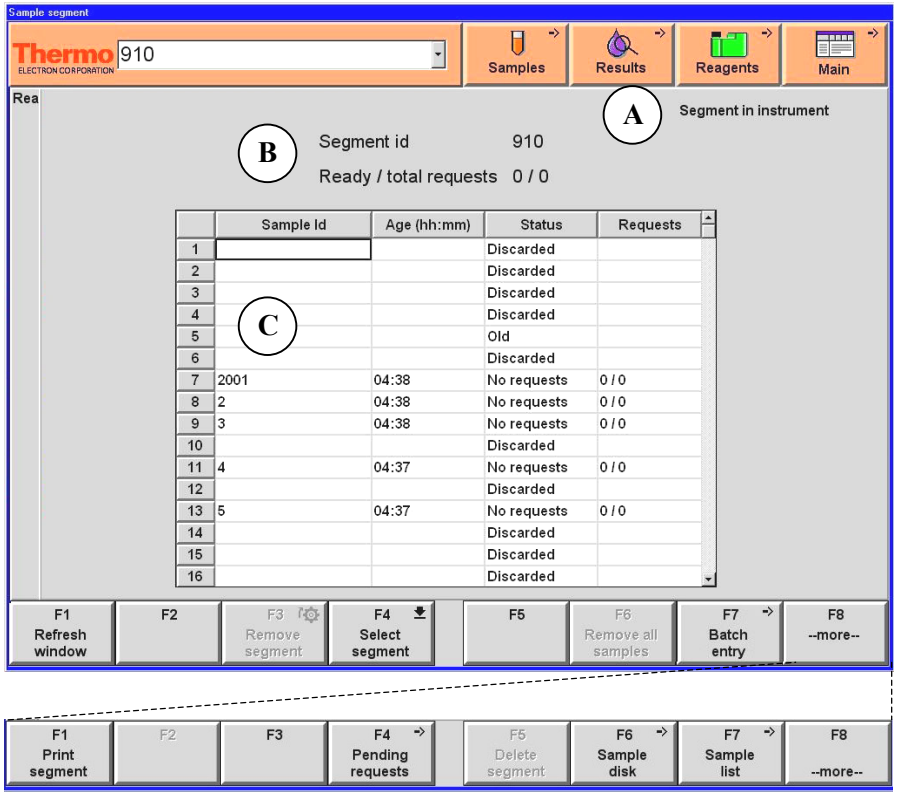
Alternatively give the sample information manually as above in item A.

DUPLICATE ID:

Same sample is in another segment.

- Activate F5, *Clear errors*, which will empty the sample data. The duplicate sample will not be analysed but the analysis of other samples in that segment will continue.

3.2.7.2 KUSTI SEGMENT



A Segment's status is seen top right:
- *Segment in instrument*
- *Please remove segment when green led is on*
- *Segment NOT in instrument*

B Segment's identification is seen. Numbers from 900 to 999 are reserved for KUSTI segments. Furthermore, the number of ready, accepted requests and the number of total requests are seen.

C Sample's identification, age, status as well as the number of ready, accepted requests and the number of total requests are seen.

The sample status can be:

- Reserved, when dispensing information has been accepted, after dispensing the sample id appears.
- Short, when a sample is missing.
- Old, when a sample/calibrator/control is older than the maximum age time given in the Configuration window (section 3.8). In this case the sample/calibrator/control must be introduced again to get tests measured.
- No requests, e.g. select the sample from the list and activate 

(F9) to give requests in the Sample/Patient entry window. Refer to section 3.2.3. If the sample is a calibrator or a control, request calibration or manual QC in the Calibration/QC selection window. Refer to section 3.4.1.
- Discarded, e.g. when dispensing has failed.

To remove the segment

Activate F3:
- when the segment is ready (= analysed and requests are accepted or rejected),
- when the instrument is not analysing.

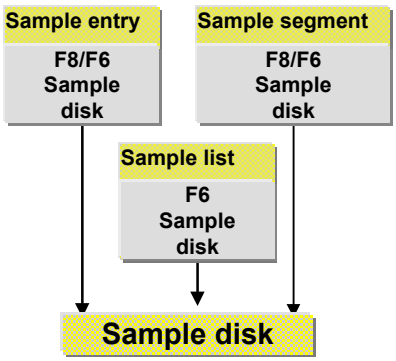
To clear the old sample data

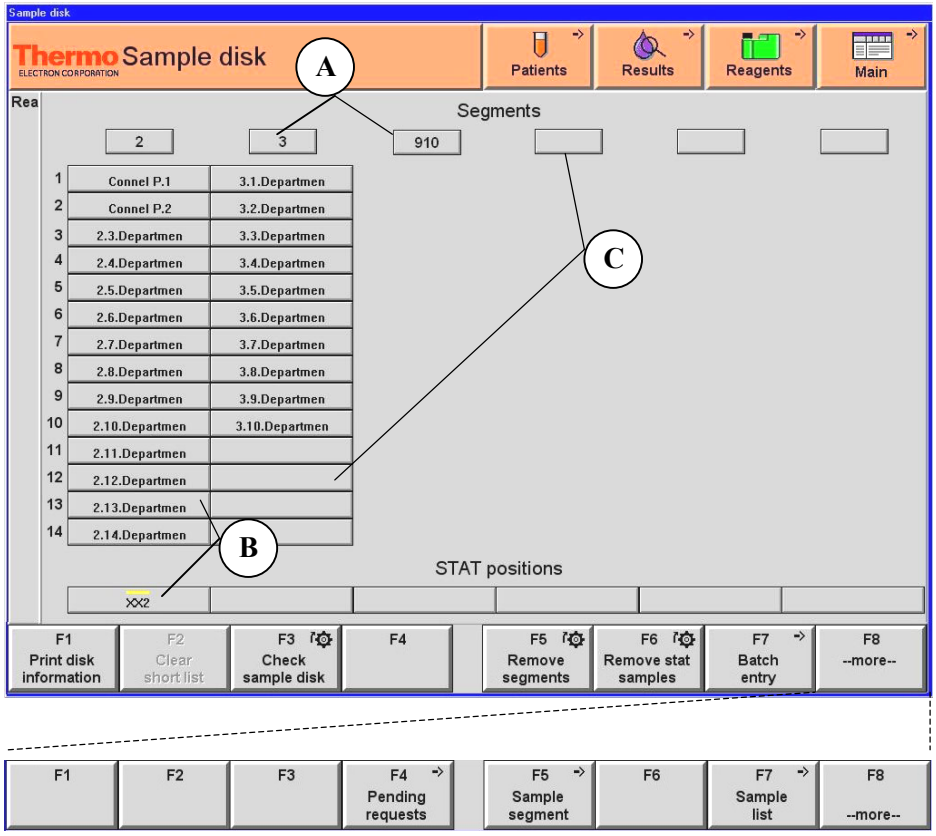
After analysing, activate F6 to clear the old sample data when the segment is no longer in the analyser.

To delete the segment

Activate F8/F5 to delete the segment id, e.g. when the segment is faulty or when the instrument has been unable to read the segment's barcode.

3.2.8 SAMPLE DISK





The status of all segments and patient samples on board is seen in this window.

A The segment's identification. Click it to open the Sample segment window to see the segment data.

B The sample's identification. Click it to open the Sample/Patient entry window to see the sample data.

C A free sample or segment position is seen as a blank button in the window.

No requests (a yellow line on the sample id button)

- Click the sample identification button or press F9 and give requests for the sample in the Sample/Patient entry window. Refer to section 3.2.2.
- If the sample is a calibrator or a control, request calibration or manual QC in the Calibration/QC selection window. Refer to section 3.4.1.

Short sample (a red line on the sample id button)

- Click the sample button, give another segment number and insert a new sample cup/ tube into another segment.

- or -

- Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. Segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

Unreadable barcode in STAT sample (a red line on the sample id button)

- Click the button and select F6, Remove stat sample. Also when the next STAT sample is given, the analyzer brings automatically the unreadable one to remove. Check the barcode, replace it if necessary, and insert sample again properly into the STAT position.

To remove segments

Select F5 to remove segments from the sample disk one after each other. Press the Esc button in the keyboard when you want to interrupt removing.

If segment is not ready, means that some requests (or one request) are neither accepted nor rejected, you must confirm to remove it during analysis.

To remove STAT samples

Select F6 to remove STAT samples from the sample disk one after each other. Press the Esc button in the keyboard when you want to interrupt removing.

You cannot remove a STAT sample during analysis if it is not ready. The sample is not ready if some requests (or one request) are neither accepted nor rejected.

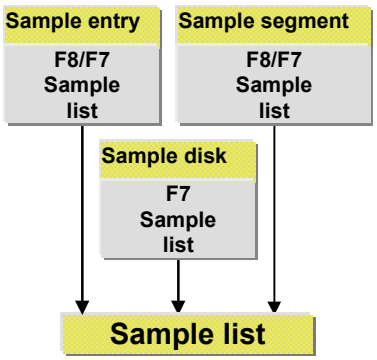
To clear short list

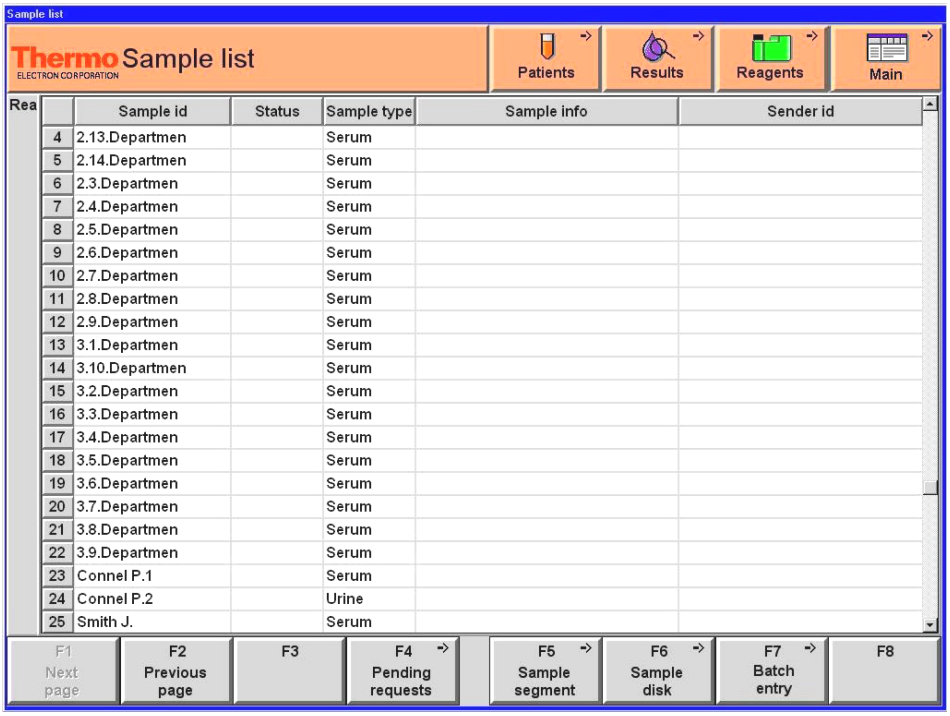
Activate F2 to clear the sample short list seen in the Main window, e.g. in case you can’t measure the sample on that day.

To check the sample disk

Activate F3 to read the barcodes of segment's and STAT's positions.

3.2.9 SAMPLE LIST





A brief preview of all samples is seen in this window.

No requests (seen on the *Status* field)

- Give requests for the sample in the Sample/Patient entry window. Refer to section 3.2.2.

- If the sample is a calibrator or a control, request calibration or manual QC in the Calibration/QC selection window. Refer to section 3.4.1.

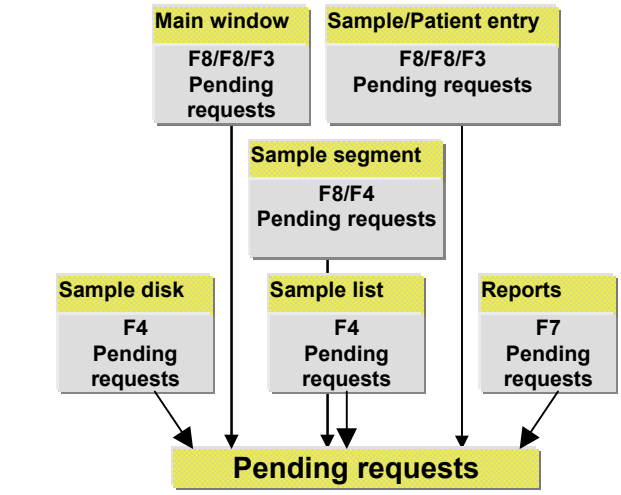
Short sample (seen on the *Status* field)

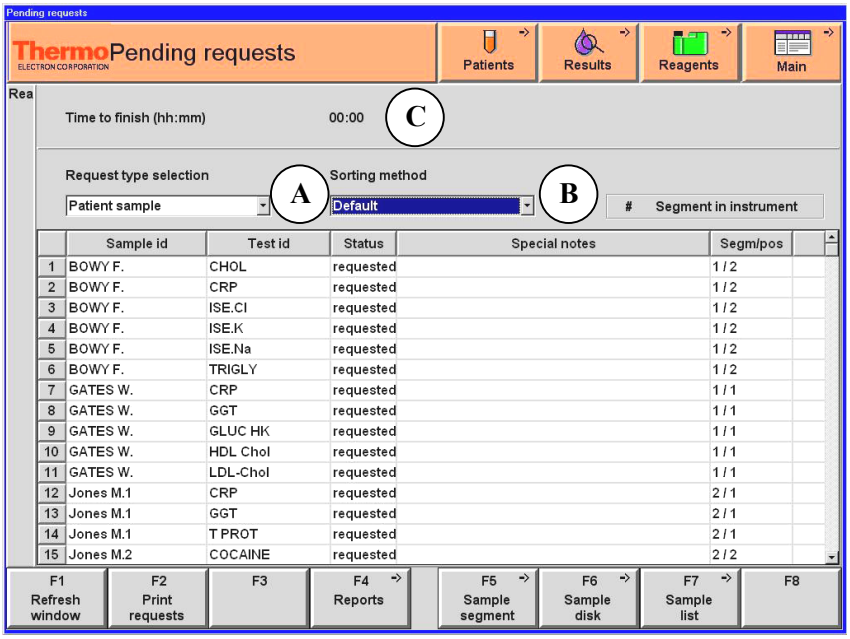
- Give another segment number to the sample in the Sample/Patient entry window and insert a new sample cup/ tube into another segment.

- or -

- Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. The segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

3.2.10 PENDING REQUESTS





Pending requests are seen in this window.

A Select the request type from the pull down menu. The alternatives are: *Patient sample*, *Control*, *Calibration*, *External* and *Calculated*.

B Select the sorting method by which the requests are seen. The alternatives are: *Default*, *Sample/Control/Calibrator id*, *Status*, *Instrument position*, *Special note*.

Default sorting method means that requests are seen in the following order:
- Asked & short samples
- Fixable & some short reagent
- Fixable & no calibration
- Fixable & current calibration has not yet been measured
- Fixable & calibration has been measured but not yet accepted
- Fixed samples
- Fixable samples
- Asked & sample in segment but not in instrument
- Asked

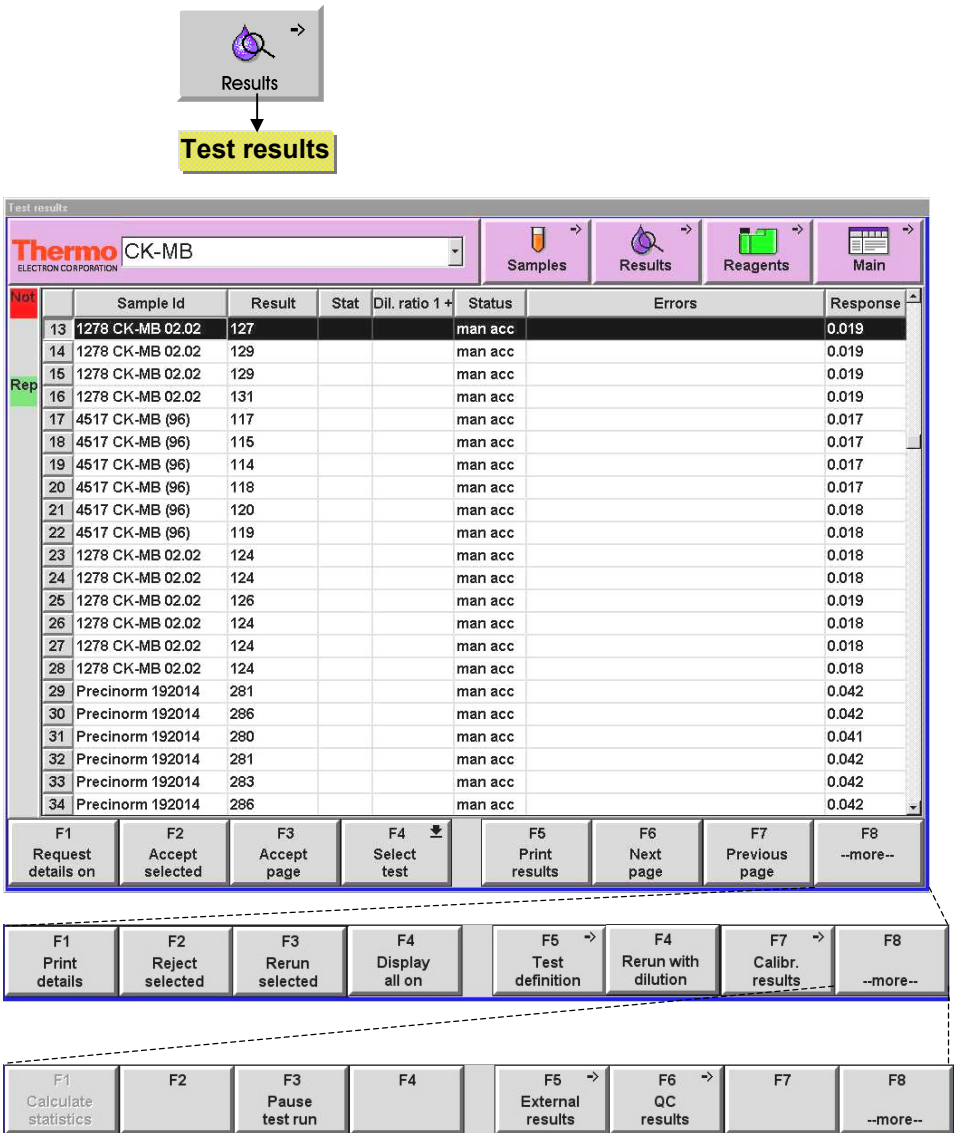
C The estimated time to complete the workload after pressing START is seen in hours (hh) and minutes (mm). With F1 you can update the time and the list.

3.3 RESULT ACCEPTANCE

This chapter describes how:
- to check,
- to accept,
- to reject and
- to rerun

results according to tests and according to samples/patients.

3.3.1 TEST RESULTS



Information seen in the TEST RESULTS window:

	The first is the result list number.
- *Sample id*	The sample identification is seen. With the calculated and external tests there is the patient identification.
- *Result*	The result is seen as a decimal.
- *Stat*	The STAT request has the sign !
- *Dil.ratio 1+*	The sample dilution is seen here as one part of a sample versus X parts of a diluent. Note that e.g. 1+4 corresponds to 1:5.
- *Status*	E.g. automatically accepted (aut acc), manually accepted (man acc), automatically rejected (aut rej), manually rejected (man rej), asked, calculated (calc), cancelled, fixable, fixed, measured.
- *R/ X/ S*	R means reanalysing, X means reanalysing with a reflex test and S means the screening test.
- *Errors*	The error messages are listed. Refer to section 3.3.3.
- *Response*	For the end-point test the response is the measured absorbance (A) from which the blank value and side wavelength value are subtracted. For the kinetic test the response is the calculated factor (A/min) from which the blank value/ blank factor and side wavelength value are subtracted. For the ISE test the response is the difference between the sample and ISE Calibrator 1 responses (mV).

Select test results: Click the mouse left button or move the cursor with the arrow keys and press Space bar. You can select several samples. When you select the same result again the selection is taken back.

With F8/F4 you can select if only unaccepted results or all results are seen in the window.

- Activate F2 to accept the selected test results. Activate F3 to accept all test results seen in the window.

- Activate F5 to print the selected or all results. On the printout you see also a mean value, a standard deviation and a CV of the results.

- Activate F8/F3 to rerun the selected test results.

- Activate F8/F6 to rerun the selected test results with dilution. Select the dilution according to ratios given in test parameters or according to given proposal or give a new ratio. The ratio can vary between 1 and 120 with 0.5 decimal. Note that e.g. 9 means that the sample is diluted 1+9 corresponding to 1:10.

- Activate F8/F2 to reject the selected test results. Rejection must be confirmed.

- Activate F8/F8/F1 to calculate a mean value, a standard deviation and a CV of the selected test results. CV is calculated also from responses if calibration is nonlinear.

Rejected QC results - incomplete batch

Rejection of QC results may be caused by
- inserting/ removing a Stat sample at the time control should be dispensed
- a short control sample - other QC results should contain an error flag 'Batch incomplete'
- ctrl-stop was pressed when the control request was analysed
- water gets short when control request was analysed.

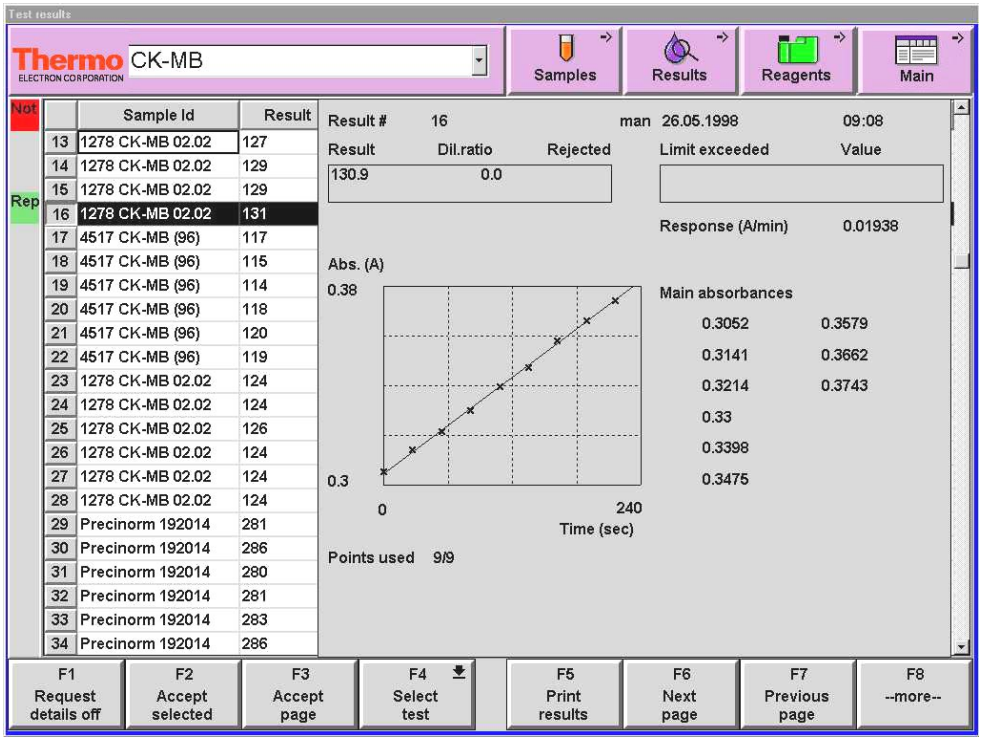
In these cases patient requests will be rerun automatically but control requests are not. Although you can see also those QC requests which are not measured.

You can still accept or reject these QC results but they are not included in cumulative QC data. To run QC requests, go to Calibr./QC selection.

Pause test run

Click F8/F8/F3 when you want to pause analysing of a test. The test is run again when the same button is clicked over or start is pressed to begin new analysis. If you want to take the test out of use, answer 'No' to the parameter 'Test in use' in the Test definition window.

3.3.1.1 RESULT DETAILS



Activate F1 to see the details of the result. Pressing the same button removes the details from the window. With F8/F1 you can print the details.

- *Result #* — The result number on the list. The date (dd.mm.yyyy) and the time (hh.mm) when the result is ready.

- *Manual dil. 1+* — If the sample has been manually prediluted the dilution is seen as one part of a sample versus X parts of a diluent. Note that e.g. 1+4 corresponds to 1:5.

- *Limit exceeded, Value* — If the result has exceeded the check limits the notes and values given in the TEST DEFINITION window are seen.

- *AE check value* — The result of antigen excess measurement when the detection of antigen excess has been selected.

- *Response* — For the end-point test the response is the measured absorbance (A) from which the blank value and the side wavelength value are subtracted. For the kinetic test the response is the calculated factor (A/min) from which the blank value/ blank factor and the side wavelength value are subtracted.
  For the ISE test the response is the difference between the sample and ISE Calibrator 1 responses (mV).

- *Blank response* — When the blank measurement is end-point the measured value is seen. When the blank measurement is kinetic the slope of the blank measurements' curve is seen.

- *Blank init.abs.* — When the blank measurement is kinetic the first measured value is seen.

- *Main absorbances* — The absorbance(s) measured in the main wavelength.

- S*ide abs.* — The absorbance measured in the side wavelength is seen if the side wavelength has been defined in the TEST FLOW window.

- *Residual net abs.* — The measured difference between the main and the side wavelengths is seen.

- *Points used* — The points used in the calculations / all points are seen if the measurement is kinetic and the curve type is linear cut.

If the result has been reanalysed also seen are:

- *Result* — The result of the request.

- *Dil.ratio* — The sample dilution as one part of sample and X parts of a diluent, e.g. 1+9 is same as 1:10.

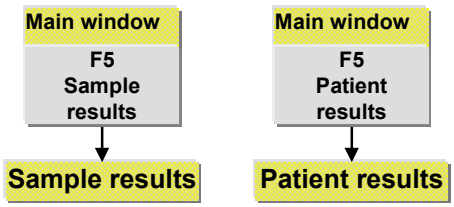
- *Rejected* — The type of rejection: if the result has been rejected manually or automatically.

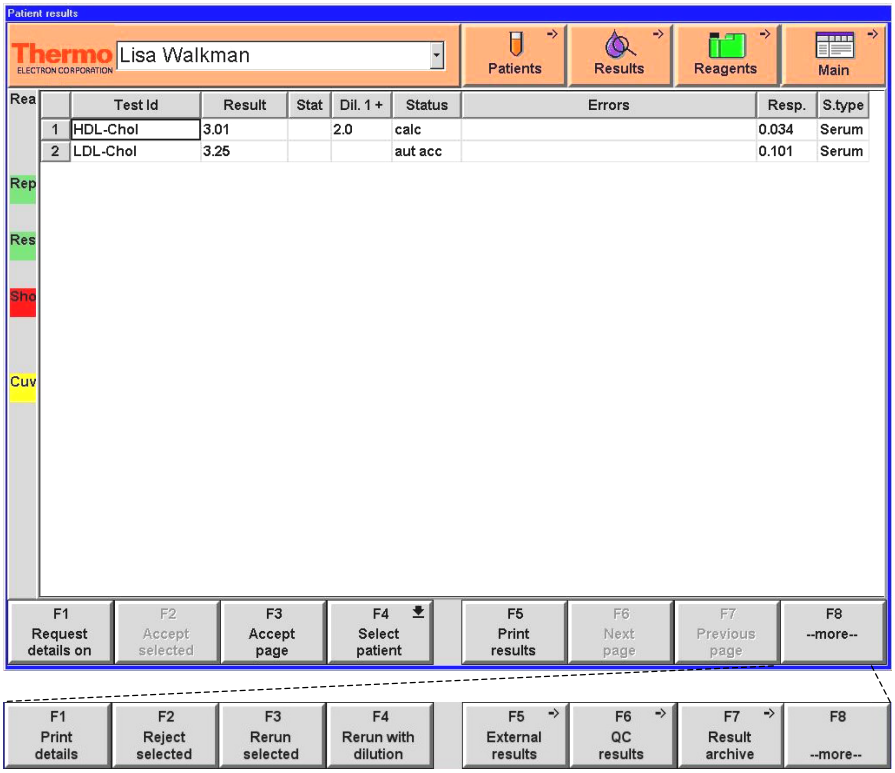
Control samples are diluted as patient samples according to primary dilution ratio. Other dilutions are not done for controls. Control requests are not reanalysed.

The measured absorbance values are seen on the graph: one measurement in the main wavelength with the end-point tests and max. 12 measurements and the response line in the main wavelength with the kinetic tests. The measurement time is seen on the x-axis of the kinetic test graph.

3.3.2 SAMPLE/ PATIENT RESULTS

The criterion for data entering and sending, sample or patient, is defined in the Configuration window.





Information seen in the SAMPLE/PATIENT RESULTS window:

The first is the result list number.

- *Test id* The test identification is seen.
- *Result* The result is seen as a decimal.
- *Stat* The STAT request has the sign !
- *Dil. 1+* The sample dilution is seen here as one part of a sample versus X parts of a diluent. Note that e.g. 1+4 corresponds to 1:5.
- *Status* E.g. automatically accepted (aut acc), manually accepted (man acc), automatically rejected (aut rej), manually rejected (man rej), asked, calculated (calc), cancelled, fixable, fixed, measured.
- *R/ X/ S* R means reanalysing, X means reanalysing with a reflex test and S means the screening test.
- *Errors* The error messages are listed. Refer to section 3.3.3.

- *Response* For the end-point test the response is the measured absorbance (A) from which the blank value and side wavelength value are subtracted. For the kinetic test the response is the calculated factor (A/min) from which the blank value/ blank factor and side wavelength value are subtracted.
For the ISE test the response is the difference between the sample and ISE Calibrator 1 responses (mV).

- *Sample type* In addition, in the Patient results window is seen the measured sample type.

☞ Select result: Click the mouse left button or move the cursor with the arrow keys and press Space bar. You can select several tests. When you select the same result again the selection is taken back.

- Activate F2 to accept the selected results. Activate F3 to accept all results seen in the window.

Only one result at a time can be asked to rerun with dilution because dilution ratios differs for different tests.

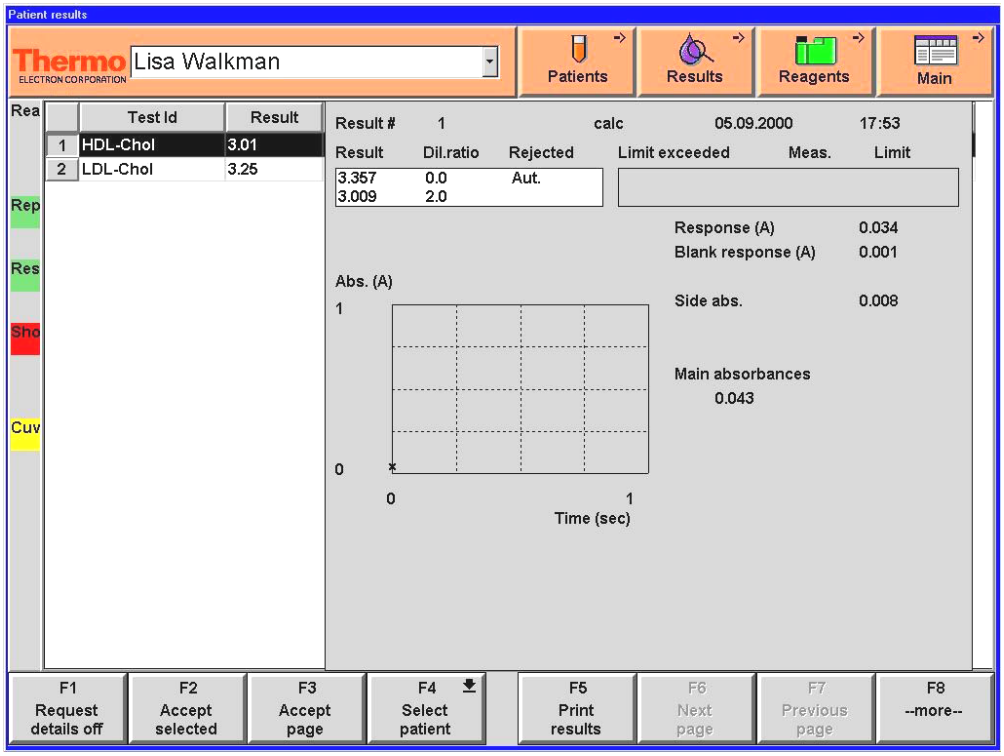
- Activate F5 to print the selected or all results.

- Activate F8/F3 to rerun the selected results.

- Activate F8/F4 to rerun with dilution the selected result. Select the dilution according to ratios given in test parameters or according to given proposal or give a new ratio. The ratio can vary between 1 and 120 with 0.5 decimal. Note that e.g. 9 means that the sample is diluted 1+9 corresponding to 1:10.

- Activate F8/F2 to reject the selected results. Rejection must be confirmed.

3.3.2.1 RESULT DETAILS



☞ Activate F1 to see the result details. Pressing the same button removes the details from the window. With F8/F1 you can print the details.

- *Result #* The result number on the list. The date (dd.mm.yyyy) and the time (hh.mm) when the result has been ready.

- *Manual dil. 1+* — If the sample has been manually prediluted the dilution is seen as one part of a sample versus X parts of a diluent. Note that e.g. 1+4 corresponds to 1:5.

- *Limit exceeded, Value* — If the result has exceeded the check limits the notes and values given in the TEST DEFINITION window are seen.

- *AE check value* — The result of antigen excess measurement when the detection of antigen excess has been selected.

- *Response* — For the end-point test the response is the measured absorbance (A) from which the blank value and the side wavelength value are subtracted. For the kinetic test the response is the calculated factor (A/min) from which the blank value/ blank factor and the side wavelength value are subtracted.
  For the ISE test the response is the difference between the sample and ISE Calibrator 1 responses (mV).

- *Blank response* — When the blank measurement is end-point the measured value is seen. When the blank measurement is kinetic the slope of the blank measurements' curve is seen.

- *Blank init.abs.* — When the blank measurement is kinetic the first measured value is seen.

- *Main absorbances* — The absorbance(s) measured in the main wavelength.

- S*ide abs.* — The absorbance measured in the side wavelength is seen if the side wavelength has been defined in the TEST FLOW window.

- *Residual net abs.* — The measured difference between the main and the side wavelengths is seen.

- *Points used* — The points used in the calculations / all points are seen if the measurement is kinetic and the curve type is linear cut.

If the result has been reanalysed also seen are:

- *Result* — The result of the request.

- *Dil.ratio* — The request dilution as one part of sample and X parts of a diluent, e.g. 1+9 is same as 1:10.

- *Rejected* — The type of rejection: if the result has been rejected manually or automatically.

The measured absorbance values are seen on the graph: one measurement in the main wavelength with the end-point tests and max. 12 measurements and the response line in the main wavelength with the kinetic tests. The measurement time is seen on the x-axis of the kinetic test graph.

3.3.3 LIST OF ERRORS

Errors appearing both with photometric and ISE tests

- *Calc error*	A calculation error has occurred. The reasons for the error are seen in the Messages window.
- *Instr. error*	Occurs only with the controls. The analyser has not been able to do the request because of a short sample, short reagent, interrupted run etc.
- *Test limit low*	The result is below the parameter 'Test limit low' given in the Test definition window.
- *Test limit high*	The result before manual dilution has exceeded the parameter 'Test limit high' given in the Test definition window.
- *Critical limit low*	The result is below the parameter 'Critical limit low' given in the Test definition window. The automatic acceptance is turned to manual.
- *Critical limit high*	The result is above the parameter 'Critical limit high' given in the Test definition window. The automatic acceptance is turned to manual.
- *Out of limit*	The response of a calibrator measurement differs from the calibration more than allowed. Refer to section 5.1.12.3.

Errors appearing with photometric tests

Concerning response:

- *Abs. high*	Measured absorbance is above the defined ‘Max allowed abs. (A)’ value given in the Configuration window.
- *Init. abs.*	The result has exceeded the parameter 'Initial absorbance high' or is below the parameter 'Initial absorbance low' given in the Test definition window. Rerun is done automatically with dilution if dilution limit is exceeded at the same time.
- *Blank resp. low*	The response of blank measurement is below the parameter 'Resp. min' given to the blank measurement in the Test flow window.
- *Blank resp. high*	The response of blank measurement has exceeded the parameter 'Resp. max' given to the blank measurement in the Test flow window.
- *Blank init abs. low*	The result of kinetic blank measurement is below the parameter 'Init. abs. min' given to the kinetic blank measurement in the Test flow window.
- *Blank init abs. high*	The result of kinetic blank measurement has exceeded the parameter 'Init. abs. max' given to the kinetic blank measurement in the Test flow window.

Concerning concentration:

- *Dil limit low*	The measurement has been carried out with the primary dilution and the result is below the parameter 'Dilution limit low' given in the Test definition window. Rerun is done automatically if no other error exist.
- *Dil limit high*	The measurement has been carried out with the primary dilution and the result has exceeded the parameter 'Dilution limit high' given in the Test definition window. Rerun is done automatically if no other errors exist.
- *Not measurable*	When a screening test is carried out it is noticed that the calculated dilution to the screened test goes over 120. The request is transferred to manual acceptance where the user decides not to measure that request. Then the request is reported with the flag 'Not measurable'.
- *Bias corr. limit*	The result of bias correction measurement is over the limits given in the Calibration parameters window. Refer to section 4.4.1.

With the end-point tests:

- *Antigen limit low*	The result is below the parameter 'AE low limit' given in the Test flow window for the AE check sample.
- *Antigen limit high*	The result is over the parameter 'AE high limit' given in the Test flow window for the AE check sample.
- *AE meas error*	Error has occurred during the antigen excess measurement, usually the sample for antigen excess measurement is short.

With the kinetic tests:

- *Bichr. net abs.*	The measured difference between the main and the side wavelengths is lower than allowed in the parameter 'Residual net abs.' given in the Test flow window for the kinetic measurement. Rerun is done automatically with dilution if dilution limit is exceeded at the same time.
- *Linearity*	With the linear cut -curve type the linear part of the curve is so short that only the first or the second point is included. The reaction is ending too early during the measurement time. The calculation of response needs always at least three points. With the linear -curve type the parameters 'Nonlinearity limits both in concentration and percent' has been achieved. Parameters are given in the Test flow window for the kinetic measurement.
- *Point(s) out of curve*	Some measured absorbance point does not fit to the line calculated according to linear regression. The point differs over 7% from the response change occurring during the reaction. In case the standard deviation of the change between the measured points is under 2 mA, the response is accepted without the flag.

For the user information

- *Cut curve*	All measured points are not used when calculating the reaction with the linear cut -curve type.

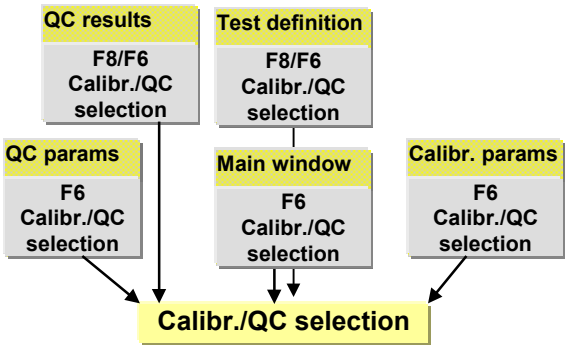
Errors appearing with ISE tests

- *Unstable*	An ISE measurement is unstable.
- *Addl meas error*	Na measurement has been failed when Li has been requested or pH measurement has been failed when Ca has been requested. Na result is needed when calculating Li result and pH result is needed when calculating Ca.

3.4 CALIBRATION AND QUALITY CONTROL

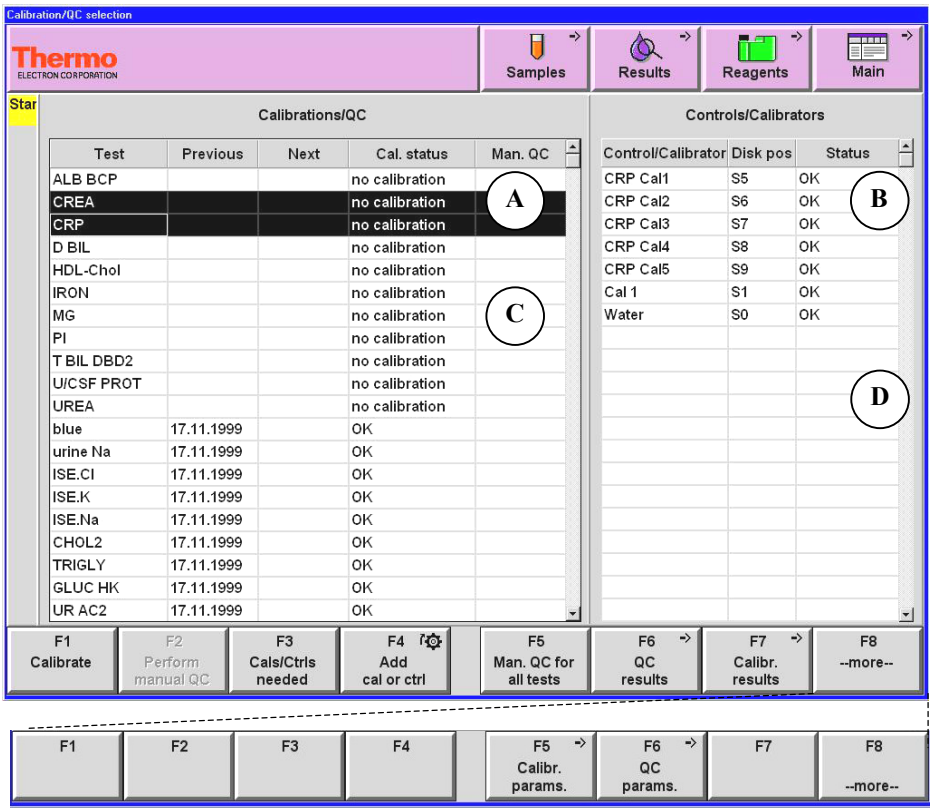
This chapter describes how:
- to check and select calibration,
- to check and select quality control,
- to accept or reject calibration results,
- to detect quality control results.

3.4.1 HOW TO CHECK/ SELECT CALIBRATION/ QC



All ISE tests in use are calibrated when any of the ISE tests are calibrated.

Two QC types are used in Konelab: Manual QC and Routine QC.
Manual QC is performed with calibration and when ever the user wants. It is meant for accurate control.
Routine QC is performed during analysis and meant to observe changing and random errors.
For parameters refer to section 4.5.



The tests are seen on the left side of the window in the order of calibration status (from top to bottom):
– tests which have no valid calibration,
– tests with the bias correction which have no valid bias,
– tests whose calibration is old,
– tests which have requested a calibration,
– tests which have acceptable calibration,
– tests whose calibration is OK.

The user must always select calibration. The analyser is not calibrating automatically.

On the test list:

- *Previous* The date of the previous accepted calibration is seen.
- *Next* The date when the next calibration should be done (obtained from the CALIBRATION PARAMETERS as *Repeat time*).
- *Cal. Status* The status of calibrations is seen.
- *Man. QC* The status of Manual QC procedure is seen.

When the test has been selected the list of calibrators for calibration and the list of controls as well as antigen excess sample for Manual qc are seen in alphabetical order on the right side of the window:

- *Disk pos* The calibrator/control/antigen excess sample position in the calibrator/control disk is seen.
- *Status* The calibrator/ control/ antigen excess sample status is seen: OK, finished or missing from the calibrator/control disk.

Calibration cannot be done if some calibrator is missing.

The user can select if Manual QC is performed with available controls when some control is missing or short. Other controls are not used instead of missing/ short control.

Ⓐ Select the test to be calibrated from the list and activate F1.

Ⓑ Activate F3 to see the status of the necessary calibrators.

Ⓒ Select the test to which the Manual qc is to be requested and activate F2.

Ⓓ Activate F3 to see the status of the necessary controls.

To perform Manual QC for all tests

☞ Select F5 to perform Manual QC for all tests, which have reagent in the reagent disk and valid controls in the instrument.

To add an ISE prime/ Washing solution sample in Konelab 20XT and in Konelab 20

☞ Activate F4, Add prime/wash when you add an ISE prime or washing solution sample during analysis. After the LED stops blinking and remains green you can open the STAT insert cover and insert the sample.

To add a calibrator/ control sample during analysis in Konelab 60 and in Konelab 30

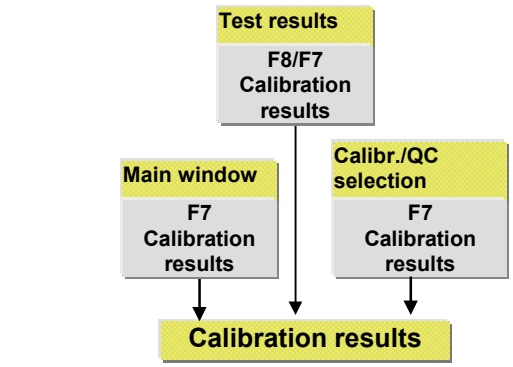
☞ Activate F4 when you add calibrator or control sample into the cal/ ctrl sample disk during analysis. Note that this will stop dispensing. In case controls are under analysis, requests must be asked again because there is no automatic rerun for them.

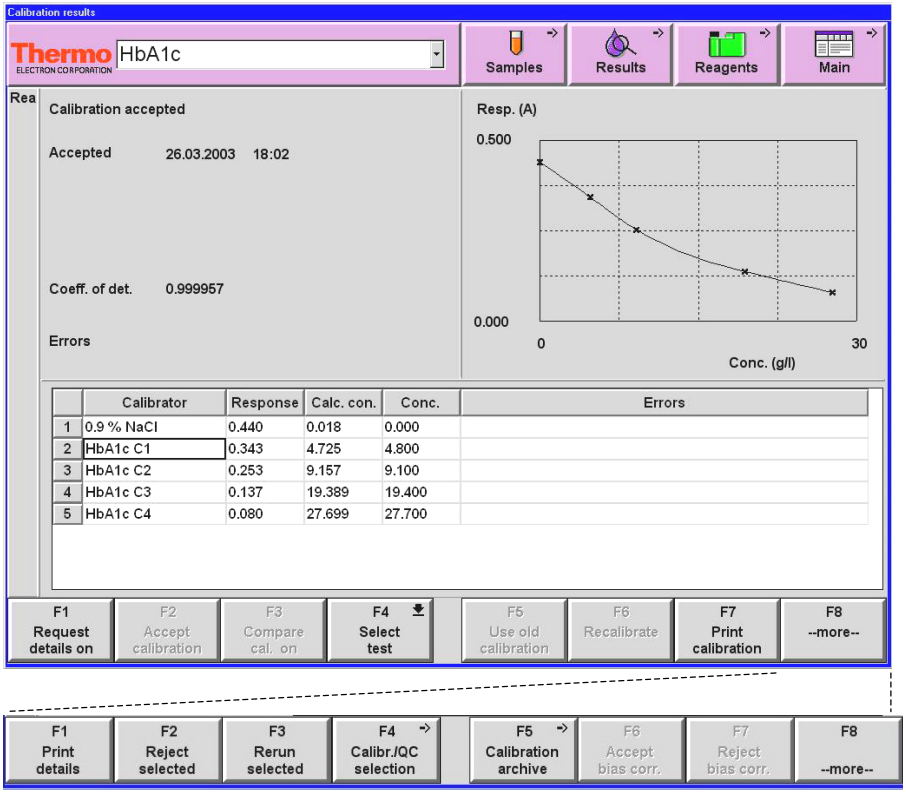
☞ If the sample is in the segment give another segment number to the sample and insert a new sample cup/ tube into another segment.

- or -

Remove the segment by F3, in the Segment window and add fresh sample to the cup/ tube in the segment. The segment is possible to remove even during analysis but when it is done, it reduces capacity because requests under analysis are re-started.

3.4.2 CALIBRATION RESULTS





The status of test calibration is seen in the window:
- no valid calibration,
- calibration pending,
- done but not accepted or
- done and accepted.

Also the acceptance time, factor, bias and possible error messages are seen as well as for nonlinear and ISE tests the coefficient of determination. For the ISE tests the slope value is seen, too.

The information of every unaccepted calibration point is seen:
- the calibrator name,
- the response,
- the concentration calculated from a new calibration,
- the concentration of the calibrator given in the calibration parameters and
- possible errors.

The list of controls is seen after calibrators. Manual qc is performed always with the calibration. Although in case the quality control batch is incomplete, unmeasured control requests are seen, too.

Both the measured calibration and that given in the test parameters are shown as graphs.

☞ Activate F2 to accept the calibration. To recalibrate, activate F6.

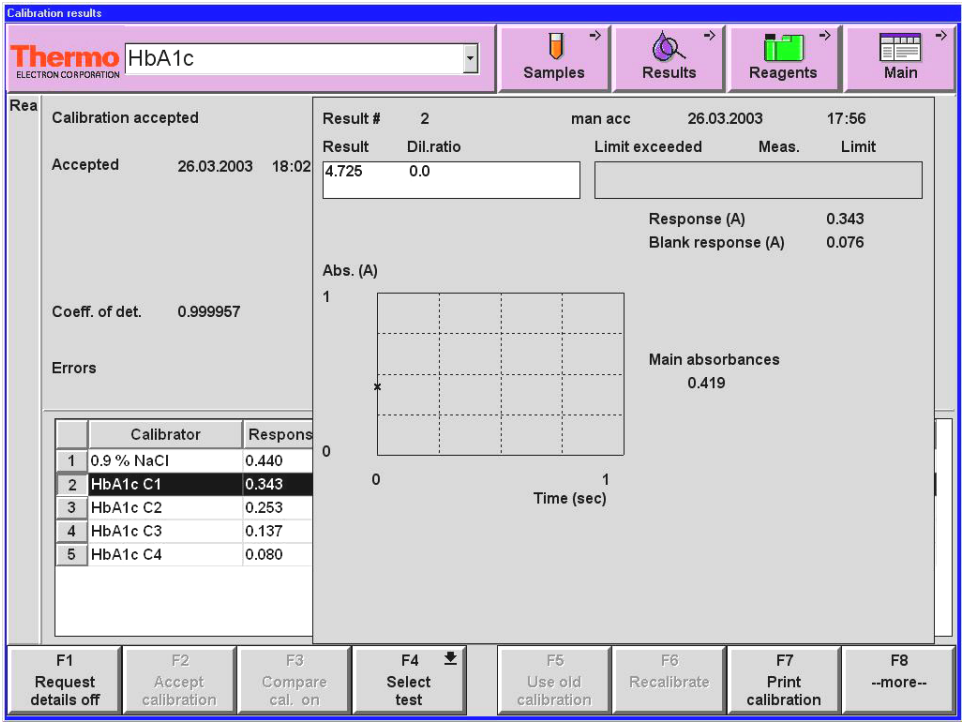
☞ Activate F3 to compare a new calibration to the old one. With the same button you can take the comparison off. You can accept old calibration in use activating F5.

☞ Activate F7 to print the calibration curve and results.

To delete calibration when it is pending

☞ Activate F5, Delete calibration, when calibration is still pending. After calibration has started, it is not anymore possible to delete it.

Checking the measurement details:



Calculation of the linear calibration needs at least one request at two different concentration levels. The nonlinear calibration needs at least one request at every concentration level. If points have been measured using duplicates, only duplicates can be rejected.

☞ Select the calibration point: Click the Calibrator from the list or move with the arrow keys and press Space bar. You can select several calibration points. When you select the same calibration point again the selection is taken back.

- Activate F1 to check the measurement details of the selected calibration point. Pressing the same button removes the details from the window. With F8/F1 you can print the details.

- Activate F8/F3 to rerun the selected calibration points.

- Activate F8/F2 to reject the selected calibration points. Calibration curve is automatically recalculated. Note that the rejected points cannot be returned once they have been rejected.

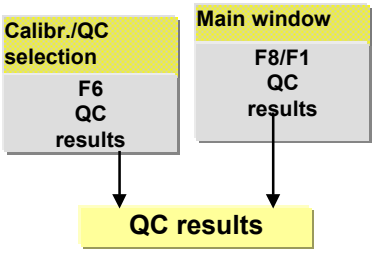
Bias correction in use:

In case Bias correction has been selected in use in the CALIBRATION PARAMETERS the measurement is repeated automatically according to the *Bias corr. repeat time* given in the parameters. Refer to section 4.4.1.

- With F8/F6 you can accept the measured bias correction in use.

- With F8/F7 you can reject the measured bias correction. In this case the previous calibration is kept valid.

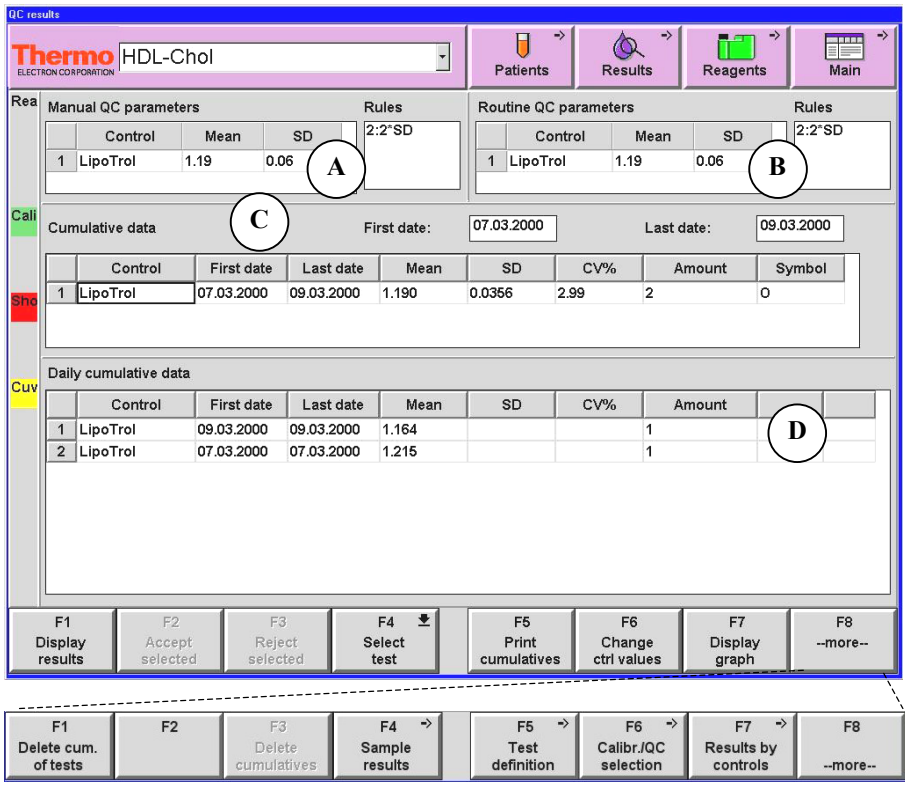
3.4.3 QUALITY CONTROL RESULTS



With F1 button you can select either cumulative data or QC results in the window (Display cumulative/ Display results).

CUMULATIVE DATA:

All accepted QC results are included to the cumulative data when Clear daily files is performed.



A Manual QC controls, their values and rules given in the parameters (see section 4.5.) are seen. You can change values by selecting F6, which suggest values measured by this instrument. To delete the cumulative data of the control from all tests after changing the control value use F8/F1.

B Routine QC controls, their values and rules given in the parameters (see section 4.5.) are seen. You can change values selecting F6, which suggest values measured by this instrument. To delete the cumulative data of the control from all tests after changing the control value use F8/F1.

C Give the date interval from which you want to see the cumulative QC results.

D Daily cumulative data includes QC results measured on that certain day. At least 50 daily results per control are seen here. The oldest data disappears automatically when 50 results/ control is exceeded.

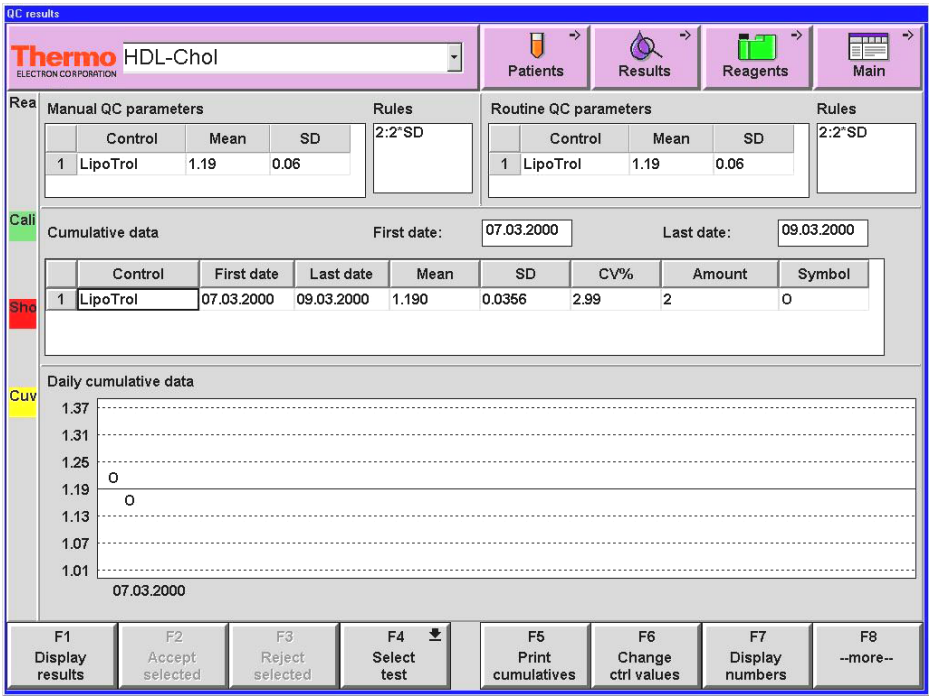
- *Control* The name of the control.
- *First date* The first day the control was measured.
- *Last date* The last day the control was measured.
- *Mean* The mean of the QC results.
- *SD* The standard deviation of the QC results.
- *CV%* QC results' coefficient of variation.
- *Amount* Number of analysed QC requests.
- *Symbol* The symbol with which the control is marked graphically.

☞ Activate F5 to print the selected controls' data.

It is recommended to delete cumulative QC data once per month.

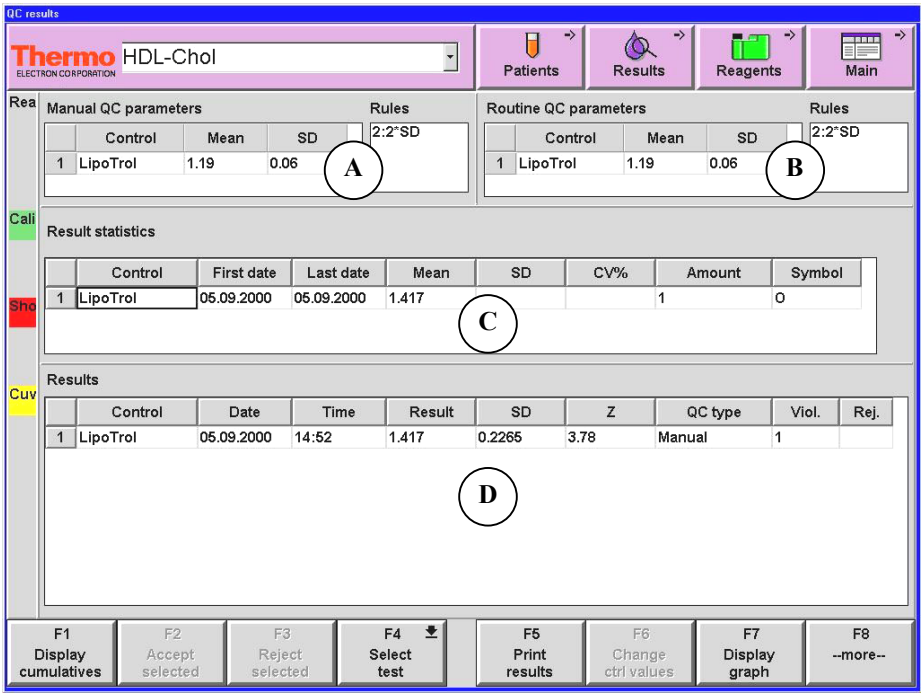
☞ Activate F8/F3 to delete the test's selected controls' daily cumulative data and cumulative data. You can set a date so that the oldest data up to that date is deleted.

☞ Activate F7 to display the data graphically.



QC RESULTS:

All QC results (accepted and rejected) measured after the latest performed Clear daily files is seen in the QC results window.



A Manual QC controls, their values and rules given in the parameters (see section 4.5.) are seen. The mean value and SD should be values measured for that control by this instrument.

B Routine QC controls, their values and rules given in the parameters (see section 4.5.) are seen. The mean value and SD should be values measured for that control by this instrument.

C Result statistics includes accepted QC results:

- *Control* The name of the control.
- *First date* The first day the control has been measured.
- *Last date* The last day the control has been measured.
- *Mean* The mean of the measured QC results.
- *SD* The standard deviation of the measured QC results.
- *CV%* Measured QC results' coefficient of variation.
- *Amount* Number of analysed QC requests.
- *Symbol* The symbol with which the control is marked graphically.

D Results:

- *Control* The name of the control.
- *Date* The day the control has been measured.
- *Time* The time the control has been measured.
- *Result* The result of a measurement as a decimal.
- *SD* The result's deviation from the control value given in the parameters.

- *Z* The reference value for the deviation, how result's deviation and control's stable standard deviation is related.

  It is calculated as follows:
  Z = (QC result - in parameters given control value)/ standard deviation

- *QC type* QC type can be Manual QC or Routine QC.

- *Viol.* The rule which has been violated. The list of x from the rule x:y*SD.

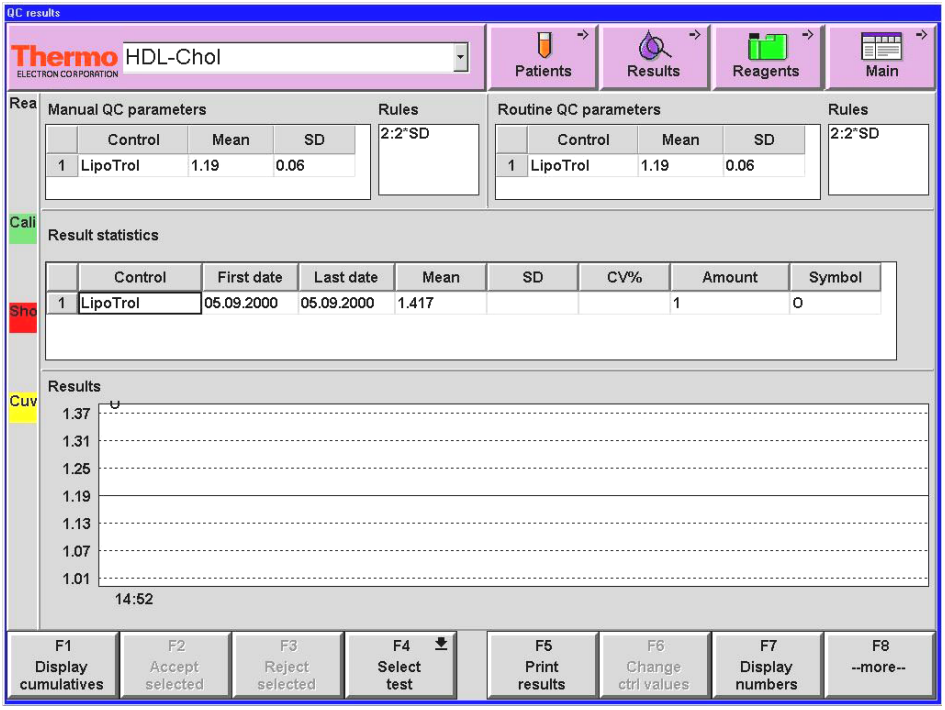
- *Rej.* If the result has been rejected is seen.

☞ Activate F2 to accept selected results, which have been rejected previously. After this *Result statistics* is recalculated.

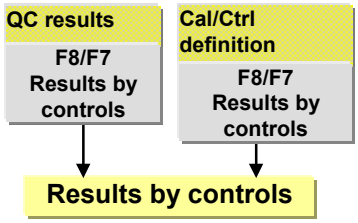
☞ Activate F3 to reject selected results, which have been accepted previously. After this *Result statistics* is recalculated.

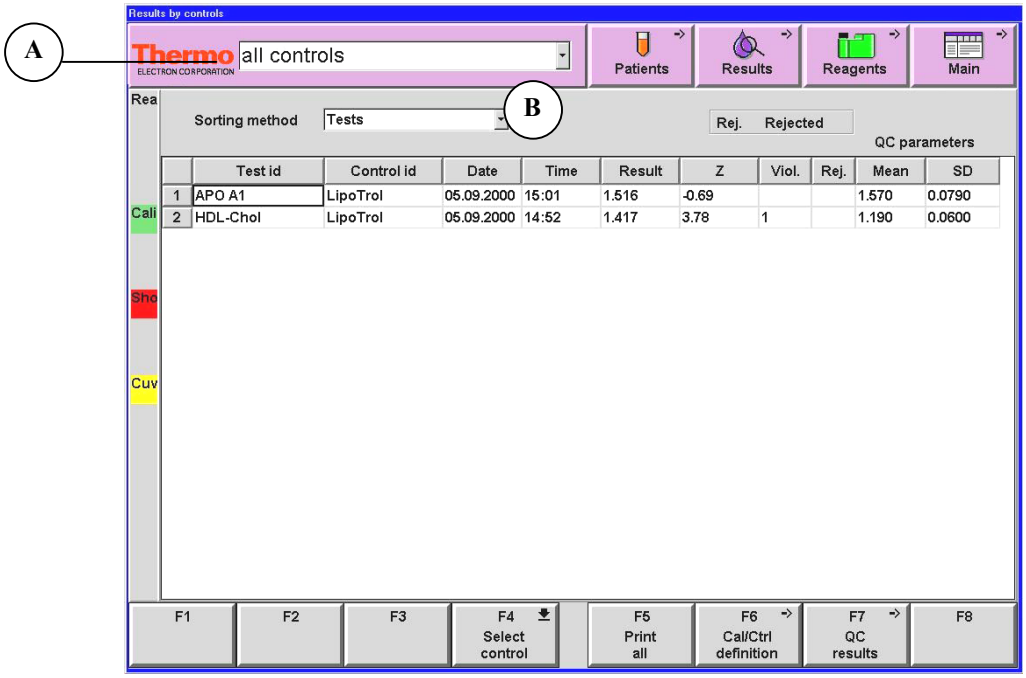
☞ Activate F5 to print the selected results. The printout includes both data and statistics.

☞ Activate F7 to display selected results graphically.



3.4.4 RESULTS BY CONTROLS





A Select all controls or one control from the list.

B Select the sorting method by which the results are seen. Alternatives are: Tests, Date & Time and Controls.

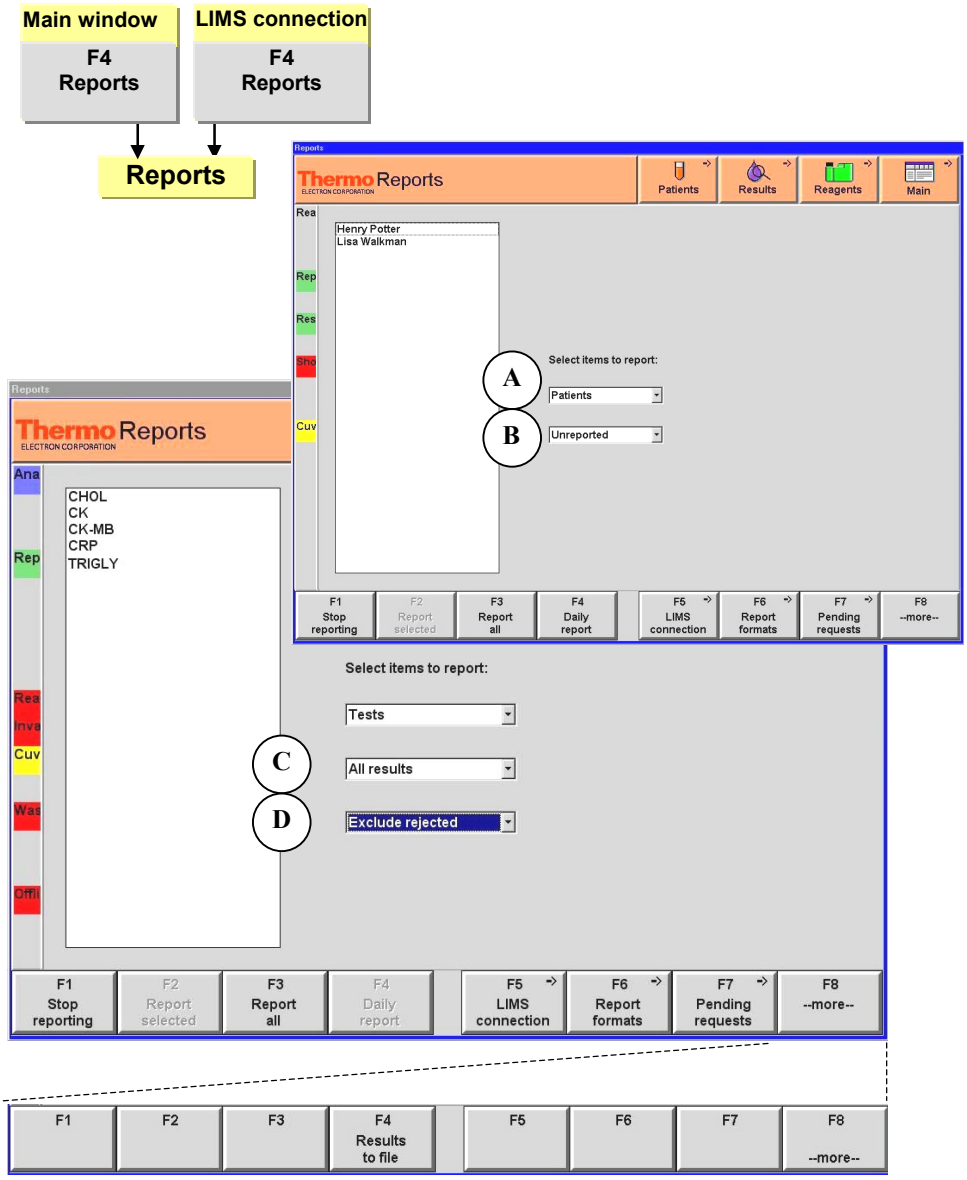
Information seen in the Results by controls window:

- *Test id* — Identification of the test is seen.
- *Control id* — Identification of the control is seen.
- *Date,* *Time* — The date and the time when the control has been measured.
- *Result* — The result of the measurement.
- *Z* — The reference value for the deviation, how result's deviation and control's stable standard deviation is related.

  It is calculated as follows:
  Z = (QC result - in parameters given control value)/ standard deviation
- *Viol.* — The rule which has been violated. The list of x from the rule x:y*SD.
- *Rej.* — If the result has been rejected it is marked with 'Rej.'.
- *Mean* *SD* — The mean and the standard deviation of the QC results given in the QC parameters.

3.5 REPORTS

Printing type, manual or automatic, is selected in the Configuration window.



A The user can select manual reports to be printed according to:
- Samples,
- Patients or
- Tests.

B The user can select which patient/sample results are reported:
- Unreported,
- Completed (all requests analysed),
- Incomplete (ready requests, not all requests are necessarily analysed),
- All (completed and incomplete).

C The user can select which test results are reported:
- Patient results,
- Control results or
- All.

D The user can select to:
- include rejected results or
-exclude rejected results into the report.

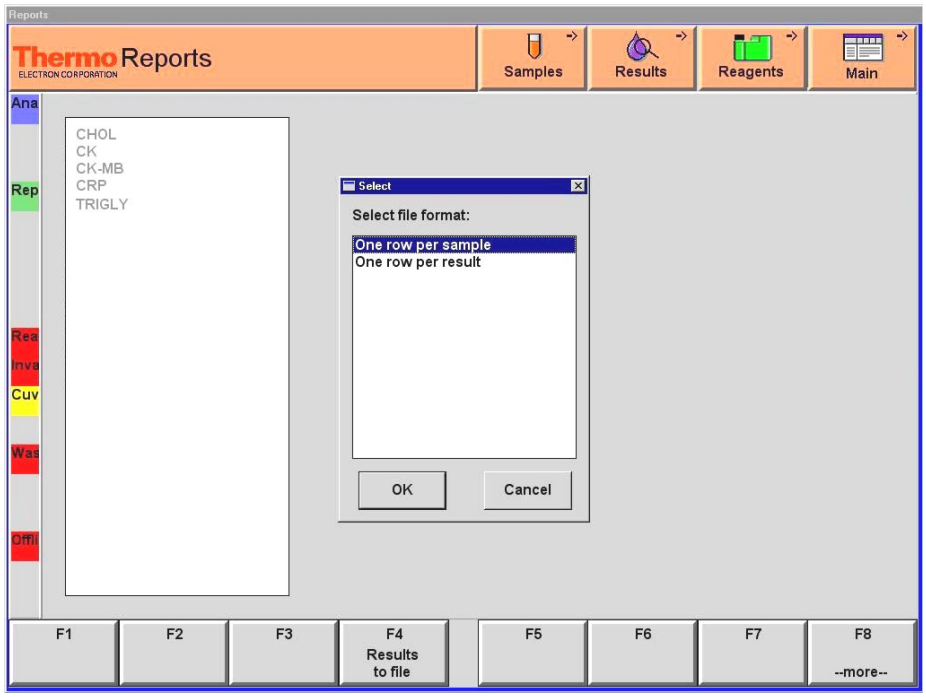
Activate F2 to report selected samples/ patients/ tests results.

Activate F3 to report all.

F4, Daily report gives a summary of results. It includes in a short form tests' names, results and dilution ratio used. More detailed information is seen in other reports.

Excel reports

With F8/F4 you can transfer results to the excel files. Excel files are seen in the folder C:\Konelab\Results.



Select either

- One row per sample where sample results are seen by tests with three decimals.
- One row per result where all sample and control results (accepted, rejected and rerun) are seen. Also control requests not done are reported.

Type the name for the file (max 30 characters). In the beginning of file is time for the oldest and the newest result. Results are reported in chronological order.

One row per result includes:

For all tests

- sample/ control identification, with calculated (patient) and external requests the patient identification is seen
- sample type, P for patient and C for control
- test's short name
- Test type, P for photometric, I for ISE, E for external, CS for calculated (sample), CP for calculated (patient)
- Result with decimals defined in Test definition + 1
- Result unit
- Result date and time in Excel format
- Stat information with ! (only for patient samples)
- Status of acceptance, AA for automatically accepted, MA for manually accepted, AR for automatically rejected, MR for manually rejected
- Error flags seen with the same code numbers as in ASTM protocol
- Test limits (min and max)

Additionally for photometric and ISE tests

- Notes for measuring, R for rerun, S for screening, X for reflex
- Dilution ratio x with one decimal (from 1 + x), no decimal for ISE tests
- Manual dilution ratio x with one decimal (from 1 + x), only for patient samples
- Response with 5 decimals

Additionally for photometric tests

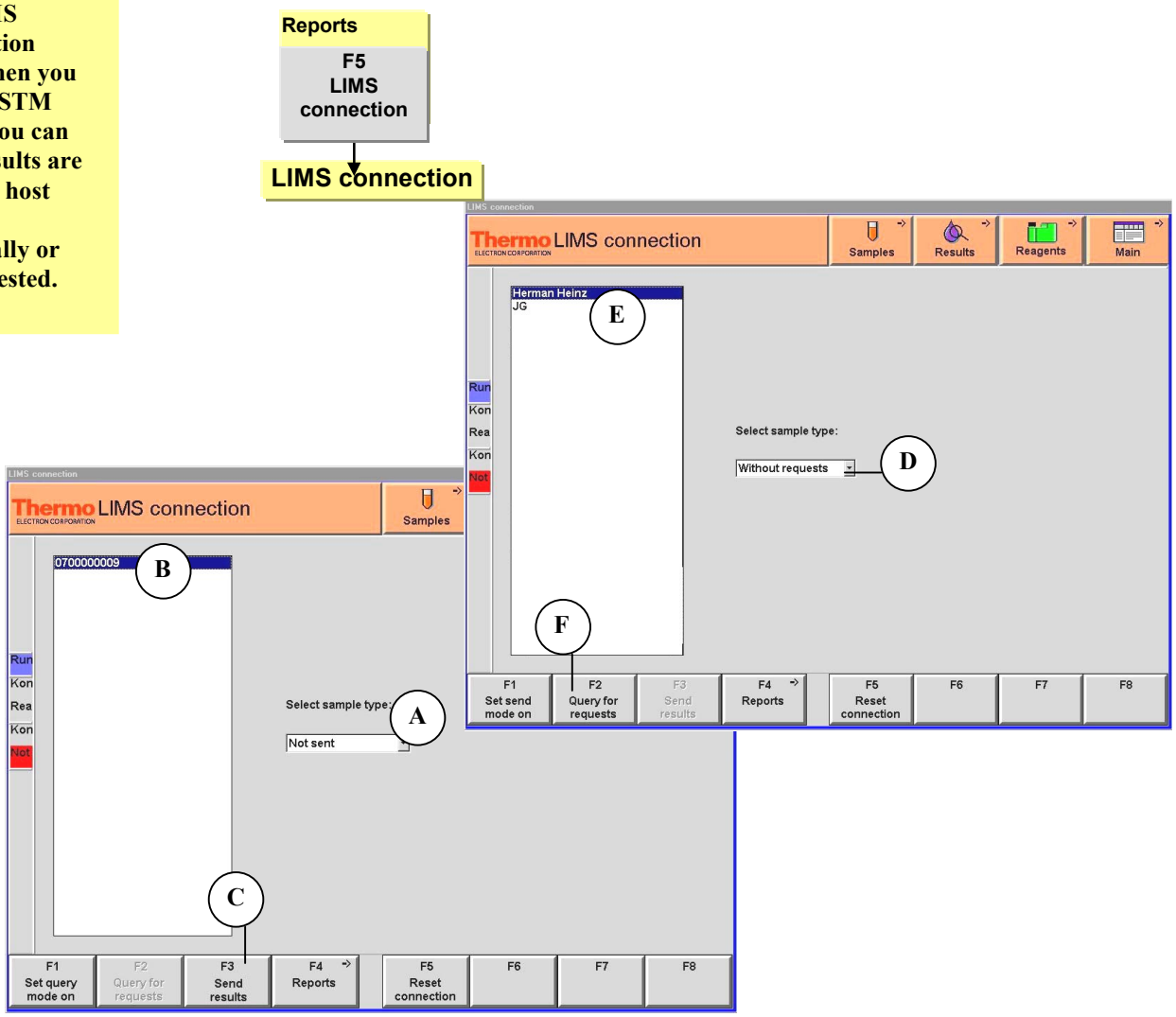
- Blank response with 5 decimals if other than water blank
- Blank init abs with 5 decimals if other than water blank
- Side absorbance with 5 decimals if measured
- Points used with kinetic measurements
- Main absorbances with 5 decimals from 1 to 12
- Antigen Excess Check value with 5 decimals if measured, only for patient samples

Additionally for ISE tests

- Calibrator voltage with 5 decimals

3.5.1 LIMS connection

In the LIMS Configuration window when you have the ASTM protocol, you can select if results are send to the host computer automatically or when requested.



With F1 you can select either send mode on or query mode on.

Send mode on

A Select sample type: either not sent or sent.

B Select sample from the list.

C Select F3, Send results.

Request mode on

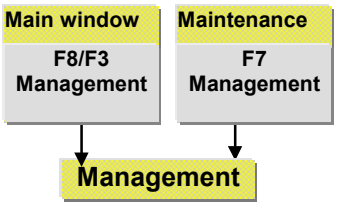
D Select sample type: without requests or others.

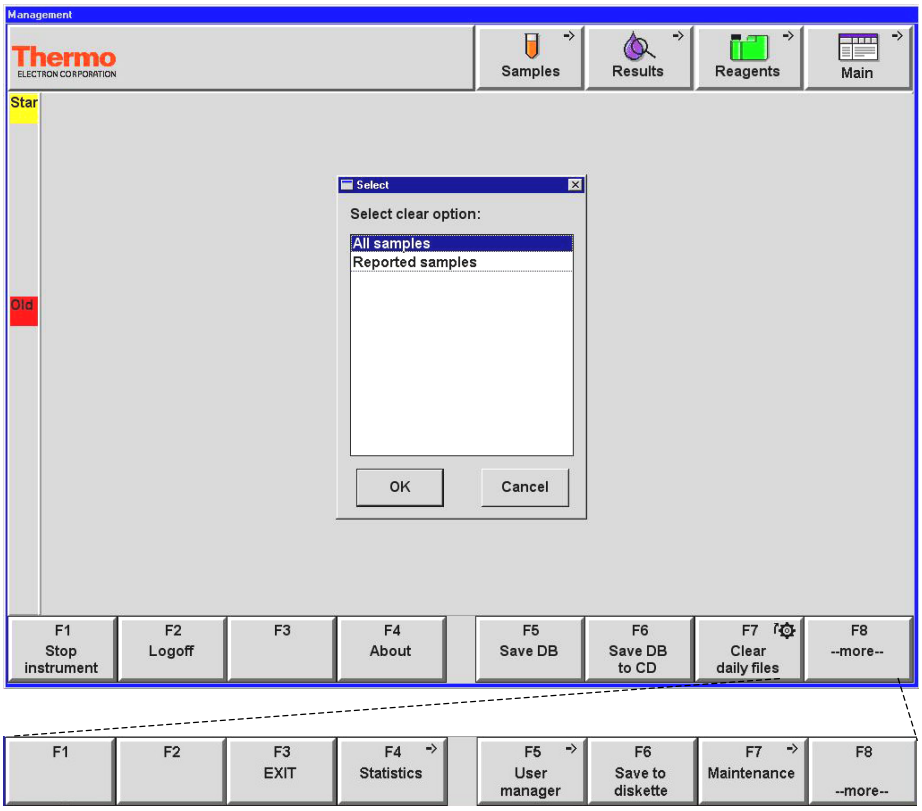
E Select sample from the list.

F Select F2, Query for requests.

With F5 you can reset the LIMS connection if it is cut off for a reason or another.

3.6 CLEARING DAILY FILES





You can clear the daily files only when analysis is not in progress.

Activate F7 when you want to clear either all or reported samples data. Clear reported removes sample/patient data and requests from reported samples/patients. Clear all does the same for all samples and in addition saves accepted QC results to the cumulative data, and if patient archive is in use, results, calibrations and reagent lots are saved to archive. See the table in next page.

Activate F2 to logoff after the daily work if user levels have been set on. The next user has to login by giving the password.

Activate F5 to save the database to the hard disk. It saves both the routine database and patient archive.

It is recommended to Clear daily files after 8000 requests (the number is not including e.g. reruns) because max of requests is 10000.

Activate F6 to save the database to CD. It saves both the routine database and patient archive. The drive of the CD must be identified in the Configuration window. Refer to section 3.8.

Activate F8/F6 to save the routine database to a diskette. The functions save calibrator and control values, calibrations, reagents, test parameters, segment ids, error messages etc. It is recommended first to clear the daily files with F7. Otherwise saving can be very slow and uses a lot of disc space. Note that the sample results are not saved.

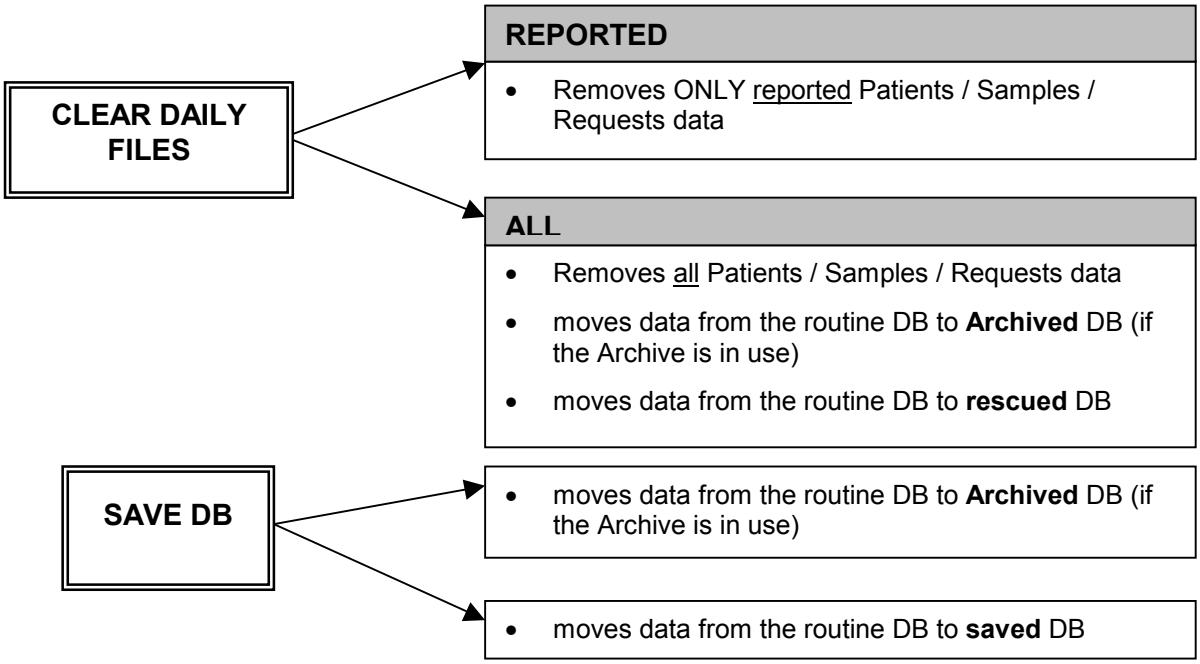
☞ Activate F1 to stop analysing immediately.

Function F4 About displays the program version of the Konelab application and when the analyser is on, the program version of the internal PC of Konelab 60 and 30.

With F8/F3 you can exit from the Konelab program when analysis is not in progress.

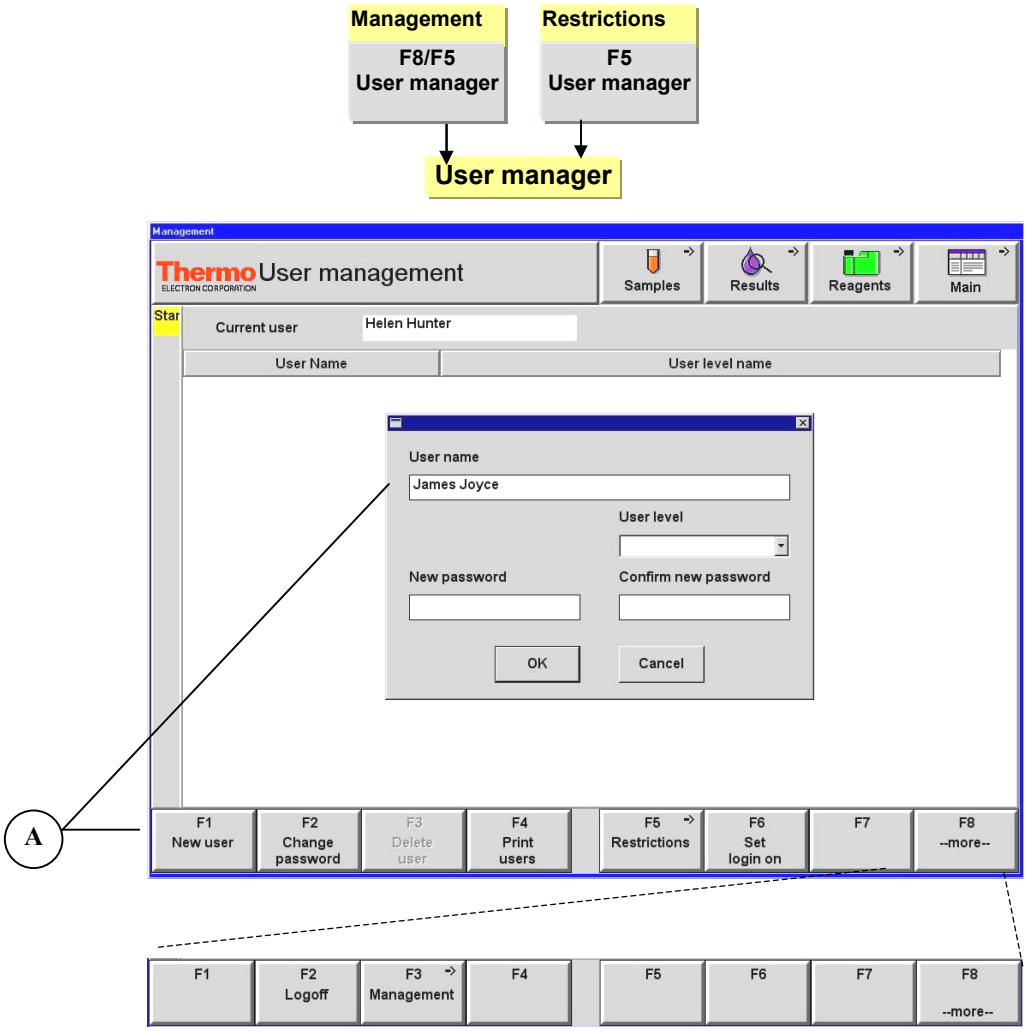
Table 1. Differences between databases.

Routine DB	**Archived DB**	**Default DB = KONELAB original DB**
Patients Samples Requests	Patients Samples Requests	
Tests parameters	Tests parameters	Tests parameters
Profiles		
Reference classes		
Calibrators library	Calibrators library	Calibrators library
Calibrations	Calibrations	
QC requests		
QC library	QC library	QC library
QC results, cumulative	QC results	
Reagent disk contents		
Reagents & lot no	Reagents & lot no	Reagents & lot no
Samples disk contents		
Statistics		
Maintenance tasks		
Users & levels		Users & levels
error messages		
Water blank values		



Saving operations can be done also through the Konelab Database Management. Refer to section 10.2.1

3.7 USER MANAGEMENT



A Select F1 to register a new user. After that, type the user name, select the user level and type the password. The user name will be printed into reports.

You do not have to be the current user to change your password.

Select F2 to change the password.

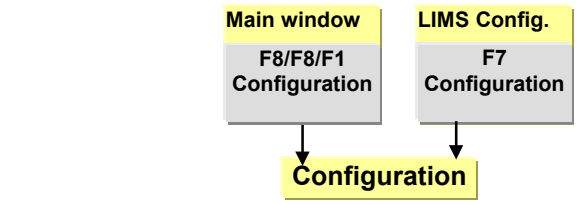
Select F8/F2 to logoff. After that a new operator has to give the password to login.

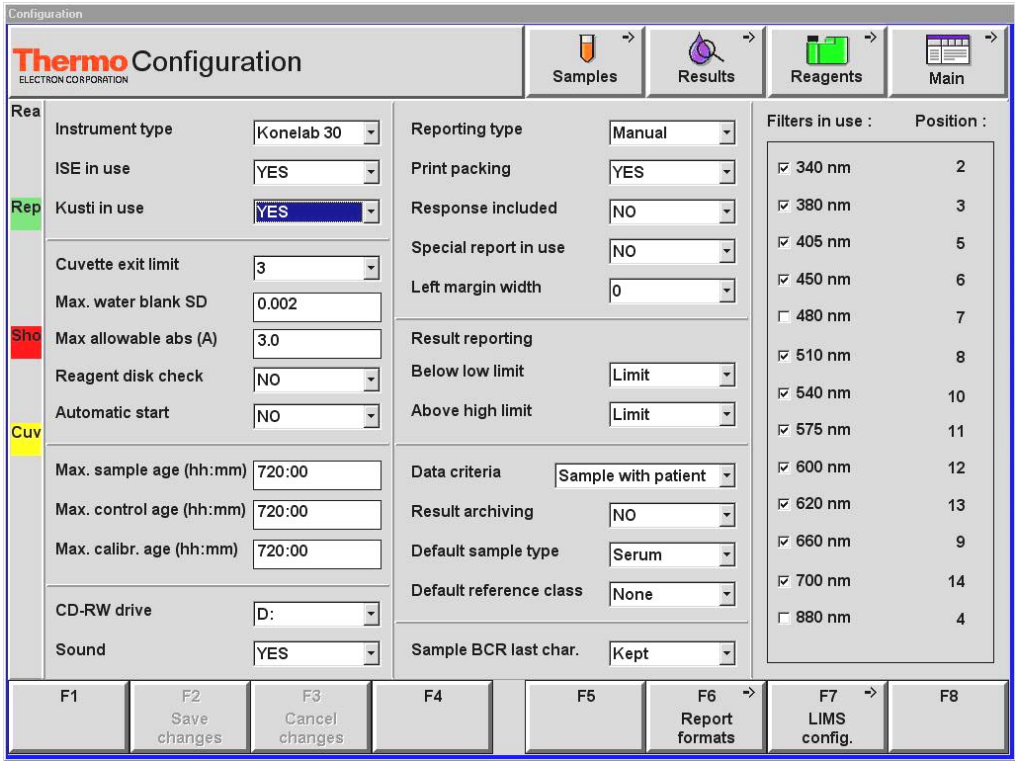
As an example being users, Konelab (in Main level) and User (in Routine level), have the password Konelab.

User levels can be set on and off by activating F6.

With F3 Users can be deleted. Only those users which rights are under the level of the current user are seen this window, e.g. the main user can create new routine users and delete old ones. User levels and rights are determined in the Restrictions window. Refer to section 4.10.

3.8 CONFIGURATION





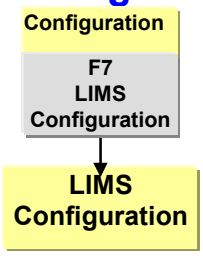
Information seen in the CONFIGURATION window:

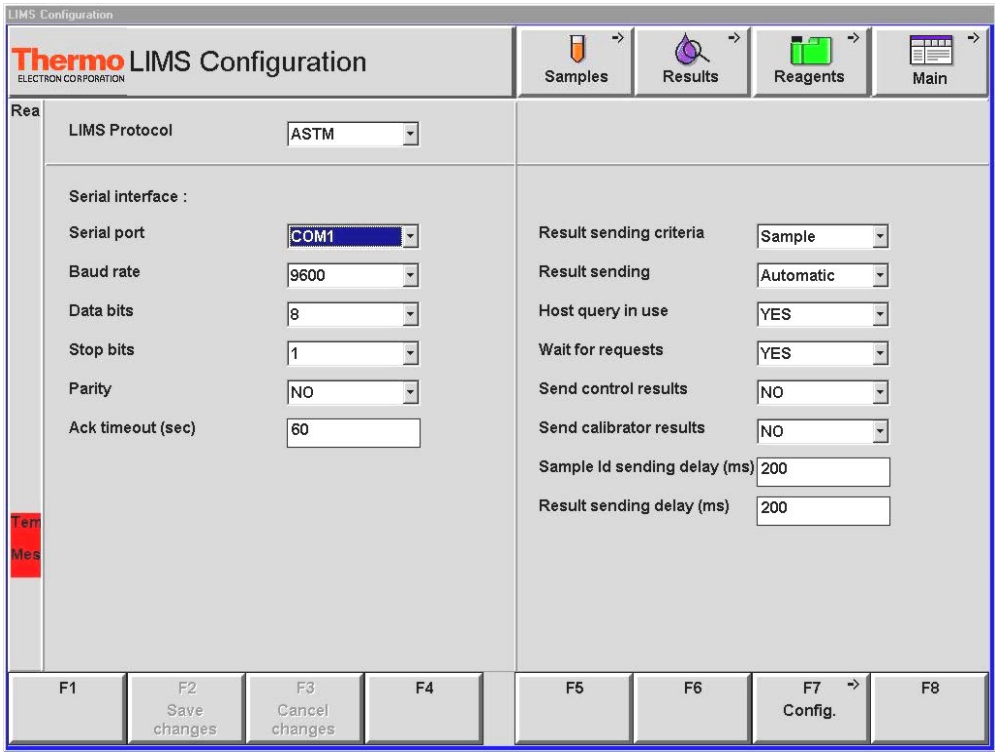
- *Instrument type*	The instrument type, Konelab 60/ 30/ 20XT/ 20, is seen.
- *ISE in use*	Connect ISE unit on or off. Changing demands rebooting.
- *KUSTI in use*	Connect KUSTI unit on or off. Changing demands rebooting.
- *Cuvette exit limit*	The maximum number of unused cuvette cells before the cuvette is allowed to discard.
- *Max. water blank SD*	The maximum allowed limit for water blank standard deviation.
- *Max allowable abs. (A)*	Type the maximum absorbance value, which is allowed. If the absorbance value given here is exceeded, an error message appears in result reports.
- *Reagent disk check*	Select if the reagent disk is checked or not (YES / NO) when the analyser is booted. The reagent data is read and the volume checked when Yes is answered.
- *Automatic start*	Connect automatic start on (yes) or off (No).
- *Max sample age*	Type the maximum allowed sample age in hours and minutes (hh:mm). The sample is marked 'Old' and is not dispensed if the time is over. Maximum allowed time can be 720 hours (1 month) and at least it must be 1 minute. Sample age concerns all samples in the segments, STAT positions and automated sample line.

- *Max control age*	Type the maximum allowed control age in hours and minutes (hh:mm). The control sample is marked 'Old' and is not dispensed if the time is over. Maximum allowed time can be 720 hours (1 month) and at least it must be 1 minute. Sample age concerns all controls in the segments, STAT positions and coming through automated sample line. The age of controls, which are in the fixed positions in the sample disk, is not monitored.
- *Max calibrator age*	Type the maximum allowed calibrator age in hours and minutes (hh:mm). The calibrator sample is marked 'Old' and is not dispensed if the time is over. Maximum allowed time can be 720 hours (1 month) and at least it must be 1 minute. Sample age concerns all calibrators in the segments, STAT positions and coming through automated sample line. The age of calibrators, which are in the fixed positions in the sample disk, is not monitored.
- *CD-RW drive*	Select the CD drive id.
- *Sound*	Select if you want to hear (YES) or not (NO) warning signals given by Konelab.
- *Reporting type*	Select if reporting is manual or automatic.
- *Print packing*	Select if the report's results are packed or not (YES/ NO). If Yes is selected the report includes more than one patient's/ sample's/test's results in one page. If No is selected one report page includes only one patient's/ sample's/ test's results.
- *Response included*	Select if the response is included in reports or not.
- *Special report in use*	Select if you use the special, configured report (Yes) or the default one (No).
- *Left margin width*	Select the left margin size in result report. It can vary from 0 to 10 columns.
- *Result reporting below low limit*	Select if the result below the low limit is reported as a limit symbol, e.g. <Low limit, or as an exact value.
- *Result reporting above high limit*	Select if the result above the high limit is reported as a limit symbol, e.g. >High limit, or as an exact value.
- *Data criteria*	Select if the data is entered and automatically reported according to patients or according to samples. Samples can be selected with or without patient. Without patient means that the patient name is neither seen in the Sample entry window nor in reports.
- *Result archiving*	Select if the result archive is used or not. If archive is taken out of use the data of it is lost. When archive is taken into use it is recreated automatically. Limited archive means that quality control, calibration and reagent lot data are archived but patient data is not.
- *Default sample type*	Select the default sample type used in Sample/ Patient entry.
- *Default reference class*	Select the default reference class used in Sample/ Patient entry.
- *Sample BCR last char.*	If the last character of sample barcode is a check character, it should be skipped in order that barcode reader in the sample disk could read sample barcode properly. If the last character is not a check character, it can be kept.

- *Filters in use, Position* Tick the installed wavelengths, the position in the filter wheel is displayed.

3.8.1 LIMS configuration





- *LIMS Protocol* The used laboratory information management protocol in online connection.

- *Result sending criteria* Select the result sending criteria, Sample / Request, in the LIMS protocol.

If the LIMS protocol is KONE Online, the following field is also seen:

- *New/ Old check in use* Select if the sample's new/ old check is used (Yes) or not (No) during the LIMS protocol.

If the LIMS protocol is ASTM, the following fields are also seen:

- *Result sending* Select if the results are sent to the host computer automatically or when requested.

- *Host query in use* Select if the host query is used or not during sample/patient entry.

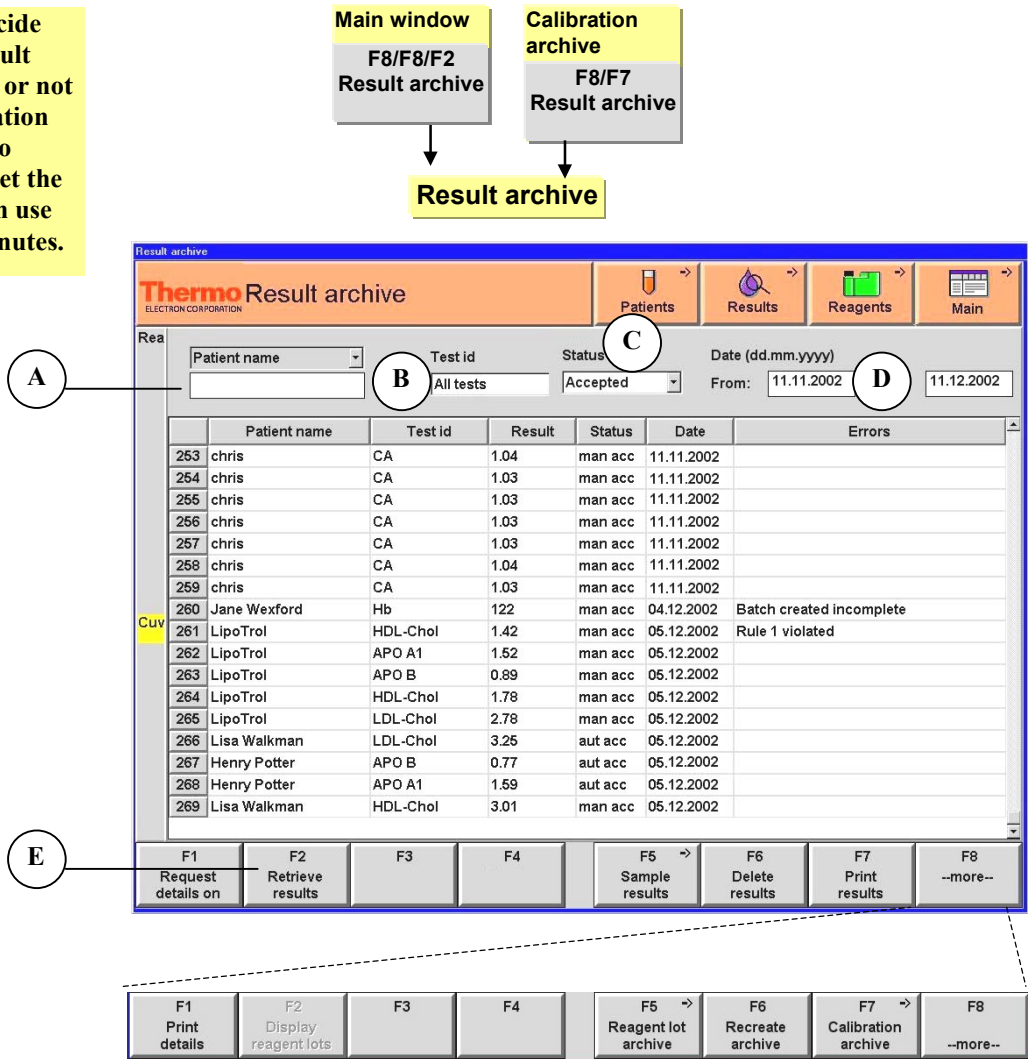
- *Wait for requests*	If Host query was selected in use then the user can select if requests are waited for or not during sample/patient entry. If 'Yes' the user is waiting for after entering the name of a new sample/patient. Otherwise the user is working and requests are coming parallel.
- *Send control results*	Select if control results are sent to the host computer or not.
- *Send calibrator results*	Select if calibrator results are sent to the host computer or not.
- *Sample Id sending delay (ms)*	The delay needed before Konelab sends sample Id to the host computer. The default value is 200 milliseconds, minimum is 0 and maximum 30 seconds.
- *Result sending delay (ms)*	The delay needed before Konelab sends sample results to the host computer. The default value is 200 milliseconds, minimum is 0 and maximum 30 seconds.

Serial Interface parameters:

- *Serial port*	Select the serial port from the pull down menu. Alternatives are from COM1 to COM4.
- *Baud rate*	Select the baud rate values between 110 and 9600.
- *Data bits*	The number of data bits can be 7 or 8.
- *Stop bits*	The number of stop bits can be 1 or 2.
- *Parity*	Select the parity checking. It can be even or odd. If checking is not wanted select NO.
- *Ack timeout (sec)*	The maximum time the response is waited for.

3.9 RESULT ARCHIVE

The user can decide whether the Result archive is in use or not in the Configuration window. Refer to section 3.8. To get the Result archive in use takes several minutes.



The Result archive includes lot of data which loads the memory capacity. That's why the user is recommended to delete results in the archive at regular intervals. After Clear daily files the user is warned if the memory capacity is too low.

Result archive includes sample and control results. New data is seen in the result archive after the Clear daily files.

The user can get max 10 000 latest results or requests at a time:

- results (accepted, rejected, rerun) and requests of a patient,
- patient and/ or control requests of a test in a definite time.

By changing the time period you can see all results.

A Type the patient name or the control id. Following the patient name with an asterisk (*), e.g. Jone*, returns all patients with a similar nomeclature. The control id must be typed exactly as it is defined in the Cal/Ctrl definition, refer to section 4.6.2.

B Select all tests or one test from the selection list to be seen.

C Select if all results or only accepted or rejected results are seen.

D Select the date interval from which you want to see results. The results from the last day selected are also included.

E Activate F2, Retrieve results to see results.

Information seen in the Result archive window:

- *Patient name/* - *Control id*	The Patient name / Control id is seen.
- *Test id*	The test is seen.
- *Result*	The result of the measurement is seen.
- *Status*	The status of request is seen.
- *Date*	The date of measurement is seen.
- *Errors*	The possible errors are seen.

To see the used reagent lots

Activate F8/F2 to see which reagent lots have been used when the selected results have been analysed.

To delete results

First, select the date to which you want to delete results and then, activate F6 to delete the data. Results from the day selected are also deleted. Deleting will take several minutes.

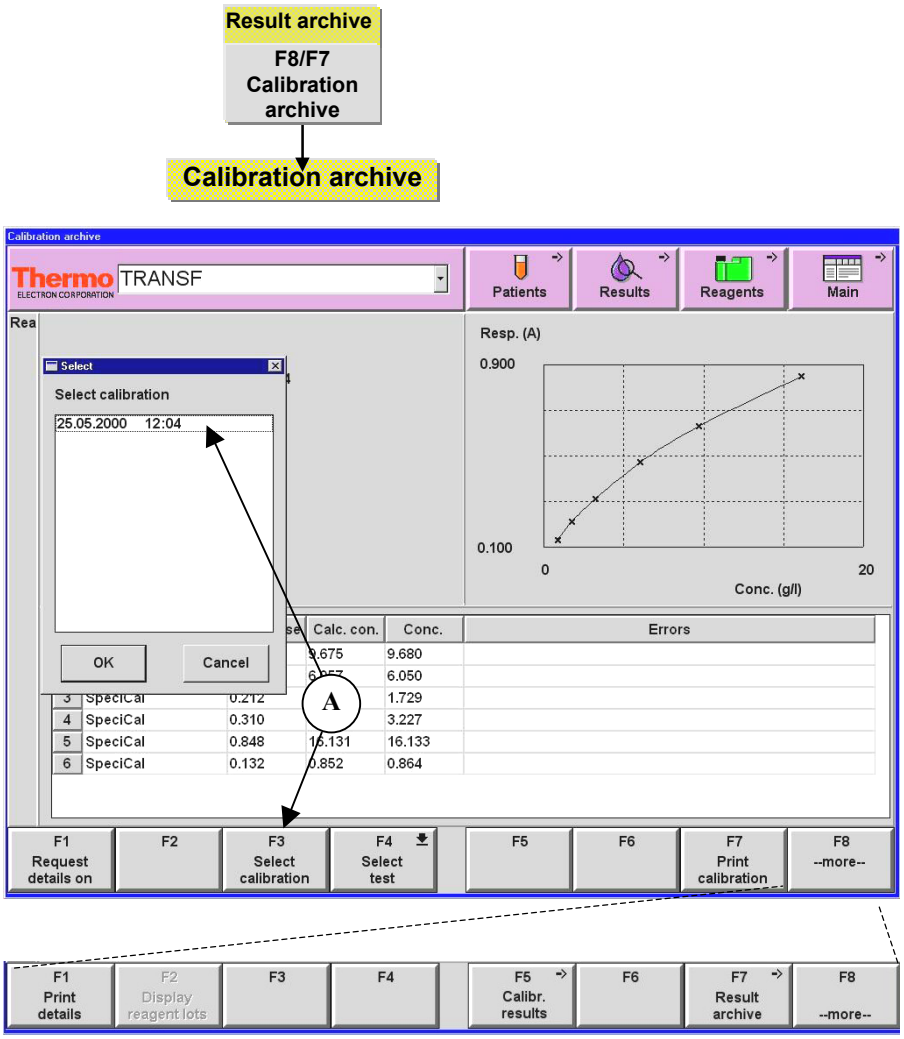
To print results

Activate F7 to print selected results or all results got from the archive. With F8/F1 you can print details from one result.

To recreate archive

Activate F8 /F6 to recreate archive. Note that all data from the old archive is lost.

3.9.1 CALIBRATION ARCHIVE

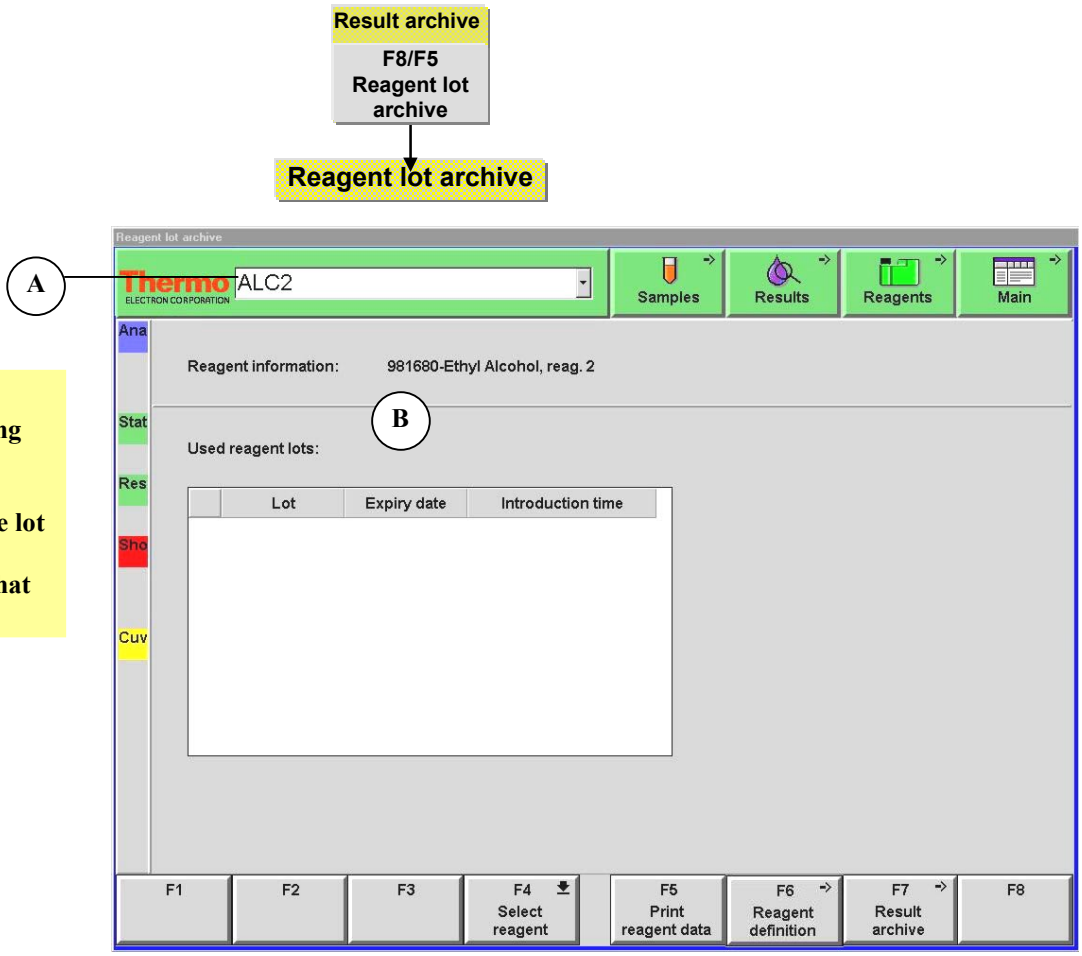


Calibration archive includes old, accepted calibrations after the Clear daily files function has been done.

A Press F3, and select calibration from the list.

With F8/F2 you can see which reagent lots have been used when the selected calibration have been done.

3.9.2 REAGENT LOT ARCHIVE



In order that the reagent lot auditing is functioning correctly, there should only be one lot number on the reagent disk for that particular assay.

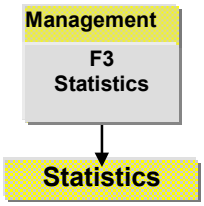
Reagent lot archive includes old reagent lots after the Clear daily files function has been done.

A Select reagent from the list.

B The reagent information and used reagent lots are seen.

☞ Select F5 to print the reagent data.

3.10 STATISTICS

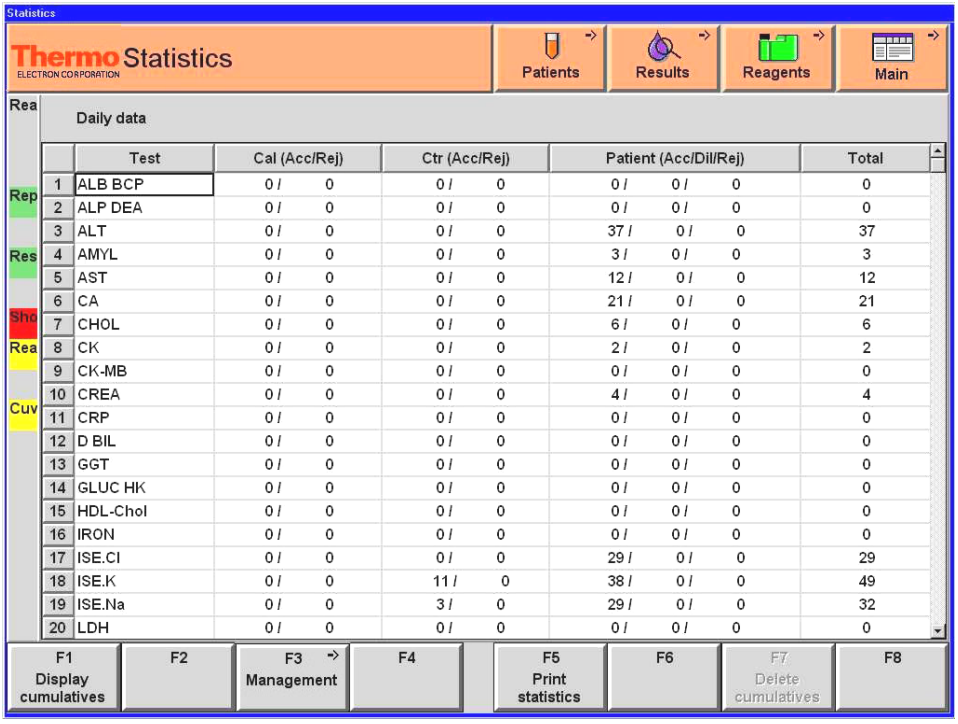


Both daily and cumulative number of accepted and rejected requests of calibrators, controls and samples are seen test by test in this window. For patient samples also diluted are counted. The test's total number of requests is seen in the end of the row.

With F1 button you can select either daily data or cumulative data in the window.

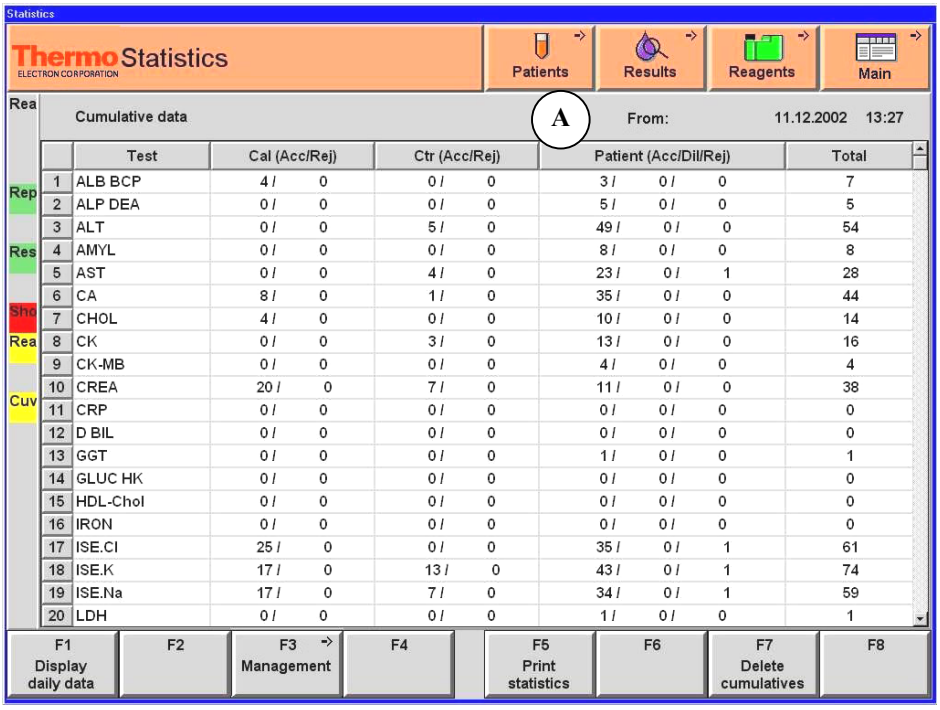
DAILY DATA:

The daily data is updated when Clear daily files is done.



Daily data includes tests in use and also those tests marked not in use which have some requests.

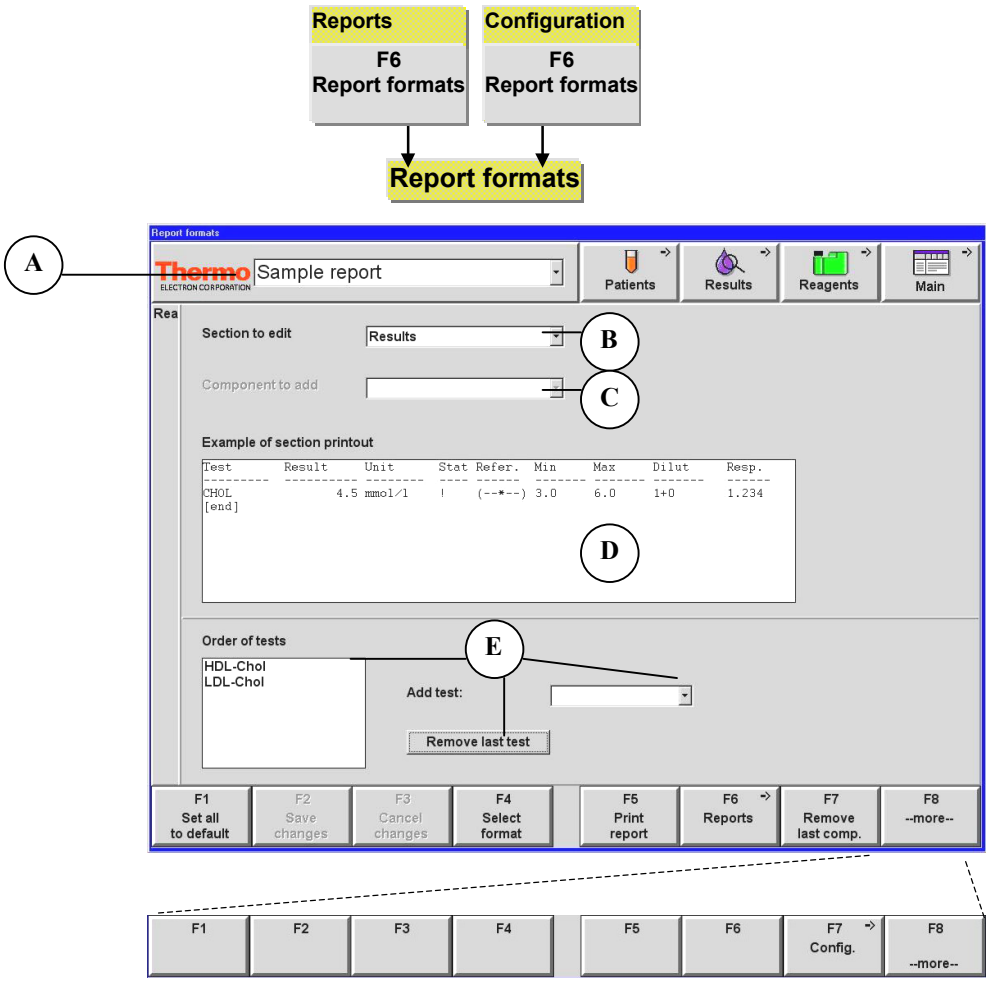
CUMULATIVE DATA:



A Cumulative data includes tests from the date seen in the window.

The cumulative data is cleared by F7, Delete cumulatives. Note that the deleting date cannot be changed. The previous deleting date is seen in the window.

3.11 REPORT FORMATS



A Select the report format. It can be:

- General header (common for the patient, sample and test reports),
- Patient report,
- Sample report,
- Test report.

B Select the report section to edit.

In case the report format is 'General header' the section can be:

- General header

In case the report format is 'Patient or Sample report' the section can be:

- Patient data,
- Sample data,
- Footer,
- External results,
- Patient calculated test's results,
- Results (includes results from sample calculated tests).

In case the report format is 'Test report' the section can be:

- Test data,
- Results.

Leave at least one component in each section in order not to confuse the format. In case you cannot format the report, the error message is given. In that case try to solve the problem with F1, setting all to default format.

C Select the component to add, e.g. in case it is patient report and patient data, the component can be patient code, sender id, birthday or empty row. Or in case it is sample data, the component can be collection date and time or entry date and time, comment or empty row.

D You can always see the example of section printout on window.

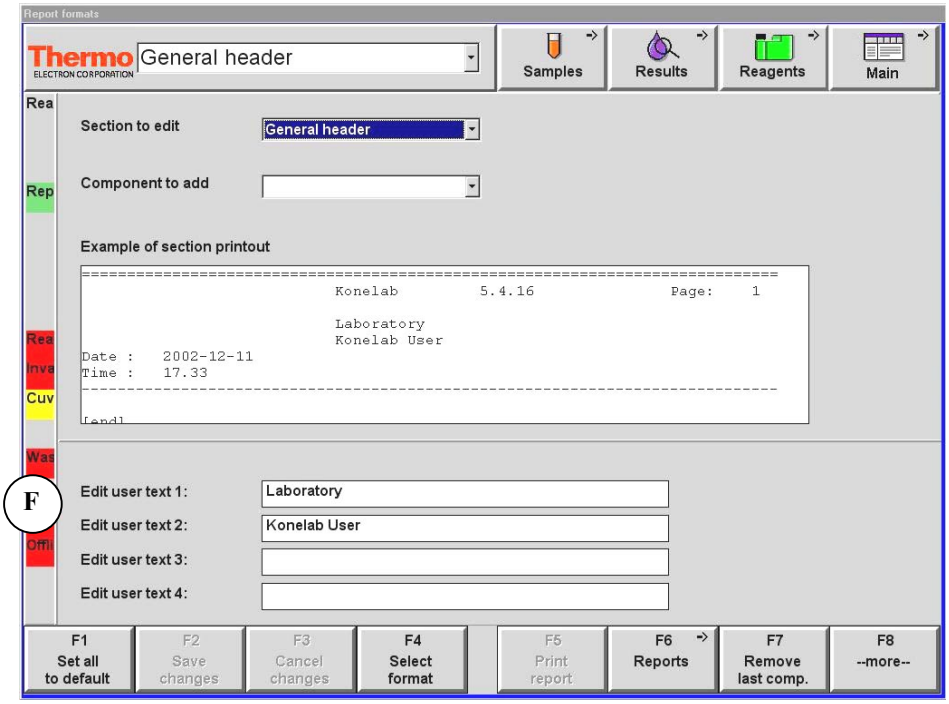
E Select from the list the tests included in the report before other tests. The test list is seen when it is question of patient or sample report and results component. The selected tests are seen as a list beside, but note that they are not reported in a list order. Tests, which are not included in the list, are reported after these tests seen in the list.
Last test can be removed from the list by pressing the button.

☞ Save the selections with F2. With F3 you can cancel the changes made after the last save.

☞ F7 removes the last component added to the report section.

☞ With F1 you can return to the default report format for all reports.

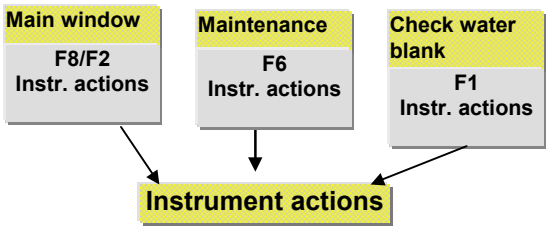
To edit user texts

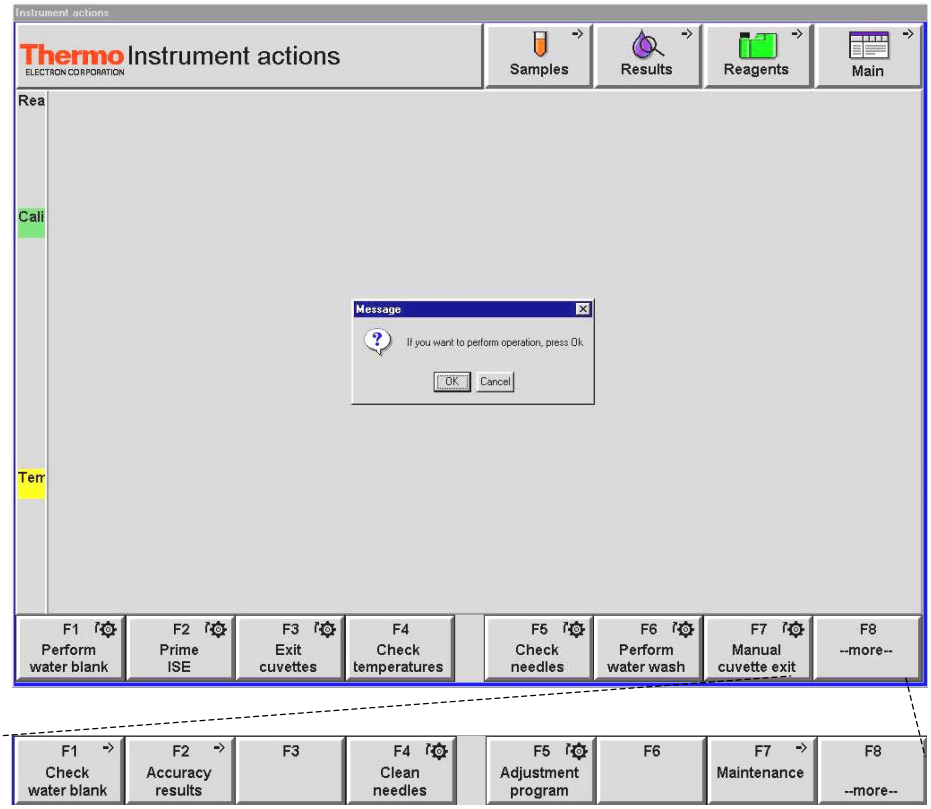


☞ Select General header.

F Edit texts compatible with reports used in your laboratory.

3.12 INSTRUMENT ACTIONS





☞ Activate F1 to perform water blank. In case the water blank is unsuccessful, it will turn the analyzer to the 'Start up needed' state.

☞ Activate F2 to fetch serum into the ISE block. Insert a 2 ml cup of ISE prime solution in the position of ISE Prime.

☞ Activate F3 to remove cuvettes from the incubator, e.g. in a special situation to remove leftover cuvettes.

After boot, the yellow label 'Temperature' is seen in the Main window until temperatures are OK. If temperatures go out of range, the 'Temperature' label turns red.

☞ Activate F4 to check temperatures. You see the channel, its temperature and status. Temperature of measuring channel, incubator and ISE unit should be 37 °C. In addition reagent and sample stations (dispensing positions) in Konelab 60 should be in 37 °C. In Konelab 30, 20XT and 20 dispensing is performed straight into the incubator. Furthermore, the temperatures of reagent and sample disk are seen. If temperature of reagent register is too warm, run manual QC and change reagents.
Temperatures are updated every time when F4 is activated.

Needles and mixers are potential sources of infectious agents. Be careful and use protective gloves always when cleaning them.

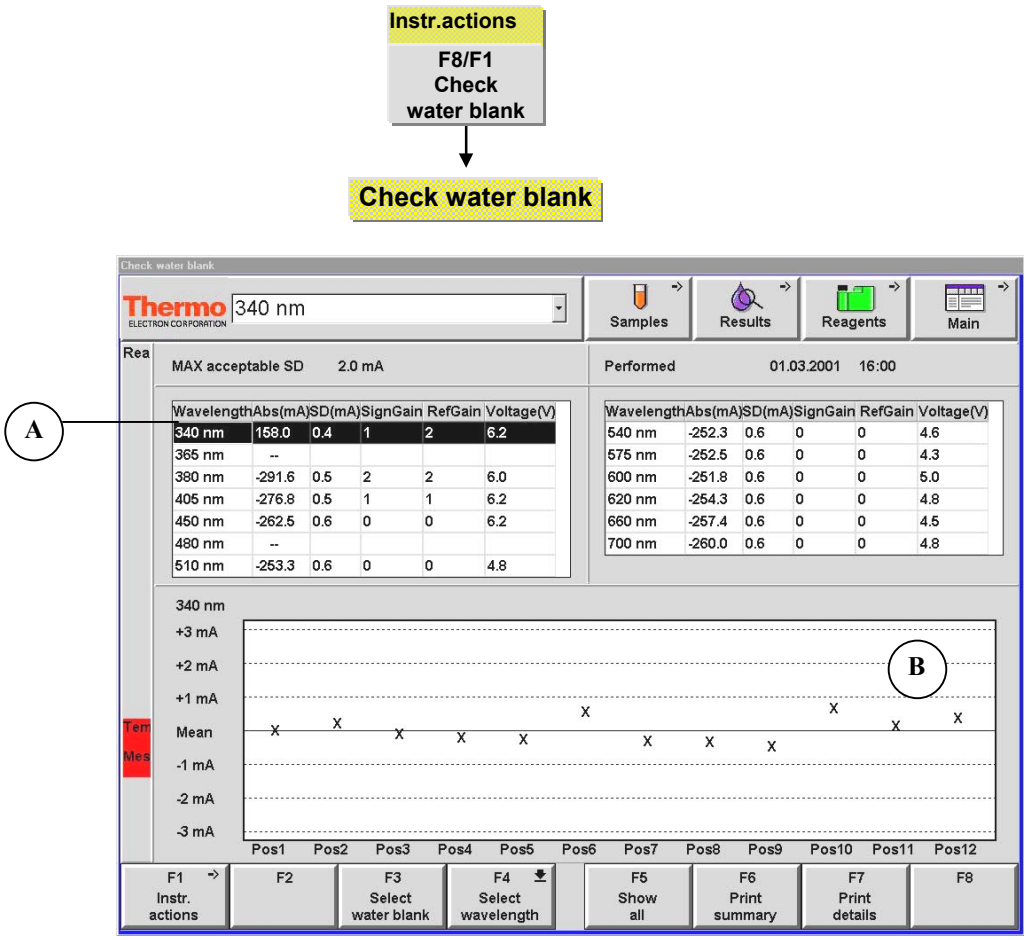
☞ Activate F5 to check needles. They are driven to the alignment point. You can check e.g. the straightness and the position of the needle. When cleaning needles, activate F8/F4. It will bring first the needles and then the mixer(s) to the position where you can clean them. When you third time press F8/F4, needles and mixer(s) go back to their washing stations.

☞ Activate F6 to perform water wash. Tubes, pumps, syringes and needles are washed with distilled water.

☞ Function F7, Manual cuvette exit is only in Konelab 60 and 60i. When there are problems e.g. with moving a cuvette because of a broken cuvette arm, you can first automatically remove the cuvette to the hole in the incubator with F7 and then remove it manually.

Adjustment program is meant for Service engineers to adjust analyser's robotics.

3.13 CHECK WATER BLANK



A Click the desired wavelength from the table or select it by F4.

B The water blank result of each cuvette position is seen graphically.

Select F5 to see all wavelengths' water blank results in a same graphic.

Select F3 and click the previous water blank measurement from the list to see.

Select F6 to print summary of the water blank results.

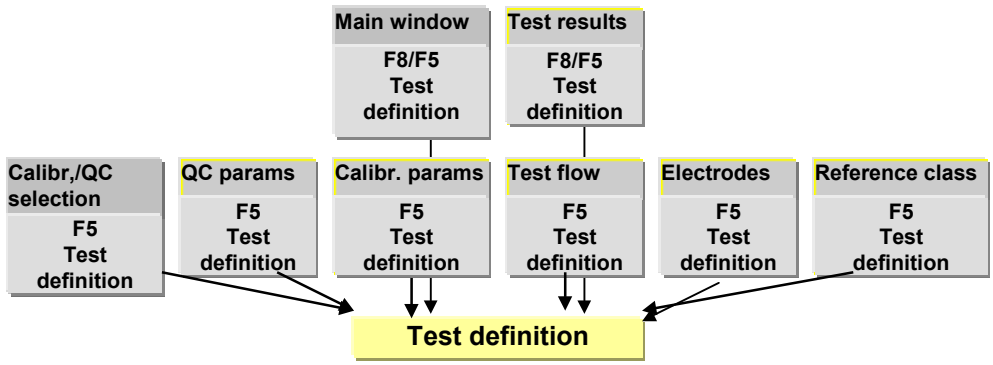
F7, Print details is meant for Service engineers to see more detailed information of water blank results.

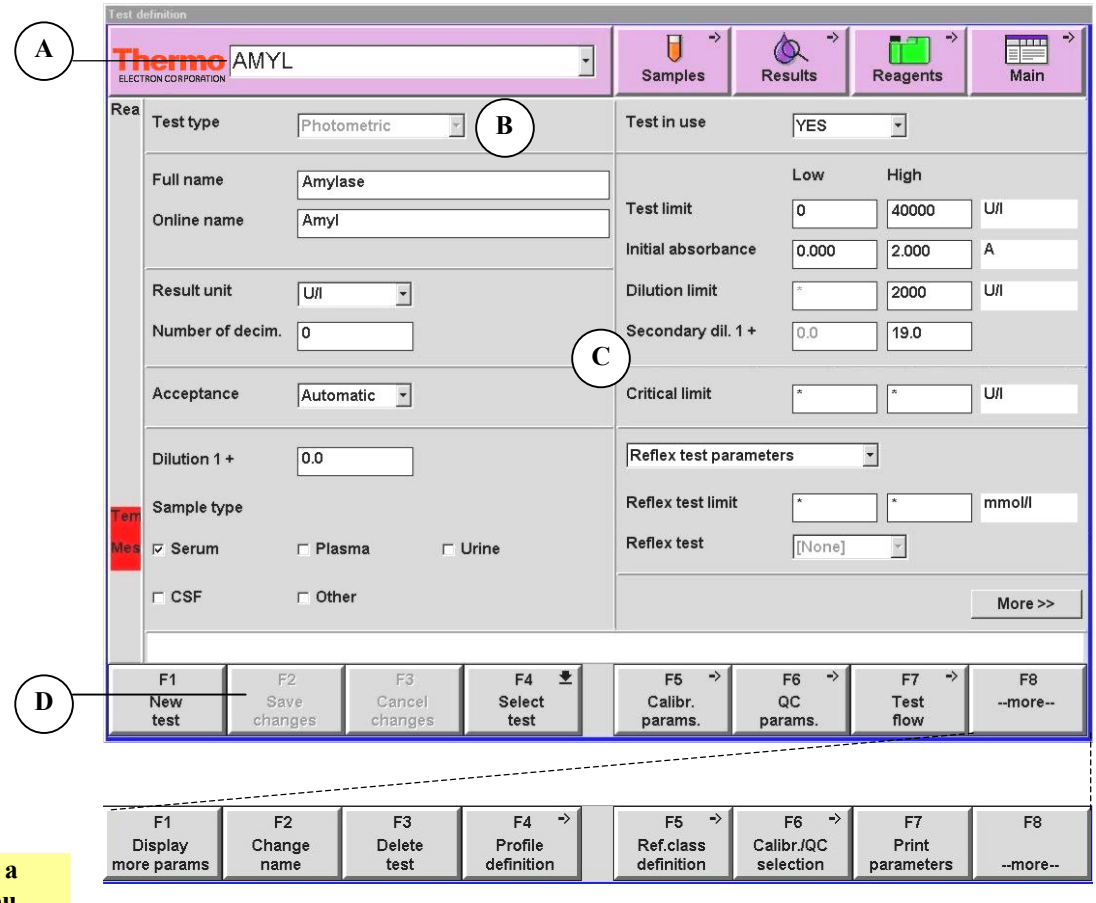
4. TESTS

This chapter describes how to edit a test's parameters.

4.1 TEST DEFINITION

You can define a new test or change the test's parameters only when analysis is not in progress and the test have no unaccepted requests.
Before editing tests, it is recommended to do Clear files in the Management window.





When you have created a new photometric test you have to give also the test flow and the calibration parameters.
With an ISE test you have to give also the calibration parameters.

Activate F1, when you start to define a new test. A question 'Do you want to copy parameters of current test?' appears. To make editing easier, answer 'Yes'. Then also calibration and quality control parameters are copied from the test seen in the window. To start to define a new test from empty table, just answer 'Cancel'.

The online name can include characters from a to z. For example characters ä, ö, ü are not valid.

A — Type the name of the test (max. 10 characters) and press ↵.
With F8/F2 you can change the name.

B — Select the test type: photometric, ISE, calculated or external test.

C — Define all parameters. Refer to sections 4.1.1. - 4.1.4.

D — Save the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

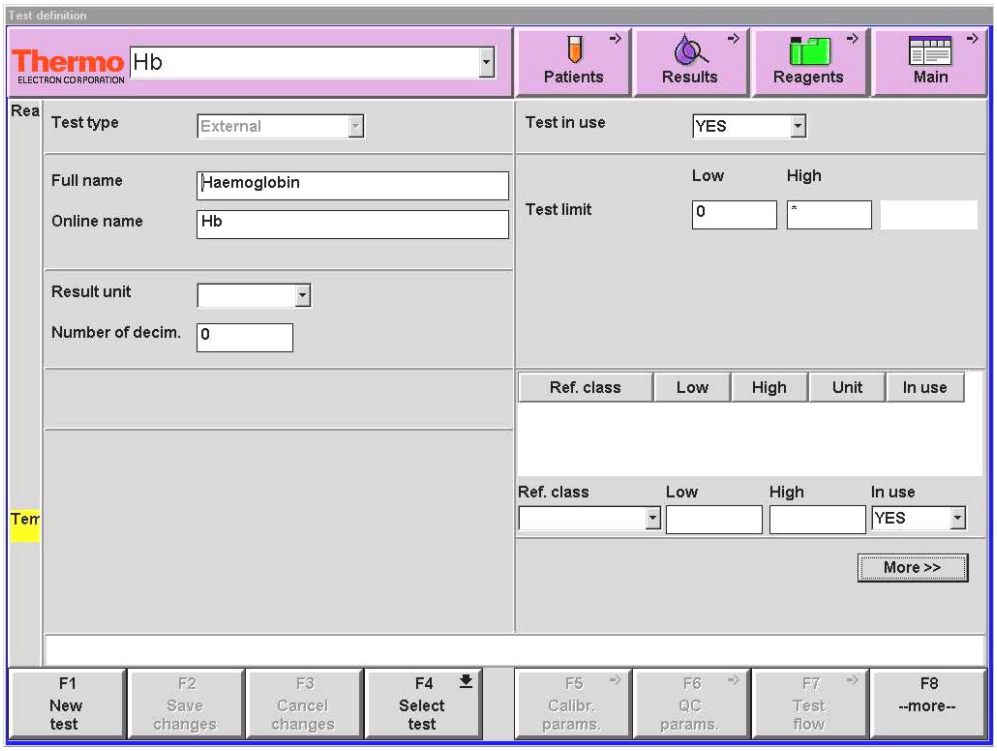
To delete the test data

Activate F8/F3 to delete the test. This also deletes the calibration and quality control parameters and the test flow parameters of the photometric test.

To print the test data

Activate F8/F7 to print parameters. You can print the current test seen in the window or tests in use or all tests.

4.1.1 COMMON PARAMETERS FOR ALL TESTS



External tests have only these common parameters. Photometric tests, ISE tests and Calculated tests have other information as well. Refer to sections 4.1.2., 4.1.3. and 4.1.4. To enter requests of external tests and to give results for them, refer to section 3.2.6.

- *Test type* — Select the test type from the pull down menu. Alternatives are: *Photometric, ISE, External, Calculated (sample)* or *Calculated (patient).*

- *Full name* — Type the test's full name. (30 characters)

- *Online name*	Type the test's name used in the online connection.	(30 characters)
- *Result unit*	Type the result unit or select it from the list. When you change the result unit, you must recalibrate the test.	(10 characters)
- *Number of decimals*	Type the number of decimals in a result.	(1 character)
- *Test in use*	Select YES/NO from the pull down menu. Only the tests in use are seen in the Sample/ Patient entry window and can be calibrated.	
- *Test limit*	Type the minimum and maximum allowable values taking into account the linearity of the method. Limits are given as decimals. The default value for the low limit is 0 and for the high limit is *. In the result acceptance windows and on reports the *'Test limit low/high'* flag informs the user that the limit has failed. A patient result is passed for manual acceptance.	(10 characters)
- *Reference class*	Type the low and high limits for the reference values as decimals. With *In use* toggle button you can decide whether the reference class is used or not. Results falling outside the reference limits are flagged during the result printout. The reference classes in use are seen first in alphabetical order followed by the classes, which have values but are not in use, also in alphabetical order. Reference classes can be max. 20 pcs and they are defined by F8/ F5.	(10 characters)

In the photometric test Test limit (high) must be > Dilution limit (high) if the dilution limit has been defined.

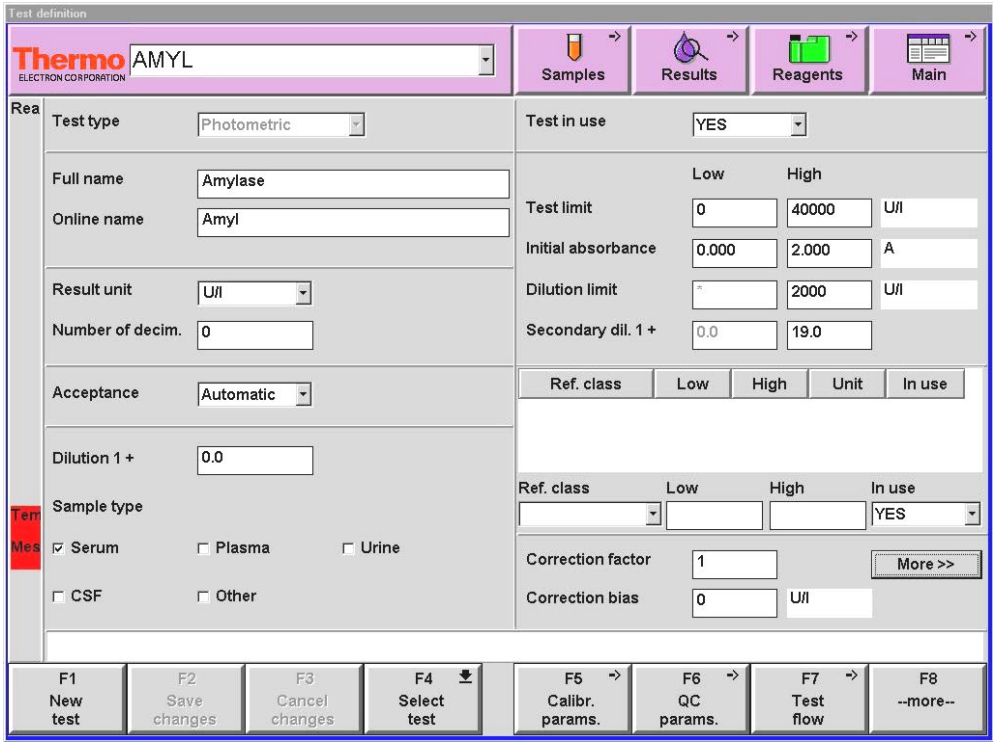
Default reference class used in Patient/ Sample entry can be defined in the Configuration window. Refer to section 3.8.

More parameters

Click the button More>> or F8/F1 Display more params.

- *Critical limit*	Type the low and high critical limits for the test. Critical limit is reference (physiological) limit for the test. If those limits are exceeded, the automatic acceptance is turned to manual. It is recommended to put something else than 0 to the low limit, so the questionable zero results can be detected. E.g. Glucose test Adult male <50 and >400 mg/dl, <2.7 and 22.2 mmol/l Adult female <40 and 400 mg/dl, <2.2 and 22.2 mmol/l the critical limits to set are: critical limit low: 2.7 mmol/l critical limit high: 22.2 mmol/l

4.1.2 PHOTOMETRIC TEST'S PARAMETERS



Common parameters for all test types are described in section 4.1.1. The parameters for the photometric test are as follows:

- *Acceptance* — Select the automatic or manual acceptance from the pull down menu. The default value is the automatic acceptance.

- *Dilution 1+* — Type the parts of a diluent versus one part of a sample. Note that, e.g. 1+9 corresponds to 1:10. The diluent can be 0 and vary between 1 and 120 with 0.5 decimal, i.e. 1, 1.5, 2…119.5, 120. This dilution is done for each test of a sample prior to analysis.
  The default value is 0.

Default sample type used in Patient/ Sample entry can be defined in the Configuration window. Refer to section 3.8.

- *Sample type* — Select the sample type with the toggle buttons. Several sample types can be selected. Alternatives are: *Serum, Plasma, Urine, CSF* and *Other*.

- *Initial absorbance* — Type the minimum and maximum allowable limits for the initial absorbances. Values can be given with three decimals. The default value for the low limit is 0 and for the high limit is *. For more information about the initial absorbance refer to section 5.1.5.

- *Dilution limit* — Type the limits in concentration units, which will prompt automatic reanalysis with automatic dilution. Values can be in decimals. The default value for the low dilution limit is 0 and for the high dilution limit it is *.

  In the result acceptance windows and reports the *'Dil.limit low/high'* flag informs the user that the limit has failed and the *'Diluted'* flag informs the user that the automatic dilution has been carried out according to the defined secondary dilution ratio.

The secondary dilution ratio can be defined only when the dilution limit has been defined.
The low secondary dilution ratio can be given only when the sample dilution is > 1+0.

- *Secondary dil. 1+*

Type the low and high values for the secondary dilution ratios for rerun analysis. Both values can be 0 and vary between 1 and 120 with 0.5 decimal. Default value for both is 0.

In case of an abnormal result (e.g. the result exceeds or falls under the dilution or the test limit) the sample is reanalysed with the dilution according to the defined high or low secondary dilution ratio.

Correction factors based on a 10 mm light path should be used.

- *Correction factor*

Type the correction factor as a decimal (max. 10 characters). Default value is 1.

The correction factor is used for calculations in the following way:

Corrected result = Corr. Factor x Result calculated according to the calibration

- *Correction bias*

Type the correction bias as a decimal (max. 10 characters). Default value is 0.

The correction bias will be subtracted from the result calculated according to the calibration in the following way:

Corrected result = (Result – Corr. bias) x Corr. factor

More parameters

☞ Click the button More>> or F8/F1 Display more params.

Reflex test parameters

- *Reflex test limit*

Type the low or the high value for the test to automatically perform a new test, i.e., a reflex test. For the other value, type *.

E.g. to perform microalbumin if U-Prot result is <1.0 g/l, set as a low limit 1.0 and as a high limit *.

E.g. to perform CK-MB if CK> 150 U/L, set as low limit * and as high limit 150.

- *Reflex test*

Select the reflex test from the list.

Screening test parameters

Both the test to be screened and screening test must be photometric. Test to be screened (=original test) cannot be part of a calculated test. Screening test cannot have a reflex test or it cannot be screened.

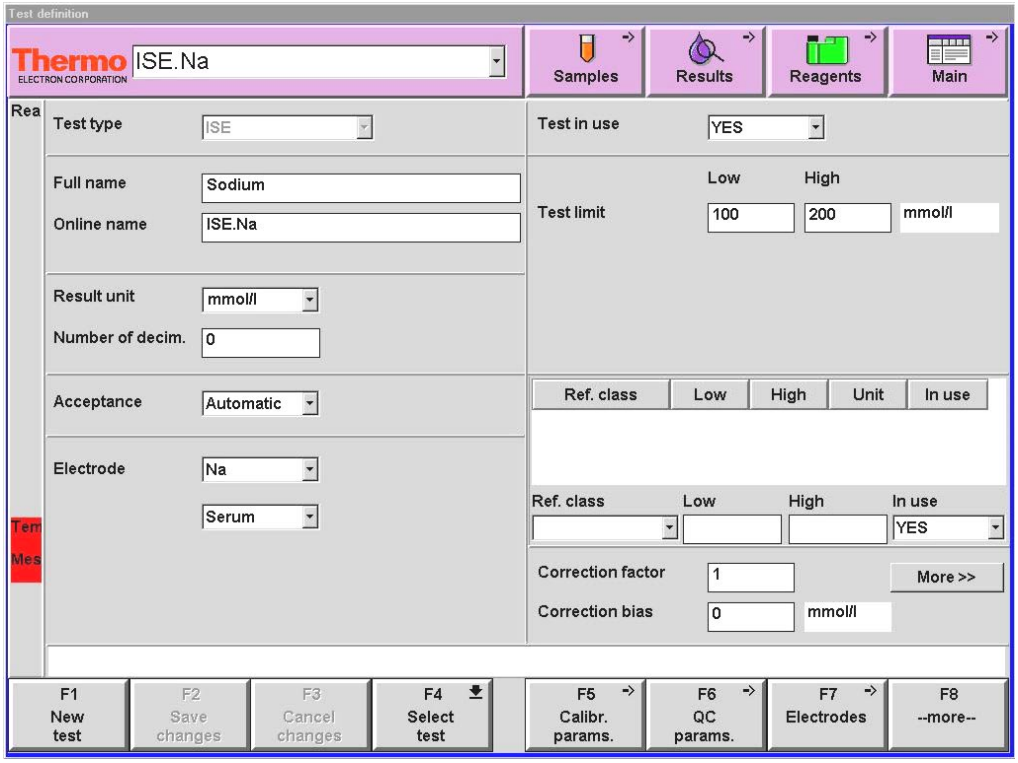
- *Screening limit*

Type the low and/or the high value for getting the right dilution ratio for the original test (= test to be screened). You can also type * for either value. If result is under the lower limit, request of original test is created with its primary dilution ratio. If result is between lower and upper limits, request of original test is created with its upper secondary dilution ratio. If the result is over the upper limit, a proposal for the dilution is calculated. The user must confirm the dilution. If the calculated dilution is over 120, the program suggests not to measure the requested test. In manual acceptance the user can still change the dilution limit. For more information, see section 5.1.14.

- *Test to be screened*

Select the test, which is screened.

4.1.3 ISE TEST'S PARAMETERS



Common parameters for all test types are described in section 4.1.1. The parameters for the ISE test are as follows:

- *Acceptance* — Select the automatic or manual acceptance from the pull down menu. The default value is the automatic acceptance.

- *Electrode* — Select the electrode from the pull down menu. Alternatives are: *K, Na, Cl, Li, Ca* and *pH*.

- *Sample type* — Select the sample type from the pull down menu. Alternatives are: *Serum* and *Urine*.

- *Correction factor* — Type the correction factor as a decimal (max. 10 characters). The default value is 1.

  The correction factor is used for the calculations in the following way:

  Corrected result = Corr. Factor x Result calculated according to the calibration

- *Correction bias* — Type the correction bias as a decimal (max. 10 characters). The default value is 0.

  The correction bias will be subtracted from the result calculated according to the calibration in the following way:

  Corrected result = (Result – Corr. bias) x Corr. factor

More parameters

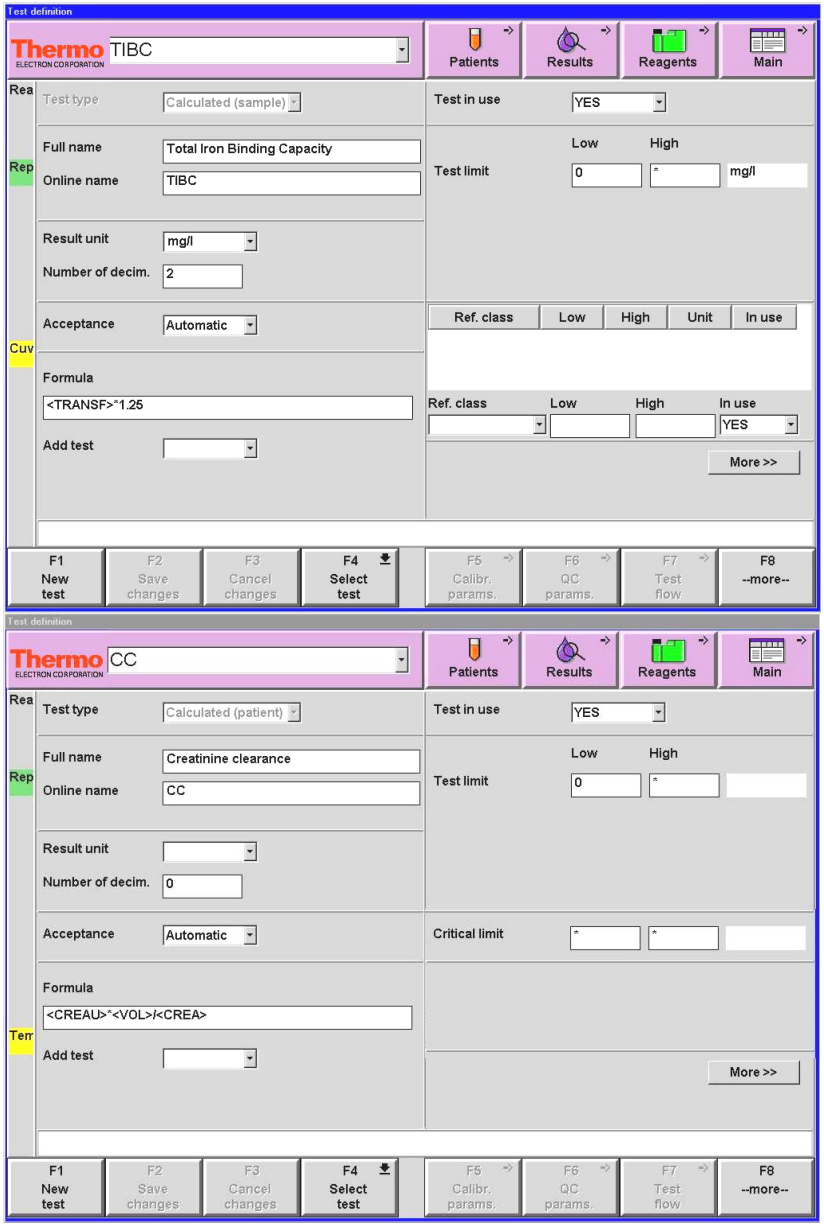
Click the button More>> or F8/F1 Display more params.

- *Reflex test limit* — Type the low or the high value for the test to automatically perform a new test, i.e., a reflex test. For the other value, type *. For example if you type the low value, type * for the high value.

- *Reflex test* — Select the reflex test from the list.

4.1.4 CALCULATED TEST'S PARAMETERS

A calculated test can be a test which needs measured sample results (Calculated (sample)) or it needs results from different samples of a patient (Calculated (patient)) or external results.



Common parameters for all test types are described in section 4.1.1. The parameters for the calculated test are as follows:

- *Acceptance* — Select the automatic or manual acceptance from the pull down menu. The default value is the automatic acceptance.

- *Calculation formula* — Give the calculation formula as a mathematical formula. The available operators for the formula are:

  \+ for addition - for subtraction
  * for multiplication / for division

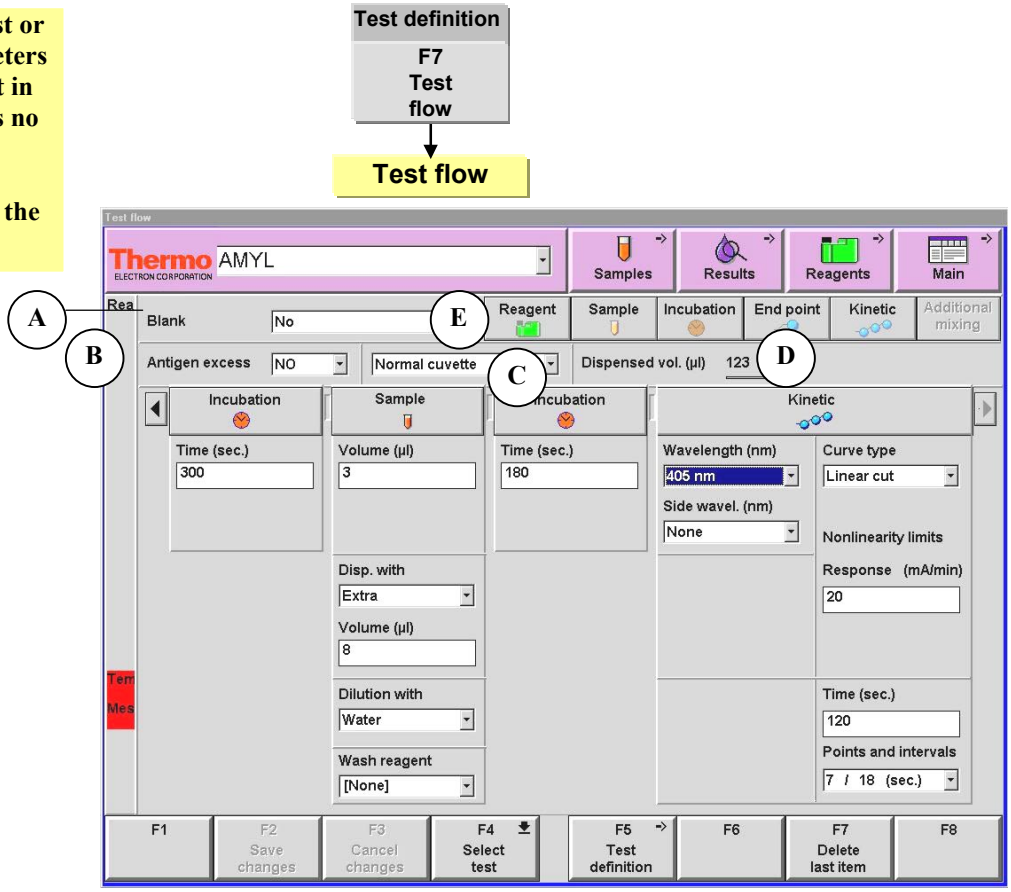
  numbers, e.g. -9.23, 7.275,
  tests selected from the test list or written to the *Add test* field.
  ( ) brackets must be used when you want some operation to be done first, e.g. (<A>/<B>)*<C> division is done first, then multiplication. If you put the same formula without brackets i.e. <A>/<B>*<C>, the multiplication is done first and division after that.

The calculation formula can have max. 5 tests.
The calculated test cannot be a part of the calculation formula.
When a test has more than one sample type defined in Test definition it cannot be used in the calculation formula of the calculated (patient) test.

To enter requests of calculated tests refer to section 3.2.5.

4.2 TEST FLOW FOR PHOTOMETRIC TESTS

You can define a new test or change the test's parameters only when analysis is not in progress and the test has no unaccepted requests. When the test flow parameters are changed the test must be calibrated.



A Select *Blank* from the pull down menu. Alternatives are:

! When *Blank* or *Antigen excess* data are changed the user must define all operations for the test flow again.

- *No*, when the water blank measured automatically during the START UP operations is used in the calculations as a blank measurement.
- *Yes*, when the user selects a measurement for the blank to be made during the test flow. The blank measurement can be end point or kinetic measurement. If the kinetic blank measurement is selected the sample measurement must also be kinetic. For further parameter details refer to sections 4.2.3. and 4.2.4.
- *True sample*, when the blank measurement is performed in a separate cuvette position. The user selects one reagent, which is replaced with the blank reagent.
- *Meas with fixed timing*, when it is important to have the same time between dispensing and measurement for every cuvette cell. Can be used in a kinetic measurement with nonlinear curve type and in an end point measurement with fixed timing.

If blank is *No* or *True sample* the test flow needs one measurement for the sample. If blank is *Yes* the test flow needs two measurements: one for blank and one for sample. If *Antigen excess* check is selected one measurement for this is needed.

For more information about the blank measurements refer to section 5.1.4.

B Select whether the *Antigen excess* is used or not from the pull down menu.

When the antigen excess detection is selected one measurement is done for it. This is always the last measurement. The antigen excess measurement is performed with the same parameters as the actual sample measurement. However, the user can define e.g. the volume of antigen excess sample. For further parameter details refer to section 4.2.5. For the meaning of antigen excess detection refer to section 5.1.11.

C — Select, how the cuvette is used, in a normal or in a fixed way. Fixed way means that dispensing is done in every second cell of a cuvette. In that way air position is between every test, and it evens temperature. Fixed cuvette is recommended for temperature sensitive kinetic tests. Normal cuvette means that every cell of a cuvette is used for dispensing.

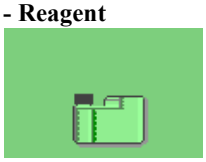
D — The total volume, which will be dispensed into a cuvette, is seen automatically during actions are selected. The minimum dispensed volume must be 100 µl and the maximum is 250 µl.

E — Select the test flow i.e. the test actions by activating the buttons at upper right in the window. When the action has been selected it is seen in the window in the order of operation. One test can have up to 20 actions.

Actions to select:

A test flow can have up to four reagent dispensing.

- Reagent



The reagent dispensing parameters are: the reagent name, the reagent volume, if the reagent is dispensed with water, reagent extra or extra with buffers, the water/ reagent extra volume and if reagent is washed before dispensing to the cuvette with some reagent. In addition, if the blank measurement type is *true sample* the user selects the replacement reagent for one reagent dispensing. Refer to section 4.2.2.

A test flow can have one sample dispensing.

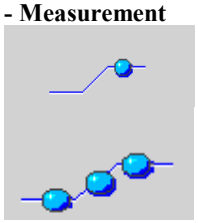
- Sample and dilution

The sample dispensing parameters are: the sample volume, if sample is dispensed with water or with sample extra, the water/ sample extra volume, if the sample is diluted with water or special diluent or washed with extra water before dispensing another sample. Refer to section 4.2.1.

- Incubation

The only incubation parameter is the time. The incubation time can vary from 15 to 3600 seconds. The default value is 120 seconds. Minimum time to reach 37°C for reagent dispensed between 100 – 200 µl is about 300 seconds.

- Measurement



The measurement can be the *End point* or *Kinetic* measurement. Other parameters for the measurement depend on the measurement type. For the blank measurement, min and max limits are defined. Refer to sections 4.2.3. and 4.2.4.

- Additional mixing

Additional mixing needs no parameters.

If you cannot save operations the reason, e.g. the missing measurement, is shown at upper right in the window.

☞ Save the operations with F2. With F3 you can CANCEL the changes made after the last SAVE.

The last action can be deleted with F7.

4.2.1 PARAMETERS FOR SAMPLE AND DILUTION

A test flow can have one sample dispensing.

The sample and dilution dispensing has the following parameters:

The max. volume of the cuvette is 250 µl.

- *Volume* — Type the sample volume that will be dispensed to the cuvette position for test reading. This can vary from 0 to 120 µl. The default value is 0 µl.

- *Disp. with* — Select from the pull down menu if a sample is dispensed with water or with sample extra. Refer to section 5.1.7.

When true sample blank has been selected the sample + sample extra volume is max. 100 µl.

- *Volume* — Type the volume of water or sample extra. When a sample is dispensed with water, the volume can vary from 1 to (120 - *Volume*). Recommendation is to give 20 µl. The default value is 5 µl.

  When a sample is dispensed with sample extra, the volume can vary from 1 to 120 µl. Recommendation is to give at least 2 x sample volume. The default value is the same as the sample *Volume* value.

- *Dilution with* — Select from the pull down menu if a sample is diluted with water or with special diluent (defined as reagent in Reagent definition). If water is selected no other parameters are asked. If special diluent is selected the parameters for sample and diluent dispensing are followed.

Note that with K60 you can wash sample with water but not with any reagent.

- *Wash reagent* — Select from the pull down menu if a sample is washed with water or some reagent before every dispensing. The marking [water] means system water and water means water in the reagent disk existing vessel. The purpose of washing is to prevent sample carry over with extra high sample concentrations. It is used e.g. with drugs. Note that the wash makes dispensing slower and effects to the capacity.

- *Raw sample disp. with*	Select from the pull down menu if a raw sample is dispensed with water or with sample extra.
- *Volume*	Type the volume of water or sample extra. The maximum volume for water is 50 µl and for sample extra is 120 µl.
- *Special diluent*	Select the special diluent (= defined as reagent in Reagent definition) from the pull down menu or type the name of the diluent to the field.
- *Diluent disp. with*	Select from the pull down menu if diluent is dispensed with water or with diluent extra.
- *Volume*	Type the volume of water or diluent extra. The maximum volume for water is 50 µl and for diluent extra is 120 µl.

4.2.2 PARAMETERS FOR REAGENT DISPENSING

The test flow i.e. the assay can include up to four reagent dispensings.

The reagent dispensing has the following parameters:

- *Reagent*	Type the reagent's name (max. 10 characters) and press ↵ or click the name from the list. One reagent can be connected up to 20 tests. If over 20 tests are needed, define a new name for the reagent and connect part of tests to that.
- *Volume*	Type the reagent's volume. This can vary from 2 to 250 µl. Default value is 2 µl.
- *Disp. with*	Select from the pull down menu if the reagent is dispensed with water, with reagent extra or with reagent extra with buffers. The default value is water. Refer to section 5.1.7.
- *Volume*	Type the volume of water or reagent extra. When the reagent is dispensed with water the volume can vary from 2 to (250 - *Volume*). The default value is 20 µl.

The max. volume of the cuvette is 250 µl.

When the reagent is dispensed with reagent extra the volume can vary from 2 to 250 µl.
The default value is the same as the reagent *Volume* value.
It is recommended to use the same volume or 20 µl less than the reagent volume selected, e.g. if the reagent volume used is 100 µl, the reagent extra volume is 80 µl.

- *Wash reagent*	If the reagent probe is washed before dispensing into the cuvette, type the washing reagent's name (max. 10 characters) and press ↵ or click the name from the list. The purpose of washing is to rinse the needle and prevent reagent carryover. Washing uses 30 µl reagent. The default selection is none. Note that reagent washing will slow down dispensing and reduce analyser throughput.
- *Repl. Reag.*	If the test has a *True sample* blank the user gives the name of the replacement reagent for one reagent dispensing. Type the name of the replacement reagent (max. 10 characters) and press ↵ or click the name from the list.

Replacement reagent is defined only for one reagent dispensing.

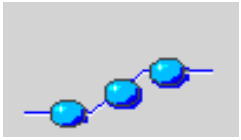
4.2.3 PARAMETERS FOR END POINT MEASUREMENT

The end point measurement has the following parameters:

- *Wavelength (nm)*	Select the main wavelength from the pull down menu. Alternatives are those wavelengths, which have been set in use in the CONFIGURATION window. The default value is 340 nm.
- *Side wavel. (nm)*	Select the side wavelength from the pull down menu. Alternatives are the same as for the main wavelength and also *None*. The default value *None* means that the measurement is monochromatic.
- *Residual net abs. (A)*	Give the value of the residual net absorbance if the side wavelength has been selected. It can be written with three decimals. The default value is 0. The residual net absorbance provides the minimum allowable difference between the absorbances measured with the main and the side wavelengths. If the difference is lower than the allowed value, the flag *'Bichr.net.abs.'* is given in the result acceptance windows and reports. For more information refer to section 5.1.10.
-*Meas. Type*	Select the measurement type from the pull down menu. Alternatives are: *Normal* and *Fixed timing*. Select *Fixed timing* if it is important to have the same time between dispensing and measurement for every cuvette cell.

Blank measurement

- Resp. min (A)	Type the minimum allowed response value for the blank measurement. The default value is 0.
- Resp. max (A)	Type the maximum allowed response value for the blank measurement. The default value * means that no checking is used.



4.2.4 PARAMETERS FOR KINETIC MEASUREMENT

The kinetic measurement has the following parameters:

- *Wavelength (nm)* — Select the main wavelength from the pull down menu. Alternatives are those wavelengths, which have been set in use in the CONFIGURATION window. The default value is 340 nm.

- *Side wavel. (nm)* — Select the side wavelength from the pull down menu. Alternatives are the same as for the main wavelength and also *None*. The default value *None* means that the measurement is monochromatic.

- *Res. net abs. (A)* — Give the value of the residual net absorbance if the side wavelength has been selected. It can be written with three decimals. The default value is 0.

  The residual net absorbance provides the minimum allowable difference between the absorbances measured with the main and the side wavelengths. If the difference is lower than the allowed value, the flag *'Bichr.net.abs.'* is given in the result acceptance windows and reports. For more information refer to section 5.1.10.

- *Curve type* — The curve type is selected from the pull down menu. The alternatives are: *Linear*, *Nonlinear* and *Linear cut*. Linear cut means that only the linear part of the curve is used for the measurement.

- *Nonlinearity limits Conc. (U/l)* — Type the rate of nonlinearity limit in concentration unit when the curve type is linear or nonlinear. The value can be decimal (max. 10 characters). The default value is 10.

- *Nonlinearity limits Percent %* — Define the maximum allowable nonlinearity for a reaction when the curve type is linear or nonlinear. It may be set from 0 to 100 %. The default value is 10 %.

  The flag '*Linearity'* in the result acceptance denotes that the nonlinearity limits both in % and concentration units have been achieved. For more information refer to section 5.1.9.

- *Nonlinearity limits Response (mA/min)* — Type the nonlinearity limit in response changing rate when the curve type is linear cut. This limit means that the points in the curve end is left out when the changing rate of reaction is calculated.

- *Time* — Type the measurement time. The default value for the linear and linear cut curve types is 120 seconds, minimum is 9 seconds for K20XT/30/60, 14 seconds for K20 and maximum is 3600 seconds.

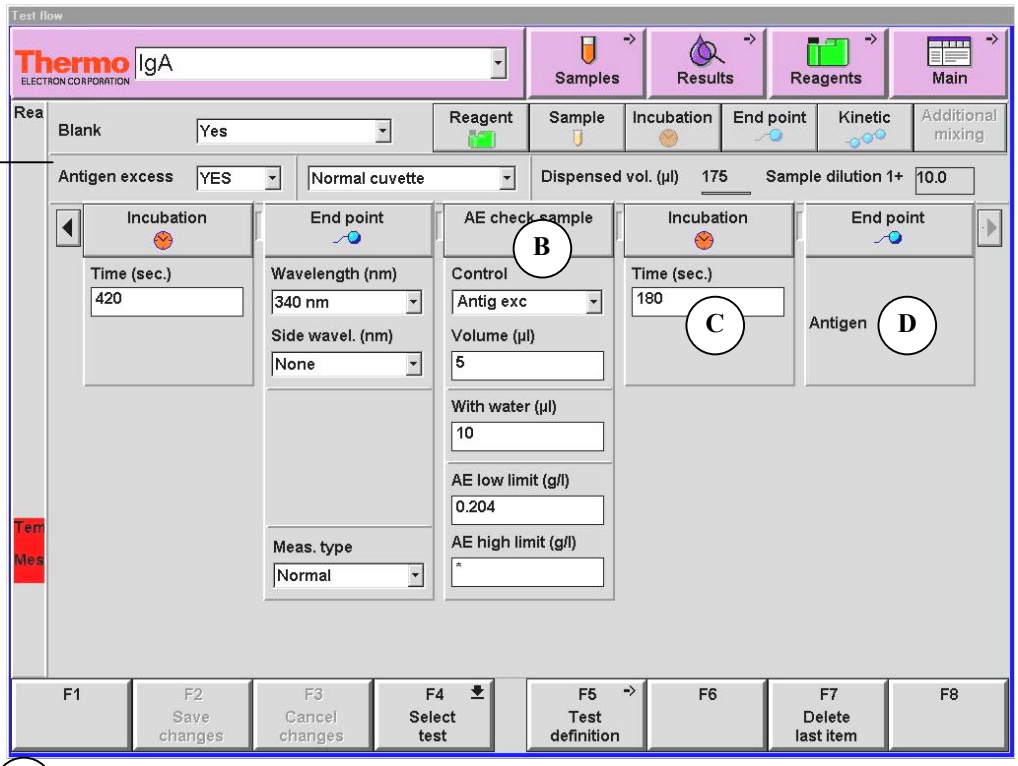
- *Points and Intervals* — The number of the measurement points and the intervals in seconds between the points is clicked from the list. The maximum number of points is 12.

When the curve type is nonlinear or linear cut the user must select at least three measurement points.

Blank measurement

- *Resp. min (A/min)*	Type the minimum allowed response value for the kinetic blank measurement. The default value is 0.
- *Resp. max (A/min)*	Type the maximum allowed response value for the kinetic blank measurement. The default value * means that no checking is used.
- *Init abs min (A)*	Type the minimum allowed initial absorbance value for the kinetic blank measurement. The default value * means that no checking is used.
- *Init abs max (A)*	Type the maximum allowed initial absorbance value for the kinetic blank measurement. The default value * means that no checking is used.

4.2.5 PARAMETERS FOR ANTIGEN EXCESS DETECTION



A Select antigen excess in use in the Test flow window.

When the measurement for the actual sample has been defined the following parameters for antigen excess detection appears automatically.

B *AE check sample*:

- *Control* — Type the name of antigen excess sample or select it from the list. The user can introduce new sample here or in the Cal/Ctrl definition window as a control sample.
- *Volume (µl)* — Type the volume of antigen excess sample. Default is the same as the actual sample volume.
- *With water (µl)* — The AE sample is always flushed with water. Type the water volume flushed. Default is 10 µl.
- *AE low limit (g/l)*, *AE high limit (g/l)* — Type the allowed lowest and highest values for the measurement change as a concentration unit. Any dilutions are not taken into consideration. Please, refer to control insert for antigen excess limits. The default value for the low limit is 0 and for the high limit is *.
  If the limits are exceeded the result is marked with an error flag.

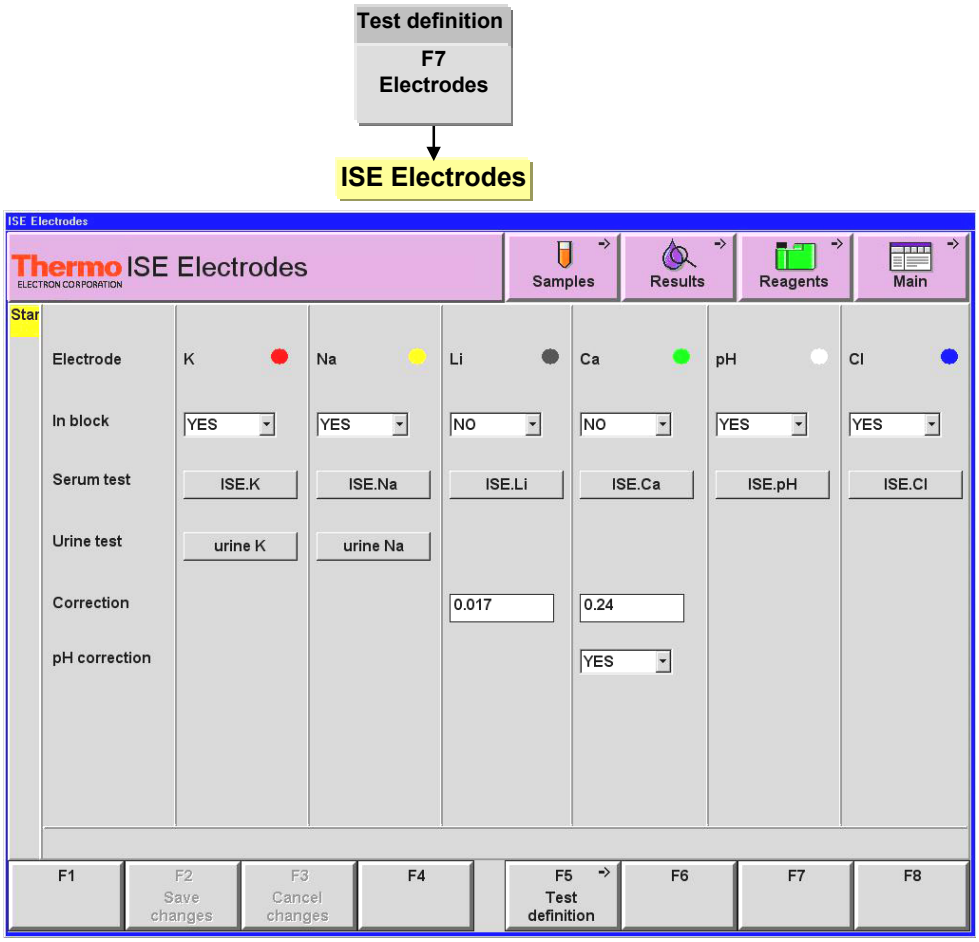
C *Incubation, Time (sec.):* Type the incubation time between the antigen excess sample dispensing and measurement. Default is the same time as for actual sample measurement.

D *End point, Antigen*: The measurement of antigen excess sample is always end point. Measurement parameters are the same as for actual sample measurement. Antigen excess measurement is always the last action of the test flow.

4.3 ELECTRODES FOR THE ISE TESTS

You can change the data of the electrode only when analysis is not in progress and the test using the electrode has no unaccepted requests.

Note that in Konelab 20XT and 20 the electrode block can include K, Na, Li and Cl.

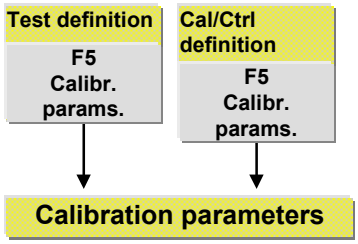


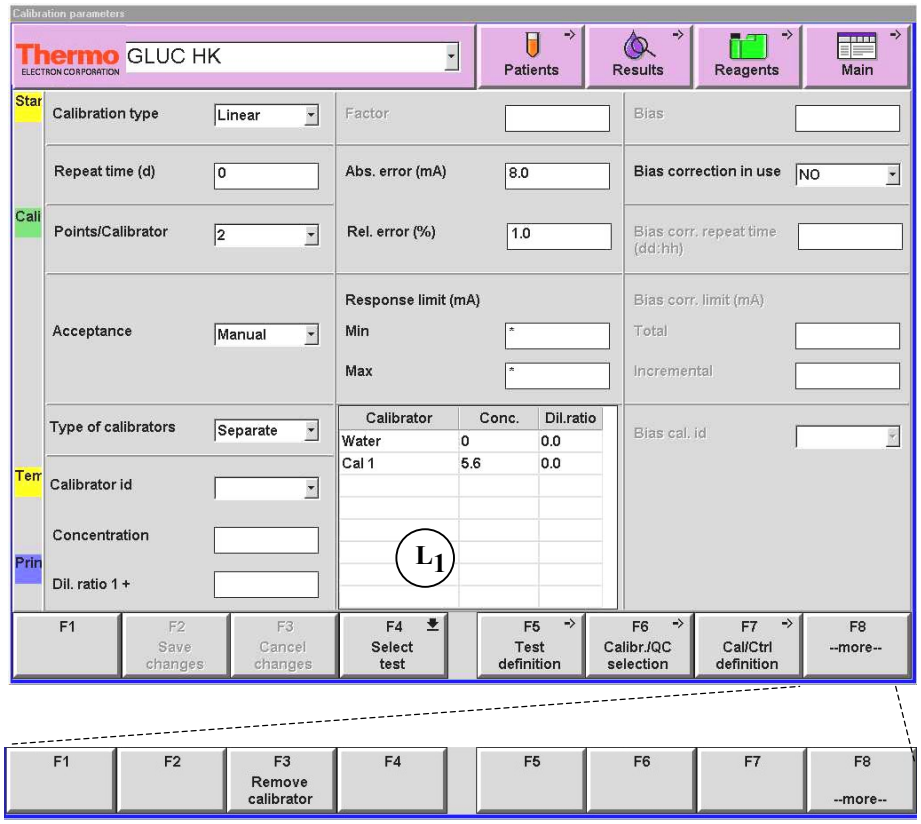
All electrodes are seen in this window.

-*Electrode*	The electrode's name and colour code is seen. The colour code is the same as in the block: - K has a red code, - Na has a yellow code, - Li has a grey code, - Ca has a green code, - pH has a white code and - Cl has a blue code.
- *In block*	Select YES/NO from the pull down menu.
- *Serum test*	The name of the electrode's serum test is in the button. Clicking the button gives the test's parameters in the TEST DEFINITION window.
- *Urine test*	The name of the electrode's urine test is in the button. Clicking the button gives the test's parameters in the TEST DEFINITION window.
- *Correction*	Correction factors for Li and for Ca are seen.
- *pH correction*	pH correction for Ca measurement can be on (Yes) or taken off (No). Refer to section 5.2.5 for detailed information of Ca measurement.

4.4 CALIBRATION PARAMETERS

You can change the test's calibration parameters only when analysis is not in progress and the test has no unaccepted requests. When calibration parameters are changed (except repeat time, acceptance, factor and bias) the test must be calibrated.





☞ Select *Calibration type* from the pull down menu. Alternatives are *Linear*, *Bias* (= linear calibration), *Nonlinear* and *None*. Refer to sections 4.4.1. and 4.4.2.

The default calibration type for the photometric test is *None* and for the ISE test it is *Linear*.

4.4.1 LINEAR, BIAS AND NONLINEAR CALIBRATION PARAMETERS

- *Repeat time (d)* — Type the calibration interval in days. It can vary from 0 to 365. The default value is 0.

  The user is reminded to calibrate after the defined calibration repeat time has been exceeded. Note that the **calibration is not made automatically**.

  Keep *'0'* if you do not want the analyser to remind you to calibrate.

- *Points/Calibrator* — Type the number of the replicates to be done at each concentration level of calibrators. It can be single, duplicate or triplicate. The default value is single.

- *Acceptance* — Select the automatic or manual calibration acceptance from the pull down menu. The default value is the automatic acceptance.

- *Type of calibrators* — Select the calibrators' type from the pull down menu. *Separate* calibrators' type means that a calibrator sample is given for each calibration point. *Series* calibrators' type means that the analyser prepares a dilution series from a stock calibrator.
  Separate is the default value. The ISE tests always use separate calibrators.

The linear calibration requires at least two calibrators and the nonlinear calibration at least three calibrators.

- *Calibrator id* — Type the calibrator's name and press ↵ or click it from the list. The list of calibrators used in the calibration (L_1) is seen in the middle of the window. The user can introduce a new calibrator here or in the Calibrator/Control definition window (refer to section 4.6.)

When separate calibrator samples are used give calibrators, concentrations and dilution ratios one after another. When dilution series is used give first calibrator and concentration and after that the dilution values in ascending order.

- *Concentration* — Type the concentration value. Use a point, not a comma as a decimal separator i.e. 5.7 is correct; 5,7 is not.

- *Dil. ratio 1+* — Type the parts of diluent with one decimal versus one part of the stock calibrator. Note that, e.g. 1+9 corresponds to 1:10. The value can be 0 and vary between 1 and 120 with 0.5 decimal. Manual dilution ratio is as default.

- *Factor* — When Bias calibration has been selected, the analyzer calculates a bias automatically from the measured calibrator, e.g., water. The user gives here an experimental or calculated factor with one decimal. The default value is 1. After changing the factor, request and accept one calibration in order to get the factor in use. If Clear Daily files is done after changing the factor before a new calibration, the factor disappears.

- *Abs. error (mA; mA/min)* — Type the maximum allowable deviation of the single calibration point from the calculated calibration curve.
  The absolute error can be given with one decimal from 0.0 to 999.0.
  The default value * means that no checking is used.

- *Rel. error (%)* — Type the maximum allowable deviation of the single calibration point from the calculated calibration curve.
  The relative error can be given with one decimal from 0.0 to 100.0.
  The default value * means that no checking is used.

- *Response limit (mA; mA/min)*

Type the minimum and maximum values for the allowed difference between the calibration's highest and lowest response. For more information refer to section 5.1.12.3., Checking criteria of the calibration.

Give the minimum and maximum allowed difference with one decimal from 0.0 to 9999.0.
Default value * means that no checking is used.

Bias correction

- *Bias corr. in use*

Select YES or NO from the pull down menu. For more information about the bias correction refer to section 5.1.12.4.

- *Bias corr. repeat time (dd:hh)*

Type the bias correction interval, which should be shorter than the calibration repeat time. The bias correction is always made automatically. Give the interval as days from 0 to 365 and hours from 0 to 24.
The default value is 1 h.

- *Bias corr. limit Total (mA; mA/min)*

Type the maximum allowed difference between the last and the first bias correction. Give the difference with one decimal from 0.0 to 99999.0.
The default value * means that no checking is used.

- *Bias corr. limit Incremental (mA; mA/min)*

Type the maximum allowed difference between the last and the previous bias correction. Give the difference with one decimal from 0.0 to 99999.0.
The default value * means that no checking is used.

- *Bias cal id*

Give the calibrator, which will be used for the bias correction. Type the existing calibrator's name (refer to section 4.6.) and press ↵ or click it from the list.
The default value for the bias calibrator is WATER.

☞ Select F2 to save the parameters. You can CANCEL the changes with F3.

To remove the calibrator

Select the calibrator from the list (L_1) and activate F8/F3 to remove it.

4.4.2 "NONE"

When the calibration type is *None* no calibration is done for the test. The user gives only the factor and bias values. Concentrations are calculated.

Factors based on a 10 mm light path should be used.

- *Factor*

Type the factor with one decimal. The default value is 1.0.

For more information about the factor refer to section 5.1.12.2.

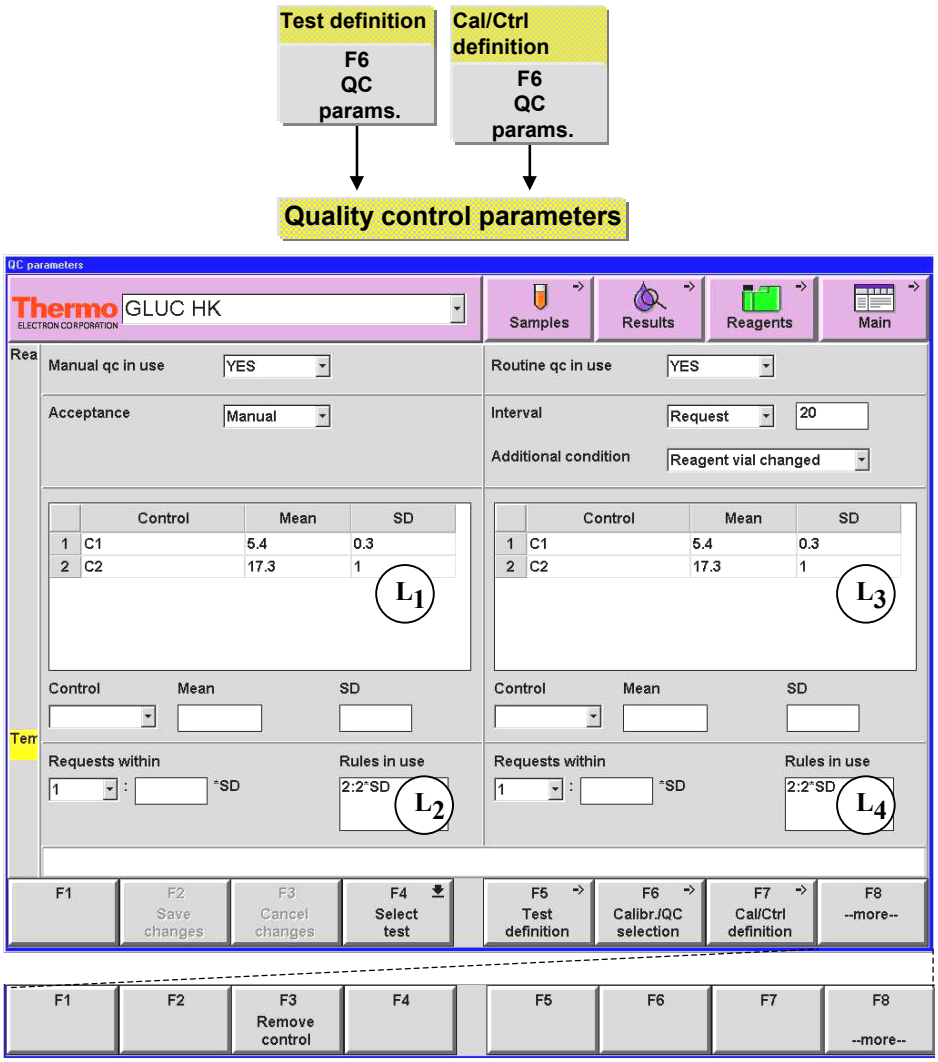
- *Bias*

Type the bias with one decimal. The default value is 0.0, for the ISE tests 1.0.

For more information about the bias refer to section 5.1.12.2.

4.5 QUALITY CONTROL PARAMETERS

You can change the test's quality control parameters only when analysis is not in progress and the test has no unaccepted requests.



There are two quality control types for which parameters can be given:

1) **Manual QC** is performed when the user requests it manually in the Calibration/QC selection window and when the calibration is done. It is meant for accurate control.

2) **Routine QC** is performed automatically during analysis after the given time period or after the given number of analysed requests. It is meant to observe changing and random errors.

- *Qc in use* Select YES or NO.

Parameters for Manual qc

Controls are analysed as a batch. Select the control as many times as you want it to be analysed.
The batch can contain up to 6 requests, i.e. the batch size can be 1 - 6.

-*Acceptance* Select *Automatic* or *Manual* from the pull down menu. The acceptance of the Manual qc can be automatic only when the test's acceptance is automatic. The acceptance of the Routine qc is the same as the test's acceptance.

- *Control* Type the control's name in the field and press ↵ or click it from the list. The user can introduce a new control here or in the Calibrator/Control definition window (refer to section 4.6.)

- *Mean* — Type the mean value of the control sample in concentration units. The minimum concentration value for the photometric test is 0 and the maximum value is 99999. For the ISE test the minimum value has to be >0. Use a point, not a comma as a decimal separator i.e. 5.7 is correct; 5,7 is not.

- *SD* — Type the calibrator deviation value of the control sample in concentration unit.

The selected controls, mean and calibrator deviation values are seen on the list (L_1).

Up to 10 rules can be in use: Only one y for each x value is allowed within the same QC type.

- *Requests within* — Give the rule/ rules according to which the control results are checked.
The rule's form is x:y*SD.
- x can be from 1 to the batch size, 2 * the batch size or R. Refer to section 5.1.13.
The number shows how many successive control requests are compared. R means that the highest and the lowest measurement in the batch are compared. R cannot be selected if batch size is 1.
- y*SD indicates the out-of-control limit, how many SD the measured control result can differ from the given mean. For example the rule 2:2*SD is violated when two successive control measurements exceeds the same control limit mean plus 2*SD or mean minus 2*SD. Note that y can also be 0, which means that the rule is violated when all measured control results are over or under the given mean value (0 can be used to detect the level of results). Refer to section 5.1.13.
The rules used are on the list (L_2) alongside.

Parameters for Routine qc

Counting of interval starts after QC batch has been requested or after boot.

- *Interval* — Select whether the interval between two routine qc runs depends on time or on the number of patient requests.
The time interval is given as hh:min. The default value is 24:00, i.e. the Routine qc is done once in 24 hours. The minimum value for the time interval is 1 minute and the maximum interval is 24 hours.
The request interval, i.e. the number of patient requests analysed, is written between 1 and 999. The default value is 20.
Also * can be given, which means that no time or requests dependent routine qc is done.

- *Additional condition* — Select if the routine qc is performed or not after the reagent vial has been changed. To get routine qc measured, do not take the old vial away when introducing the new one.

The *Controls* and rules (*Requests within*) are given in the same way as for the Manual qc.

To remove the control or the rule

When the qc type is "in use" saving is possible only when controls and rules have been given. Routine qc needs also the interval.

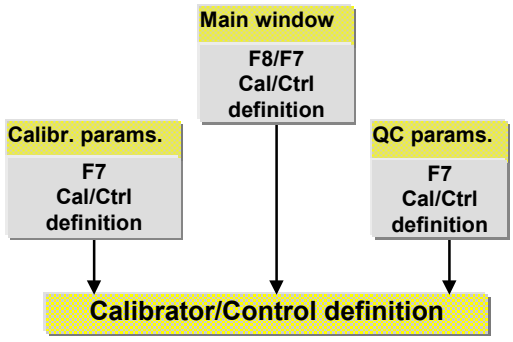
Select the control (L_1/L_3) or the rule (L_2/L_4) from the list and activate F8/F3.

☞ Save the parameters with F2. The data is saved and the cumulative qc values of removed controls are deleted.

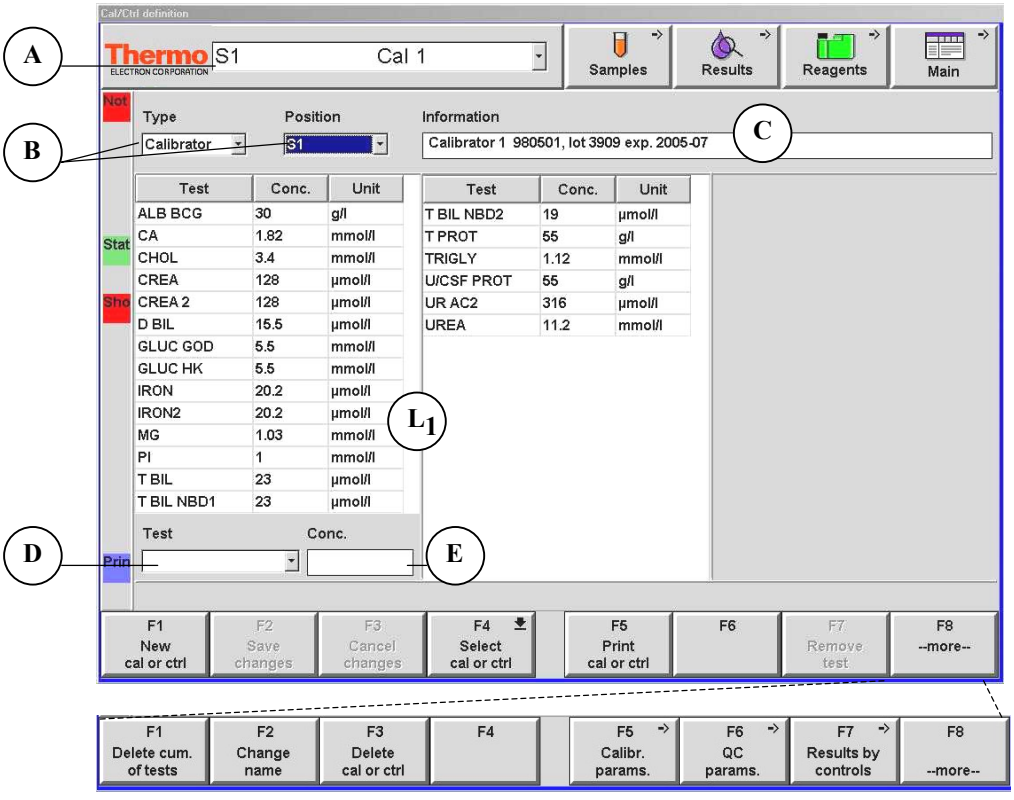
With F3 you can CANCEL the changes made after the last SAVE.

4.6 CALIBRATOR/CONTROL DEFINITION

The data of the calibrators/ controls can be changed only when analysis is not in progress and the test's calibrator/ control values can be changed only when the test has no unaccepted requests.



4.6.1 CALIBRATOR DEFINITION



A Type the identification of a new calibrator sample (max. 10 characters, cannot start with a number) and press ↵. With F8/F2 you can change the name.
If you use same names as on the calibrator/control disk, i.e. S0, S1...S19. The position is given automatically in this case.

B Select *Type*: *Calibrator* from the pull down menu. In Konelab 60/ 30 the first free position from the calibrator/ control disk is given as default. You can change the *Position* by selecting a new one from the pull down menu.

Position is left without fixing in Konelab 20XT/ 20 and can be left without fixing in Konelab 60/ 30. In this case a calibrator sample can be inserted in a segment or in a STAT position. Introduce a calibrator sample as a normal sample in the Sample/ Patient entry window.

C Additional *Information* about the calibrator can be given (max. 60 char.).

D Type the existing test's name in the *Test* field and press ↵ or click it from the list. Note that you cannot create a new test here.

E Type the concentration value of the calibrator for that test. The minimum concentration value for the photometric test is 0 and the maximum value is 99999. The concentration value for the ISE test has to be >0.

The given tests, calibrator concentration values and concentration units are seen on the list (L_1).

Use a point, not a comma as a decimal separator i.e. 5.7 is correct; 5,7 is not.

☞ SAVE the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

To remove the test from the list

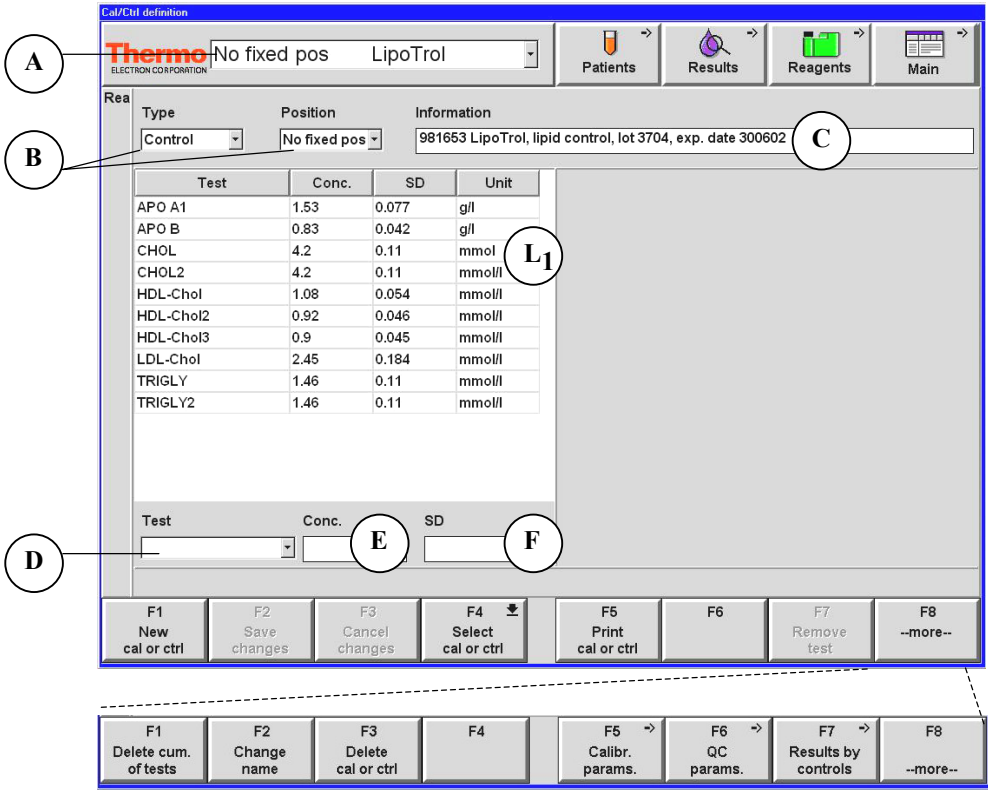
Select the test from the list (L1) and activate F7.

☞ Note that you cannot remove the test if the calibrator is used in the test's calibration procedure. To remove it, go first to Calibration parameters with F8/F5, select the calibrator from the list and remove it with F8/F3. Introduce a new calibrator - a calibration needs at least two calibrators in the test - and save changes with F2. Refer to section 4.4 for Calibration parameters and 4.5 for QC parameters. After this, the test can be removed in the Cal/Ctrl definition window.

To delete the calibrator data

☞ Activate F8/F3 to delete the calibrator data.

4.6.2 CONTROL DEFINITION



A Type the identification of a new control sample (max. 10 characters, cannot start with a number) and press ↵. With F8/F2 you can change the name. If you use same names as on the calibrator/control disk, i.e. C1...C19. The position is given automatically in this case.

B Select *Type*: *Control* from the pull down menu. In Konelab 60/30 the first free position from the calibrator/ control disk is given as default. You can change the *Position* by selecting a new one from the pull down menu.

Position is left without fixing in Konelab 20XT/ 20 and can be left without fixing in Konelab 60/ 30. In this case a control sample can be inserted in a segment or in a STAT position. Introduce a control sample as a normal sample in the Sample/ Patient entry window.

C Additional *Information* about the control can be given (max. 60 char.).

Use a point, not a comma as a decimal separator i.e. 5.7 is correct; 5,7 is not.

D Type the existing test's name in the *Test* field and press ↵ or click it from the list. Note that you cannot create a new test here.

E Type the concentration value of the control for that test. The minimum concentration value for the photometric test is 0 and the maximum value is 99999. The concentration value for the ISE test has to be >0.

F Type the standard deviation of the control for that test.

The tests, control concentration and standard deviation values and concentration units are seen on the list (L_1).

☞ SAVE the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

To remove the test from the list

Select the test from the list (L1) and activate F7.

☞ Note that you cannot remove the test if the control is used in the test's quality control procedure. To remove it, go first to QC parameters with F8/F6, select the QC from the list and remove it with F8/F3. Refer to section 4.5 for QC parameters. After this, the test can be removed in the Cal/Ctrl definition window.

When you change the QC value check the cumulative data in the QC results window (section 3.4.3.) and the QC parameters (section 4.5.).

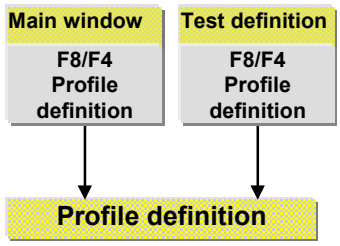
When concentration values of the QC have been changed

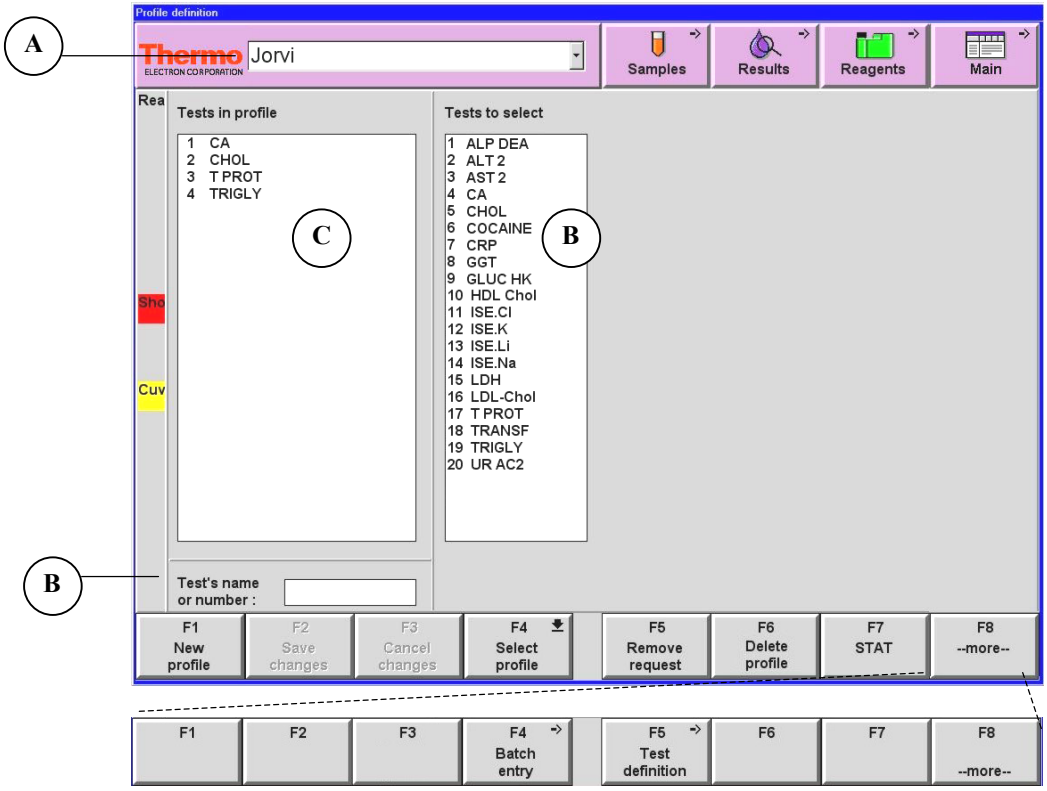
☞ Activate F8/F1 to delete the cumulative data of the control from all tests when the control value has been changed.

To delete the control data

☞ Activate F8/F3 to delete the control data.

4.7 PROFILE DEFINITION





Calculated test (sample) can be included in the profile. External test cannot be.
Profile is always concerning only one sample.

A Type the identification of a new profile (max. 10 characters) and press ↵.

B Type the existing test's name or number in the field and press ↵ or click the test's name from the list.

C The selected tests are seen as a list with the order number and a test name.

Inserting a STAT test in a profile

Activate F7 to define a test as a STAT test in a profile. In the window appears a text !Stat ON. After that select a test as usual (B). Stat tests are marked with the sign !.

To return to the normal mode activate F7 (STAT off) again. Editing a new profile also turns a STAT mode to the normal mode.

To remove a request from a profile

Select the test from the list (C) and activate F5.

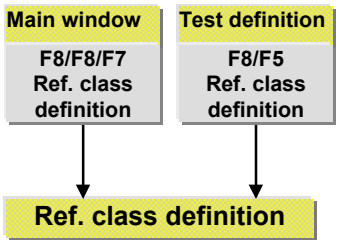
☞ SAVE the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

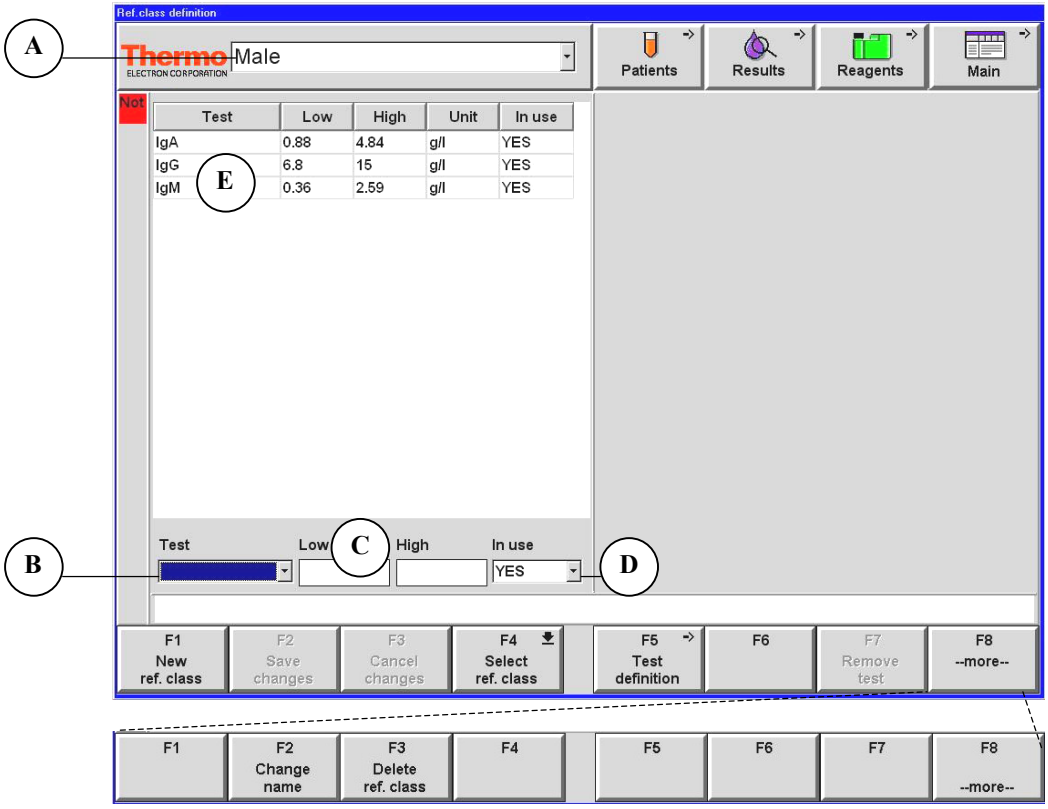
To delete a profile

To delete profile, activate F6.

4.8 REFERENCE CLASS DEFINITION

Default reference class used in the Patient/ Sample entry cannot be deleted. It is defined in the Configuration window. Refer to section 3.8.





A Type the identification of a new reference class (max. 10 characters) and press ↵. With F8/F2 you can change the name.

B Type the existing test's name in the field and press ↵ or click the test's name from the list.

C Give the low and the high reference value for the test.

D Select whether the test is used or not in the reference class.

E The given tests, their reference values and if tests are in use or not in the reference class are seen as a list. The unit used is given automatically according to Test definition.

To remove a test from a reference class

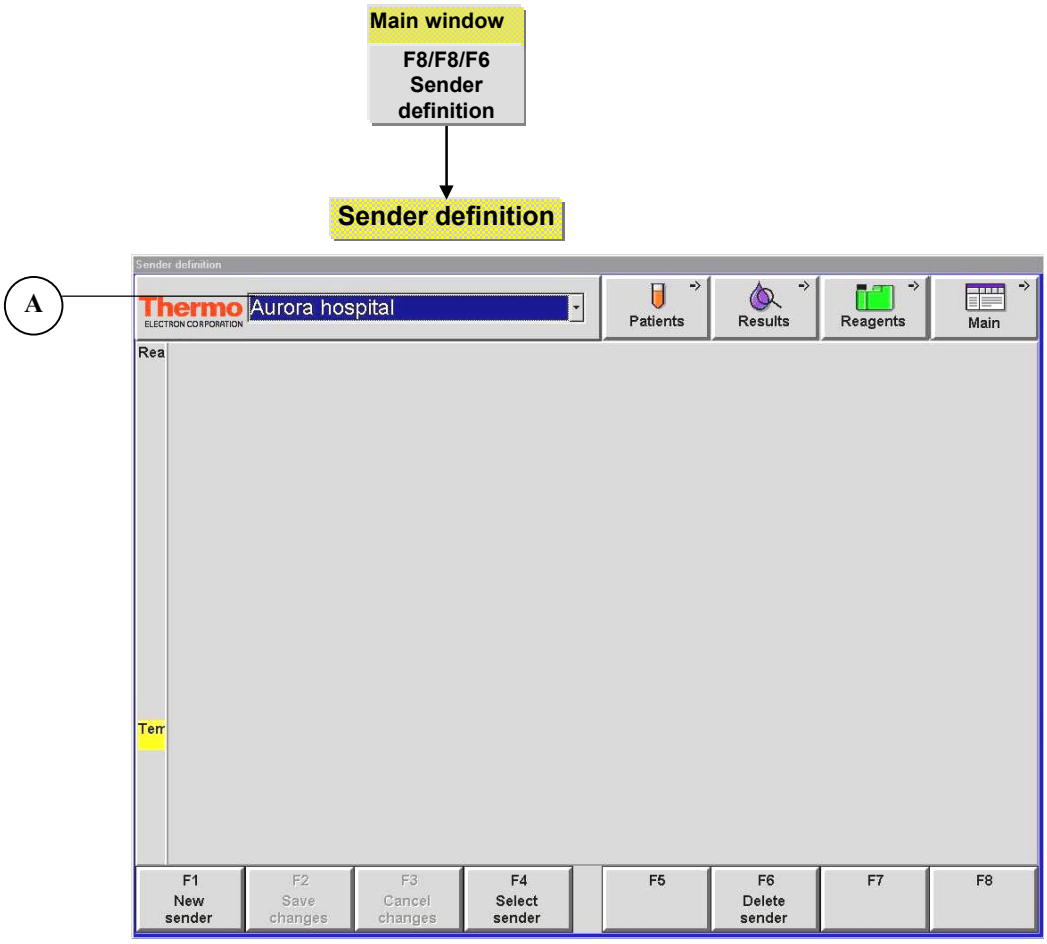
Select the test from the list (E) and activate F7.

☞ SAVE the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

To delete a reference class

To delete a reference class, activate F8/F3.

4.9 SENDER DEFINITION

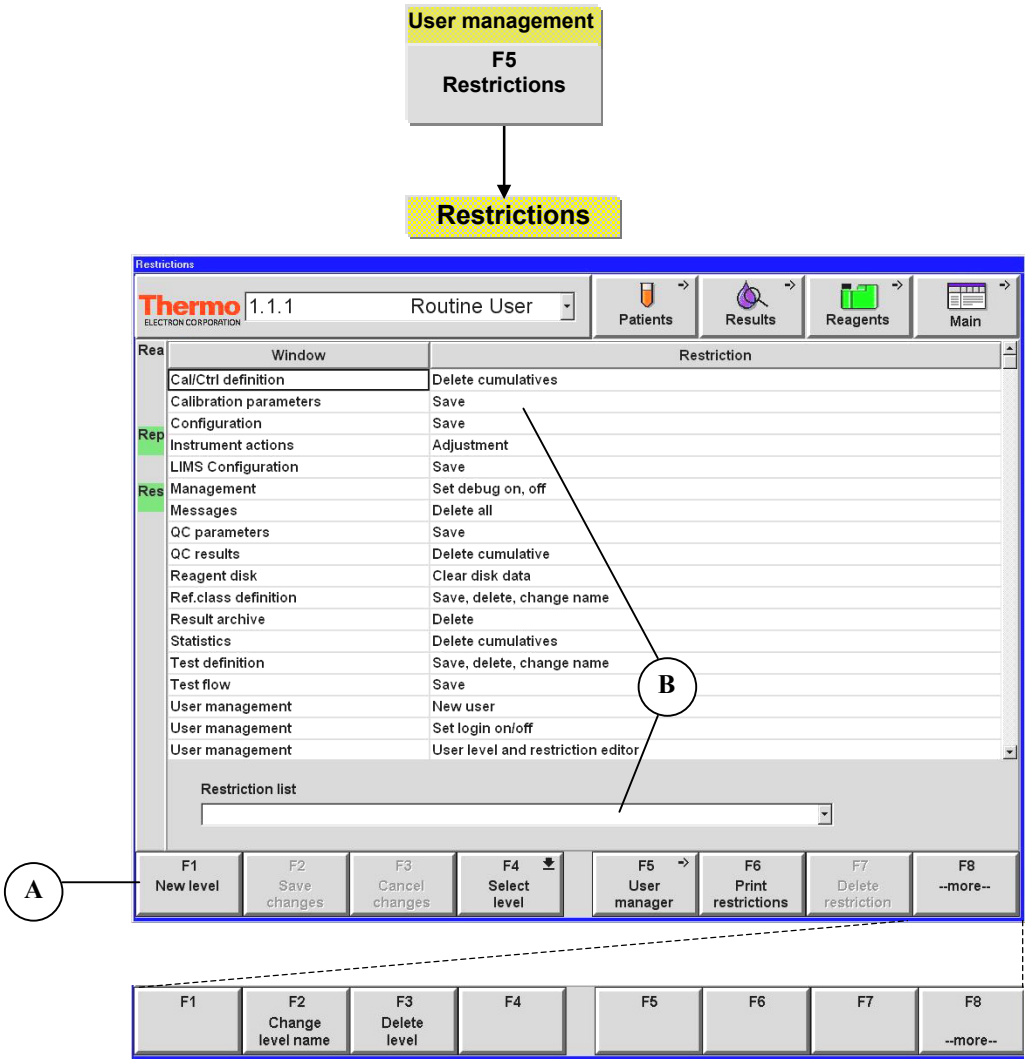


A Type the identification of a new sender and press ↵. The sender name is seen in the Sample/Patient entry window and in reports.

To delete a sender data

To delete a sender data, activate F6.

4.10 USER LEVEL DEFINITION



A Select first F1 to create a new user level. After that, type the level name and select the level id, e.g. the chemist is 1.1 and the operator 1.1.1. The level name can be changed with F8/F2.

B Select limitations for the level from the restriction list. After selection they are seen in a list.

List of lockable keys		Locked keys	
Window	**Keys**	**Main user level**	**Routine user level**
Cal/Ctrl definition	Delete cumulatives		X
Cal/Ctrl definition	Save, delete,change name		X
Calibration parameters	Save		X
Calibration results	Accept, recalibrate, delete, reject, rerun		
Calibration results	Accept bias, reject bias		
Calibration/QC selection	Calibrate		
Configuration	Save		X
External results	Save		

List of lockable keys		Locked keys	
Window	**Keys**	**Main user level**	**Routine user level**
Instrument actions	Adjustment		X
Instrument actions	Water wash, prime ISE, exit cuvettes, check needles, water blank		
Instrument actions	Accuracy results		X
LIMS Configuration	Save		X
Management	Clear db		
Management	Set debug on, off		X
Management	Exit		
Management	Save db		
Messages	Accepts		
Messages	Delete all		X
Profile definition	Save, delete profile		
QC parameters	Save		X
QC results	Accept, reject		
QC results	Delete cumulatives		X
QC results	Change control values		X
QC results	Delete cum. of tests		X
Reagent definition	Save, delete, change name		X
Reagent disk	Clear disk data		X
Ref. Class definition	Save, delete, change name		X
Report formats	Save		X
Result archive	Delete		X
Result archive	Recreate archive		X
Sample results	Accepts, reject, reruns		
Sample segment	Delete segment		X
Sender definition	Save, delete		X
Statistics	Delete cumulatives	X	X
Test definition	Save, delete, change name		X
Test definition	Test flow/ Electrodes		
Test flow	Save		X
Test results	Accepts, reject, reruns		
User management	Set login on/off	X	X
User management	New user		X
User management	User level and restriction editor		
Maintenance	Save		

☞ SAVE the data with F2. With F3 you can CANCEL the changes made after the last SAVE.

To delete a restriction

Select restriction from the list and activate F7.

To delete a user level

To delete the user level, activate F8/F3. Note that levels can be deleted only sequentially, i.e. first the lowest level's latest one.

5. PRINCIPLES OF OPERATION AND ANALYSIS

5.1 PHOTOMETRIC MEASUREMENT

5.1.1 OPERATION PRINCIPLE

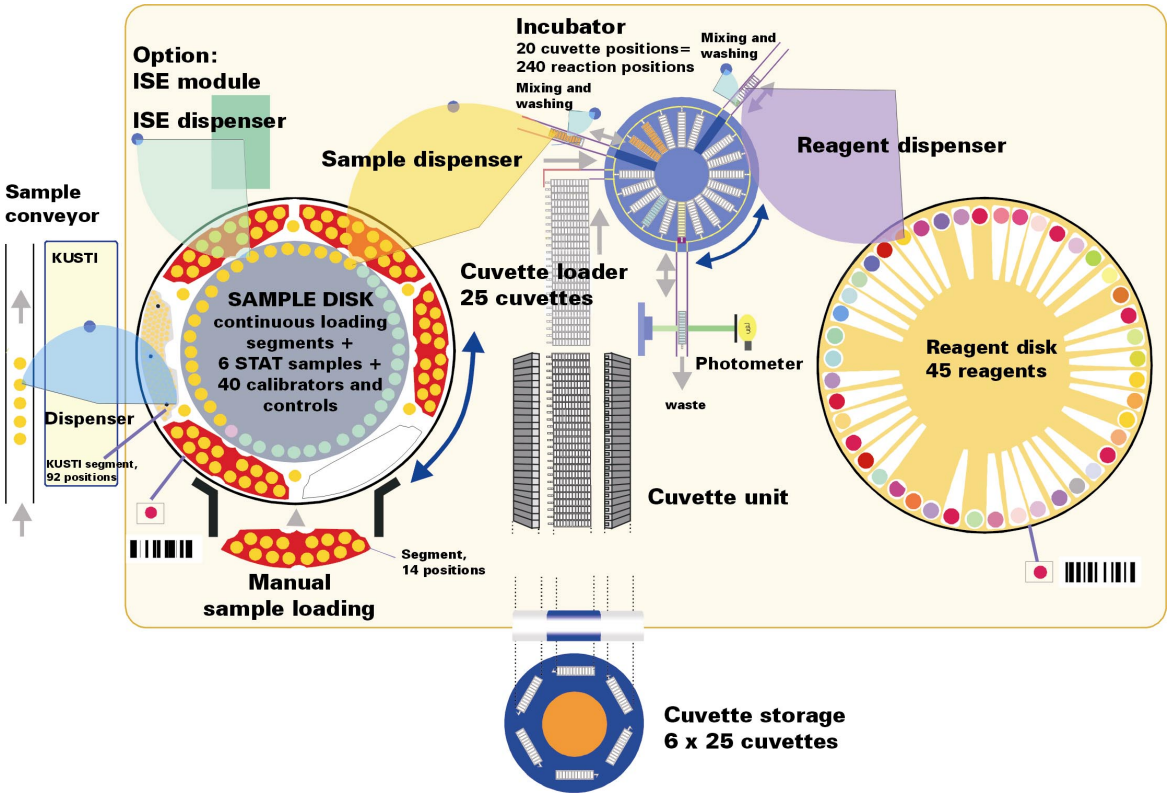


Figure 5-1: Photometric analysis proceeding in Konelab 60

The cuvette is moved from the loader into a free slot in the incubator. When the incubator rotates in Konelab 60, the cuvette is moved to the dispensing positions where the dispensing arms dispense sample and reagents appropriate to the test. Mixing takes place in both dispensing positions.

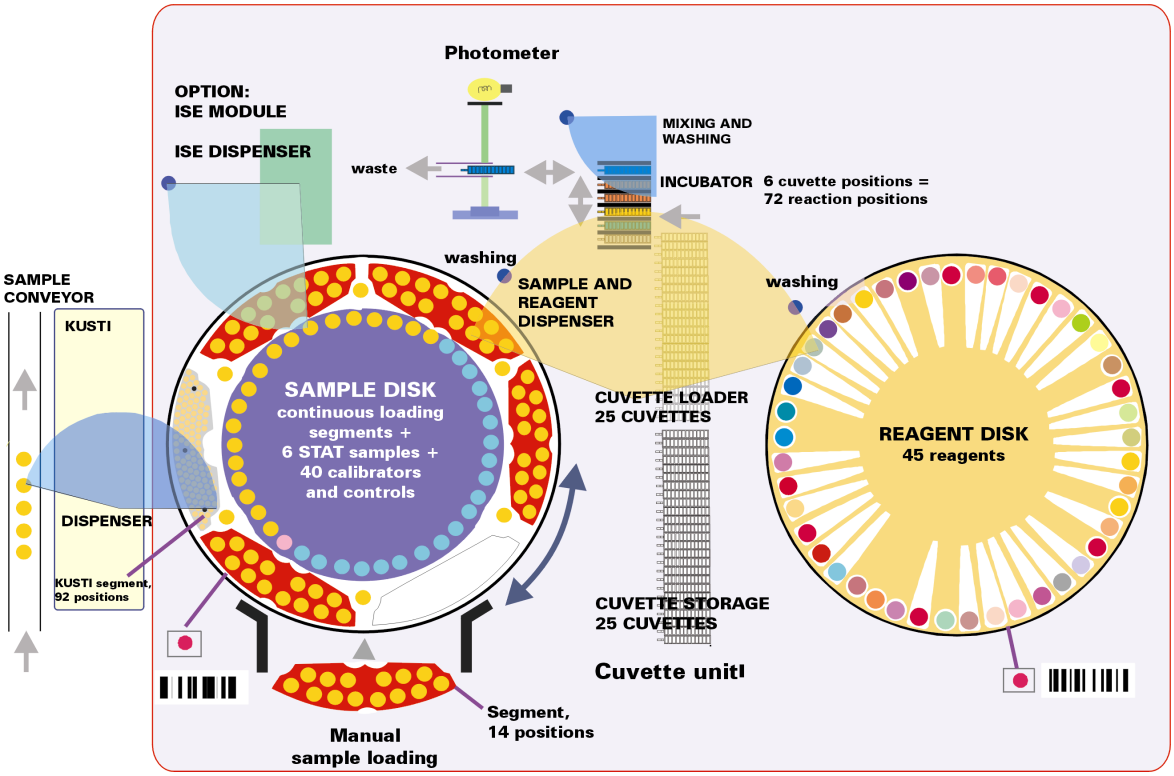


Figure 5-2: Photometric analysis proceeding in Konelab 30

In Konelab 30 the cuvette is moved into the incubator where the dispensing arm dispenses sample and reagents appropriate to the test. The mixer performs efficient mixing.

The cuvette is then moved through the photometer. The photometer measures the absorbance of each cell of the multicell cuvette. It is possible to make a fixed measurement, i.e. so that the time between dispensing and measurement is the same with every cell of a cuvette.

In the kinetic measurement the absorbance measurement is repeated as many times as defined in the test parameters during the given time. The maximum number of the measurements is 12 and the maximum time is 60 minutes.

After measurement the cuvette is discarded into the waste compartment.

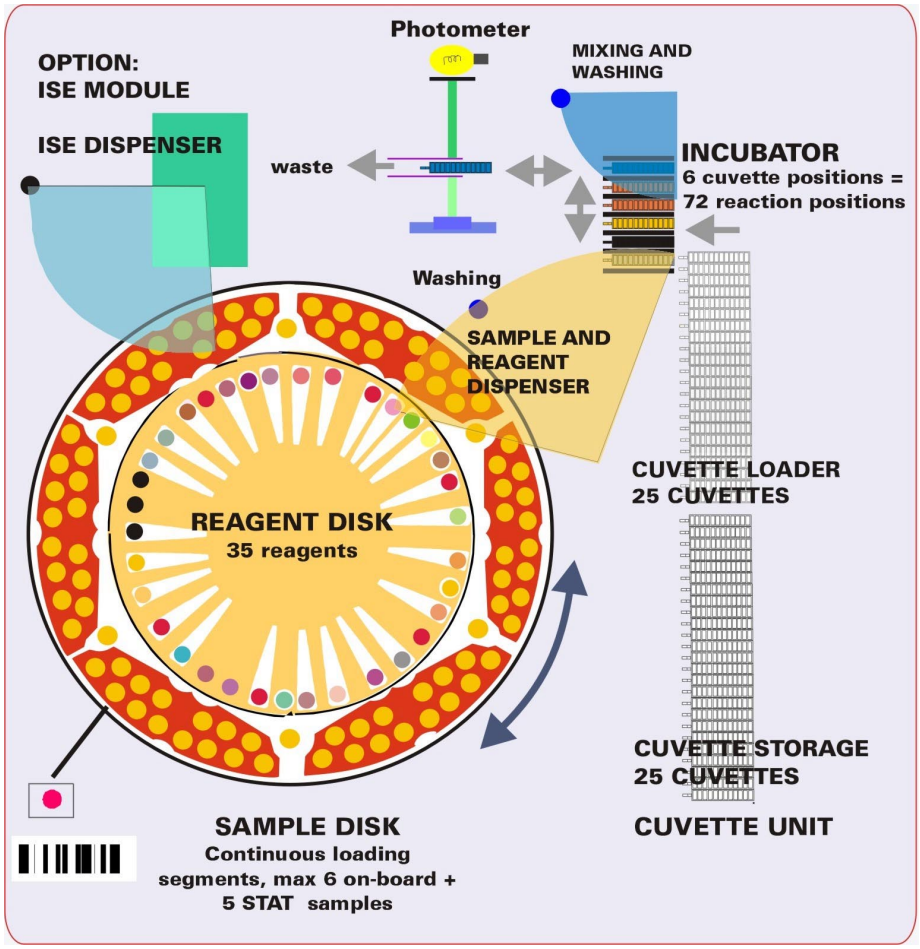


Figure 5-3: Photometric analysis proceeding in Konelab 20XT

In Konelab 20XT the cuvette is moved into the incubator where the dispensing arm dispenses sample and reagents appropriate to the test. The mixer performs efficient mixing.

The cuvette is then moved through the photometer. The photometer measures the absorbance of each cell of the multicell cuvette. It is possible to make a fixed measurement, i.e. so that the time between dispensing and measurement is the same with every cell of a cuvette.

In the kinetic measurement the absorbance measurement is repeated as many times as defined in the test parameters during the given time period. The maximum number of the measurements is 12 and the maximum time is 60 minutes.

After measurement the cuvette is discarded into the waste compartment.

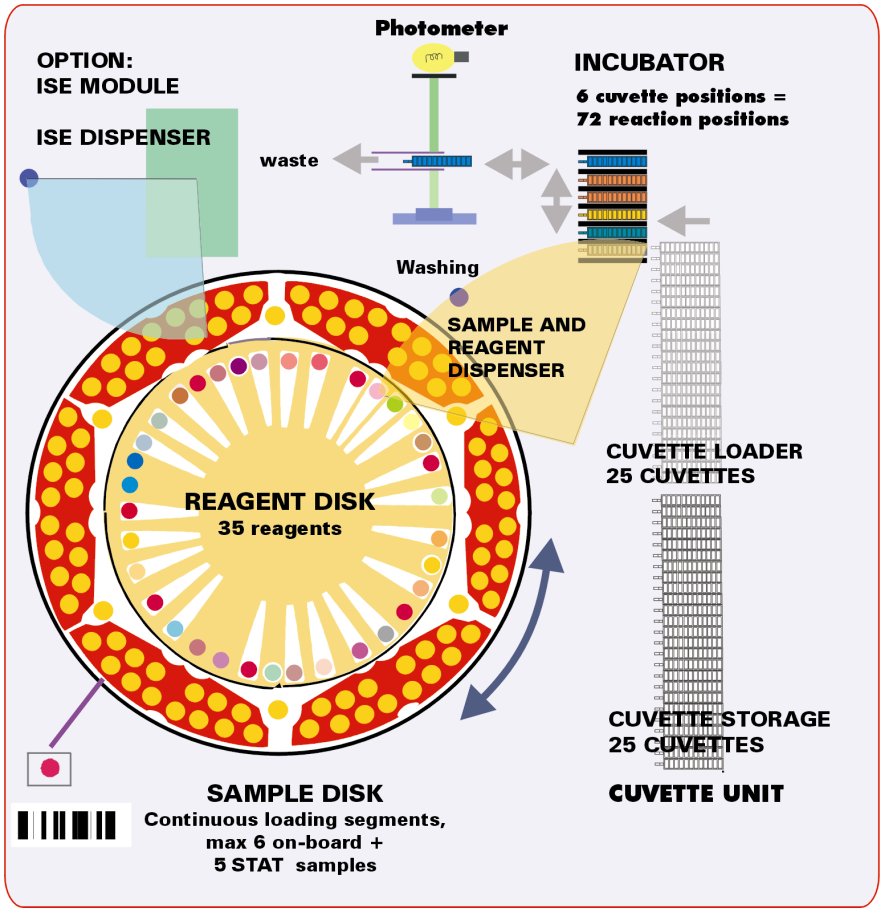


Figure 5-4: Photometric analysis proceeding in Konelab 20

In Konelab 20 the cuvette is moved into the incubator where the dispensing arm dispenses sample and reagents appropriate to the test. The oscillation of the dispensing needle in the cuvette cell performs mixing.

The cuvette is then moved through the photometer. The photometer measures the absorbance of each cell of the multicell cuvette. It is possible to make a fixed measurement, i.e. so that the time between dispensing and measurement is the same with every cell of a cuvette.

In the kinetic measurement the absorbance measurement is repeated as many times as defined in the test parameters during the given time period. The maximum number of the measurements is 12 and the maximum time is 60 minutes.

After measurement the cuvette is discarded into the waste compartment.

5.1.2 PHOTOMETER

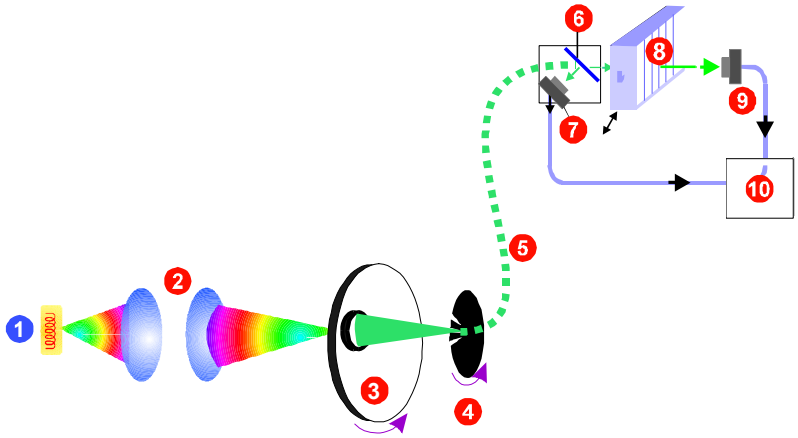


Figure 5-5: Schematic of the photometer

1. Halogen lamp
2. Condensing lenses
3. Filter wheel
4. Light chopper
5. Quartz fibre
6. Beam divider
7. Reference detector
8. Multicell cuvette
9. Signal detector
10. Measurement electronics

The light passes from the lamp through the condensing lenses to the interference filter. The plane surface of the first condensing lens is coated with the material, which reflects heat and infrared light. The filters are mounted on a filter wheel. In the standard instrument there are 15 positions for filters.

After the filter the light is converted into a stream of light pulses by the chopper. Then the light is directed via the quartz fibre through the focusing lens and the slit to the beam divider.

The beam divider divides the light into two parts. A certain amount is reflected to the reference detector, which monitors the light level fluctuations. The main part of the light goes through the liquid in the cell to the signal detector, which measures the amount of light after absorption.

5.1.3 ABSORBANCE

The primary analytical response is measured as absorbance, A (end point measurement) or absorbance change per minute, ΔA/min (kinetic measurement).

The absorbance values are evaluated on the basis of the light intensities of non-absorbing (blank) and absorbing samples. This evaluation can be formulated by the following equation:

$$A = \log [(I_O / I) \times (I_r / I_{o,r})]$$

where A = absorbance value
I_o = light intensity after a blank cell
I = light intensity after a test cell
r = refers to the intensity of the reference signal which monitors the lamp intensity

Even though the light path of the cuvette cell in the Konelab is 7 mm the absorbance readings are modified to correspond with the 10 mm light path.

In the kinetic measurement absorbance readings are measured against blank values as many times as defined in the test parameters. The maximum number of the measurements can be 12. The first value is subtracted from the second value to obtain the absorbance difference over the defined time interval.

The data of the kinetic measurement is fitted to a straight line by using the method of least squares or the linear regression. The ΔA/min is the slope of this line.

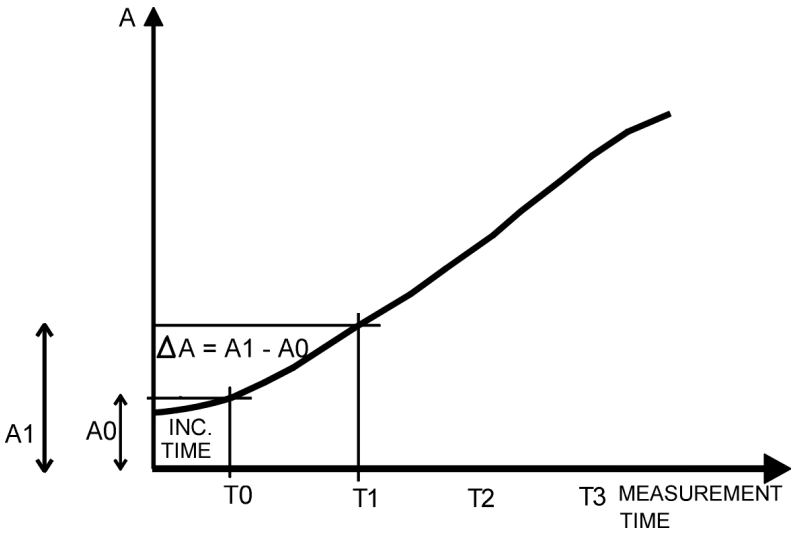


Figure 5-6: Absorbance change ΔA in the kinetic determination

5.1.4 BLANK MEASUREMENTS

The blank type for the test is selected in the TEST FLOW window.
Alternatives are:
- *No*, when the water blank measured during Start up is used in the calculations as a blank measurement.
- *Yes*, when the user selects a measurement for the blank to be made during the test flow. The blank measurement can be end point or kinetic measurement. If the blank measurement is selected kinetic the sample measurement must also be kinetic.
- *True sample*, when the blank measurement is performed in a separate cuvette position. The user selects one reagent, which is replaced with the blank reagent.
- *Meas with fixed timing*, when it is important to have the same time between dispensing and measurement for every cuvette cell. Can be used in a kinetic measurement with nonlinear curve type and in an end point measurement with fixed timing.

Water blank is measured automatically during START UP operations. In the water blank measurement one cuvette is filled with water and every cell is measured against all wavelengths.
The standard deviation (SD) in absorbances for the cuvette will be calculated. If SD is below 2 mA the response is subtracted from the response of the sample measurement, otherwise the error message is given.

During the test flow before the primary sample measurement, a blank measurement can be selected. It will reduce effect of reagent contamination or reagent deterioration. The user can select a measurement for the blank after reagent dispensing, after sample dispensing or after incubation. The response of the separate blank measurement is subtracted from the response of the primary sample measurement.

Test result = (S_{abs} – Water blank $_{abs.}$) – (B_{abs} – Water blank $_{abs.}$)

$S_{abs.}$ = Sample absorbance
$B_{abs.}$ = Blank absorbance

A True sample blank measurement is similar to the primary sample measurement but one reagent is replaced with some low absorbing reagent. The user defines replacement reagent for one reagent dispensing. Primary analysis is done in one cuvette cell and the other analysis with replacement reagent is made in another cell. Both cuvette positions are measured and the response of the true sample blank measurement is subtracted from the response of the primary sample measurement. The replacement reagent has low absorbance in the used wavelength and the purpose of the measurement response subtraction is to eliminate the effects of turbidity or colour.

5.1.5 INITIAL ABSORBANCE

Initial absorbance limits assure reliable measurements with a safe initial absorbance level.
- Turbid sample or a very high concentration in increasing reactions can cause too high initial absorbance.
- Deteriorated reagents or a very high activity in decreasing reactions can cause too low initial absorbance. Minimum value may be negative.

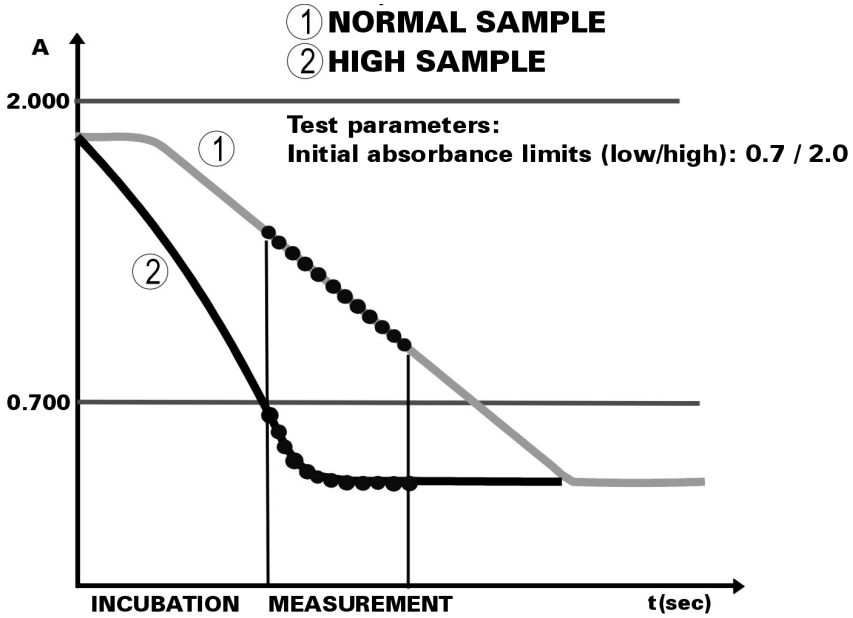
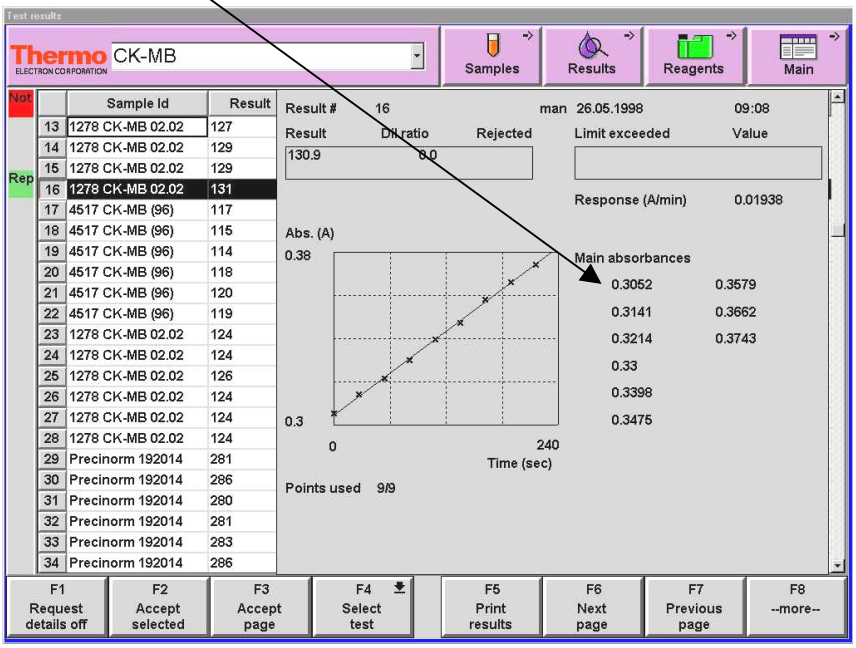


Figure 5-7: In the reaction curve the initial absorbance value is not within the predefined limits. The message 'Init.abs.' is given and manual acceptance is requested.

Initial absorbance values are given in the Test definition window. E.g. to the CK-MB test the low value is 0.0 and the high value is 1.5 A. The user can check the value which the instrument is using in the initial absorbance detecting. It is the first value in the Main absorbances list seen in result details.



5.1.6 BICHROMATIC MEASUREMENT

The result of the measurement may be evaluated from the bichromatic absorbance, which is the absorbance difference between the main wavelength and the side wavelength:

$A_{BICHROM.} = A_{\lambda 1} - A_{\lambda 2}$

where λ_1 = main wavelength

λ_2 = side wavelength

5.1.7 DISPENSING

Konelab 60 has separate dispensers for samples, reagents and ISE tests. Konelab 30, 20XT and 20 has common dispenser for samples and reagents but separate for ISE tests. The dispensers are equipped with a level detector, which ensures that there is enough sample/reagent for the analyses requested. The level detector also controls the depth of immersion of the needle into the sample cup.

A sample is dispensed either into a new cuvette or into the partly used cuvette. One cuvette consists of twelve reaction cells.

The sample/ reagent can be dispensed to the cuvette with water or with a sample/ reagent extra. The water volume is dispensed to the cell with the sample/ reagent. The extra volume is discarded after the real volume is dispensed. Dispensing with water is recommended for the end point measurement, and dispensing with extra is recommended for kinetic measurement.

Reagents can be dispensed also with reagent extra with buffers. When dispensing, the real reagent volume is dispensed first to the cuvette, then reagent extra is discarded and after that follows three buffers (4 µl each, air in between), which are also discarded. The purpose of dispensing with reagent extra with buffers is to prevent reagent dilution even better than dispensing with reagent extra. Dispensing with buffers is slower, and effects to the capacity of analyzer.

Dilution of a sample/ calibrator

Predilution is done in a cuvette position with a diluent which can be water from the fluidic system or a special diluent placed as a reagent in the reagent disk. The analyser will do the calculation of raw sample and diluent volumes. **The user can only set the diluted volume to be dispensed**.

Raw sample volume when doing sample predilution:

Raw sample volume is calculated according to the following formula:

Raw sample volume = (50 µl + diluted volume needed)/ dilution ratio

50 µl = a fixed volume, not editable, corresponding to dead volume of a cuvette position

Diluted sample volume needed = volume dispensed into the cuvette position + extra volume

Dilution ratio is equal to 1+x, e.g. 1+10 dilution is 11

Final raw sample volume will be increased to a whole even number, e.g. 6.8 µl will be raised to 8 µl

5.1.7.1 Calibration with series of dilution from one stock calibrator

Example: Transferrin test, Type of calibrators: Series, Dilution ratio 1 + 55, 27, 14, 7, 4, 2

Sample volume 3 µl dispensed with extra sample 20 µl = 23 µl of diluted sample but we also need in the cuvette position 50 µl dead volume, so we need at least 73 µl diluted sample.

73/56 = 1.4 = 2 µl raw sample
73/28 = 2.6 = 3 µl raw sample
73/15 = 4.9 = 6 µl raw sample
73/8 = 9.1 = 10 µl raw sample
73/5 = 14.6 = 16 µl raw sample
73/3 = 24.3 = 26 µl raw sample ⇒ Total = 63 µl raw sample

5.1.7.2 Calibration with separate calibrator

Example: Protein in urine, Type of Calibrators: Separate, Dilution 1 + 40

Sample volume is 3 µl when we actually need 53 µl (= 3 µl diluted sample + 50 µl cuvette dead volume) of the diluted sample.

Dilution: 53/41 = 1.29 = 2 µl raw sample

2 µl raw sample is dispensed from the cup with 80 µl water (=40 times dilution) to the cuvette position. From that cuvette position 3 µl diluted sample is dispensed with 10 µl water to another cuvette position which is the actual reaction position.

5.1.7.3 Patient sample dilution

Example: Apo B

Dilution 1 +	**10**	Dilution limit (✎= lot dependent)	**0,010**		**0,260**	**g/l**
Sample type		Secondary dil. 1+	**2**		**50**	

Sample		dilution
Volume (µl)	&	Raw S. with
18		**WATER**
		Volume (µl)
		30
Disp. with		Special dil.
EXTRA		**Spedil**
Volume (µl)		Disp. with
20		**EXTRA**
Diluent		Volume (µl)
SPECIAL		**20**

We need as dilution volume in the cuvette = dead volume + sample volume + extra sample.

In this example Total dilution volume is = 50 + 18 + 20 = 88 µl

Primary dilution is 1+ 10
From 88 µl we take from the sample cup 8 µl (= 88/(1+10))
In order to flush this 8 µl to the cuvette position, we will use 30 µl of Water.
To complete the dilution we will use some Specimen diluent (Spedil), the volume of specimen diluent to cuvette position is 88 – 8 – 30 = 50 µl. To dispense this 50 µl of Specimen diluent we use 20 µl of Extra Specimen diluent.

Secondary dilution 1 + 50
From 88 µl we cannot take (88/51)µl, which means 1.7 µl of raw sample. We can take 2 µl of sample, in that case we need 100 µl diluent
We will dispense 2 µl raw sample with 30 µl water and complete the dilution with 70 µl (=100 – 30) of Specimen diluent. To dispense this 70 µl of Specimen diluent, we use 20 µl of Extra Specimen diluent.

5.1.8 INCUBATION TIME

The incubation time is the time from the dispensing of the first position of the cuvette to the next action in the test flow i.e. next dispensing (sample or reagent) or measurement. Incubation temperature is the same as the measurement temperature.

5.1.9 LINEARITY CHECK OF THE KINETIC MEASUREMENT

5.1.9.1 CURVE TYPE LINEAR

Linearity check is done by sub-dividing absorbance points into two sections. Absorbance points are divided by (n/2) +1 where n is the number of measurement points. In case 12 points are measured it is divided to two 7 points sections. The first section consists of first (n/2) + 1 points and the second section consists of last (n/2) +1 points.

The slope ΔA1 is calculated by drawing the straight line through absorbance readings of the first section and the slope ΔA2 through the second section. The overall slope of all absorbance values is defined as Ao and is derived by drawing the straight line through all points by the method of least squares.

The nonlinearity of the reaction is now tested in two ways: the exceeding of the limits both in percents and in concentration units is checked.

The reaction will be flagged as nonlinear and the percentage nonlinearity calculated if both limits (% and conc.) have been achieved:

a)[$(\Delta A_1 - \Delta A_2)/\Delta Ao$] x 100 > predestined limit (Parameter *Nonlinearity (%)*),

b) the results in concentration units calculated according to the slopes A1 and A2 differ from each other more than the predestined limit (Parameter *Nonlinearity (Conc.)*)

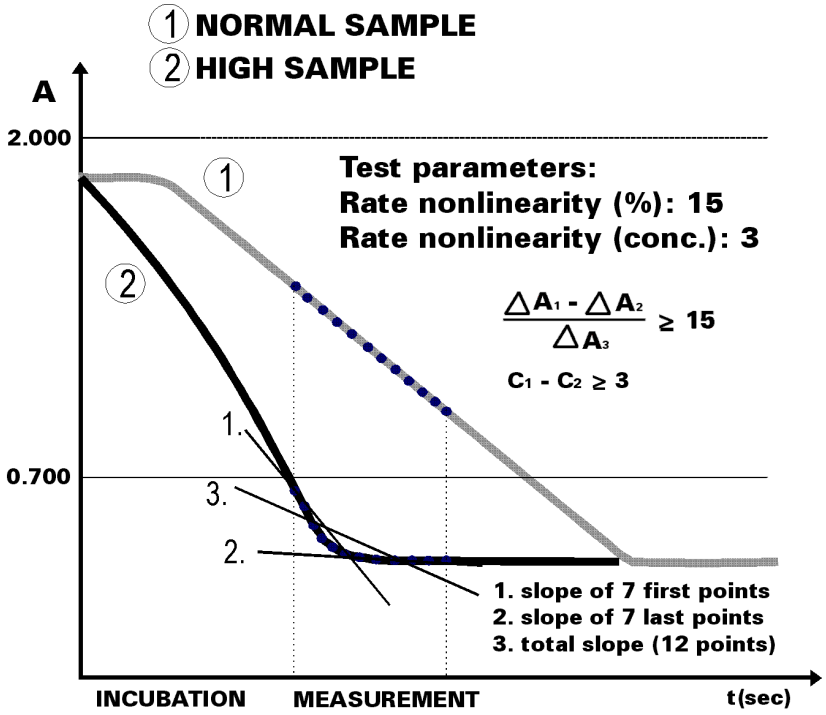


Figure 5-8: Linearity check of a kinetic reaction with the curve type linear. Both Nonlinearity limits (%) and (conc.) have been exceeded.

5.1.9.2 CURVE TYPE LINEAR CUT

In the kinetic measurement the curve type is linear cut if the reaction is complete during the measurement time. Linear cut means that only the linear part of the curve is used for the measurement i.e. those points, which are in the reaction area. In the following example they are the first six points.

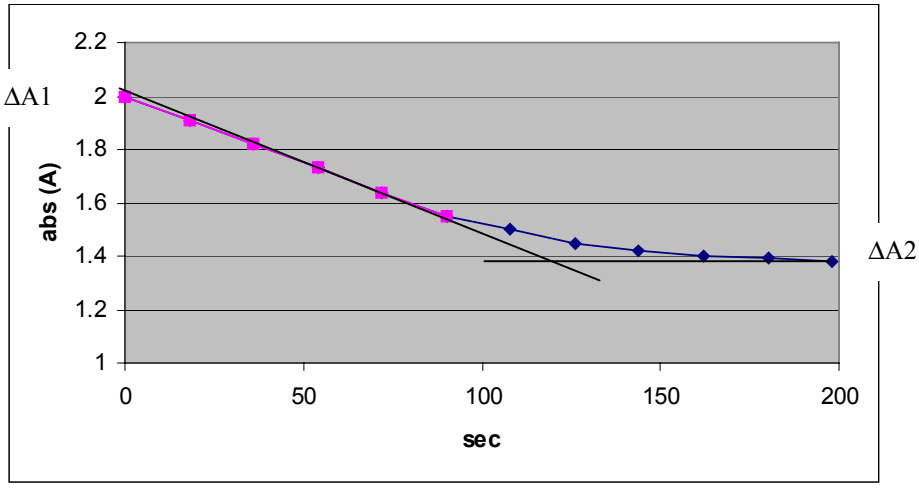


Figure 5-9: Linearity check of a kinetic reaction with the curve type linear cut. The slope of the first three measured points and the slope of the last three measured points are detected.

To find out where the reaction is complete, the slope of the first three points and the slope of the last three points are detected. The slope ΔA_1 is calculated by drawing the straight line through the first three absorbance readings and the slope ΔA_2 through the last three absorbance readings.

If the absolute value |ΔA1 - ΔA2| > Nonlinearity limits Response (mA/min) all absorbance points cannot be used when calculating the response. Nonlinearity limits Response (mA/min) is given in the Test flow window.

When |ΔA1| > |ΔA2| the turning point of the reaction will be sought. In the example above the turning point is after the 6th point (about after 100 sec) so the first six points will be used for calculating the response. The result will be flagged with the 'Cut curve' flag.

The calculation of response needs at least three points. If the turning point is after the first or the second absorbance point the reaction is flagged with the 'Linearity' flag. The most common cause is that the reaction is so quick that it ends before the measurement time. In that case the sample should be diluted and re-measured.

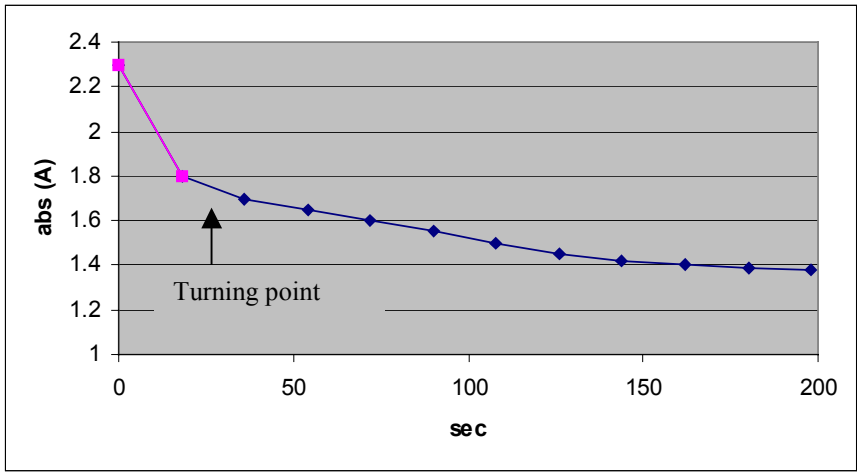


Figure 5-10: The reaction turning point is after the second measurement point, the Linearity flag is seen.

The reaction will be flagged as erroneous if |ΔA1| < |ΔA2|, the chemical reaction rate must decrease during the measurement time.

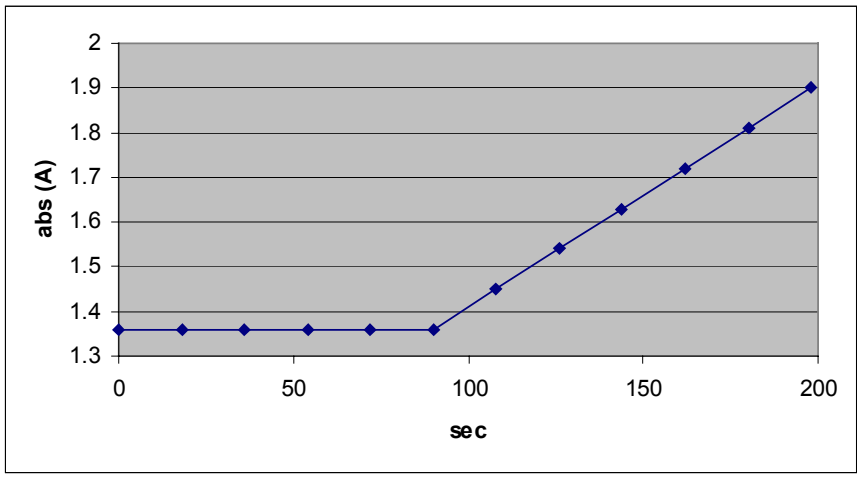


Figure 5-11: In this example the reaction starts after 90 seconds, the Linearity flag is seen.

5.1.9.3 DATA QUALITY CHECK FOR BOTH CURVE TYPES: LINEAR AND LINEAR CUT

The quality of the measured absorbance points, which are used for calculating the response of the kinetic reaction, is checked.

If the measured absorbance points do not fit to the line calculated according to linear regression, the 'Point(s) out of curve' flag is seen. The goodness of fit is evaluated as following:

If (Stdev (mA) / Window (mA)) > 7 % the error flag is given.

Stdev = standard deviation of the absorbance points from the calculated line, in the example below 325 mA

Window = the change of absorbance during the measurement, in the example below 990 mA

In case the Stdev (mA) is small, under the acceptable standard deviation limit (normally 2 mA measured by the water blank), the response will be accepted without flag.

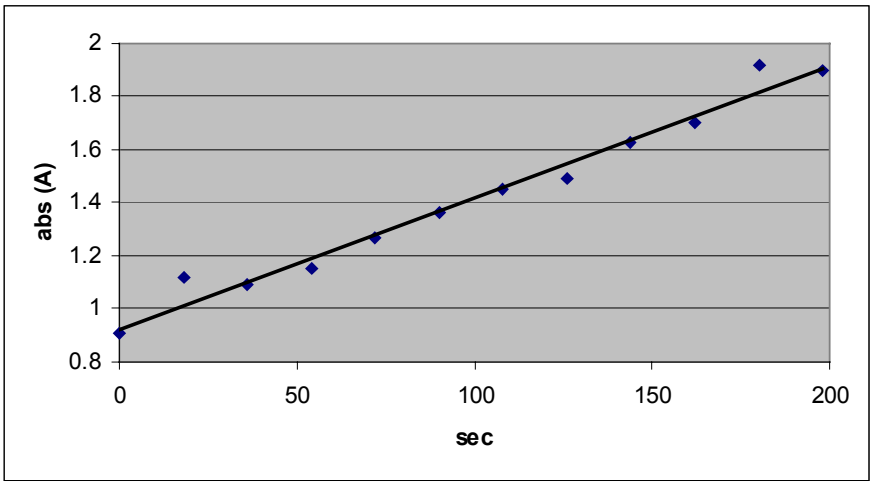


Figure 5-12: The quality of the measured absorbance points is evaluated. The points 2 and 11 are out of the linear regression line, the 'Point(s) out of curve' flag is seen.

5.1.10 RESIDUAL NET ABSORBANCE

***) Net Res. Abs. is calculated from the last measured point of the linear part of the curve.**
In case of cut curve it does not take the last point measured but the last point from linear curve.

The residual net absorbance provides the minimum allowable difference between the absorbances measured with the main and the side wavelenghts. For example it is suited for checking NADH consumption in AST and ALT tests, see Figure 5-13 for bichromatic checking of the *Res. net.abs.*

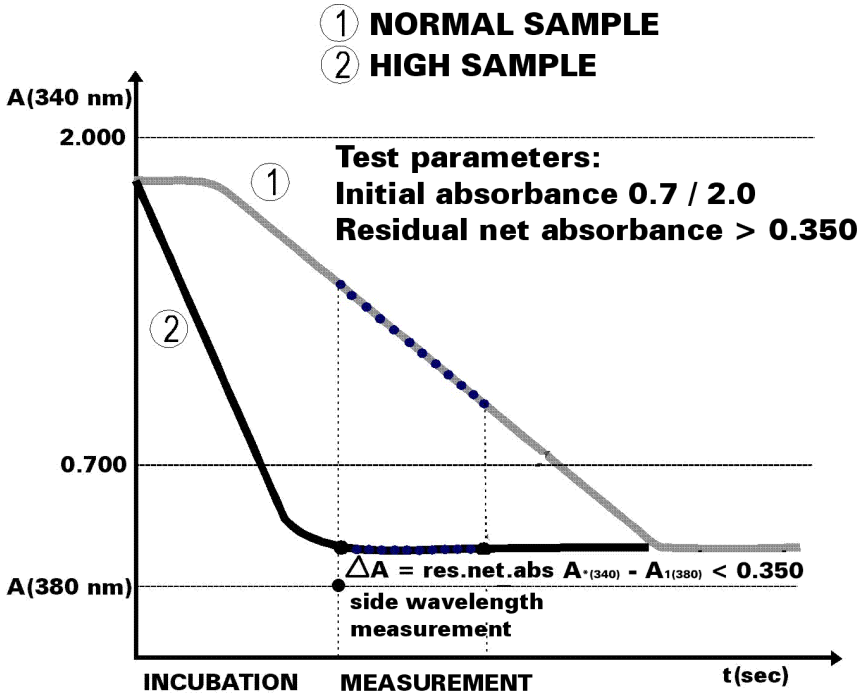


Figure 5-13a: Initial absorbance value is not within the limit and residual net absorbance value is below the limit, the messages 'Init.abs.' and 'Bichr.net.abs' are given. Manual acceptance is requested.

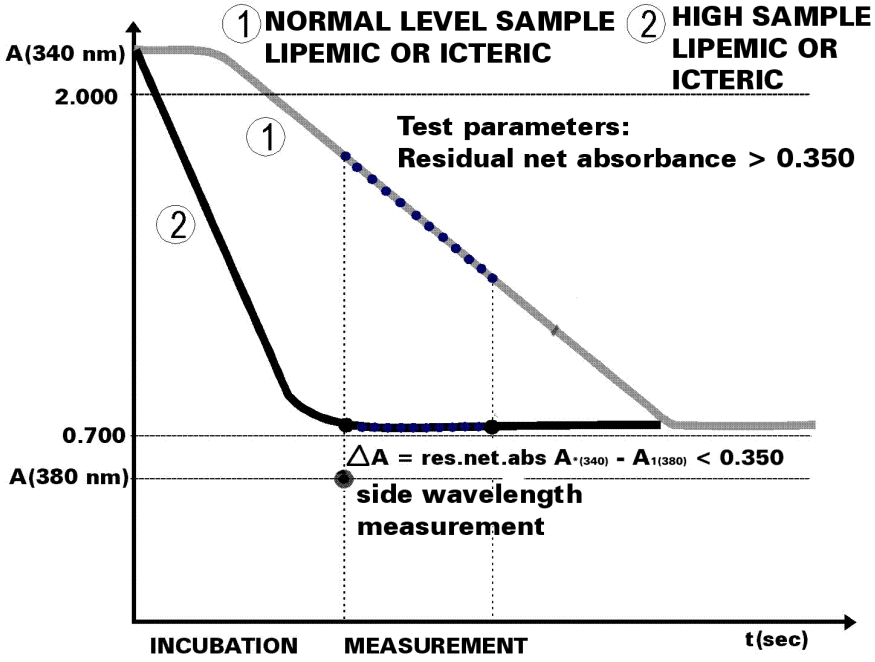


Figure 5-13b: Residual net absorbance is below the limit. Because of lipemia or icteria the high level sample does not cause the initial absorbance message. In this case the high concentration level can be detected only by means of bichromatic measurement. The message 'Bichr.net.abs' is given and manual acceptance is requested.

5.1.11 ANTIGEN EXCESS CHECK

WHAT DOES THE ANTIGEN EXCESS MEAN?

Immunological reaction between antibodies in the reagent and antigens in the sample causes the formation of a complex, a 'lattice' containing several molecules. If the complex is relatively large (as a result of cross-linking) it becomes insoluble and therefore precipitates.

Typically antibodies are divalent i.e. there are two specific areas which react with antigens. This allows cross-linking.

CONDITIONS

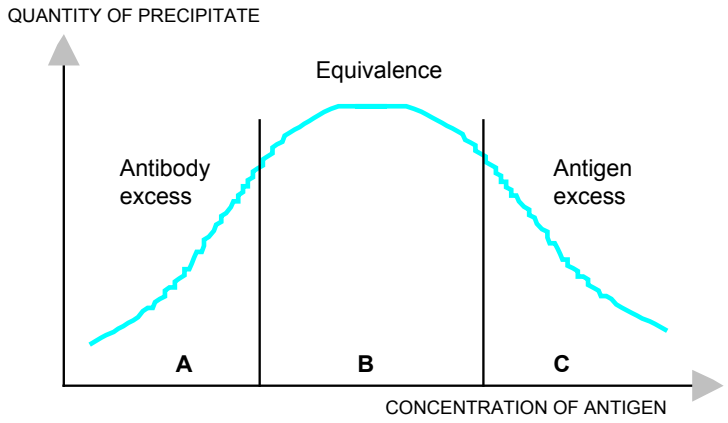


Figure 5-14: The classical precipitation curve

A. ANTIBODY EXCESS

There are enough antibodies in the reagent to saturate all sites of the sample's antigens without cross-linking. In Figure 5-13 part A of the curve represents this condition: larger complexes do not form, no precipitation occurs, measured signal is low.

B. EQUIVALENCE

The turbidity increases because of cross-linking during the addition of the antigen to the antibody. The antigen and the antibody are said to be in equivalence when all molecules are cross-linking. The area B in Figure 5-13 represents this situation: larger particles are formed, precipitate formation is maximal, measured signal is maximal.

C. ANTIGEN EXCESS

If the antigen is present in large excess, each antibody molecule binds two separate antigen molecules without cross-linking. In Figure 5-13 part C of the curve represents this condition: precipitation does not occur, measured signal is minimal.

Although the antigen concentration of the patient sample is high, the given result is erroneously low. The antigen excess condition is detected and the sample should be reanalysed with secondary dilution.

Note that in extremely rare case it may occur that the dilution limit is passed under due to very large antigen excess. Then the low secondary dilution limit is taken into use and the sample is concentrated even if the antigen excess has been detected. In this case the manual dilution is needed. While diluting the sample manually note that the analyser dilutes every sample automatically with primary dilution ratio (e.g. 1 + 10) before analysis - also those manually diluted samples.

CHECKING OF THE ANTIGEN EXCESS CONDITION

A sample of known concentration (=AE check sample) is introduced as a control sample in the Cal/ctrl definition window. It is added into the cuvette cell after the actual sample measurement. This additional, AE check sample is dispensed with distilled water, which volume can be defined in the Test flow window (refer to section 4.2.5). The default volume for water is 10 µl. The measurement of antigen excess sample is always end point done with the same wavelength as actual sample measurement.

In case of antibody excess there are free antibodies in the mixture. They will form a precipitate with the antigen in the additional sample and a rise of concentration is detected.

If antigen excess is detected measurement is repeated according to High and Low secondary dilution ratio parameters. The user is informed about the conditions with 'Antigen Excess' note in the result acceptance windows.

In the antigen excess condition free antibody sites are not available and the addition of antigen does not cause more precipitation. A significant increase in the concentration is therefore not detected. However, because of the complexity of the immunological reactions, the addition of the antigen may cause a minor rise of concentration also in case of antigen excess condition. Therefore proper choice of the concentration of the added sample as well as careful determination of the check limits are of great importance.

The measurement of IgA is used as an explanatory case for secondary dilution ratio parameters in the following example.

The calibration range in the calibration curve of IgA in Figure 5-15 is 0.04 - 0.77 g/l. The lowest reliable sample response is equal to the lowest calibration point response, and the highest reliable sample response is equal to the highest calibration point response. Thus, with the primary dilution ratio 1 + 10 the measurement range of IgA is 0.44 -8.47 (= 11 x 0.04; 11 x 0.77).

Usually, if the sample response is below the lowest or over the highest calibration point, the result would be approximated from a linear curve with a slope determined from the first or last point of the calibration curve. To obtain a more reliable determination for very low or high concentrations, the High and Low secondary dilution ratio parameters must be given.

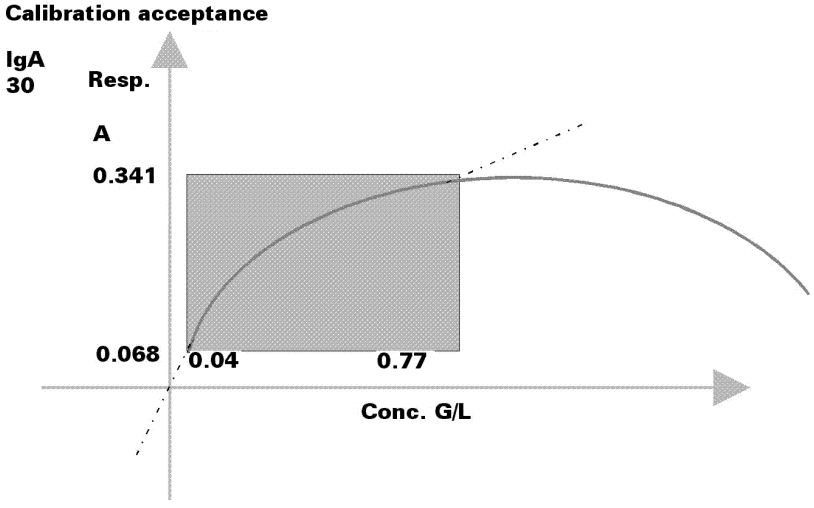


Figure 5-15: The shape of the calibration curve

Sample response is lower than the response of the first calibration point:

The primary dilution ratio of IgA is 1 + 10. If the sample response is lower than the response of the first calibration point, the sample is analysed again with 'Low Secondary 1 + '. Thus it is possible to measure patient sample concentrations from 0.041 g/l (= 2.3 / 56) g/l.

Sample response is higher than the response of the last calibration point:

In this case the test will be rerun with higher dilution according to the parameter 'High Secondary 1+ '.

Calibration curve for IgA in Figure 5-14 has been obtained from a stock calibrator (concentration 2.3 g/l), with the following dilution series:

Dilution series	Concentration g/l
1+55	0.04
1+27	0.08
1+14	0.15
1+7	0.29
1+4	0.46
1+2	0.77

For IgA:

Patient samples can be measured with:

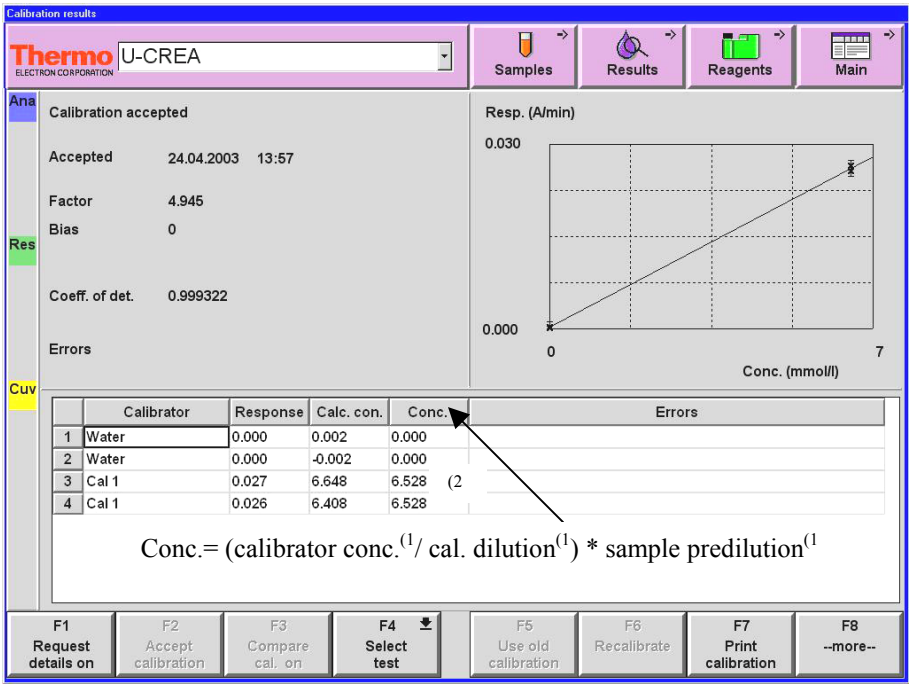
Concentrations between:	Used dilution:
0.04 - 0.44 g/l	Low Secondary 1 + 0
0.44 - 8.47 g/l	Dilution 1 + 10
8.47 - 62.37 g/l	High Secondary 1 + 80
Note: Reference values for IgA = 0.9 - 4.5 g/l	

5.1.12 CALIBRATION

5.1.12.1 LINEAR, BIAS AND NONLINEAR CALIBRATION

Linear calibration

Factor and bias which determine the linear calibration curve (see Fig. 5-16) are automatically calculated according to the linear regression from the measured calibrator samples (at least with two different concentrations).



1) These values are set in the Test definition.

2) In this example calibrator concentration is set = 0.128
Primary dilution of the sample is set 1+50
=> it displays 6.528 = 0.128 * 51 and for the calculation it uses 0.128 because the calibrator is not diluted but the sample is diluted 1+50.

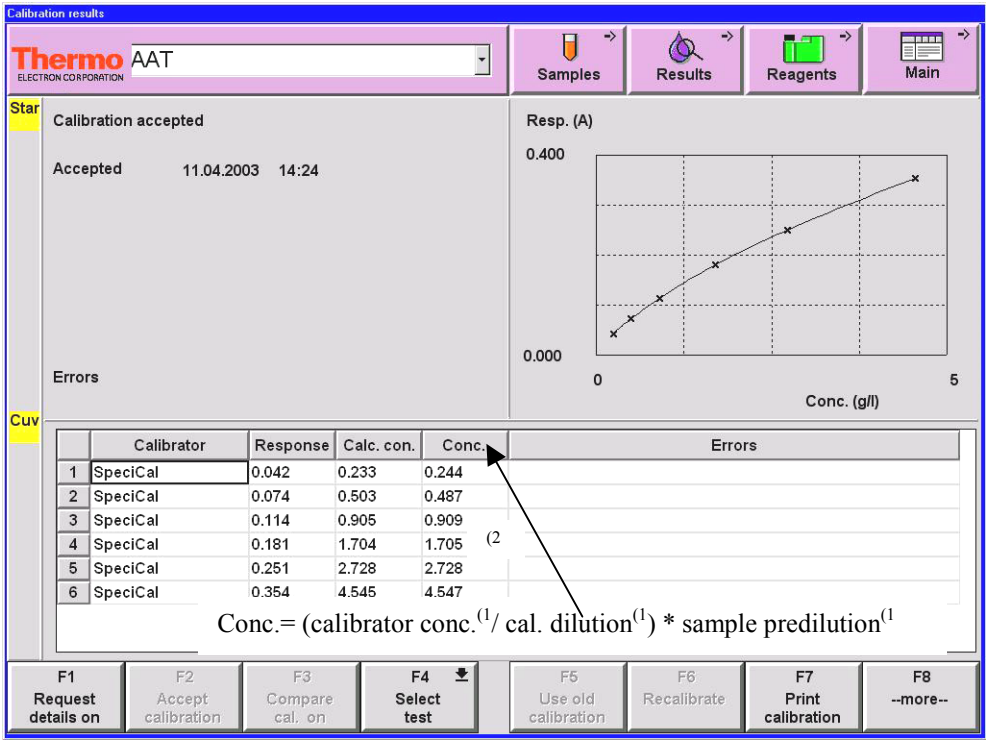
Bias calibration (= Linear calibration)

The analyzer calculates a bias automatically from the measured standard of zero concentration. The user gives a theoretical, experimental or calculated factor.

Nonlinear calibration

For the evaluation of the nonlinear calibration curve the analyser uses the spline function fit. The spline function consists of different polynomial functions going from one calibrator to another. These different functions join near the calibrator points so that a smooth continuous curve is generated.

The coefficient of determination value, seen in the calibration results, shows how well the spline function fits to the measured data. See the explanation of the coefficient of determination in section 5.2.3.



1) These values are set in the Test definition.

2) In this example the values are obtained after these calculations:
   0.244 = (1.24/56) * 11
   0.487 = (1.24/28) * 11
   0.909 = (1.24/15) * 11
   1.705 = (1.24/8) * 11
   2.728 = (1.24/5) * 11
   4.547 = (1.24/3) *11

5.1.12.2 NO CALIBRATION - FACTOR AND BIAS

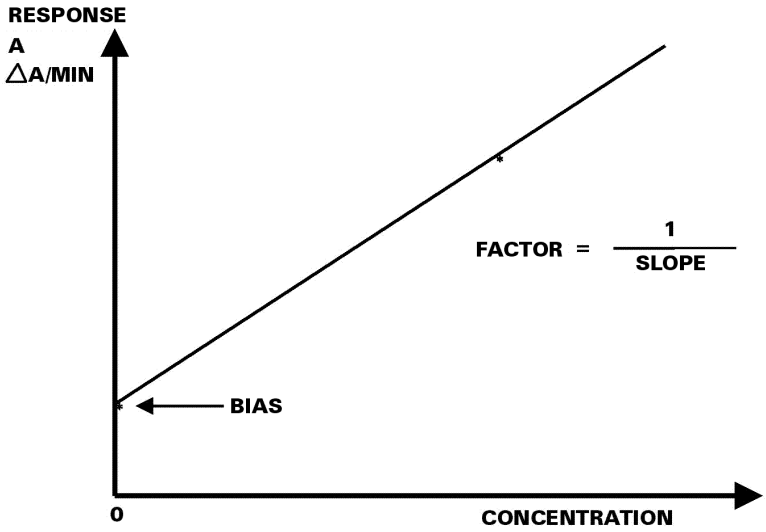


Figure 5-16: Factor and bias

When the calibration type is *None* no calibration is done for the test. The user gives only factor and bias values. Concentrations are calculated according to the equation:

RESULT = FACTOR x (Response - BIAS)

Response = absorbance or the change of absorbance per minute.

5.1.12.3 CHECKING CALIBRATION CRITERIA

The total calibration error should correspond to the expected statistical fluctuations in the measured response of the calibrator sample.

Spline curve does not go through all calibrator points but joins near them within the defined error limits.

Error estimate (EE) is calculated using the following equation:

$$EE = \sqrt{E_a^2 + [(E_r \times RP)/100]^2}$$

where: E_a = absolute error (mA)
E_r = relative error (%)
RP = response (mA)

If a calibrator measurement differs from the calibration more than the error estimate, the note *'Out of limit'* is shown in the calibration acceptance windows.

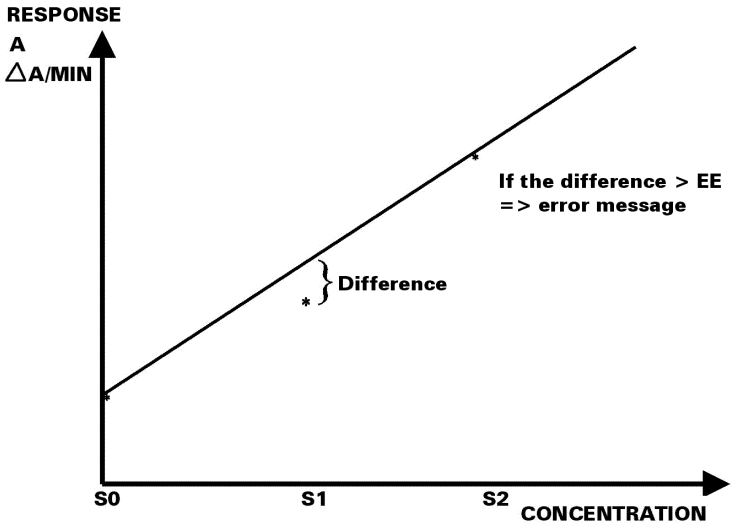


Figure 5-17: Checking the error estimate

Fitting factor shows how good the evaluated curve is compared to EE. The following equation defines the fitting factor:

$$F = 1/n \sum_{i=1}^{n} [(f_i - r_i)^2 / (EE)^2]$$

where F = fitting factor
f_i = response calculated from the evaluated spline curve corresponding with Calibrator i
r_i = measured response
EE = error estimate
n = number of calibrators

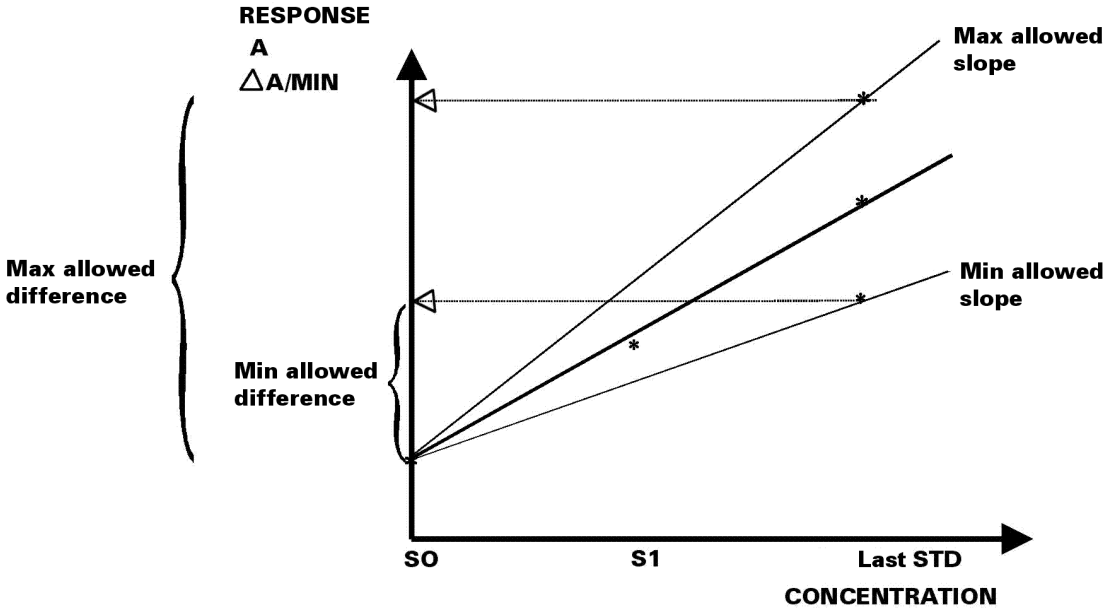


Figure 5-18: Minimum and maximum response limits for the calibration

5.1.12.4 BIAS CORRECTION

The calibration may be checked and corrected by measuring one calibrator.
Then the calibration curve is shifted to go through the measured point.
In the linear calibration the factor will remain the same and the shape of the nonlinear calibration curve will remain, only the 'bias' of the curve will change.

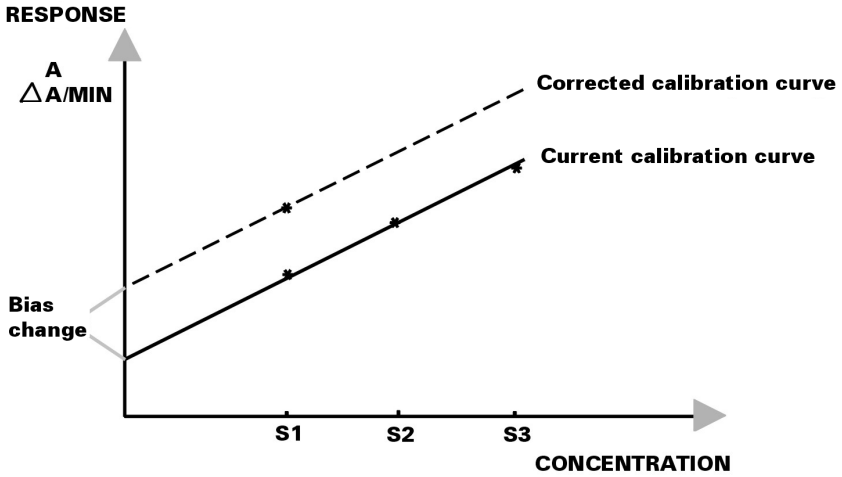


Figure 5-19: Bias correction using calibrator I

5.1.13 QUALITY CONTROL

5.1.13.1 QUALITY CONTROL RULE

The form of the quality control rule

x:y*SD

- x shows how many successive control requests are compared,
- y shows how many SD the measured control result can differ from the given mean value.

Batch size

Controls are analysed as a batch. In the Quality Control parameters the control must be selected as many times, as is necessary to be measured. The batch size can be from 1 to 6 requests.

X value is dependent on the batch size

When the batch size is:

The message "Incomplete QC batch" is given if the QC batch includes less requests than should be according to the rules. You can see also those QC requests which have not been measured.

- 1 x can be 1 to 12
- 2 x can be 1, 2, 4, 6, 8, 10, 12 or R
- 3 x can be 1, 2 of 3, 3, 6, 9, 12 or R
  - 1 means that every measurement is detected separately,
  - 2 of 3 means that the rule is violated if two of batch's three measurements violate the rule,
  - 3 means that the rule is violated if all measurements of the batch violate the rule,
  - 6 means that measurements of two batch are compared.
- 4 x can be 1, 2 of 4, 3 of 4, 4, 8, 12 or R
- 5 x can be 1, 2 of 5, 3 of 5, 4 of 5, 5, 10 or R
- 6 x can be 1, 2 of 6, 3 of 6, 4 of 6, 5 of 6, 6, 12 or R.

R value

R means that the highest and the lowest measurement in the batch are compared. When R has been selected, the quality control rule is violated when the difference between the biggest and the smallest deviation is over the selected y*SD.

Example 1: - the rule is R:2*SD
- the biggest measured deviation is 1.1*SD
- the lowest measured deviation is -1.1*SD

⇒ The difference between the deviations is 2.2*SD, so the rule is violated because the difference is bigger than 2*SD given in the rule.

Example 2: - the rule is R:2*SD
- the biggest measured deviation is 1.4*SD
- the lowest measured deviation is -0.8*SD

⇒ The difference between the deviations is 2.2*SD, so the rule is violated because the difference is bigger than 2*SD given in the rule.

5.1.13.2 SOME EXAMPLES TO SELECT QUALITY CONTROL RULES

A. Rules to detect systematically occurring errors

For example 2:2*SD, 3:1*SD, 4:1*SD, 6:0*SD, 8:0*SD, 10:0*SD and 12:0*SD

Inaccurate calibrators, poor calibration, inadequate blank, deteriorated or old reagents, drift of detectors, changing of instrument's components, wrong temperature etc. can cause errors occurring systematically.

The rules 2:2*SD and 3:1*SD can be used within a material if it is of interest to monitor systematic changes at one level, such as the high or low end of the working or linear range.

Rules to detect over the batch

The rules 4:1*SD, 6:0*SD, 8:0*SD, 10:0*SD are used to detect systematically occurring errors over the batch.

B. Rules to detect random errors

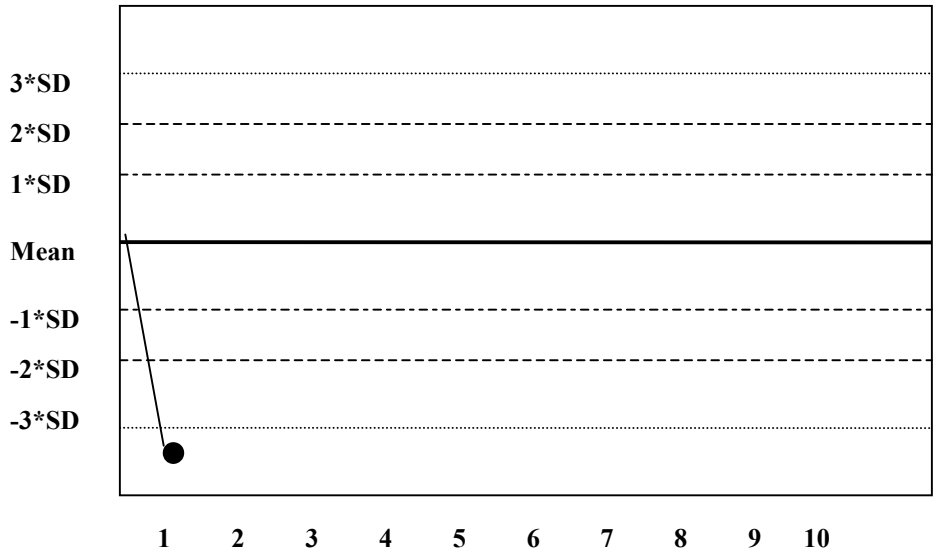
For example: 1:2.5*SD, 1:3*SD, 1:3.5*SD and R:4*SD

Poor mixing, air bubbles or particles in reagent, dispensing errors, optical problems etc. can cause random errors.

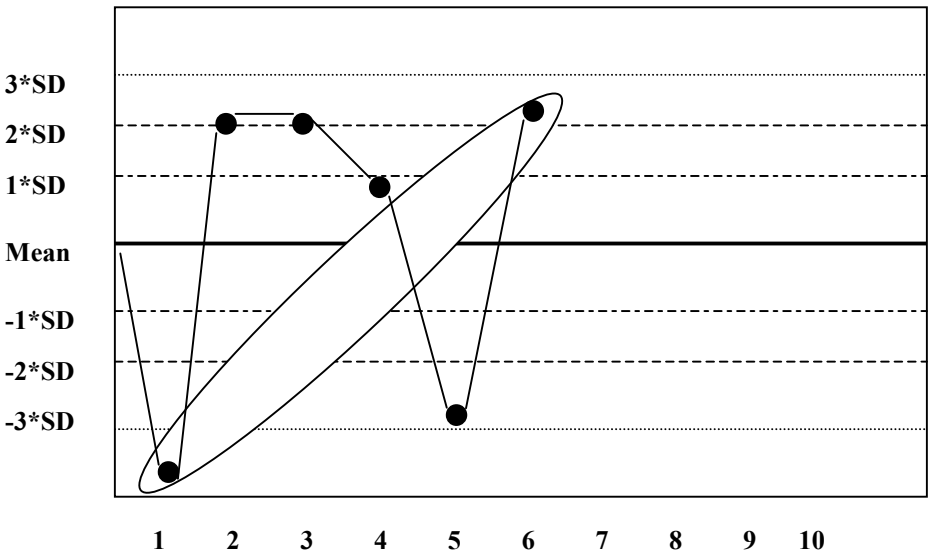
The control material can cause random errors seen in many tests with the same control sample.

5.1.13.3 SOME EXAMPLES OF RULE VIOLATIONS

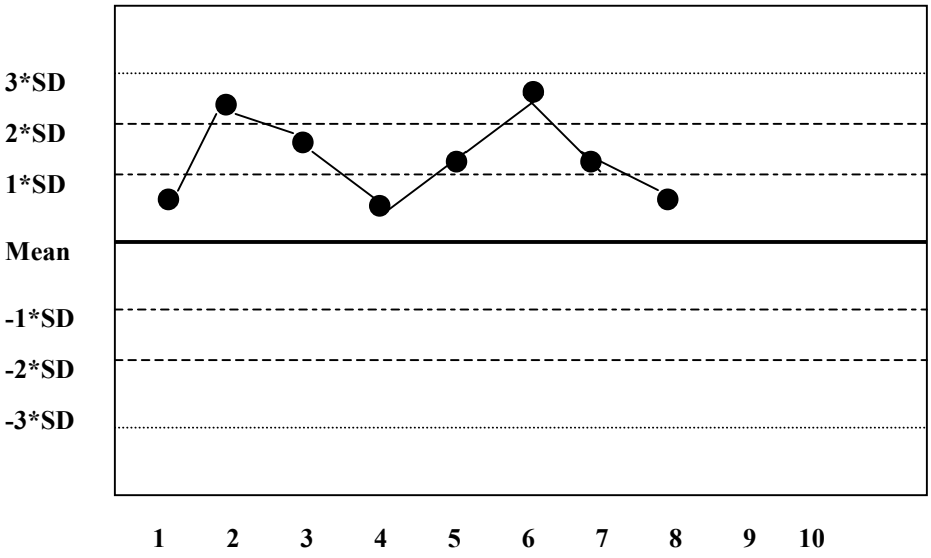
Example 1: When the rule is 1:3*SD a run is rejected if a single control measurement exceeds the mean plus or minus 3*SD.



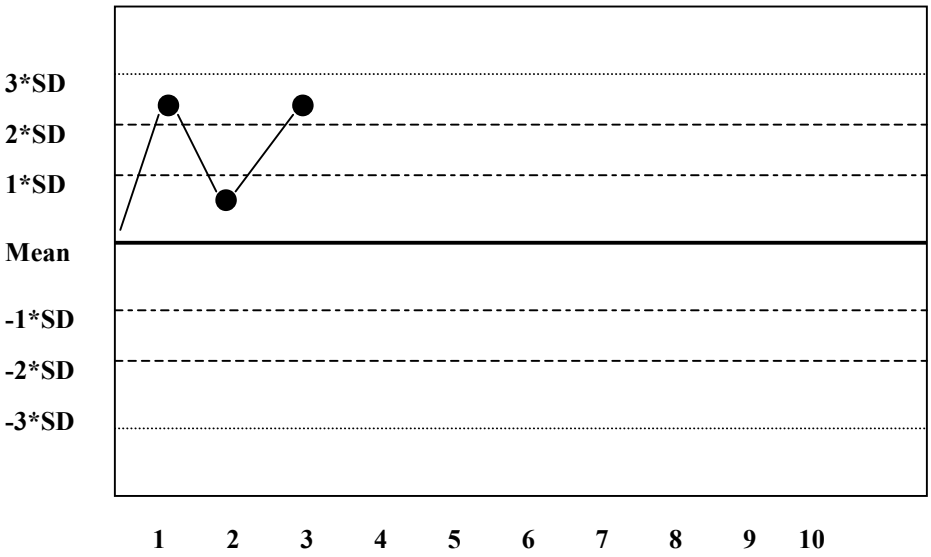
Example 2: When the rule is R:4*SD a run is rejected if one control measurement in a batch exceeds the mean plus 2*SD and another control measurement exceeds the mean minus 2*SD.



Example 3: When the rule is 8:0*SD a run is rejected if 8 consecutive control measurements fall on one side of the mean.



Example 4: When the rule is 2:2*SD a run is rejected if 2 control measurements in the same batch exceed the same mean plus 2*SD or mean minus 2*SD.



5.1.13.4 RESULT ACCEPTANCE

A test is in a manual acceptance when:

- a test, a calibration or a Manual QC has been defined as manual acceptance,
- a test defined as automatic acceptance has a QC failure

A test's automatic acceptance is changed to manual when:

- some controls belonging to the batch cannot be performed,
- some control is short,
- any of the control requests cannot be analysed,
- a control request has a measurement error, e.g. init. abs.
- a control rule is violated.

The acceptance is changed back to automatic when quality control results are accepted (or rejected) manually or after reboot.

5.1.14 SCREENING TEST

Note that screening test is not used in Konelab applications at the moment.

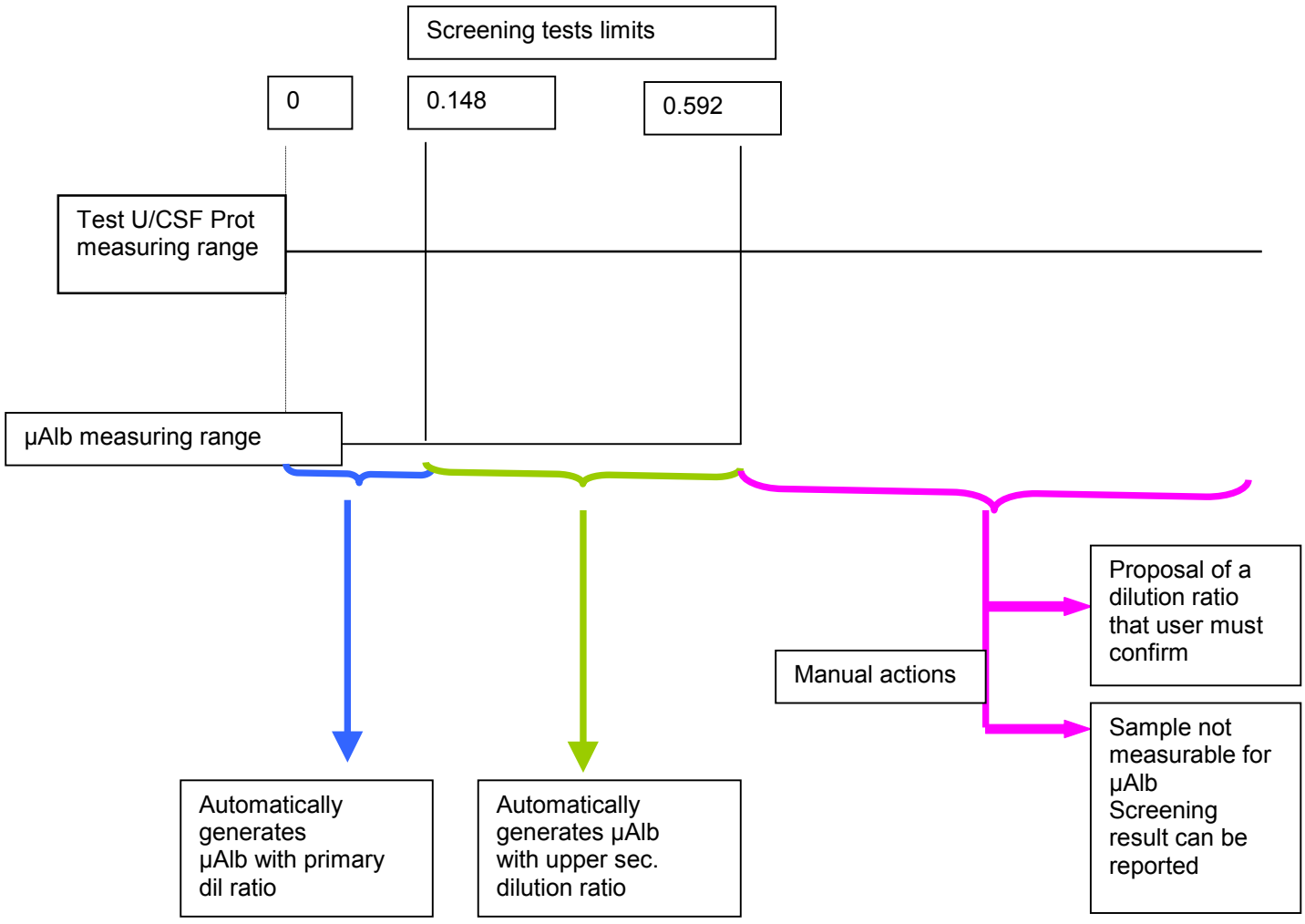
The purpose of screening test is to increase safety of methods.
It can be used e.g. with tests such as microalbuminuria. Concentration of albumin in urine range from 5 mg/l in healthy individuals to up to several tens g/l in patients with nephrotic syndrome. When microalbuminuria assay is performed with unknown samples, samples of very high albumin concentration might give falsely low values because of antigen excess. By using a suitable screening test these high samples might be detected and correctly diluted.

There are two tests involved with the analysis:

- Original test (or "Test to be screened"): the final result of this test will be reported, e.g. microalbuminuria
- Screening test: the auxiliary test, which is used for getting the right dilution ratio for the original test, e.g. U/CSF Prot

Test parameters of screening test contain the following screening parameters:

- Test to be screened: connection to the "original test"
- 2 screening limits: the result of screening test is compared against these values:
  - If result < lower limit, request of original test is created with its primary dil. ratio
  - If lower limit < result < upper limit, request of original test is created with its upper secondary dil. ratio
  - If upper limit < result, a proposal for the dil. ratio is calculated (user must accept this proposal)



The flow of one request is the following:

1. Request of "original test" arrives from LIMS or is entered in Sample entry.
2. When this request is detected, request of "screening test" is generated instead of the "original test". Request of "screening test" is denoted with special sign 'S'.
3. Request of "screening test" is analyzed the normal way. It may be for example diluted.
4. When result of "screening test" is accepted, request of "original test" is created. Result of "screening test" is used for determining the right dilution ratio for "original test". If the dilution ratio would be beyond the dilution capabilities of Konelab, request of "original test" is marked with error "Not measurable", and it is reported as such. (The user may also decide to accept result of "screening test", in which case result of "screening test" is reported and request of "original test" is not created.)
5. If request of "original test" was created with valid dilution, the request is analyzed the normal way.
6. When result of "original test" has been accepted, it is reported to LIMS and/or printer. Result of "screening test" is not normally reported.

5.2 ISE MEASUREMENT

5.2.1 OPERATION PRINCIPLE

The Konelab measures:
- Na, K and Cl in serum and plasma,
- Na and K in urine,
- Li, which is offered as an option, in serum and plasma.
– Ca and pH in Konelab 60 and 30, which are offered as an option, in serum and plasma.

The measurement is done with the direct ISE technique. The measured sample activity is compared to the activity of calibrators, which are adjusted to mimic activity normally found in serum samples.

The electrode block is comprised of the measurement electrodes and the reference electrode. The potentials produced at each membrane are measured once every second.

One dispensing arm, one pump and one 500 µl syringe are provided for the ISE measurement in Konelab 60 and 30. In Konelab 20XT and 20 one dispensing arm and FMI pump perform the ISE measurement. A sample is aspirated through the needle from the sample cup. The sample is moved to the electrode block where the measurement takes place.

Sample measurement is followed by ISE Calibrator solution 1 measurement. The ISE dispensing pump transfers ISE Calibrator solution 1 from the bag to the block. At the same time the sample is discarded. After the measurement ISE Calibrator solution 1 is pumped through the needle to the waste.

The tubes and the measurement channel of the ion selective electrode block are washed with the Washing Solution. The solution is dispensed via the dispensing arm into the block. From there it is pushed by the ISE washing pump into the wastewater container. The washing procedure is done during the STAND BY function.

5.2.2 MEASUREMENT PRINCIPLE

Each ion-selective electrode has an electrode -specific membrane. The membrane will attract the desired ion to the membrane phase when the sample solution comes into contact with it. The potential of each ion-selective electrode is measured against the reference electrode. The potential difference is developed at the electrode membrane. This potential (in mV) is read and amplified sequentially. It should reach the 'steady state' stage within a given time interval. If the measurement does not stabilise in an allowed time the measurement is repeated once. In case of repeated instability an error message is given.

5.2.3 CALIBRATION

A two-point calibration is performed for the ISE tests. Low (ISE Calibrator solution 2) and high (ISE Calibrator solution 3) calibrators are placed in the sample cups and are transferred with the dispensing arm. Normal calibrator (ISE Calibrator solution 1) is transferred from the bag to the block by the ISE dispensing pump.

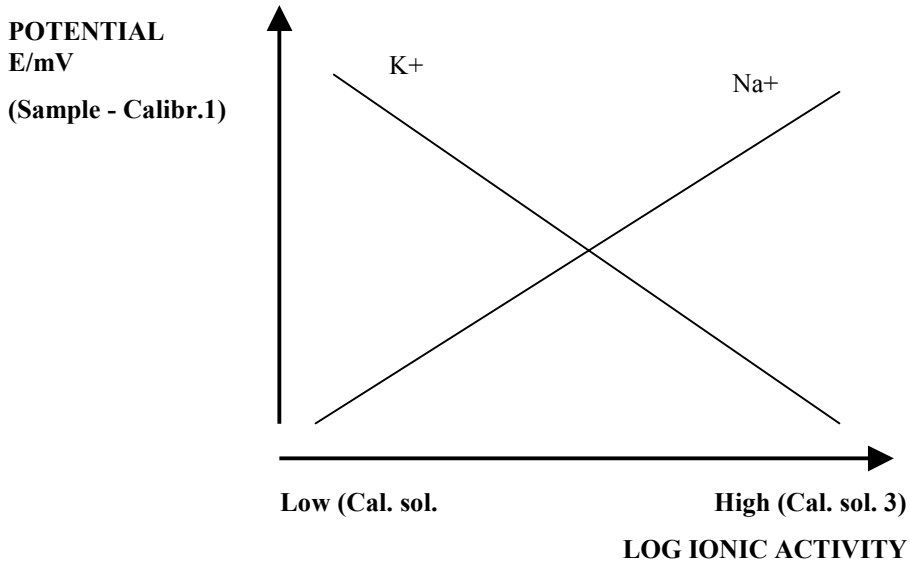


Figure 5-20: Principle of the calibration

Using the known concentrations of low calibrator (ISE Calibrator solution 2) and high calibrator (ISE Calibrator solution 3) and the measured responses (Figure 5-19) draws the slope of the curve.

The slopes (Figure 5-21), the potential difference between the high and the low calibrators, should be within the predestined limits. When the slope value goes down to the low limit and a Stand by with the Washing Solution process doesn't raise it, the life time of the electrode will be finish soon.

***Table 5-1**: Allowed limits for the slopes in serum and in urine mode*

SERUM MODE				URINE MODE	
Na^+	3.5 - 6.8	Ca^{2+}	11.0 - 21.0	Na^+	20.0 - 40.0
K^+	12.0 - 21.0	pH	20.0 - 40.0	K^+	85.0 - 115.0
Cl^-	-2.3 - -7.0	Li^+	10.0 - 19.0		

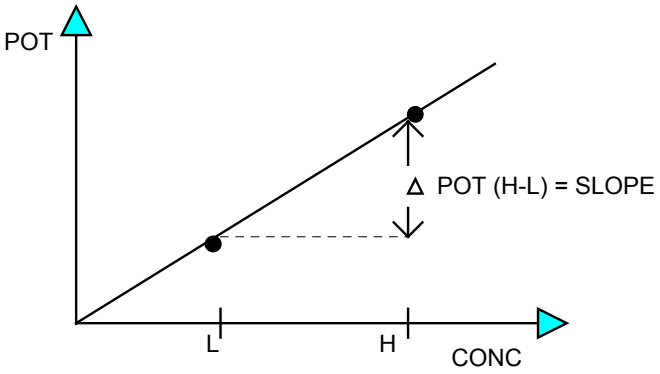
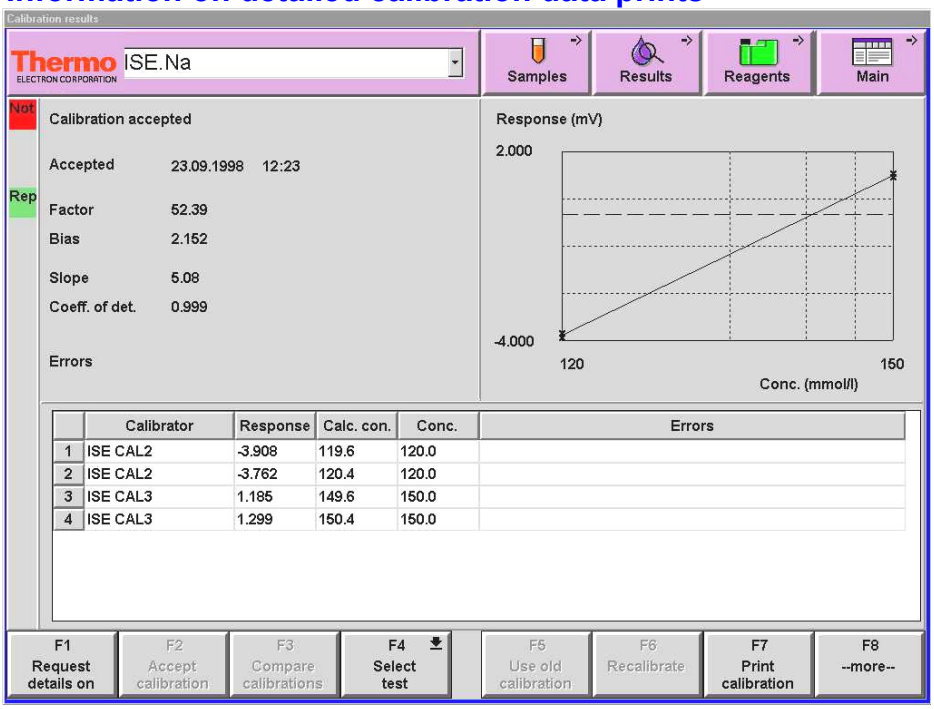


Figure 5-21: Calculation of the slope

Information on detailed calibration data prints



The detailed calibration data includes concentrations of ISE Calibrator solution 2 (L, low) and ISE Calibrator solution 3 (H, high), response values (H, L) of the calibrators, slope (H-L) and the coefficient of determination (see the explanation on the next page). Two parallel control measurements are not allowed to deviate too much from one to another.

It is recommended to check that response values (H, L) are within the following limits:

Calibrator solution	Serum, ISE Cal3 (High)	Serum, ISE Cal2 (Low)	Urine, ISE Cal4	Urine, ISE Cal3
Na^+	1.0 - 2.2	-2.41 - -4.69	18.75 - 37.49	1.0 - 2.8
K+	-6.96 - -12.18	5.04 - 8.82	-76.19 - -103.07	-6.96 - -12.18
Cl^-	-0.53 - -1.61	1.77 - 5.39		
Ca^{2+}	5.5 - 10.5	-5.5 - -10.5		
pH	-1 - +1	20 - 40		
Li^+	5.1 - 9.68	-4.6 - -9.6		

Check the electrodes if the values are not in the range.

The following equations explain the values on the calibration acceptance window:

$r_N - r_H = r_1$ corresponds to 1. response

$r_N - r_L = r_2$ corresponds to 2. response

where r_N = response of the normal calibrator (ISE Calibrator solution 1)
r_L = response of the low calibrator (ISE Calibrator solution 2)
r_H = response of the high calibrator (ISE Calibrator solution 3)
slope = $r_2 - r_1$

The coefficient of determination

The coefficient of determination (r2) compares estimated and actual y-values (responses), and ranges in value from 0 to 1. If it is 1 (one) , there is a perfect correlation in other words there is no difference between the estimated y-value (response) and the actual y-value (response). At the other extreme, if the coefficient of determination is 0, the regression equation is not helpful in predicting a y-value.

Calculation of the coefficient of determination

In the linear fitting of the calibration, Konelab software calculates for each point the squared difference between the y-value (response) estimated for that point and its actual y-value (response). The sum of these squared differences is called the residual sum of squares.
Konelab software then calculates the sum of the squared differences between the actual y-values (responses) and the average of the y-values (responses), which is called the total sum of squares (regression sum of squares + residual sum of squares).
The smaller the residual sum of squares is, compared with the total sum of squares, the larger the value of the coefficient of determination, r2, which is an indicator of how well the equation resulting from the regression analysis explains the relationship among the variables.

5.2.4 SAMPLE MEASUREMENT

Sample potential ES is measured first immediately followed by the potential measurement of ISE calibrator 1, EN.

$E_N - E_S = r_s$

The activity of the sample is calculated by using r_s and the calibration curve.

5.2.5 Ca^{2+} MEASUREMENT

In case of calcium, only approximately 50% of the analyte are freely ionised in normal serum and plasma. 40% of the remainder is bound to proteins and 10% to ligands such as citrate and bicarbonates. Using ISE, calcium activity is measured directly, with a normal range approximately half of that of "total calcium". Only the ionised fraction is biologically active, why it is considered physiologically and clinically more relevant than total calcium.

Concentration of the ionised calcium varies with pH of the sample. When the sample is exposed to air, CO2 will escape and affect the pH of the sample and the degree of the ionisation of calcium. Because of this samples should be treated as anaerobically as possible or when this is not possible a pH corrected calcium value should be reported. (Refer to section 7.3.2 for detailed description regarding anaerobic sample handling.)

The correction value is seen in the ISE Electrodes window. Refer to section 4.3.

With Konelab a Ca^{2+} result adjusted to pH 7.4 can be obtained. The adjusted value is calculated with the equation:

$$Ca^{2+} \text{ at } 7.4 = Ca^{2+}_S \times 10^{-0.24(7.4-pH_s)}$$

where Ca^{2+}_S = measured Ca^{2+} activity of the sample

pH_S = measured pH of the sample

5.2.6 Li^{+} MEASUREMENT

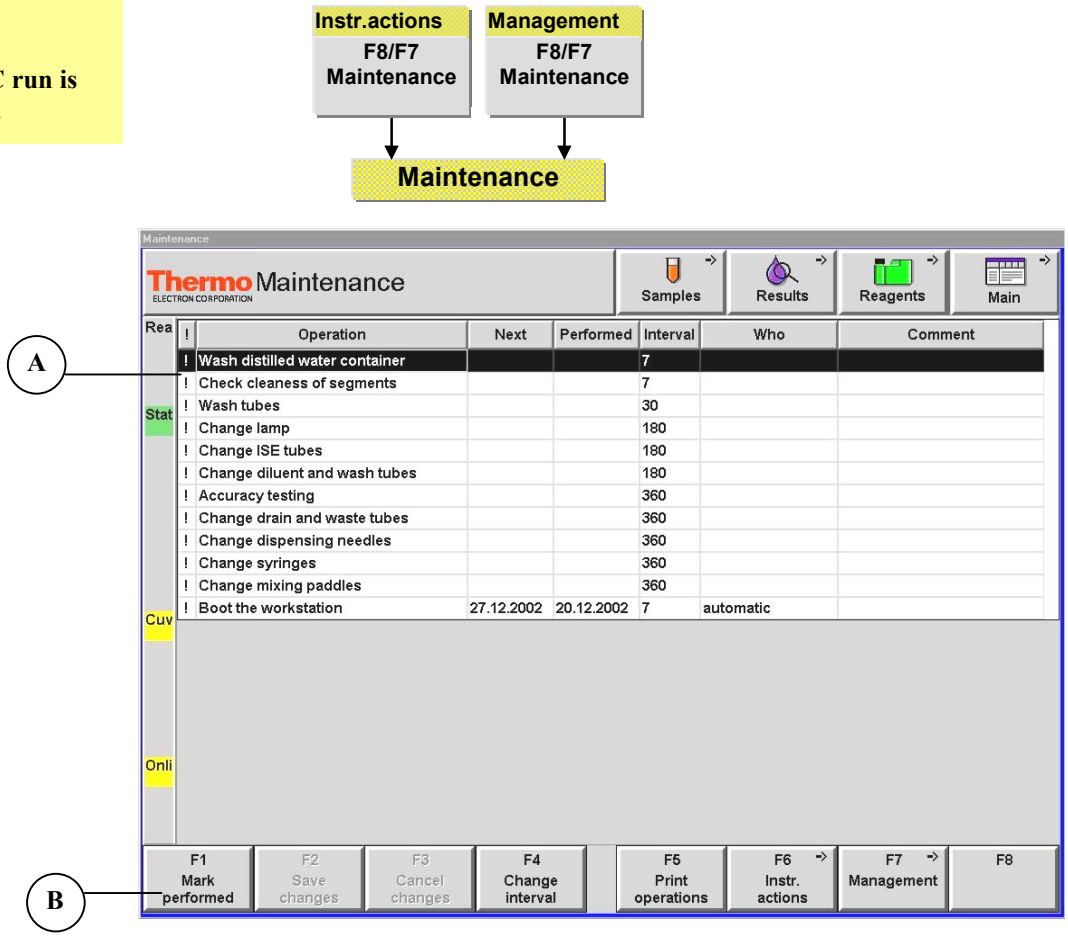
Measurement of lithium from serum or plasma is used for therapeutic drug monitoring for manic depressive patients on lithium therapy. No lithium is found in normal plasma or serum from healthy individuals.

Measurement of lithium using a lithium ion-selective electrode requires the presence of a sodium ion-selective electrode. The relationship is described by the selectivity coefficient 0.017 seen in the ISE Electrode window, refer to section 4.3. The value of the selectivity coefficient is a default value, which must not be changed.

6. MAINTENANCE

6.1 MAINTENANCE WINDOW

After each maintenance procedure, QC run is recommended.



The Maintenance window provides a check table for maintenance procedures. The maintenance operations are seen in the order of urgency. To see the recommended preventive maintenance intervals, refer to section 6.3.

Information seen in the Maintenance window:

- *!* The exclamation mark reminds the operator of outstanding maintenance tasks.
- *Operation* Description of the maintenance task to be done.
- *Next* The date for the next maintenance operation.
- *Performed* The date when operation has been performed.
- *Interval* The interval of the operation in days.
- *Who* The name of the person who performed the task. When the workstation is booted, the task in the list is updated automatically.
- *Comment* Any comment concerning operation.

A Select the maintenance operation.

B Activate F1 to mark the task performed. Give your name and any comment concerning the operation. The date performed and the date for the next operation are updated automatically.

☞ Save changes with F2. With F3 you can cancel the changes made after the last save.

To change the interval

☞ Select F4 to change the interval of the maintenance operation. The interval is given as days. You can insert * if you do not want to record an interval, e.g. accuracy testing.

6.2 DAILY & WEEKLY & MONTHLY MAINTENANCE

6.2.1 CLEANING AND CHECKING STRAIGHTNESS OF NEEDLES AND MIXERS AND CLEANING WASH WELLS

Needles and mixers should be cleaned and the straightness checked carefully every day and especially after a mechanical failure. Cleaning can be done after the STAND BY procedure. Also washing wells should be cleaned daily.

☞ Select F8/F4 Clean needles from the Instrument actions window. When you select it first time, the needle(s) will come to the position where you can clean it. Second time will bring the mixer(s) to the position where you can clean it, and third time will return needle(s) and mixer(s) back to their washing stations.

Clean the needles with tissue moistened with Washing solution (4.5% hypochlorite) or with 50-60% spirit and distilled water. The wells can be cleaned with cotton sticks.

! Only distilled water or 50-60% spirit is allowed to clean the surfaces of the analyser. Do not use any detergent or spray.

6.2.2 CLEANING THE DISPENSING TABLE

☞ Wipe the dispensing table daily with tissue moistened with distilled water. Wipe spillage with 50-60% spirit.

6.2.3 WASHING SEGMENTS

Wash segments to remove all splashing. They can be washed in the washing machine. A spare set of bar code stickers is available.

6.2.4 WASHING THE DISTILLED WATER AND WASTEWATER CONTAINERS

Once a week the distilled water container should be carefully washed with spirit (50-60%) and rinsed with distilled/ deionized water.

Clean the wastewater container, after emptying it, with spirit (50-60%) and tap water. Put one large spoon of Chloramine T (Trihydrate) 99% into the empty wastewater container to prevent a bacterial growth.

6.2.5 BOOTING THE WORKSTATION

Boot the workstation once a week to get the system work faster. During Start up the user is reminded to check the Maintenance actions if the workstation has not been booted in a week time. After booting, the actions list is updated automatically.

☞ Exit from the Konelab program in the Management window with F8/F3.

☞ Shut down the computer (the button Start: Shut down in the left corner of the window). Switch off the mains of PC.

☞ Switch on the mains of the PC.

☞ Login: Check that the domain name is Konelab and enter password Konelab. Konelab program starts automatically.

6.2.6 WASHING TUBES

The FMI pump should never be run without liquids.

The liquid sensor should not be immersed in the Washing solution. Be also careful that the liquid sensors of distilled water and wastewater do not touch each other.

Do not use Washing solution including brij, because it can disturb some tests after washing.

Washing of the tubes should be performed once a month. The FMI pumps are cleaned in the same procedure.

☞ Remove the distilled water container.

☞ Pour 100 ml of diluted (1:5) Washing solution (=4.5% hypochlorite, delivered in number 980929) into a beaker and place water tubes into it. In case of Konelab 60, 150 ml of Washing solution is needed.

☞ Choose two times from the Instrument Actions F6, Perform water wash.

☞ Place the tubes in another beaker filled with deionized water (approximately K60 needs 700 - 850 ml; K30 350 – 450 ml and K20XT/ 20 300 – 350 ml) and repeat the function, Perform water wash 5 - 6 times to flush out the remaining Washing solution. The tubes must be in solution and the drawer must be closed, otherwise the wastewater collector will overflow.

☞ Place the tubes back into the distilled water container and repeat the operation, Perform water wash 2 – 3 times.

6.2.7 IN CASE OF A HIGH RISK SAMPLE

Analyze a known infection-risk sample at the end of the run.

☞ Use a separate waste vessel.

☞ Perform Stand by immediately after the analysis of the sample.

☞ Add Chloramine T to the waste vessel. Treat waste as other dangerous waste in the laboratory.

☞ Wipe the needles with Washing solution (=4.5% hypochlorite) or with spirit (50 – 60 %).

6.3 MAINTENANCE PROCEDURES

Recommended Preventive Maintenance Interval

Only Service Engineer trained by Clinical Chemistry & Automation Systems business from Thermo is allowed to do the maintenance procedures.

The manufacturer's recommendation to do the preventive maintenance (=PM) is based on the usage of the instrument in the following way:

No. of PM/ year	No. of tests/ day	Actions to be done/ Kits to be used
1	Up to 250	12 months
2	250 - 1500	6 months + 12 months
4	>1500	2 x 6 months + 2 x 12 months

Based on the experience from local conditions the distributor can make exception from these recommendations but exception must not deteriorate the reliability of instrument or accuracy of test results.

6.3.1 MAINTENANCE KITS

984036 6 MONTHS MAINTENANCE KIT FOR KONELAB 20 AND 20i

984072	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984115 6 MONTHS MAINTENANCE KIT FOR KONELAB 20XT AND 20XTi

984105	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984004 6 MONTHS MAINTENANCE KIT FOR KONELAB 30 AND 30i

984023	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984007 6 MONTHS MAINTENANCE KIT FOR KONELAB 60 AND 60i

984021	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984028	**6 MONTHS ISE Complete tubing for Konelab 20i and 20XTi**	
984070	ISE Tubing kit	1 pc
984020	**6 MONTHS ISE Complete tubing for Konelab 30i and 60i**	
984097	**12 MONTHS MAINTENANCE KIT FOR KONELAB 20 AND 20i**	
984015	Syringe 500 µl grip fix	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984072	Diluent and wash tubes	1 pc
984071	Drain/ waste tubes	1 pc
981481	Halogen lamp	1 pc
840551	Dispenser ground wire 500	1 pc
984114	**12 MONTHS MAINTENANCE KIT FOR KONELAB 20XT AND 20XTi**	
984122	Syringe 500 µl AD	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984105	Diluent and wash tubes	1 pc
984106	Drain and waste tubes	1 pc
984012	Mixing paddle	1 pc
981481	Halogen lamp	1 pc
840551	Dispenser ground wire 500	1 pc
984096	**12 MONTHS MAINTENANCE KIT FOR KONELAB 30 AND 30i**	
981269	Syringe 500 µl	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984023	Diluent and wash tubes	1 pc
984022	Drain/waste tubes	1 pc
981481	Halogen lamp	1 pc
984012	Mixing paddle	1 pc
840551	Dispenser ground wire 500	1 pc
570343	Dust filter for the internal PC	1 pc
984098	**12 MONTHS MAINTENANCE KIT FOR KONELAB 60 AND 60i**	
981269	Syringe 500 µl	2 pcs
984093	Dispensing needle (reagent/sample)	2 pcs
984021	Diluent and wash tubes	1 pc
984022	Drain/waste tubes	1 pc
981481	Halogen lamp	1 pc
984012	Mixing paddle	2 pcs
840551	Dispenser ground wire 500	1 pc
570343	Dust filter for the internal PC	1 pc
984029	**12 MONTHS ISE MAINTENANCE KIT for Konelab 20i and 20XTi**	
984070	ISE Complete tubing	1 pc
984011	Dispensing needle	1 pc
840551	Dispenser ground wire 500	1 pc

984006	**12 MONTHS ISE MAINTENANCE KIT for Konelab 30i and 60i**	
984020	ISE Complete tubing	1 pc
984011	Dispensing needle ISE	1 pc
981269	Syringe 500 µl	1 pc
984076	**12 MONTHS MAINTENANCE KIT for KUSTI**	
984073	Dispensing needle	1 pc
984069	Tubing kit	1 pc
981577	**INSTRUMENT ACCURACY TESTING KIT**	
	Accuracy solution kit	1 pc
841537	Verification protocol	1 pc
841214	Accuracy test procedure –description	1 pc

6.3.2 REPLACING THE LAMP ASSEMBLY

The lamp, and to a certain extent interference filters, degrades slowly with time.

WARNING! The direct ultraviolet radiation from the lamp is dangerous for the eyes and skin.
Do not touch glass surfaces of the lamp. The lamp house can be hot.

Figure 6-1: Location of the lamp housing is behind the front panel

A halogen lamp is delivered with the code number 981481.

☞ Change the lamp when the power is turned off.

☞ Open the instrument's front panel. Refer to Figure 6-1. Inside the analyzer, behind the black door is the actual lamp assembly: Open the lamp house's door.

☞ To remove the old lamp first spread the metal clips by moving them slightly outward up to the notches. Refer to Figure 6-2. Then pull the lamp assembly out.

Remove the old lamp assembly (the lamp fitted with the metal collar) from the grey socket. Discard the old lamp assembly.

☞ Install a new lamp assembly into the socket holding the metal collar.

Spread the metal clips by moving them slightly outward up to the notches as shown in Figure 6-2.

Then place the assembly into the lamp compartment so that the notch on the metal collar aligns with the positioning pin in the compartment wall. Simultaneously with other hand release the metal clips. Check that they will return to the original locations.

After changing the lamp, perform the function F1 Start-up.

The lamp is pre-focused and normally will not need adjustment.

In case the following messages appear, you need to adjust the focus of the lamp:

- Poor water blank
- Not enough light

Before adjusting, make sure that these messages do not come because of bubbles in the fluidic circuit or dirty in cuvettes.

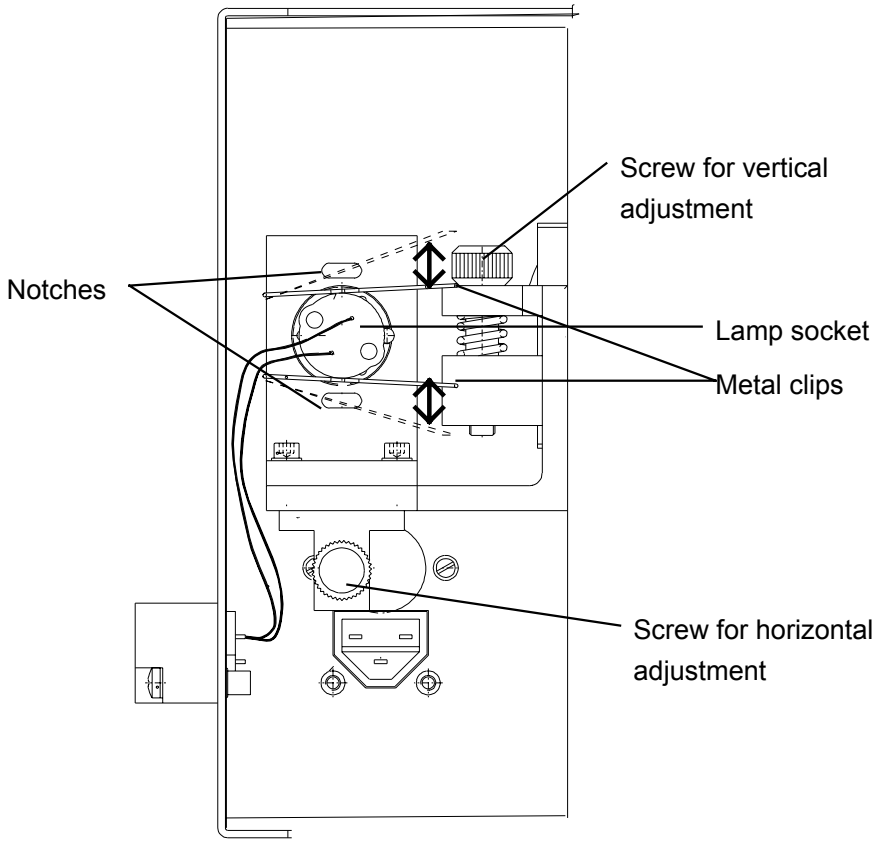
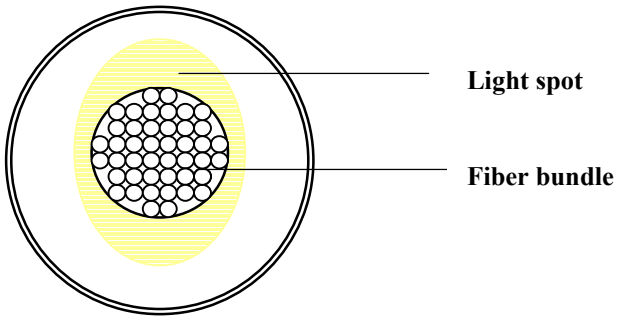


Figure 6-2: The lamp assembly attached with the metal clips: the metal clips are opened when removing the lamp and released when installing a new lamp.

If adjustment is needed, it is done through the Instrument actions window: F8/F5 Adjustment program: 3 Measuring unit: 2 Filter disk/ beam alignment.

When filter disk/ beam alignment is selected the instrument is first driving the filter wheel to its first position. Adjust the beam of the lamp so that it is positioned into the middle of the filter with the adjustment program.
The filter wheel turns to its empty position. Adjust the light spot so that the fiber bundle is seen in the middle of it (refer to Figure next page). Adjustment is done with the horizontal and vertical screws in the lamp assembly.



Close the door of the lamp housing and the instrument panel.

6.3.3 REPLACING INTERFERENCE FILTERS

CAUTION: Do not put your hand into the analyzer when the light chopper is rotating.

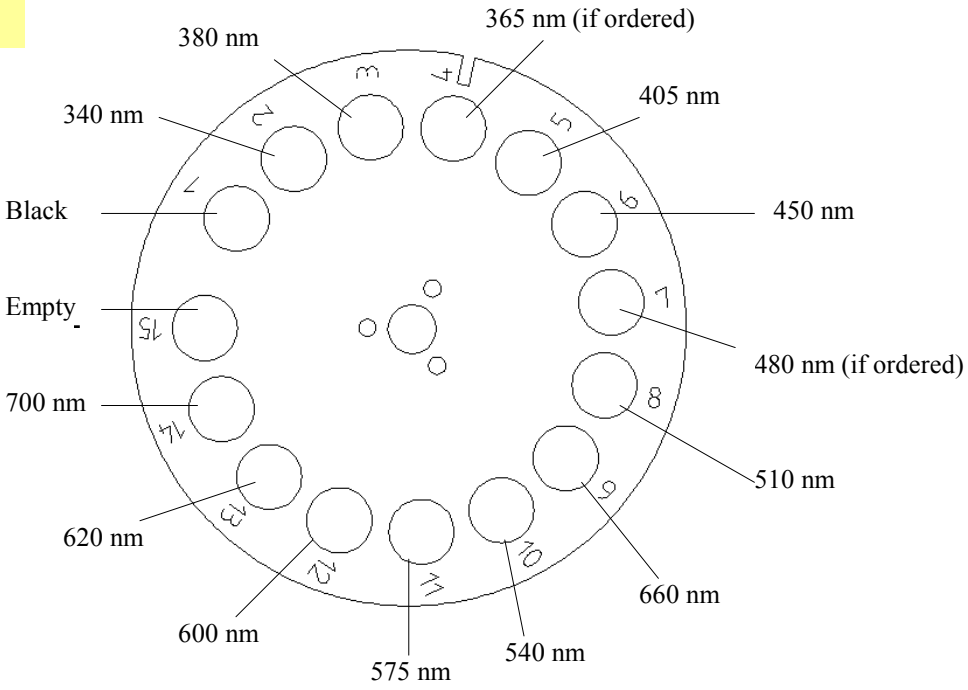


Figure 6-3: Interference filters are attached to the filter wheel. The wheel is in front of the lamp compartment. The wheel positions are numbered from 1 to 15.

The lamp voltage is adjusted automatically during Start up. The values of lamp voltages and signal and reference gains are seen in the window Check water blank. Refer to section 3.13.

Possible **gain values** are: 0, 1, 2, 3, 4, 5. When the gain is low the filter is good. With 340 the gain is usually 3 or 4. When 5, the filter or lamp or focus is obstructed or getting old and must be changed. With 380 the gain is usually 2 or 3. With all other filters 1, 2 or 3. Sometimes even 0.

The lamp voltage is 0 when the filter position is empty.

Change filters when the analyser is switched off.

☞ Open the door of the lamp housing. Detach the lamp house shield by unscrewing the crosshead screws.

☞ Loosen the filter by unscrewing the holder from the wheel.

☞ One side of the interference filter is coloured the other is silver. Install a new interference filter so that the silver surface is facing the light source.

☞ Attach the lamp house shield with the screws and close the lamp housing door.

6.3.4 REPLACING A SYRINGE

Checking criteria:

The connections should be tight. Air collecting in the barrel or tubes and free, solid material on the piston tips, indicate the need for a syringe change. Syringes should be changed once a year.

6.3.4.1 KONELAB 60 AND 30

Syringes for K60 and 30 are delivered with the code number 981269.

☞ Change the syringe when the system is in STAND BY. Make sure that the piston is in the upper position.

☞ Loosen the bottom screw (1). Loosen the retaining screw (3), which attaches to the block. Pull out the syringe, piston and cylinder. Detach the tubes by unscrewing the fittings on the both sides of the syringe (4); refer to Figure 6-4.

CAUTION! Tightening the screws (1), (3) in the wrong order and when the piston is in the down position may break the cylinder.

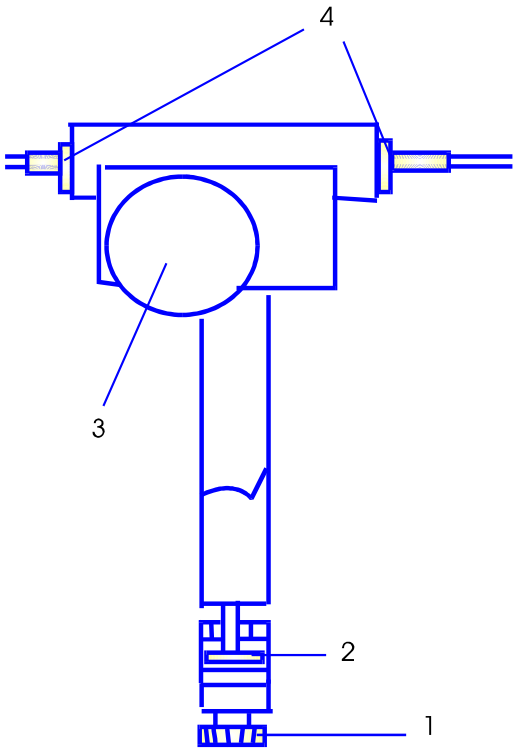


FIGURE 6-4a: The syringe unit of KI60 and 30

1. *Screw*
2. *Clamp*
3. *Screw*
4. *Fittings*

☞ Take a new syringe.

☞ Screw the fittings with the tubes on the both sides of the syringe. Ensure that the connections are watertight.

☞ Place the syringe into the clamp. Ensure that the syringe is straight.

☞ Tighten the retaining screw (3) and then the holding screw (1) in this order.

6.3.4.2 KONELAB 20XT AND 20

Syringe for K20XT is delivered with the code number 984122 and for K20 with the code number 984015. Note that these two syringe types are different and they are not compatible with each other.

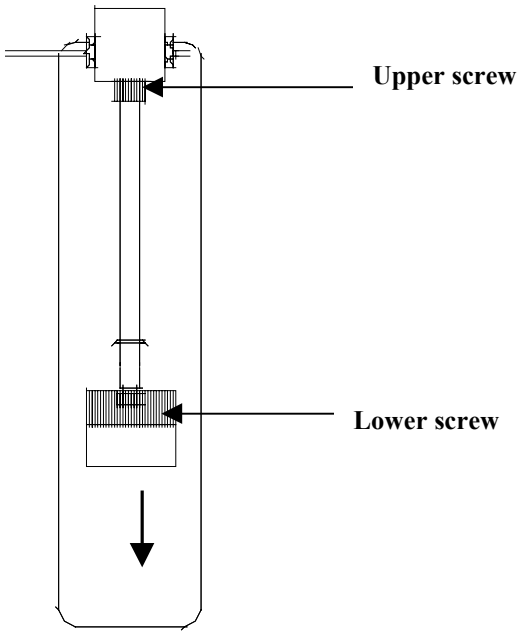


Figure 6-4b: The syringe unit of Konelab 20XT and 20

☞ Change the syringe when the system is in STAND BY.

☞ Loosen the lower screw. Draw it down so that the piston is not following.

☞ Loosen the upper screw and take the old syringe out. Replace it with a new one. Tighten the upper screw.

☞ Push the lower screw up, tighten it and make sure that it draws the piston properly.

6.3.5 REPLACING NEEDLE UNITS

Dispensing needle(s) for sample/ reagent dispenser arm(s) are delivered with the code number 984093.

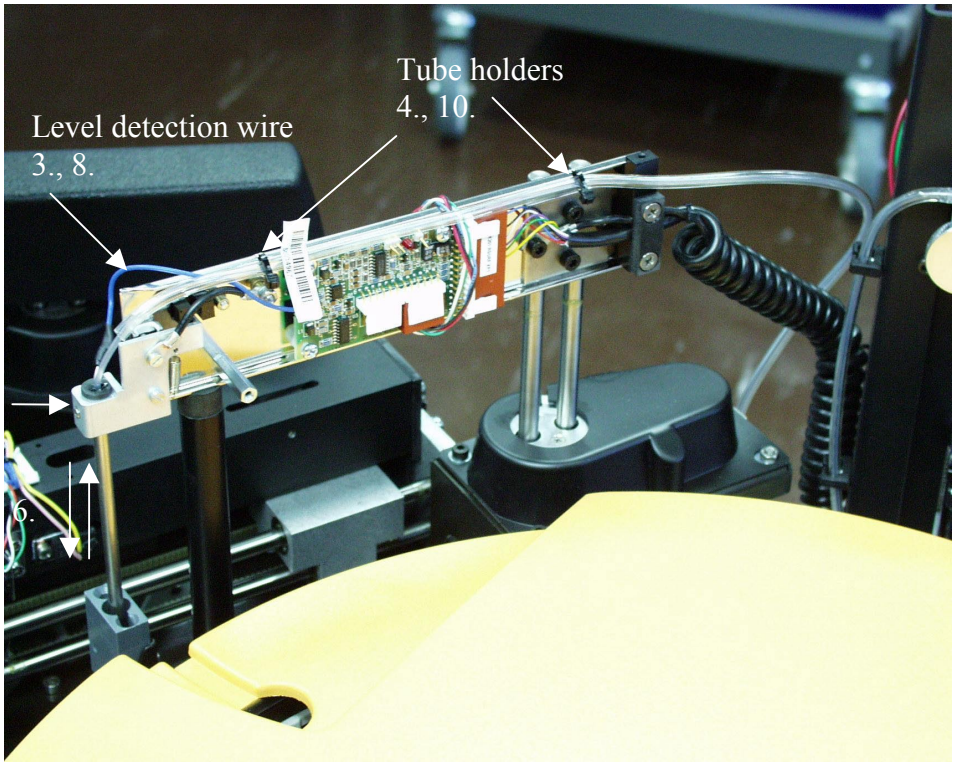
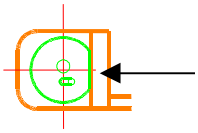
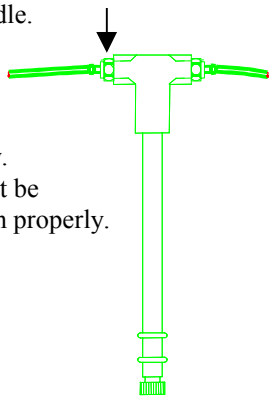


Figure 6-5a: Reagent dispenser arm of Konelab 60 (KUSTI dispenser arm has the same structure)

1. Remove the dispenser arm cover by detaching the three Allen screws on both sides and top of the cover.
2. Detach the needle tube from the syringe.
3. Detach the level detection wire from the connector in the needle.
4. Detach the tube from holders at the arm.
5. Open the screw at the needle holder.
6. Remove the needle and replace it with a new needle assembly. Note the alignment: the even side of the needle assembly must be alongside with the dispenser arm so that the needle goes down properly.





7. Close the screw at the needle holder.
8. Connect the level detection wire to the connector in the needle assembly.
9. Connect the tube to the syringe.
10. Attach the tube to holders at the arm.
11. Check that the needle assembly is properly in place. Attach the cover to the dispenser arm. The right position of the needle can be checked with F5 in Instrument actions window.
12. Perform water wash, F6 in Instrument actions window to wash the needle.

NOTE: After assembly, a trained Service Engineer should check general positions, test wash and cuvette positions of needle adjustments through the Adjustment program. Refer to Konelab Service Manual section 2.1.5.3 for K60 reagent dispenser, section 2.1.6.3 for K60 sample dispenser, section 2.2.7.1 for K30 dispenser, section 2.4 for K20XT dispenser and section 2.3.8.1 for K20 dispenser.

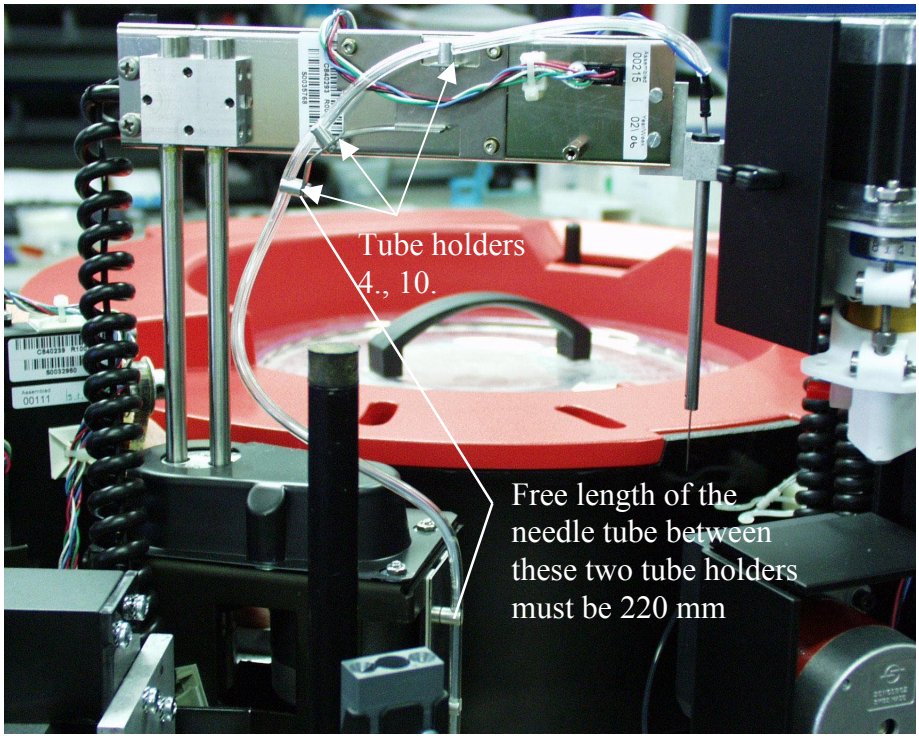


Figure 6-5b: Sample dispenser arm of Konelab 60

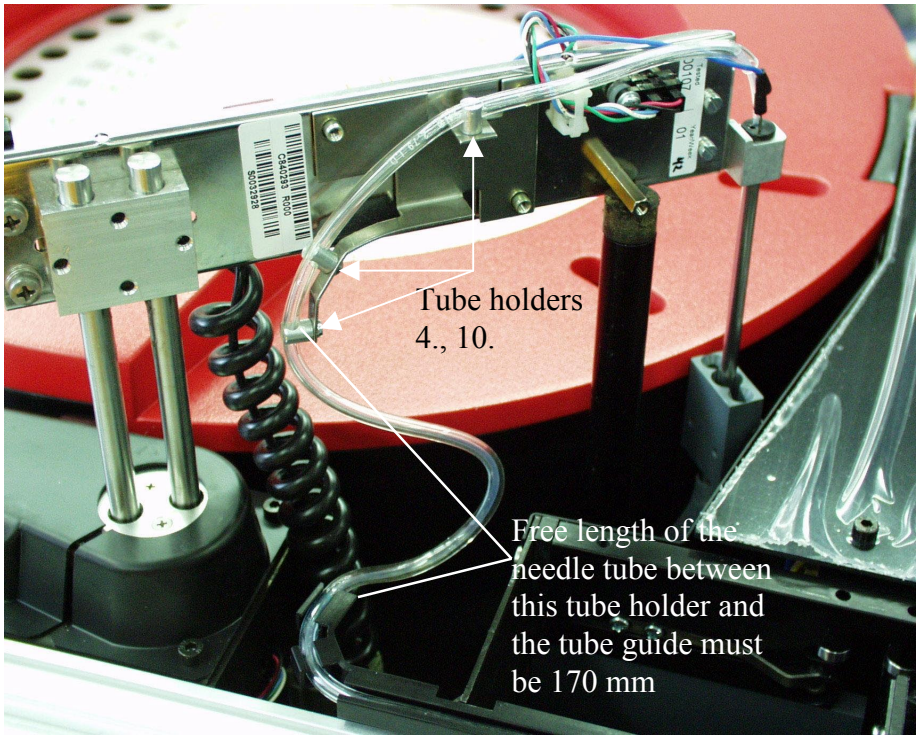
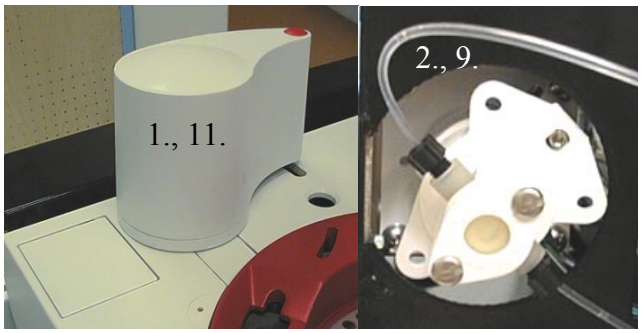


Figure 6-5c: Sample/ reagent dispenser arm of Konelab 30(Konelab 20XT and 20 arm has the same structure)

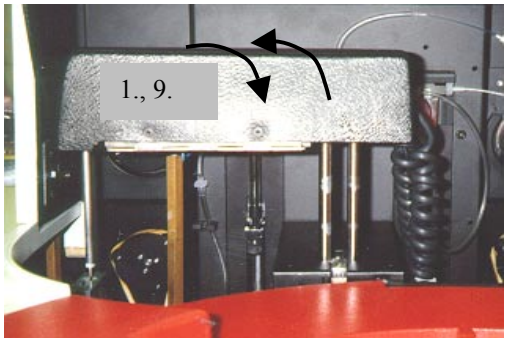
KUSTI dispensing needle

Dispensing needle for the KUSTI module is delivered with the code number 984073.



1. Lift the KUSTI cover up.
2. Detach the needle tube from the FMI pump found behind the door in front of the instrument.
3. Detach the level detection wire from the connector in the needle.
4. Detach the tube from holders at the arm.
5. Open the screw at the needle holder.
6. Remove the needle and replace it with a new needle assembly. Note the alignment: the even side of the needle assembly must be alongside with the dispenser arm so that the needle goes down properly.
7. Close the screw at the needle holder.
8. Connect the level detection wire to the connector in the needle assembly.
9. Connect new tube to the FMI pump.
10. Attach the tube to holders at the arm.
11. Check that the needle assembly is properly in place. Attach the cover to the dispenser arm. The right position of the needle can be checked with F5 in Instrument actions window.
12. Perform water wash, F6 in Instrument actions window to wash the needle.

Dispensing needle for ISE dispenser arm is delivered with the code number 984011.



Cover of ISE Dispenser arm

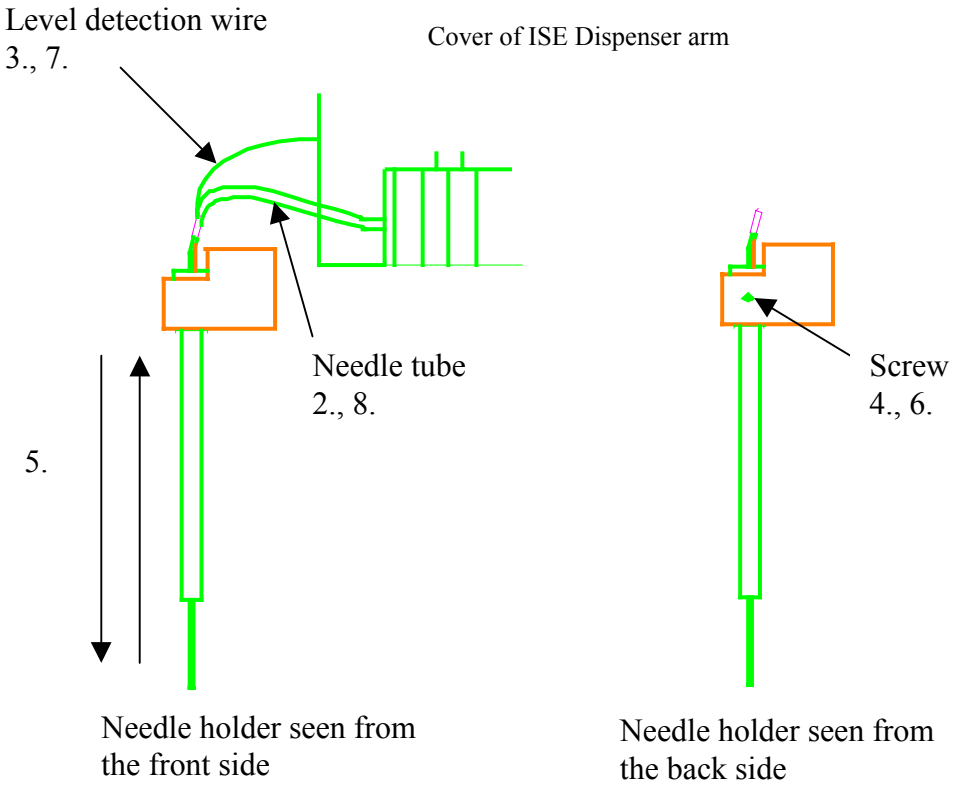


Figure 6-6: An ISE needle assembly

1. Open the cover of the ISE dispenser arm. The cover is hinged, so it is easy to turn open.
2. Detach the needle tube from the end slice of the ISE block.
3. Detach the level detection wire from the connector in the needle.
4. Open the screw at the back of the needle holder.
5. Remove the needle and replace it with a new needle assembly. Note the alignment: the even side of the needle assembly must be alongside with the dispenser arm so that the needle goes down properly.
6. Close the screw at the needle holder.
7. Connect the level detection wire to the connector in the needle assembly.
8. Connect the tube to the end slice.
9. Check that the needle assembly is properly in place. Close the cover of the ISE dispenser arm. The right position of the needle can be checked with F5 in Instrument actions window.
10. Perform water wash, F6 in Instrument actions window to wash the needle.

6.3.6 REPLACING MIXING PADDLES

Mixing paddle(s) for mixer arm(s) are delivered with the code number 984012.

Figure 6-7: When replacing mixing paddles in Konelab 60, lift the whole of the top cover and support with the bearing rod. In Konelab 30 and 20XT is only necessary to open the upper cover.

Mixer adjustments must be checked after assembling. Refer to Service Manual section 2.4 for K20XT mixer positions, section 2.2.7.2 for K30 mixer positions, section 2.1.5.4 for K60 reagent mixer positions and section 2.1.6.4 for K60 sample mixer positions.

☞ The mixing paddle is secured with a screw. There is no need to remove the mixing arm's cover.

☞ Assemble a new mixing paddle. Fasten the screw.

6.3.7 REPLACING TUBES

If the tubing shows signs of deterioration e.g. poor liquid flow, cracking or flat tubes it must be changed.

Recommended changing interval for pump tubes and diluent and wash tubes is twice a year. Drain and waste tubes are recommended to change once a year.

You can change tubes only when the analyser is switched off.
Do not touch the tubing while analysis is in progress.

SOME GUIDELINES WHEN CHANGING THE TUBING:

☞ Remove the distilled water container.

☞ Perform twice Water wash, F6 in Instrument actions to remove the liquids from the tubing before changing.

☞ After changing, replace the distilled water container.

☞ Perform 'Water wash' twice, F6 in Instrument actions prior to starting analysis. This will fill the tubes with distilled water. Check the tightness of the tube connections and that there are no air bubbles in the tubes.

6.3.7.1 REPLACING PUMP TUBES

Konelab 20XT

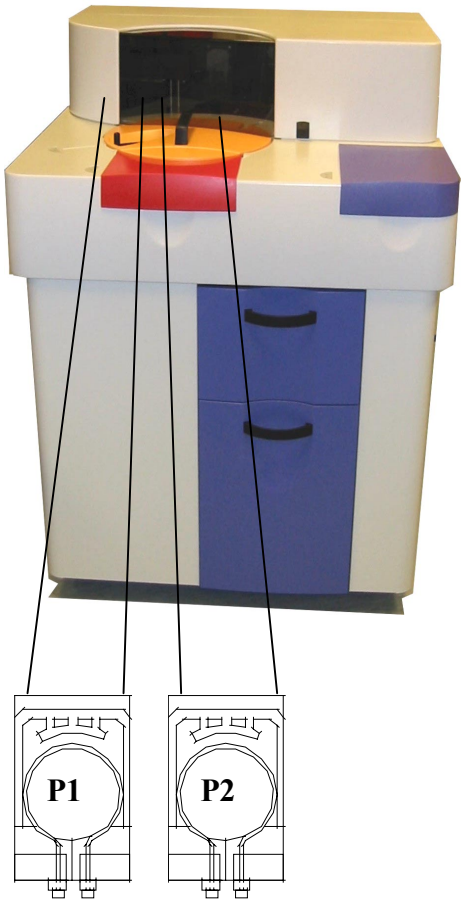


Figure 6-8a: The places of pump tubes in Konelab 20XTi

Konelab 20XTi includes two FMI pumps and two conventional pumps.

P1 ISE Washing pump, for outside washing of the ISE dispensing arm needle.

P2 Washing pump, for washing of the mixer.

Inside of the both Washing pump cover is a short yellow ismaprene tube. Refer to section 6.3.7.4. Replacing ISE tubes to replace it.

Konelab 20

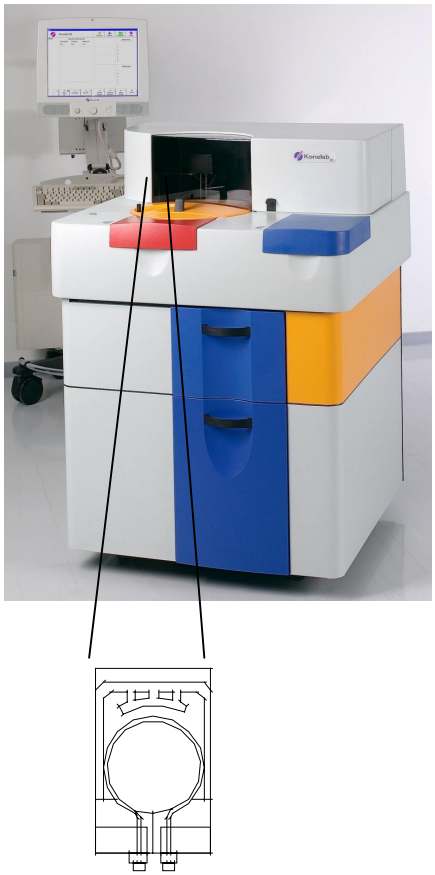


Figure 6-8b: The place of the ISE washing pump in Konelab 20i

Konelab 20i includes two FMI pumps and one conventional pump, ISE Washing pump, for outside washing of the ISE dispensing arm needle.

Inside of the ISE Washing pump cover is a short yellow ismaprene tube. Refer to section 6.3.7.4. Replacing ISE tubes to replace it.

Pump tubes are included in:
- 984023 diluent and wash tubes for K30 and 30i,
- 984021 diluent and wash tubes for K60 and 60i,
- 984020 ISE Complete tubing kit for K30i and 60i

Konelab 60 and Konelab 30

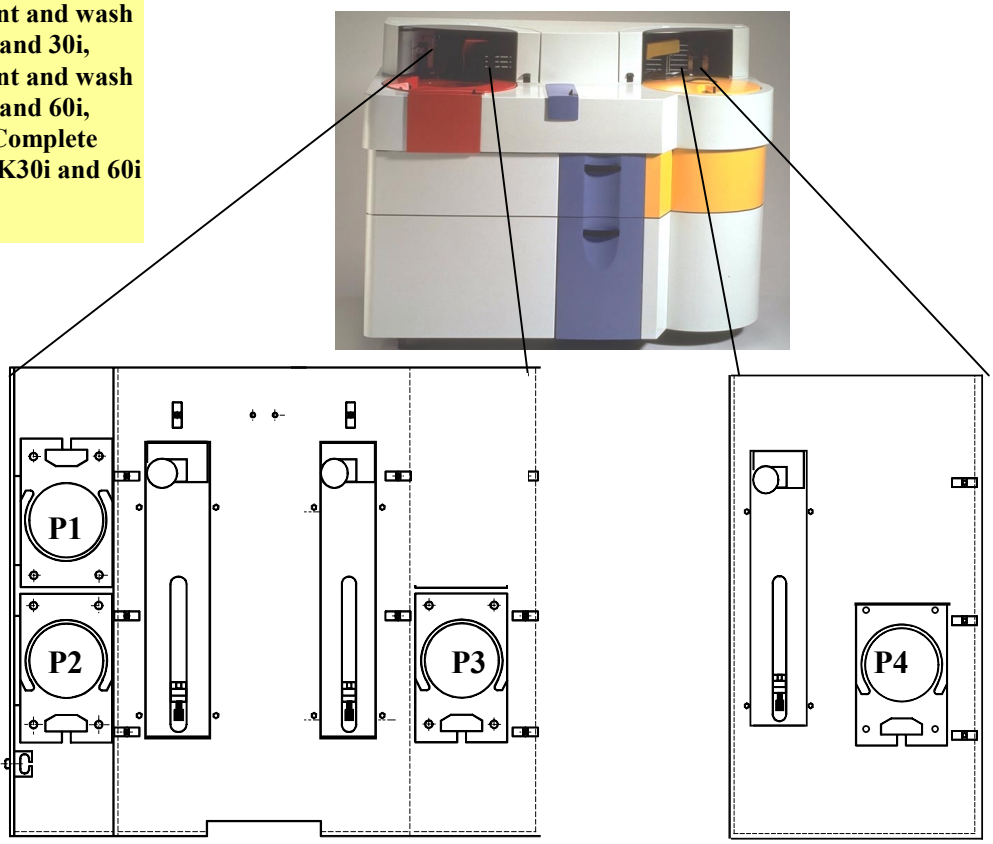


Figure 6-9a: The places of pump tubes in Konelab 60i

Pump tubes are delivered separately with the code numbers:
- 980306 (transparent PVC tube with grey bridges for ISE dispensing pump) and
- 981342 (yellow ismaprene tube with lilac bridges for washing pumps)

P1; ISE dispensing pump is used to transfer a sample and ISE Calibrator solution 1 to the ISE block and after measurement to the waste.

P2; Washing pump is used for outside washing of the ISE dispensing arm needle.

P3; Washing pump is used to wash the sample mixer.

P4; Washing pump is used to wash the reagent mixer.

Washing pump tubes (P2, P3 and P4) are yellow ismaprene tubes and they have lilac bridges, ISE dispensing pump tube (P1) is a transparent PVC tube and it has grey bridges.

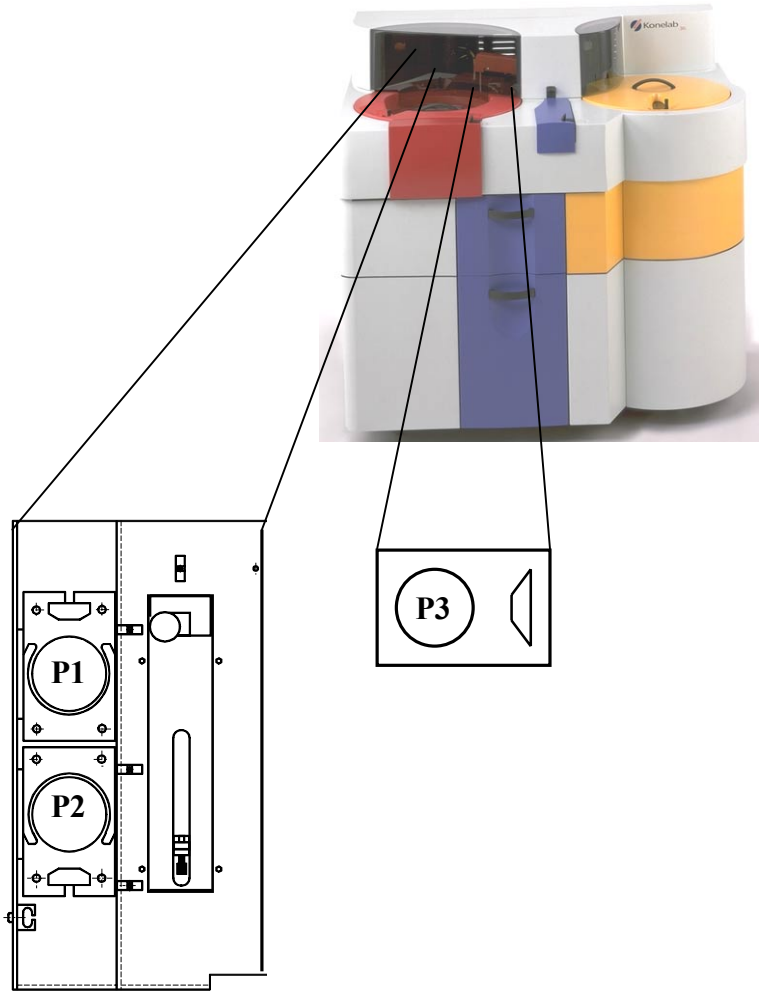


Figure 6-9b: The places of pump tubes in Konelab 30i

P1; ISE dispensing pump is used to transfer a sample and ISE Calibrator solution 1 to the ISE block and after measurement to the waste.

P2; Washing pump is used for outside washing of the ISE dispensing arm needle.

P3; Washing pump is used to wash the mixer.

Washing pump tubes (P2 and P3) are yellow ismaprene tubes and they have lilac bridges, ISE dispensing pump tube (P1) is a transparent PVC tube and it has grey bridges.

TO REMOVE THE OLD TUBE IN KONELAB 60 AND 30

☞ Pull up the tube and lift the collar from the notch. Refer to Figure 6-10.

☞ Manually rotate the pump clockwise. Simultaneously pull the tube out.

☞ Detach the tube from the fittings.

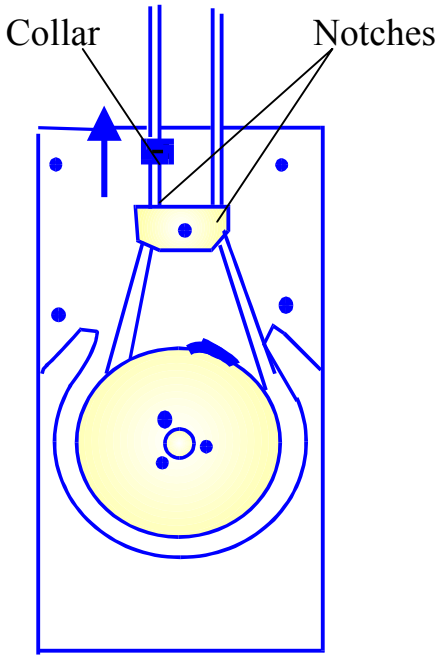


Figure 6-10: Removal of the pump tube

Install the tubes in a reverse order to removal

Make sure that the pump tube isn't twisted.

☞ Attach the tube to the fittings.

☞ Position the tube against the steering roller and rotate the pump clockwise. Let the rotation of the pump feed the tube. Do not stretch it.

☞ Lift the collar into the notches.

☞ Check that the tube is on every steering roller.

☞ Rotate the pump to check the water feed.

Diluent and wash tubes are delivered for Konelab 60 with the code number 984021.

6.3.7.2 REPLACING DILUENT AND WASH TUBES

Refer to Figures 6-11, 6-13, 6-15 and 6-17 for location of tubes and to Figures 6-12, 6-14, 6-16 and 6-18 to see the configuration of tubes.

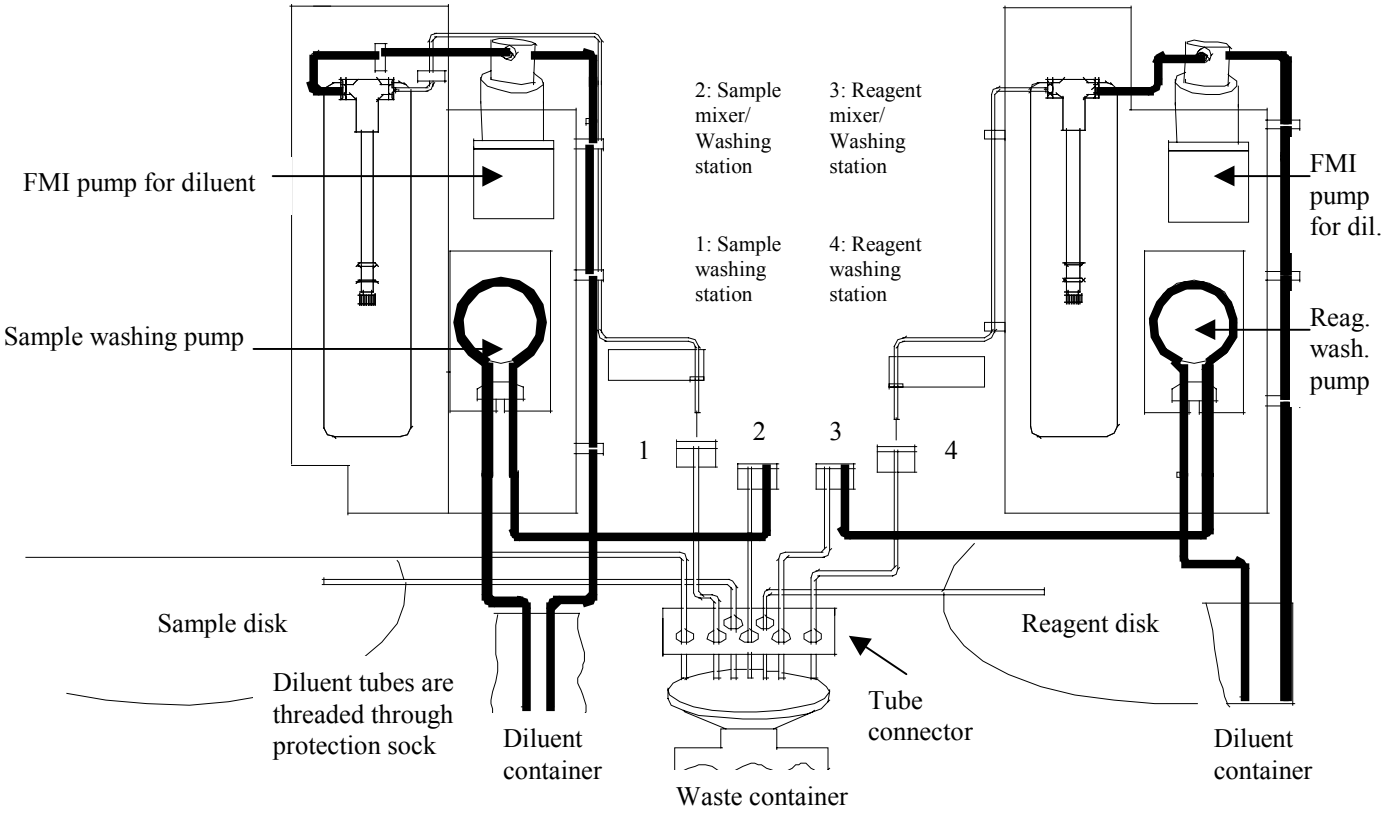


Figure 6-11: Location of diluent and wash tubes in Konelab 60

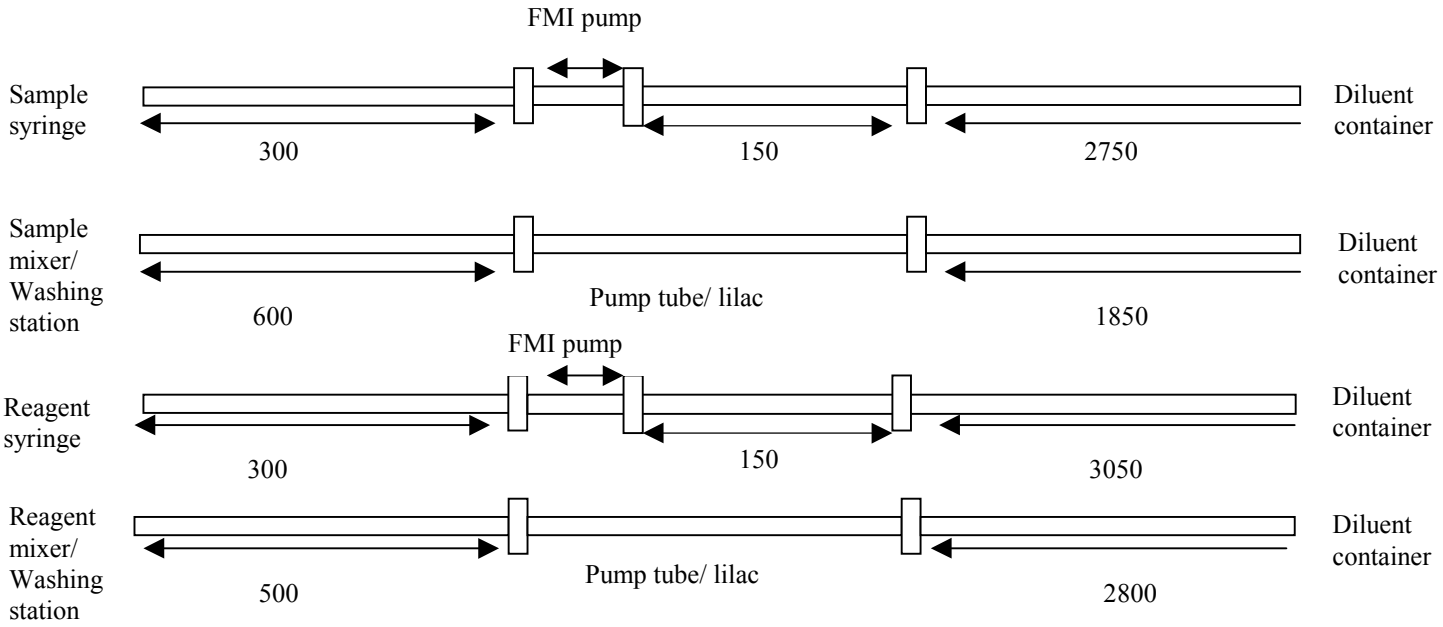
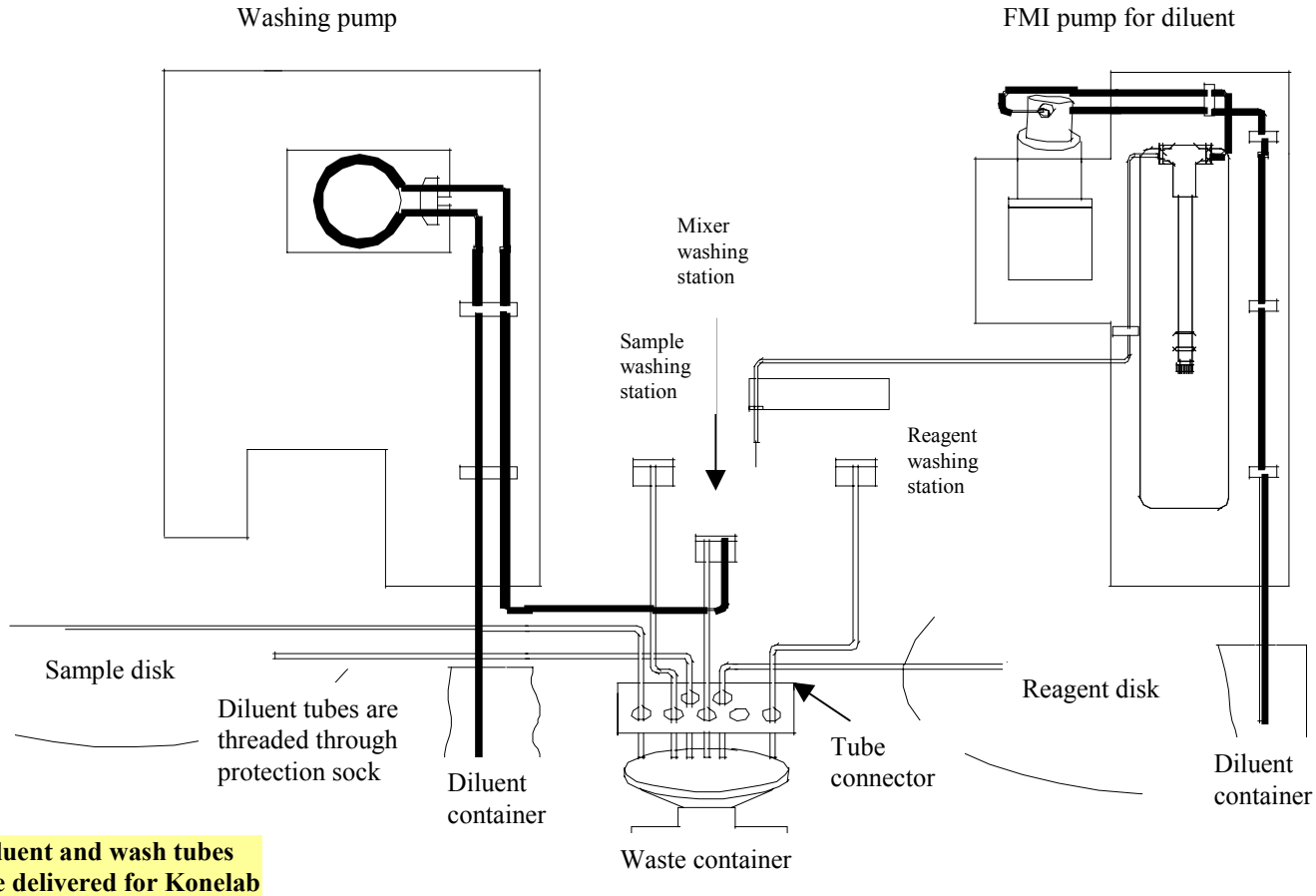


Figure 6-12: Diluent and wash tubes (984021) in Konelab 60



Diluent and wash tubes are delivered for Konelab 30 with the code number 984023.

Figure 6-13: Location of diluent and wash tubes in Konelab 30

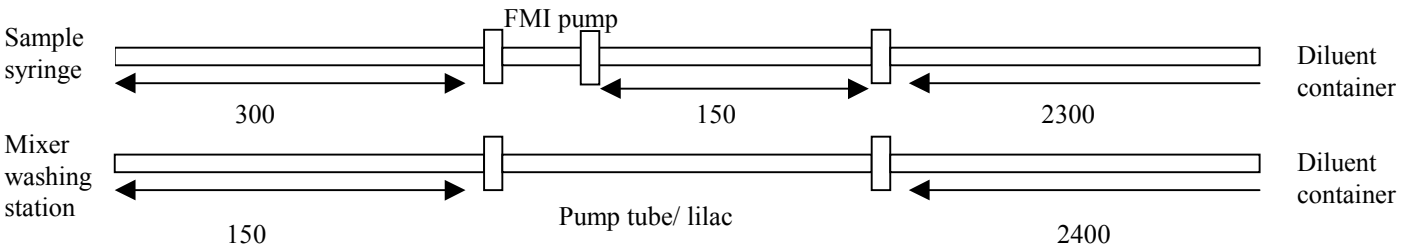
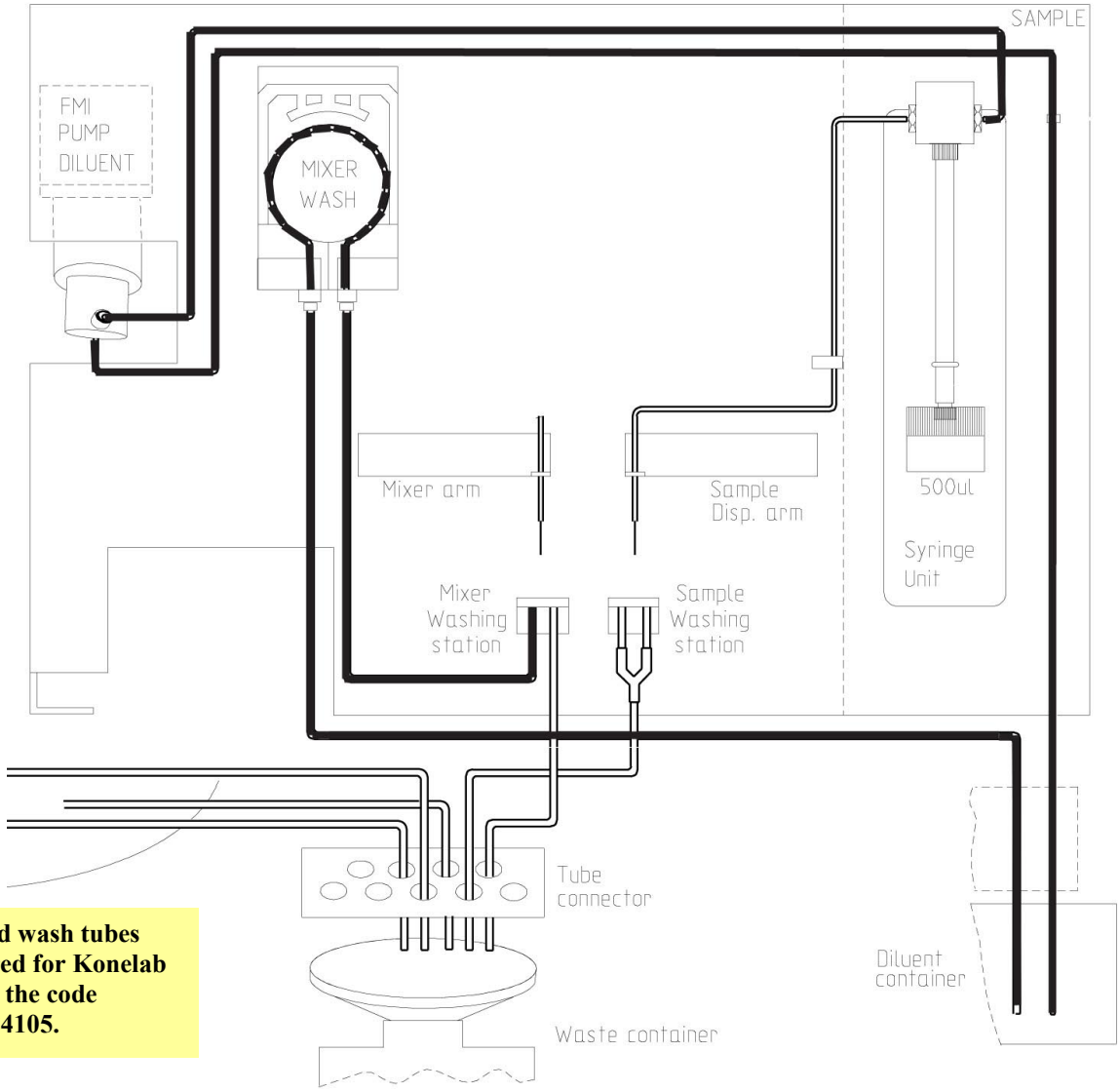


Figure 6-14: Diluent and wash tubes (984023) in Konelab 30



Diluent and wash tubes are delivered for Konelab 20XT with the code number 984105.

Figure 6-15: Location of diluent and wash tubes in Konelab 20XT

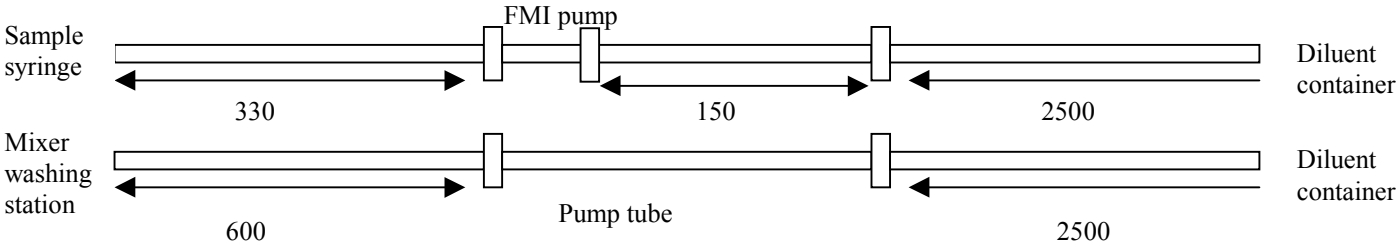


Figure 6-16: Diluent and wash tubes (984105) in Konelab 20XT

Diluent and wash tubes are delivered for Konelab 20 with the code number 984072.

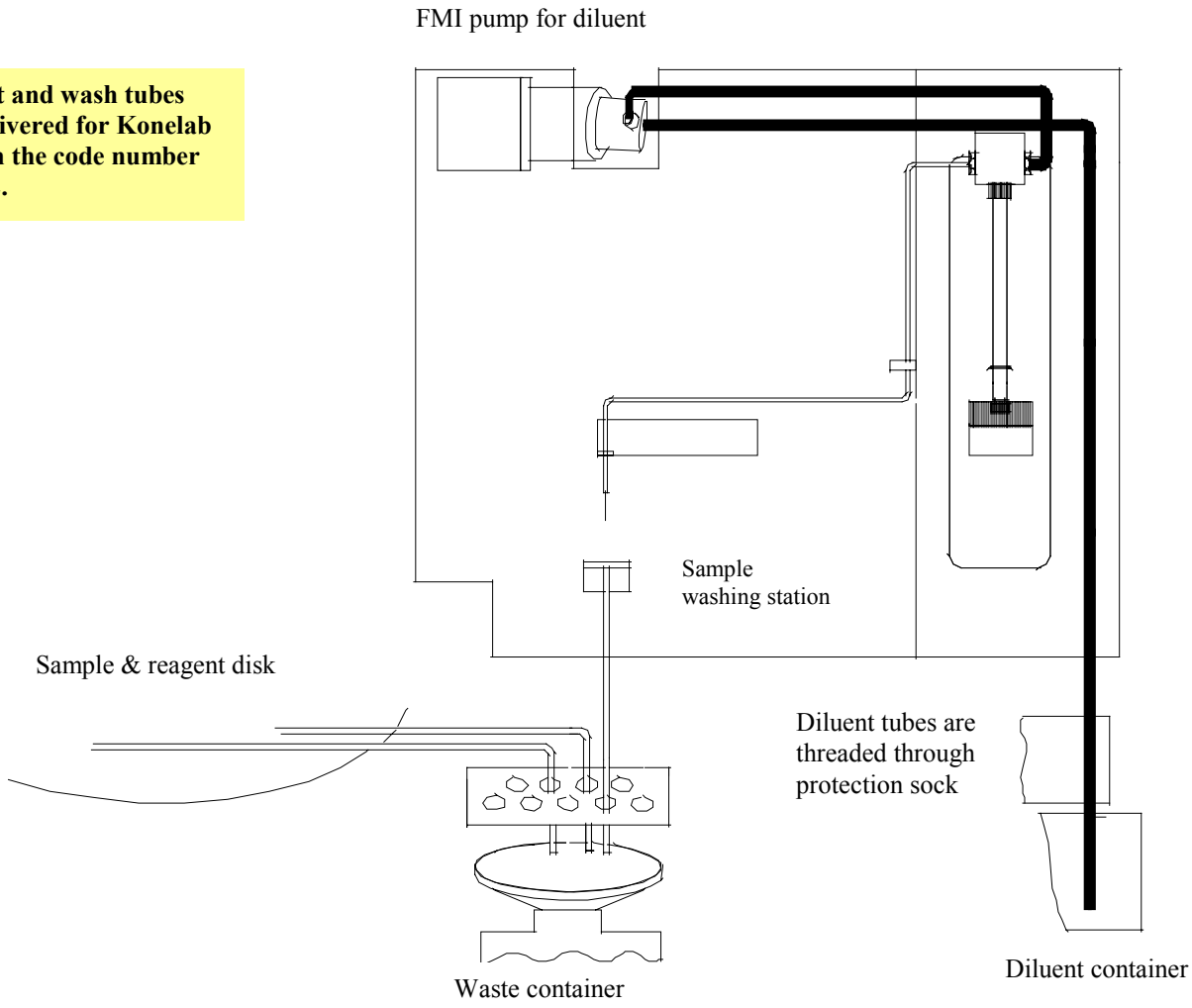
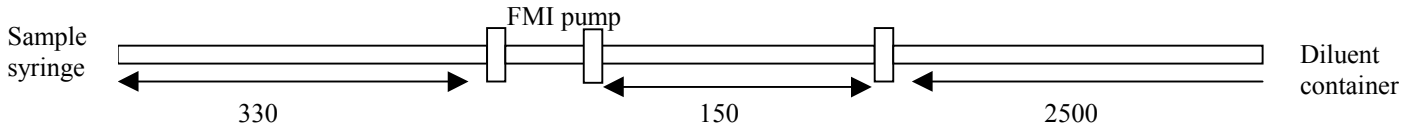


Figure 6-17: Location of diluent and wash tubes in Konelab 20



Those tubes which other end is in the diluent water container can be put in their places using the help of the old ones: Connect the new tube to the old one using a fitting and draw the old tube so that the new tube follows. Detach the old tube from the new one and discard the old tube.

Figure 6-18: Diluent and wash tubes (984072) in Konelab 20

☞ Detach the old tubes from the connectors. Tweezers may help detaching. In Konelab 60 is necessary to open the middle part of the back panel which is fastened with screws.

☞ Install new tubes to the connectors.

6.3.7.3 REPLACING DRAIN AND WASTE TUBES

Drain and waste tubes for K60 and K30 are delivered with the code number 984022.

Refer to Figures 6-19, 6-21, 6-23 and 6-25 for location of tubes and to Figures 6-20, 6-22, 6-24 and 6-26 to see the configuration of tubes. In Konelab 60 and 30 one tube comes from the sample disk and another tube from the reagent disk to the wastewater container. They are for condensation, and it is not necessary to change them. In Konelab 20XT and 20 there are two similar tubes coming from the combined sample & reagent disk.

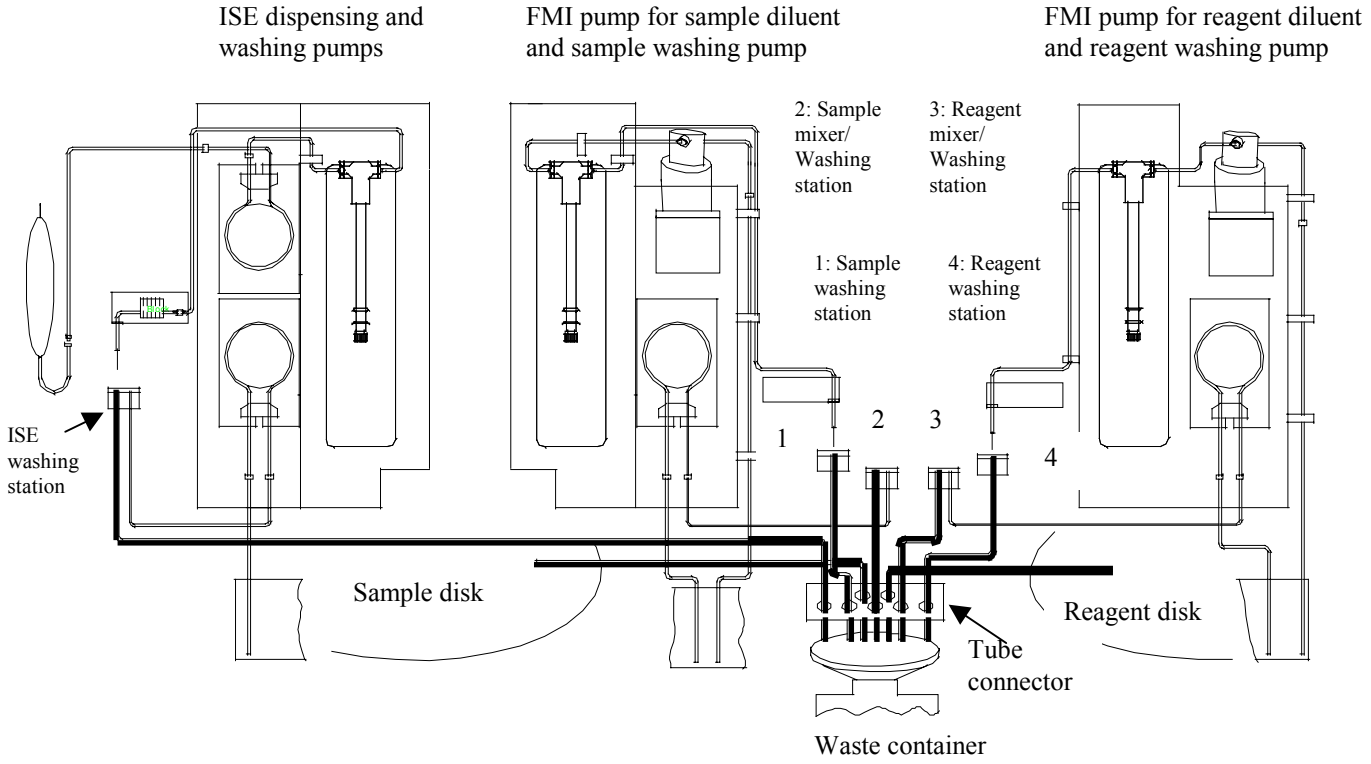


Figure 6-19: Location of drain and waste tubes in Konelab 60i

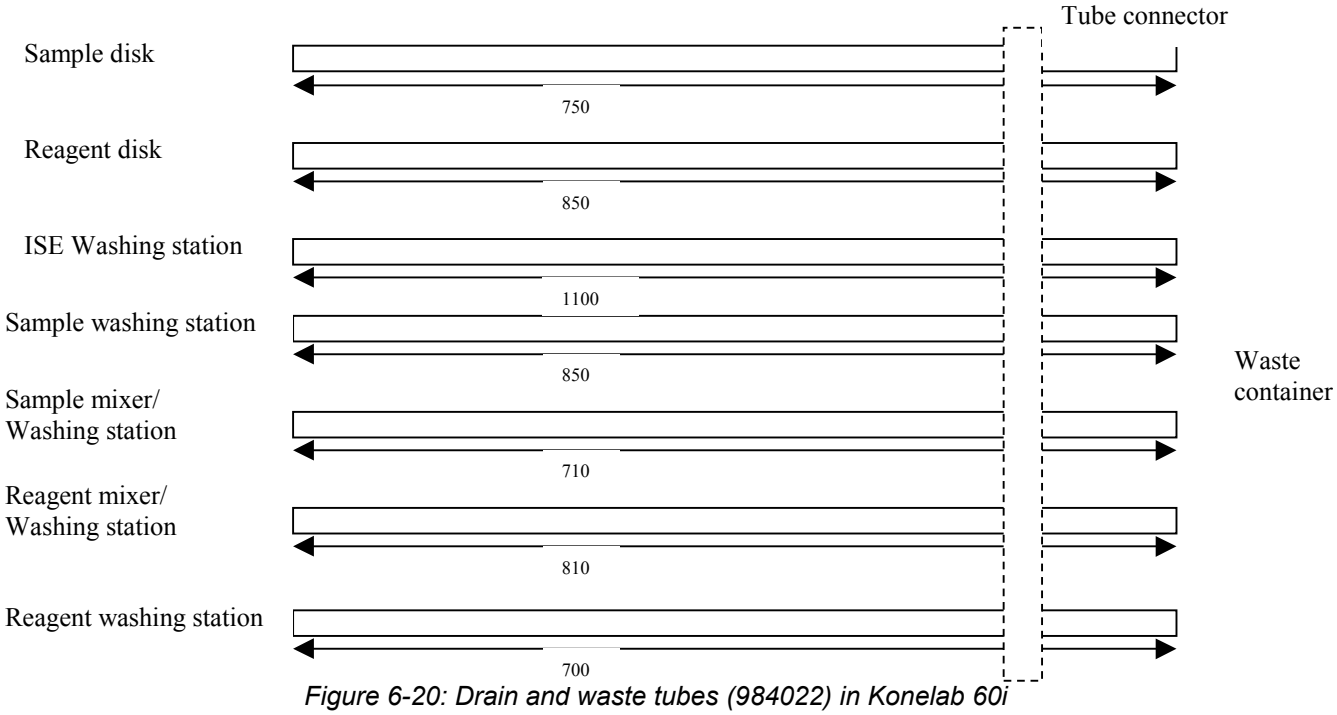


Figure 6-20: Drain and waste tubes (984022) in Konelab 60i

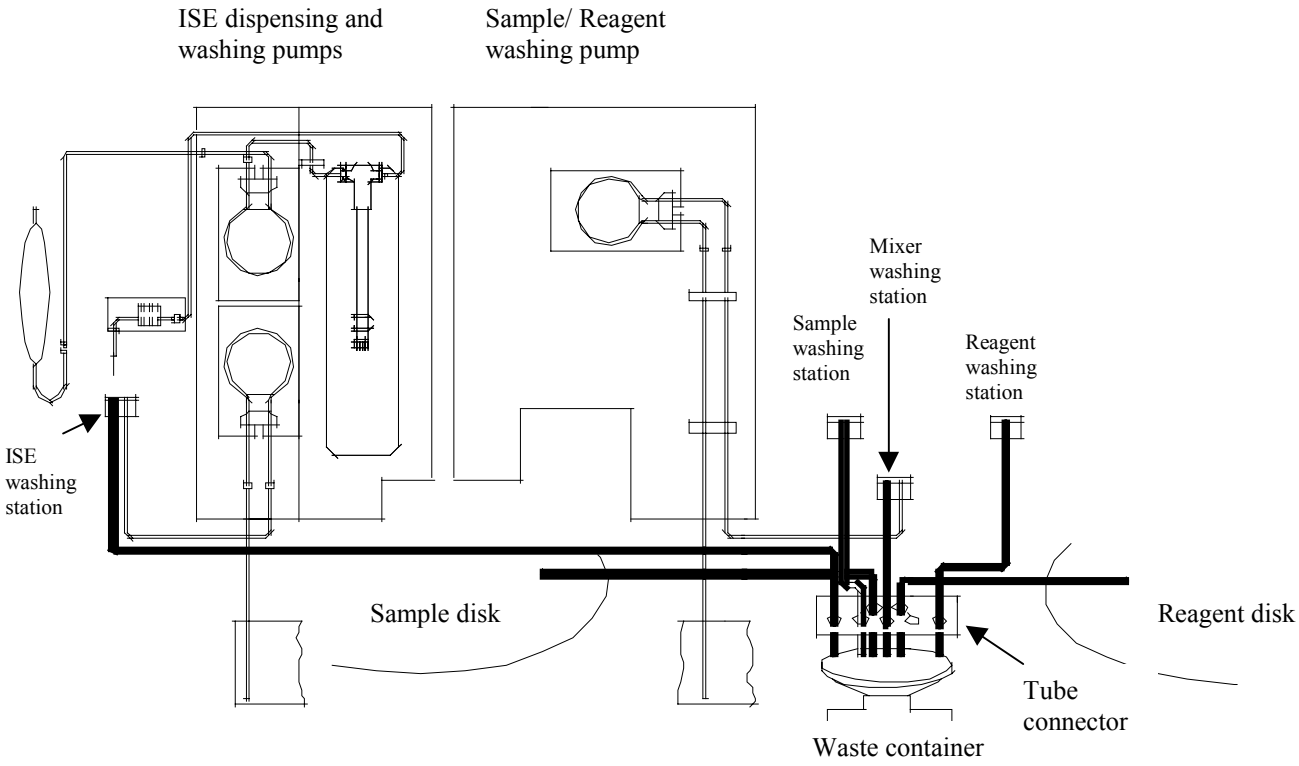


Figure 6-21: Location of drain and waste tubes in Konelab 30i

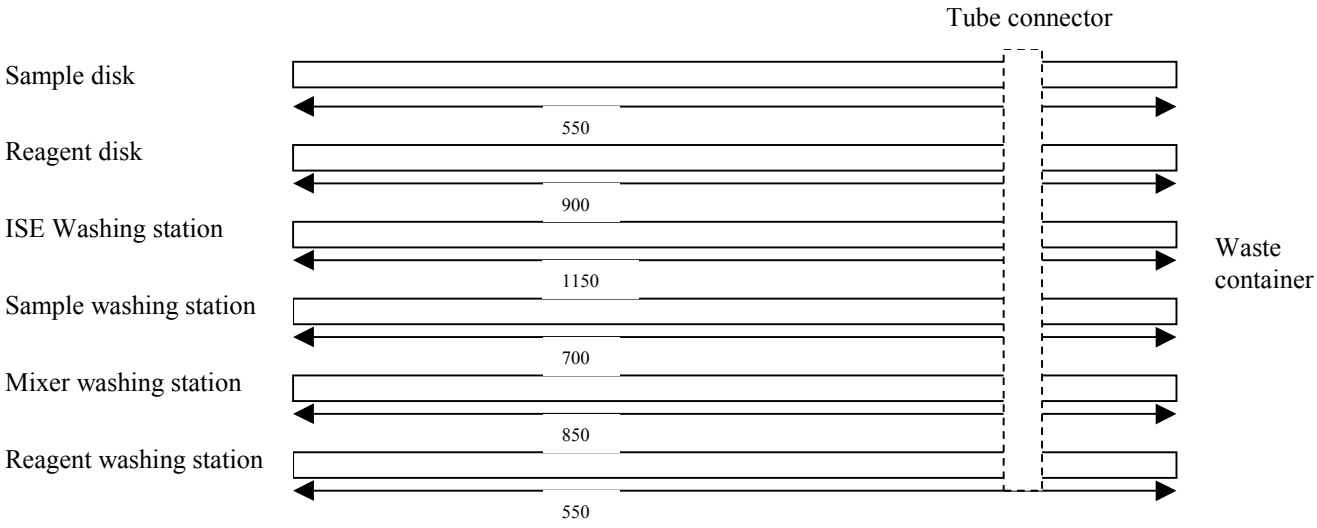
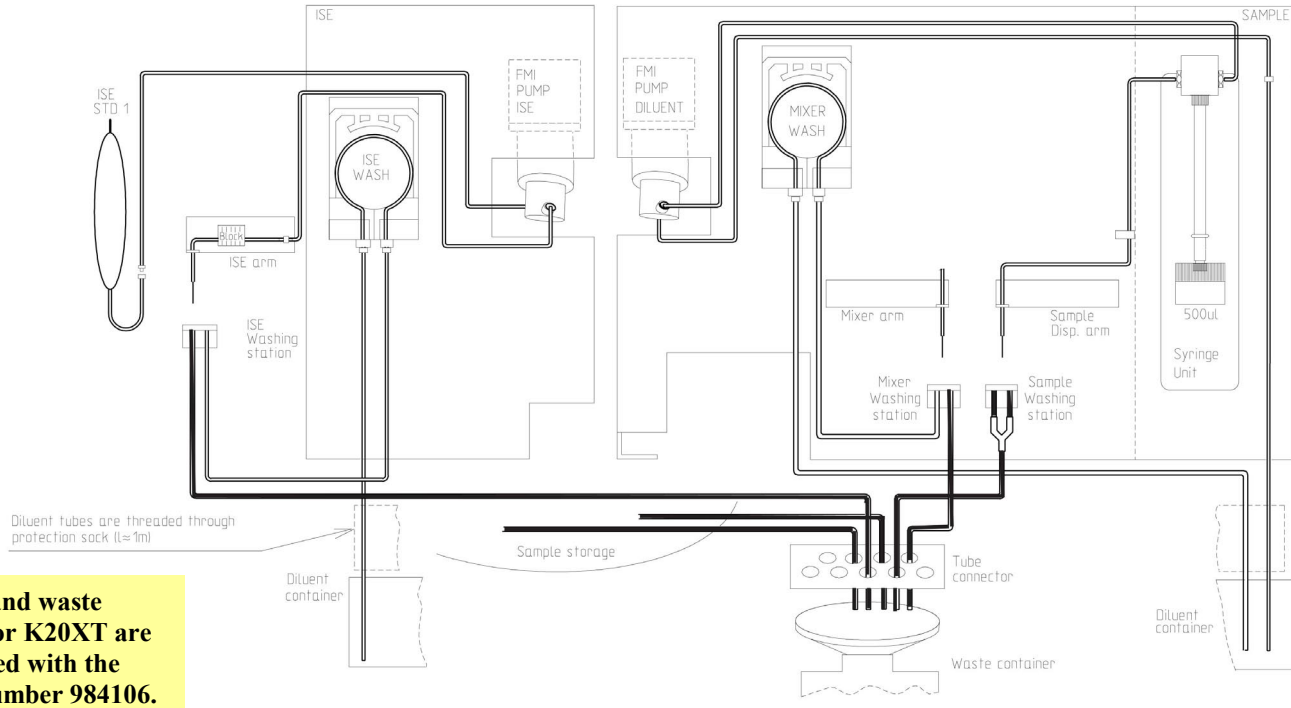


Figure 6-22: Drain and waste tubes (984022) in Konelab 30i

The right side panel (under the reagent disk) needs to be open in Konelab 60 and 30. It is fastened with screws. In Konelab 30 the back panel also needs to opened to locate the mixer waste tube.



Drain and waste tubes for K20XT are delivered with the code number 984106.

Figure 6-23: Location of drain and waste tubes in Konelab 20XTi

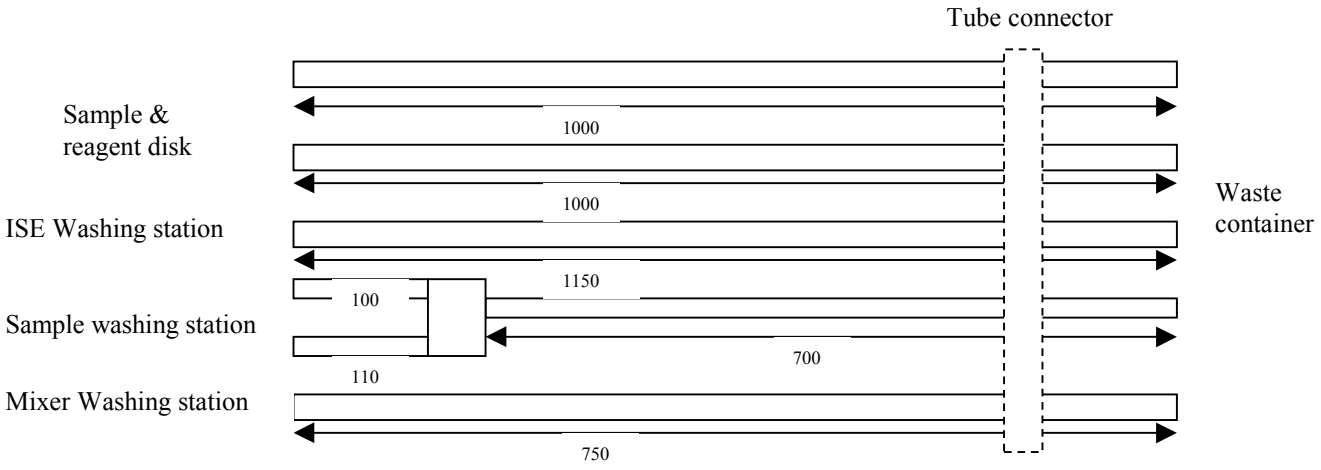


Figure 6-24: Drain and waste tubes (984106) in Konelab 20XTi

Drain and waste tubes for K20 are delivered with the code number 984071.

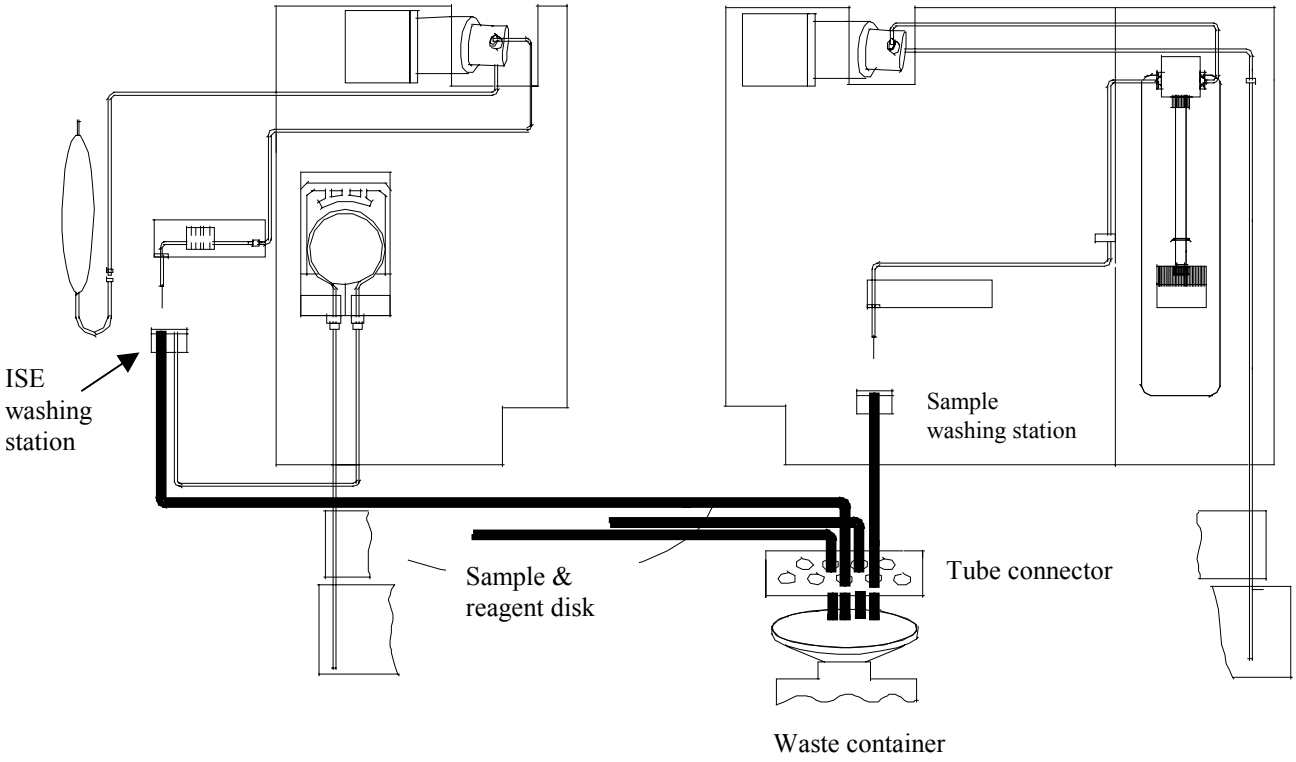


Figure 6-25: Location of drain and waste tubes in Konelab 20i

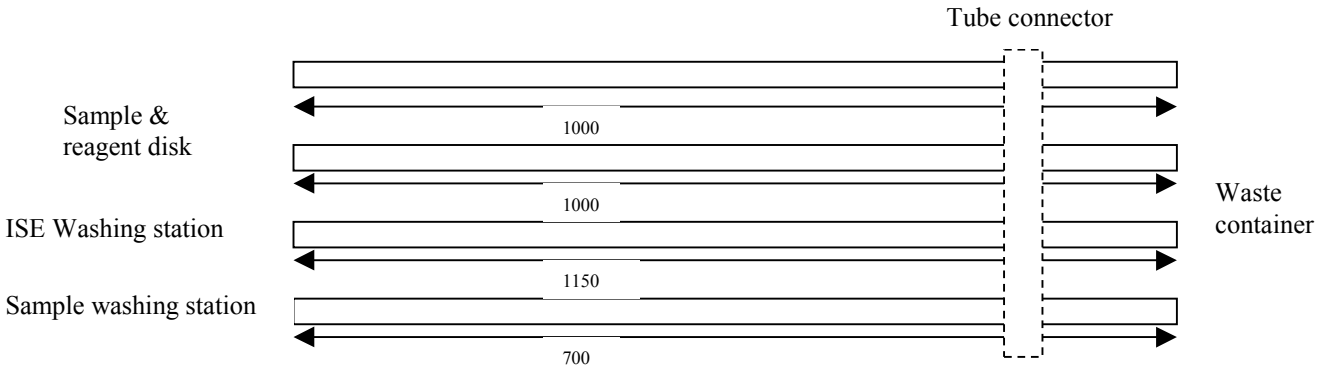


Figure 6-26: Drain and waste tubes (984071) in Konelab 20i

Install new tubes using the help of the old ones: Connect the new tube to the old one using a fitting (the end in the wastewater container) and draw the old tube so that the new tube follows. Detach the old tube from the new one and discard the old tube.

Set the new tube into the fitting and reposition the tube connector.

6.3.7.4 REPLACING ISE TUBES

ISE tubes for K60 and 30 are delivered with the code number 984020.

Pump tubes for K60 and 30 are delivered separately with the code numbers 980306 (transparent PVC tube with grey bridges for diluent pump) and 981342 (yellow ismaprene tube with lilac bridges for washing pump).

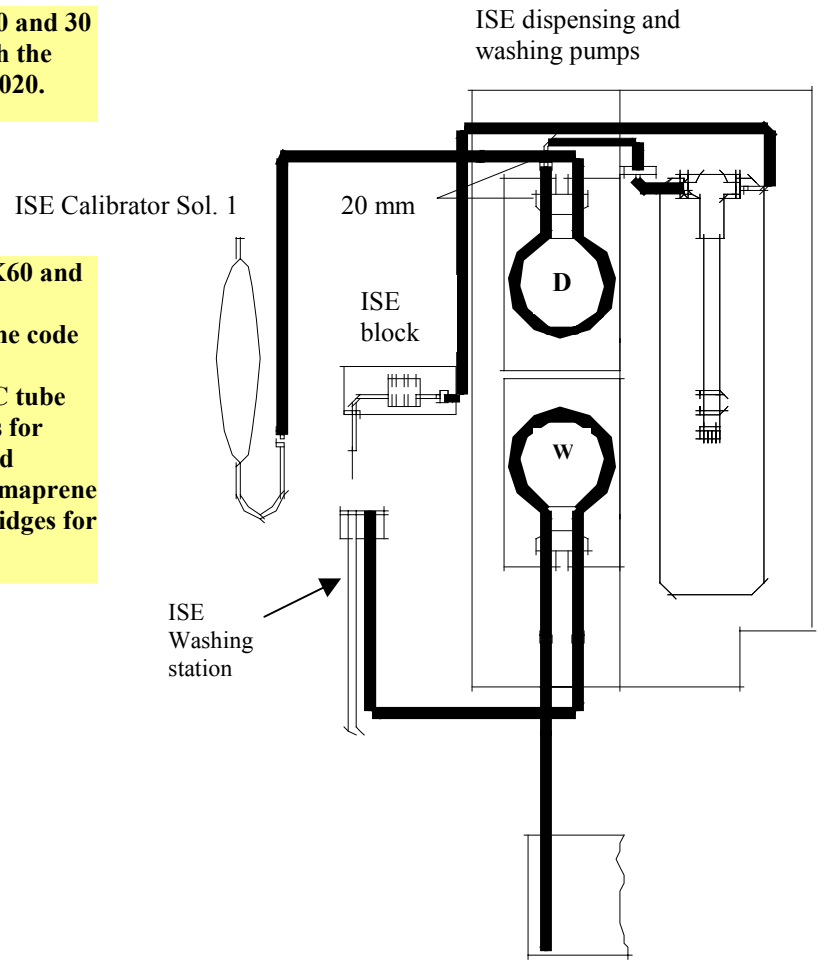


Figure 6-27: The places of ISE Complete tubing in Konelab 60i and 30i

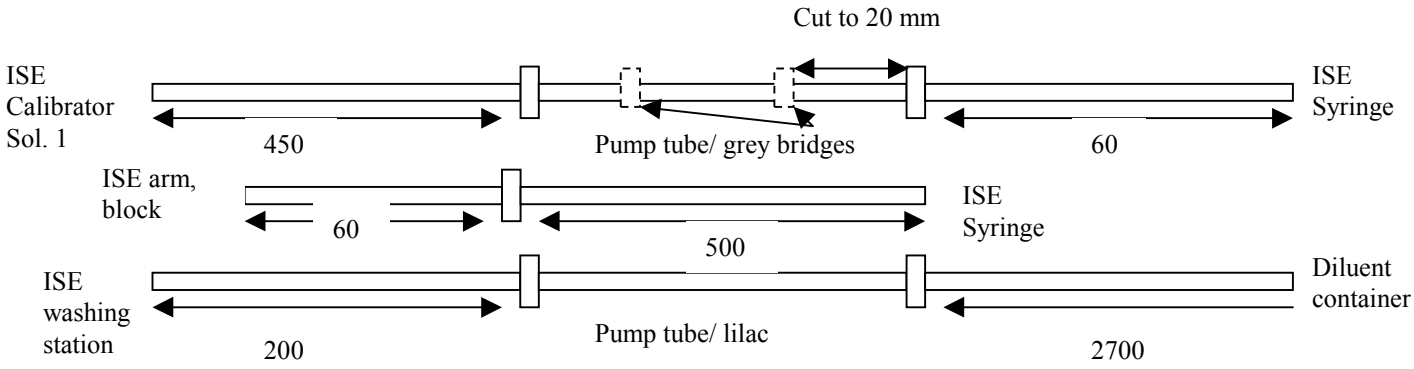


Figure 6-28: ISE Complete tubing (984020)in Konelab 60i and 30i

☞ Detach the old tubes from the connectors. Tweezers may help detaching. The tube between the wash pump and the diluent water container can be put in its place using the help of the old one: Connect the new tube to the old one using a fitting and draw the old tube so that the new tube follows. Detach the old tube from the new one and discard the old tube. In Konelab 30 is needed to open the middle part of the back panel. It is fastened with screws. Install new tubes to the connectors.

ISE tubes for K20XT and 20 are delivered with the code number 984070.

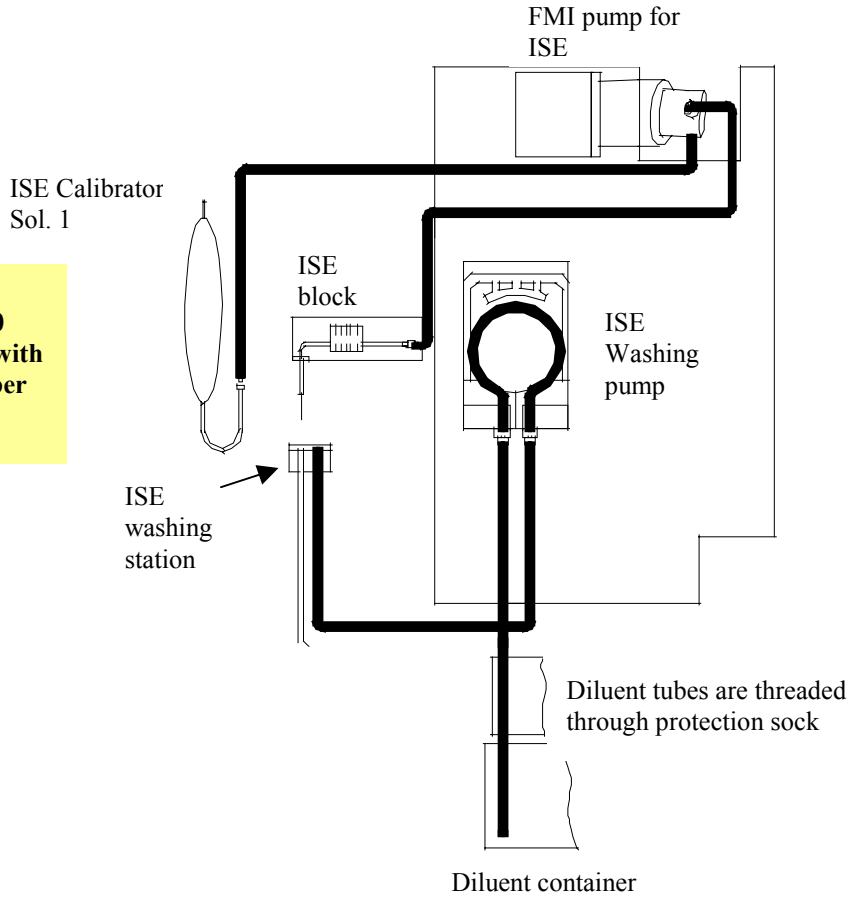


Figure 6-29: The places of ISE complete tubing in Konelab 20XTi and 20i

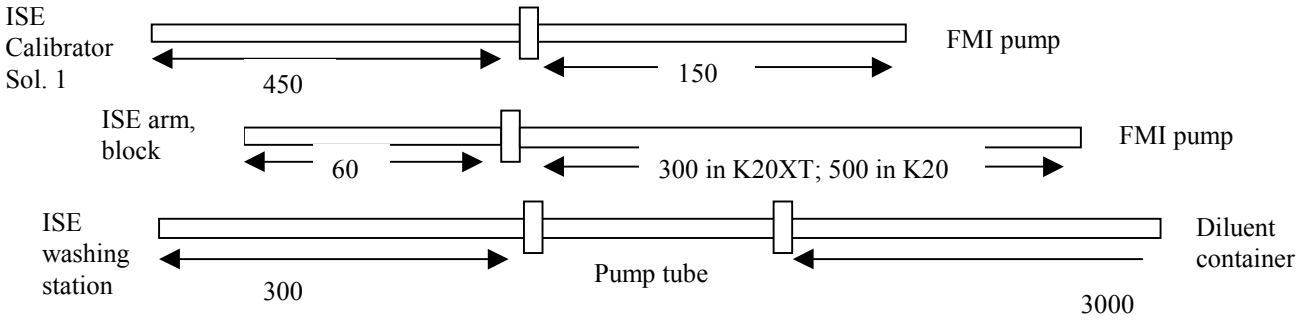
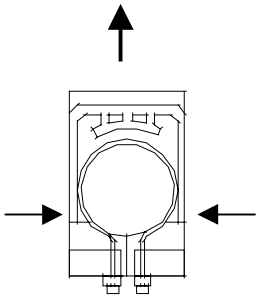
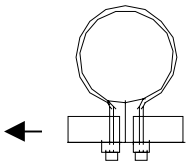


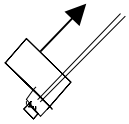
Figure 6-30: ISE Complete tubing (984070) in Konelab 20XTi and 20i

Detach the old tubes from the connectors. Tweezers may help detaching. The tube between the wash pump and the diluent water container can be put in its place using the help of the old one: Connect the new tube to the old one using a fitting and draw the old tube so that the new tube follows. Detach the old tube from the new one and discard the old tube. Install new tubes to the connectors.

To replace the ISE washing pump tube

1.) 

2.) 

3.) 

Inside ISE washing pump cover is a short yellow tube. To replace it:

1) First press the cover from both sides and lift it up.

2) Then draw the gray, plastic holder outwards.

3) Push the gray, plastic holder up so that you can see the end of the tube.

4) Replace the tube and connect the holder and cover in their places.

6.3.7.5 REPLACING KUSTI TUBES

KUSTI tubes are delivered with the code number 984069.

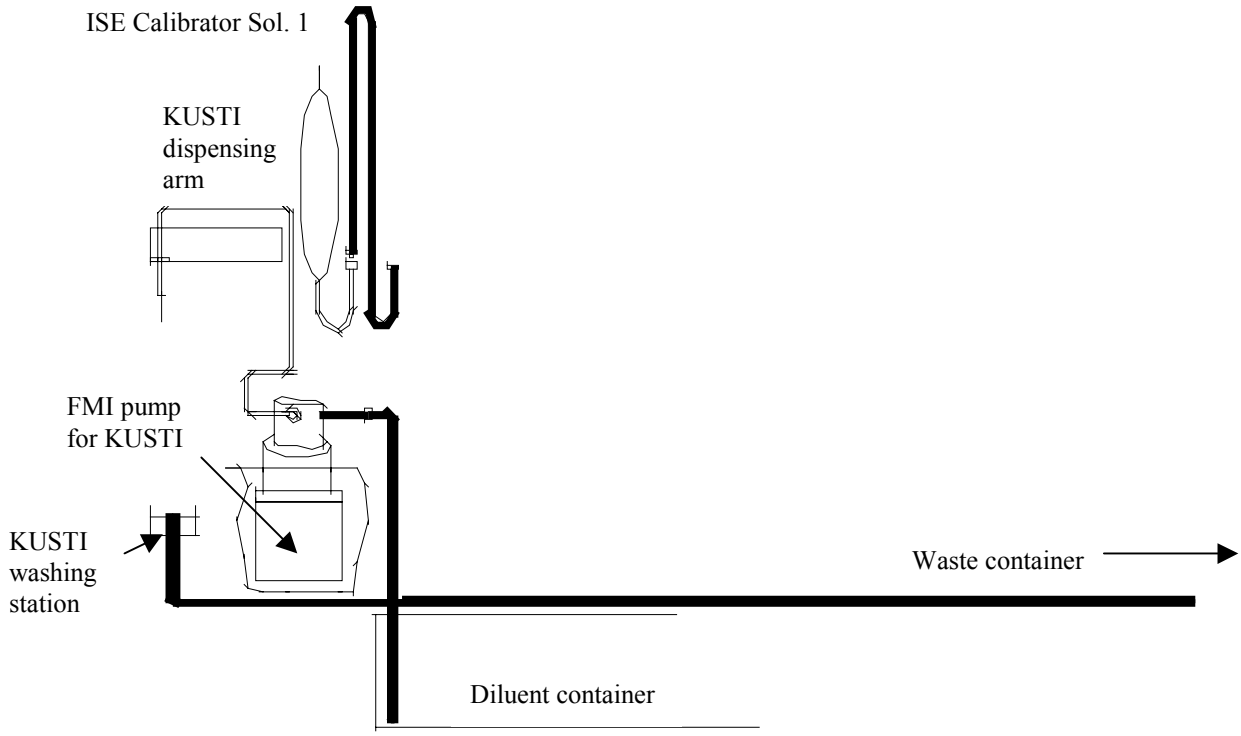


Figure 6-27: The places of KUSTI tubes

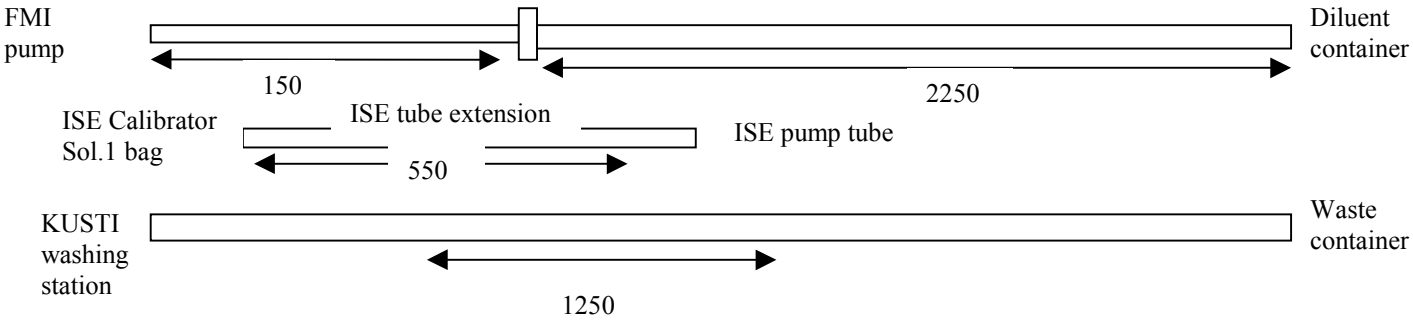


Figure 6-28: KUSTI Complete tubing (984069)

Detach the old tubes from the connectors. Tweezers may help detaching. The wash tube between the FMI pump and the diluent water container, and the waste tube between KUSTI washing station and waste container can be put in its place using the help of the old one. Connect the new tube to the old one using a fitting and draw the old tube so that the new tube follows. Detach the old tube from the new one and discard the old tube.

Install new tubes to the connectors.

6.3.8 REPLACING ELECTRODES

Deionized water or other solvents must never be in contact with the membranes. Store the electrode block so that the measurement channel is empty.

The expected lifetime of electrodes is shown in the following table. The main criterion for replacing is unsatisfied quality control values. The allowed values for the ISE tests' calibrations are seen in section 5.2.3.

Electrode	Months or	Samples
Cl	6 - 8 or	10 000
Ca	4 - 6 or	8000
Li	4 - 6 or	8000
K	8 or	10 000
Na	12 - 18 or	20 000
pH	12 - 18 or	20 000
Ref	8 - 12 or	20 000

Replacing an electrode:

An electrode should be removed and replaced by a new electrode when performance becomes unsatisfactory.

When assembling electrodes or replacing an electrode, either use new o-rings or place the old rings in the same positions they were earlier. There must always be an o-ring between two electrodes.

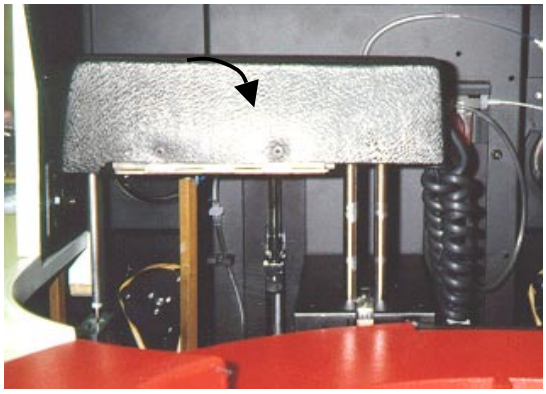


Figure 6-29: The ISE dispensing arm

☞ Turn the cover of the ISE dispensing arm so that you can see the position of the block. The cover is hinged, so it is easy to open.

☞ Disconnect the signal wires and caps from the connecting pins of the measuring electrodes (colour coded). It is not necessary to disconnect the sample detection and grounding wires from the connectors in the end slices.

☞ Release the electrode block turning the lever and detach the block from the end slices.

☞ Press the end slices together to keep the liquid line closed.

☞ Detach only the electrode that needs replacement. Follow the instructions in sections 9.6.1. - 9.6.2. for the material, installation and assembling.

☞ Fill the Installation and Warranty Sheets of the electrode. These sheets are enclosed to each Electrode Kit.

After positioning the electrode block do the following:

After replacing an electrode a pre run of sera must be analysed with subsequent new calibration.

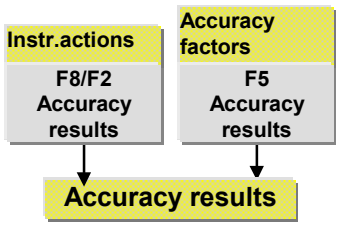
☞ Carry out START UP. Give some ISE requests and enter sera as sample.

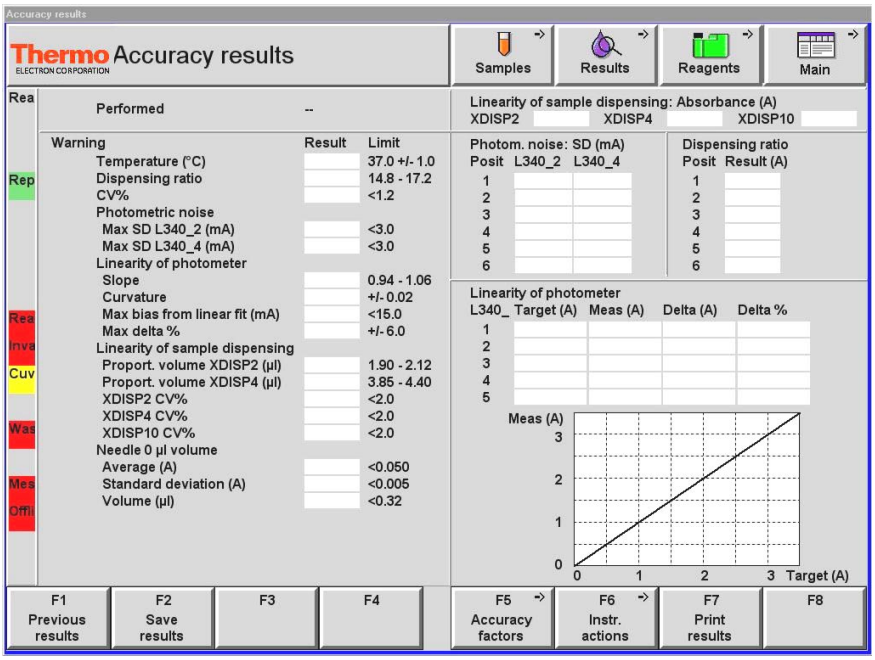
☞ Check the detailed calibration data in the Calibration results window for all those electrodes that has been changed.

☞ If problems occur, check the connections of the electrodes and ISE calibrator 1. Recalibrate in the Calibration / QC selection window.

When calibration is successful, a pre run of 10 sera should be analysed with subsequent new calibration before analysing patient samples.

6.4 ACCURACY RESULTS

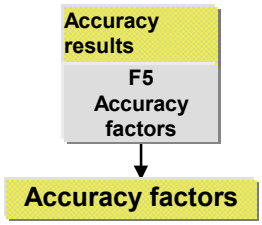


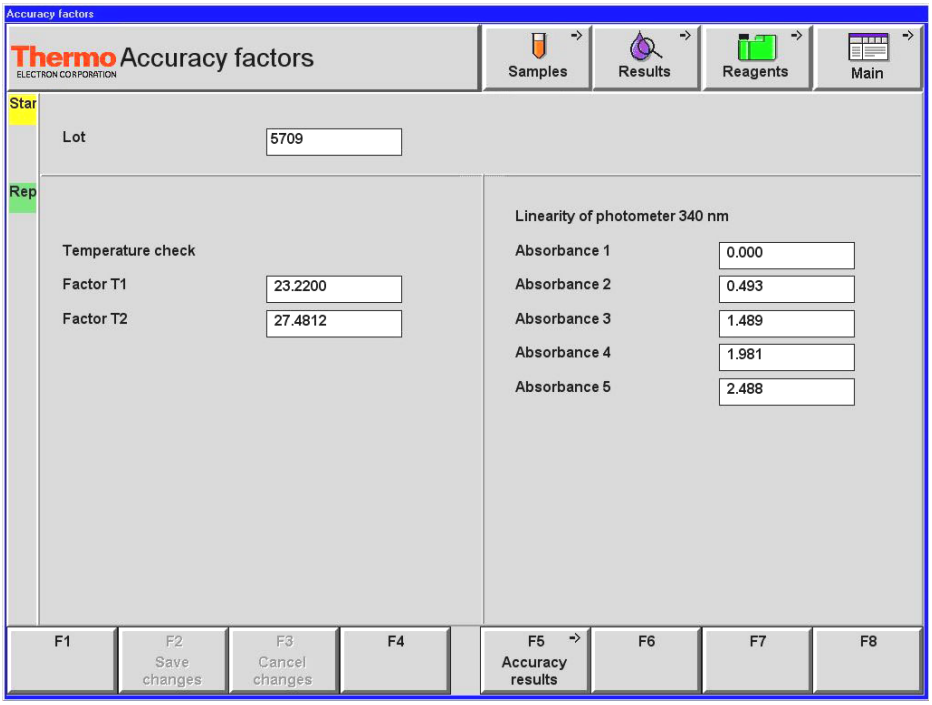


After the preventive maintenance and once per year it is recommended to perform accuracy measurements to check the condition of instrument. Results of these measurements are seen in this window. Results come automatically from the measurement database.

See section 6.3.1 for the equipment needed for the Accuracy test.

6.4.1 ACCURACY FACTORS





Accuracy measurements are carried out using the accuracy solution kit. Authority measures values of these solutions. Lot dependant factors, affecting accuracy result calculations, are given in this window.

7. INTERFERENCES OF SAMPLES

7.1 GENERAL

Visually inspect samples. Visible clotting must be avoided. Bubbles in sample cups affect erroneous results because surface detector in the sample probe cannot find liquid properly. Remove bubbles away, e.g. by pipetting.

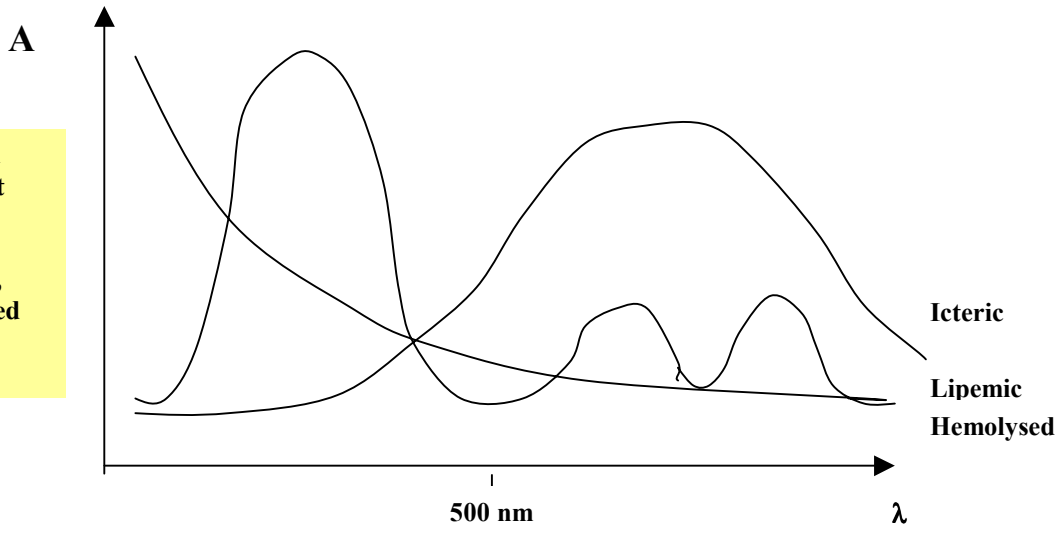
If sample has been frozen after smelting, it must be mixed thoroughly before use.

When centrifuging and handling samples, the instructions of tube manufactures must be followed.

7.2 MEASUREMENT INTERFERENCE WITH THE ORIGIN FROM THE SAMPLE ITSELF

Absorbance spectra of the three most typical sample related interference in photometrical applications.

For more detailed information about measurement interference in Konelab methods, refer to CE marked reagent inserts.



(Literature source: Tietz Fundamentals of Clinical Chemistry ed. by Carl A. Burtis and Edward R. Ashwood, 4 th edition)

7.2.1 HEMOLYSIS

Visible effect:	Sample is reddish (hemolysis is visible if the haemoglobin content > 20 mg/dl in serum/plasma).
Reason:	Broken erythrocytes (haemoglobin has escaped from inside the red blood cells).
Cause:	Too big stasis during sample collection. Wrong puncturing of the vein: the needle is not in the vein during sampling. The sample tube is held in wrong position: the sample is not allowed to run down along the sidewalls of the sample tube, but instead spurts into the vessel. The sample was not allowed to coagulate long enough before centrifugation. The sample was stored too long before plasma/serum was separated from erythrocytes.
Effect:	Slight hemolysis has little effect on most test values. Sever hemolysis cause a slight dilutional effect on those constituents that are present at a lower concentration inside the erythrocytes than in plasma. However, a marked effect may be observed for those constituents that are present at a higher concentration in erythrocytes than in plasma. This is the case for particularly plasma concentrations or activities of aldolase, total acid phosphates, lactate dehydrogenase, isocitrate dehydrogenase, potassium, magnesium and phosphate. The inorganic phosphate in serum increases rapidly as the organic esters in the cells are hydrolysed. Aspartate aminotransferase activity is increased by 2% for each 10 mg/dl increase in haemoglobin concentration. Haemoglobin of 10 mg/dl increases serum lactate dehydrogenase by ~10% and serum potassium by ~0.6%.
Compensation/ avoidance:	Although the amount of free haemoglobin could be measured and a calculation made to correct test values affected by haemoglobin, this is not feasible because of contribution of other factors, the impact of which is difficult to assess. Hemolysis may affect many unblanked or inadequately blanked analytical methods.

7.2.2 ICTERUS (JAUNDICE)

Visible effect:	Sample is greenish.
Reason:	Sample is discoloured because of bilirubin accumulation and staining. A yellow discoloration is visible when the serum total bilirubin concentration reaches 2 to 3 mg/dl (34 to 51 µmol/l).
Cause:	Jaundice or icterus may be the first (and often only) manifestation of liver disease.
Effect:	Falsely low results, such as creatinine due to bilirubin participating in the chemical reaction.

7.2.3 LIPEMIA

Visible effect:	Sample seems 'milky' or opaque.
Reason:	Sample is opaque because of high concentration of fats (chylomicrons, lipoproteins, triglycerides, cholesterol).
Analytical cause:	Recent food ingestion (fatty meal, alcohol ingestion).
Effect:	Due to turbidity caused by fat: typically falsely elevated results or problems with kinetic measurements.
Compensation/ avoidance:	Samples should be collected from fasting patients (12 hour-fasting). The safest way to remove lipemia is by centrifugation. Slight lipemia can be removed by centrifugation (8000 – 10000G) and strong lipemia by ultracentrifugation (about 100 000 G).

7.3 SAMPLE PREHANDLING TO REMOVE PROTEINS OR OTHER COMPONENTS

7.3.1 PROTEIN REMOVAL FOR GLUCOSE MEASUREMENTS

Red cells are using glucose. If glycolysis is not inhibited in the sample, e.g. collecting samples in sampling tubes containing glycolysis inhibitor, glucose is continuously consumed and results will be falsely decreased. Also if whole blood samples need to be stored for more than 1 hour (storage in the fridge) the actions described below should be taken.

Precipitation using perchloric acid:

50 µl sample (whole blood) to 500 µl of precipitant (0.33 mol/l perchloric acid). Perform measurements in duplicates. Mix carefully and centrifuge the sample. In case the sample is not clear after centrifugation the reason can be insufficient mixing and/or too low G-values for the centrifugation. Repeat mixing and centrifugation.

NOTE: Calibrators and controls should be treated with the same procedure in order to compensate for the dilution and allow the instrument to report results directly without recalculation.

NOTE: Be careful that the application takes into consideration that the sample has gone through removal of protein. For example attention should be paid to the final ratio of sample volume to total volume in the cuvette. Additionally the dilution limit should be checked.

7.3.2 LOW DENSITY LIPOPROTEINS (VLDL & LDL) REMOVAL FOR UNDIRECT HDL CHOLESTEROL MEASUREMENTS

Be careful to use the parameters purposed to the particular HDL method.

HDL- and LDL- cholesterol are generally measured from serum and plasma with the direct method. In case of indirect HDL –cholesterol measurements, the LDL- and VLDL-cholesterol fractions as well as the chylomicrons need to be removed from the sample. This is done using a precipitating agent. From supernatant, HDL-cholesterol is measured with the normal Total Cholesterol method.

The precipitation procedure (to remove undesirable components):

The used precipitant:

- Dextransulfate: 500 µl serum + 50 µl precipitant (5 ml bottle with powder).
NOTE: The dissolved reagent has limited stability and it should be stored at room temperature!

+ Take exact amount of serum into a new tube.

+ Add the exact amount of precipitant.

+ Mix carefully immediately (e.g. using a Vortex mixer).

+ Allow to precipitate at room temperature the given time.

+ Centrifuge the sample => use correct G-value and time (e.g. 5000G for 10 minutes).

Sample should now be clarified.

7.4 SPECIAL PRECAUTIONS FOR ISE TESTS

7.4.1 SUMMARY OF IMPORTANT PRECAUTIONS

GENERAL

Use only ISE Calibrator solutions supplied by Thermo Electron.

Do not attempt to the sample any other than Thermo Electron calibrator solution as an 'external' calibrator.

Do not enter other solutions than human serum, plasma or urine, QC sera or ISE Calibrator solution as a sample.

Keep the ISE compartment cover always closed during operation.

After handling of electrodes run QC.

SAMPLES

Haemolysis is visible in serum and plasma samples if the hemoglobine value is about 0.5 g/l. This corresponds to 0.17 mmol/l of extra potassium recovery in the sample.

Store samples closed.

Broken erythrocytes (haemolysis) affect potassium results because potassium concentration of intracellular fluid is higher than that of extra cellular fluid. If 1 % of erythrocytes is haemolysed the hemoglobine value will be about 1.5 g/l which corresponds to 0.5 mmol/l extra potassium recovery in sample.

The effect of haemolysis is not significant on Na^+ and Cl^- concentration in the sample due to low Na^+ and Cl^- content in intracellular fluid compared with Na^+ and Cl^- content in extra cellular fluid.

Serum/Plasma:

☞ Do not aspirate samples if clotting is evident, especially if no anticoagulant was used.

☞ Do not measure haemolysed specimens.

☞ After sample taking, mix all samples gently to avoid potassium leakage from the cells.

☞ All calcium and pH samples should be treated anaerobically.

☞ Li^+ values may be changed if the plasma/serum is left on the cells and stored refrigerated. Use separated plasma/serum.

QUALITY CONTROL MATERIAL

Do not use control sera which contain organic preservatives or stabilisers (e.g. polyethylene glycol), since this may irreversibly damage the electrodes.

Use deionized water to reconstitute lyophilised control material.

Avoid control material which contains big amounts of salicylates (>25 mg/dl) or benzoate. However, if used, analyse these samples intermittently throughout the run, not back to back.

Avoid quaternary ammonium compounds, like TMA if you have a Li^+ electrode in the block.

WASHING

Do not use any other washing solutions than those supplied by Thermo Electron (with the code number 984030).

SWITCHING OFF

Always perform the STAND BY function with enough washing solution before switching the mains off.

7.4.2 SAMPLE HANDLING

Sodium, Potassium, Chloride and Lithium

Heparin preparations may vary from one manufacturer to another. Each laboratory should standardise their procedure.

☞ Serum may be assayed directly. Visible clotting and haemolysis must be avoided. If serum samples are stored, mix the samples thoroughly before use. Store the samples closed.

Vigorous shaking or prolonged standing of unseparated whole blood samples will result in potassium leakage from red cells and a subsequent rise in the potassium level.

☞ Plasma must be anticoagulated with heparin. The amount recommended is 10 - 25 IU/ml. Do not use EDTA or citrate plasma when measuring Ca^{2+}.

☞ Li^{+} values may change if the plasma/serum is left on the cells and stored refrigerated. Use separated plasma/serum.

Calcium and pH

Several methods have been employed to treat the calcium and pH samples:

☞ Collect the sample anaerobically into a heparinized sample tube and store on ice without contact with air. Measure as soon as possible (within one hour). Evacuated heparinized sample tubes have been found suitable for this purpose.

- or -

☞ Collect the sample anaerobically into non-heparinized sample tube and transport to the laboratory on ice without any contact with the air. Then allow to clot for thirty minutes. Centrifuge the specimen and measure the serum as soon as possible (within thirty minutes). Alternatively the serum can be stored for several days anaerobically in filled air tight tubes before measurement.

Ca-heparin is not recommendable when calcium is measured unless the amount of calcium in the heparin can be determined. Other heparin cause about 1 % suppression of ionised calcium when 10 U/ml of heparin is used.
In order to avoid binding of calcium to heparin, a calcium titrated sodium heparin is recommended.

Ionised calcium and pH samples are recommended to be treated anaerobically. Contact with air will cause CO_2 loss from the sample which will alter the sample's pH. This in turn will alter the degree of ionisation of calcium.

The *"IFCC Recommendation on sampling, Transport and Storage for the Determination of the Concentration of Ionised Calcium in Whole Blood, Plasma and Serum", Eur.J. Clin. Chem. Clin. Biochem. Vol 29, 1991*, gives the following recommendations regarding measurement of ionised calcium:

"The substance concentration of ionised calcium (Ca^{2+}) in whole blood, plasma or serum preanalytically may be affected by pH changes of the sample, calcium binding by heparin and dilution by the anticoagulant solution. pH changes in whole blood samples can be minimised by anaerobic sampling to avoid loss of CO_2, by measuring the sample as soon as possible or by storing it in iced water to avoid lactic acid formation. c_{Ca2+} and pH should be determined simultaneously if serum or plasma samples are used."

SAMPLING:

Ionised calcium can be measured from arterial capillary or venous blood. Venous sampling should preferably take place without a tourniquet, since stasis as well as any muscular action like 'pumping' cause changes of the ionised calcium concentration.

If plasma is to be measured, heparin is the best anticoagulant to be used. The use of calcium titrated heparin is the best available in order to minimise calcium binding (can be used up to 50 IU/ml). The heparin should be titrated to an ionised calcium concentration corresponding to the mid point of the reference range in plasma. If heparin preparations without calcium titration are used, the heparin amount should not exceed 15 IU/ml.

To assure the correct amount of heparin in commercially available heparinized sampling tubes or capillaries and to avoid dilution affects caused by anticoagulant solutions, the sampling vessel should be filled with blood completely. E.g. evacuated heparinized sample tubes have been found suitable.

Careful mixing immediately after sampling is necessary, in order to ensure proper anticoagulation. Mixing can be achieved by rolling syringes between the hands, by moving a mixing rod along the full length of the capillary tube with a magnet, or by inverting sampling tubes repeatedly.

SAMPLE HANDLING:

Serum or plasma must be separated from erythrocytes within 1 hour. In separated serum or plasma preferably a pH corrected value should be determined (c_{Ca2+} pH=7.4). c_{Ca2+} (7.4) can be determined from serum or plasma without significant change if samples have been stored in plain glass tubes at 4°C for 1 week or at -20°C for 6 weeks.

7.4.3 ISE CALIBRATOR SOLUTIONS

ISE Calibrator solutions are provided in,

1:	**4 x 400 ml**	**984031**
2 +3:	**4 x 20 ml**	**984035**
4:	**2 x 20 ml**	**984034**

Only ISE Calibrator solutions provided by Thermo Electron should be used in the system. These calibrator solutions are adjusted for ionic strength and pH. Other aqueous calibrator solutions will not necessarily produce correct results. Flame photometry calibrator solutions often employ additives for viscosity adjustment which may damage the electrodes.

7.4.4 QUALITY CONTROL MATERIAL

Sodium, Potassium, Chloride and Lithium

Control sera containing big amounts of organic stabilisers such as polyethylene glycol must be avoided since this material may irreversibly damage the membranes of the electrodes.
Big amounts of salicylates and benzoate may damage the Cl^- electrode. This effect is at least to some extent reversible.
Quaternary ammonium compounds, such as TMA, may poison the Li^+ electrode and hence they should be avoided.

The best materials for assessing accuracy and precision are quality control sera for which ISE values are quoted. Manufacturers may fail to indicate the nature of the instrumentation used to assign values (direct, indirect etc.) This may cause differences in the result level for some instrument. Preferably the values should have been assigned using the same technique as the Konelab is using i.e. direct ISE.

☞ Lyophilised control sera should be made up using deionized water. Sera showing excessive turbidity should be avoided. The age of the sera after reconstitution should not exceed that quoted by the manufacturer.

☞ Avoid control material which contains big amounts of salicylates (>25 mg/dl). However, if used, analyse these samples intermittently throughout the run, not back to back. Salicylates cause drift of Cl^- electrode results when repeatedly introduced to system.

Recommended quality control sera:

Konelab Select-ion (High, Normal, Low)

Konelab Abtrol

Konelab Nortrol

Pathonorm (High, Low) and Seronorm by Nycomed

Humtrol and Longtrol by Labquality

Calcium

In serum only about 50 % of total calcium is in the free ionised form. The rest is bound to proteins (40 %) or complex bound (10 %) to ligands such as bicarbonate and lactate. Most quality control material quote only the value for total calcium and not for Ca^{2+}. Predicting the value for Ca^{2+} for these controls is not straight forward, since the fraction of calcium bound to proteins is additionally pH dependent. These quality controls can be used, but Ca^{2+} has to be individually assessed.

8. ERROR MESSAGES & TROUBLE SHOOTING

8.1 GENERAL

The analyser's internal PC and workstation's PC communicate with each other through the Ethernet cable using the protocol TCP/IP. The first one receiving a message at the workstation is TRAREC (transmit/ receive). TRAREC sends messages to the internal PC.

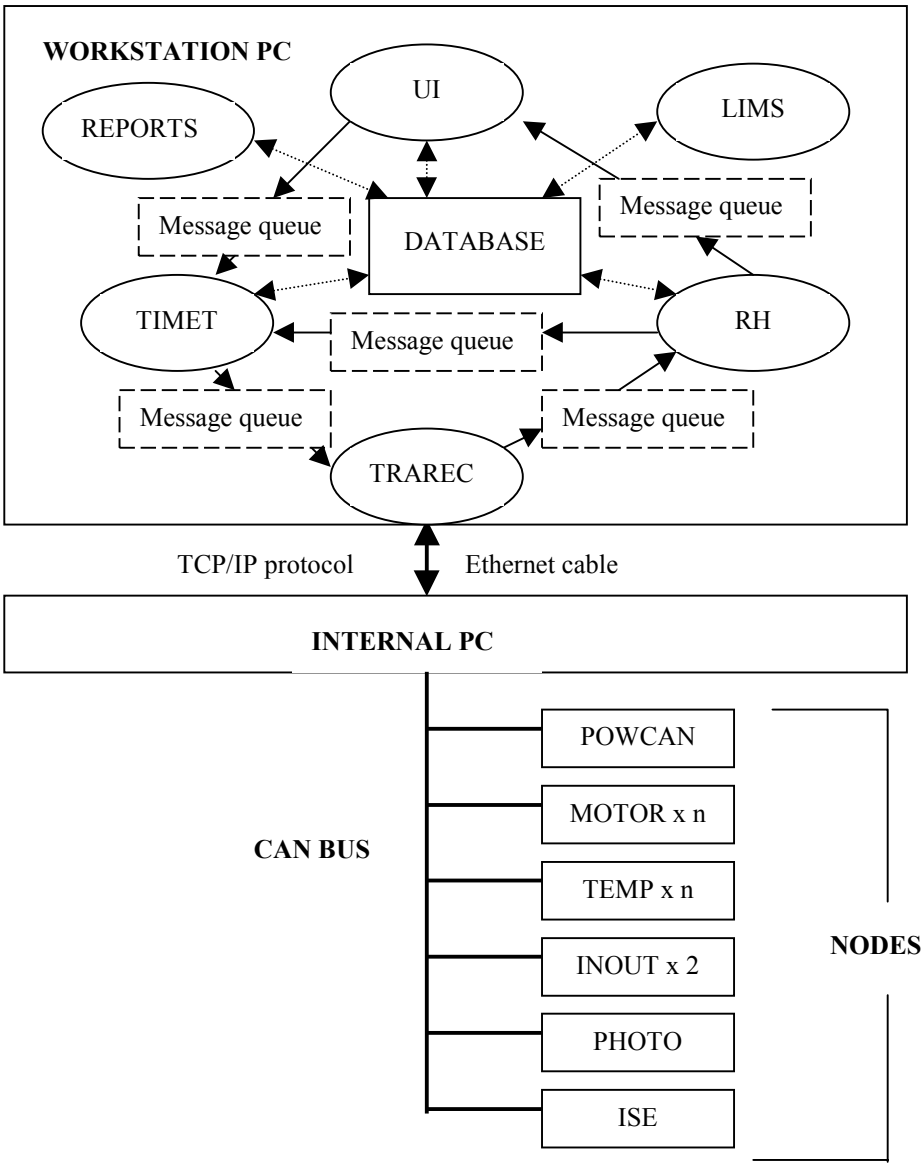


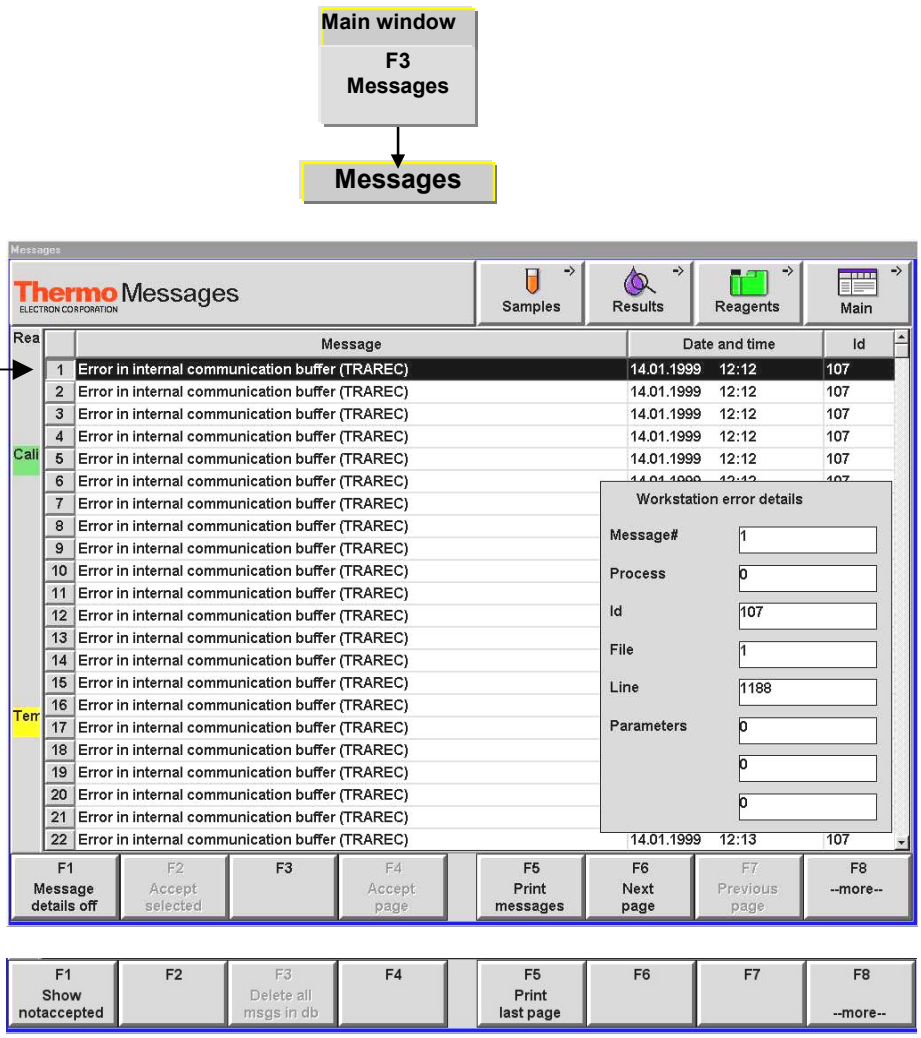
Figure 8-1: The pattern of communication inside the workstation PC and between the analyser's internal PC and workstation PC.

TRAREC re-sends messages in a queue to the response handler (RH). In addition of response handler, other parts, which handle messages at the workstation side, are user interface (UI), timetable (TIMET), laboratory information management system (LIMS) and reports. All these parts are operating with the workstation database and to handle messages in a correct order the database must be locked after each message. Refer to Figure 8-1 on the previous page.

The transmitted message is framed with the software codes and this framed message is called a packet. See e.g. the message 102.

8.2 CHECKING MESSAGES

When you contact a Service engineer, please take the details of error messages!



Messages informed in the Main window and all messages in the database are seen in the Messages window.

Information seen in the MESSAGES window:

	The first is the message list number.
- *Message*	The explanation of the message.
- *Date and time*	The date and time when the message was sent.
- *Error nbr*	First is the process number (e.g. 0), which sent the message; immediately followed by the numbers, which identifies the error (e.g. 107).

You can select with F8/F1 whether all messages or those messages, which are not yet accepted, are seen.

Activate F1 to see the details of the message. Pressing the button again removes the details from the window.

Detailed information from the message:

- *Message #* The number in the message list.
- *Process* The process identification, which sent the message.
- *Error nbr* The number, which identifies the error.
- *Error id* The data of the event place: the identification of the unit, the position and serial number of the board, the number of the file and the line in the file.
- *Parameters* Parameter number.
- *Status* Status number.

To print messages

Activate F5 to print messages. With F8/F5 you can print the last page of messages.

To remove the message

Activate F2 to accept and remove the selected message from this window and from the Main window.

Activate F4 to accept and remove all messages seen in the window.

Activate F8/F3 to delete all messages from the database.

8.3 ERROR MESSAGES

8.3.1 ERROR MESSAGES FROM THE WORKSTATION

8.3.1.1 MESSAGES FROM THE ANALYSER, MESSAGES TO THE ANALYSER (0 - TRAREC)

2	FULL MESSAGE QUEUE DETECTED (TRAREC)
3	MESSAGE QUEUE STAYS FULL (TRAREC)
4	CANNOT OPEN MESSAGE QUEUE (TRAREC)
5	NO FREE MESSAGE BUFFER AVAILABLE (TRAREC)
6	INTERNAL MESSAGE BUFFER ERROR (TRAREC)

☞ Software's internal communication error. Restart the workstation. Refer to section 8.4.1.

In case the instrument is switched off and the message 105 appears, no action is necessary.

101	INSTRUMENT HAS BEEN CLOSED
102	CANNOT SEND PACKET TO INSTRUMENT
103	WRONG PACKET SIZE FROM INSTRUMENT
104	INSTRUMENT COMMUNICATION ERROR: WRONG END
105	CANNOT RECEIVE PACKET FROM INSTRUMENT

Communication fault between the workstation and the analyser.

☞ Possible causes

E.g. switching off the instrument (normal case), software problem, error in updating, faulty cable or broken board.
- Reboot the instrument. If the problem persist, check the Ethernet cable connection. If it is OK call service.

106	ERROR IN READING FROM MESSAGE QUEUE (TRAREC)
107	ERROR IN INTERNAL COMMUNICATION BUFFER (TRAREC)

☞ Software's internal communication error. Restart the workstation. Refer to section 8.4.1.

999	TRAREC ERROR MESSAGE %u - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.1.2 TIME TABLE (1 - TIMET)

1002	FULL MESSAGE QUEUE DETECTED (TIMET)
1003	MESSAGE QUEUE STAYS FULL (TIMET)
1004	CANNOT OPEN MESSAGE QUEUE (TIMET)

☞ Software's internal communication error. Restart the workstation. Refer to section 8.4.1.

1011	CALCULATION ERROR: ZERO DIVIDER (TIMET)
1012	CALCULATION ERROR: LOG FROM NEGATIVE (TIMET)
1013	CALCULATION ERROR: TOO HIGH EXPONENT (TIMET)

Warning that the incorrect initial value for a calculation has been detected. The calculation cannot be done. E.g. calibration is not successful and test's automatic acceptance is changed to manual.

1021	DATABASE LOCK ERROR (TIMET)

☞ Internal software problem with the database. Analysis will stop after requests under analysis are completed. Press START to continue analysis. If the problem persists, restart the workstation. Refer to section 8.4.1.

1022	ERROR WHEN DOING DATABASE OPERATION (TIMET)
1031	WRONG DATA FROM DATABASE (TIMET)
1032	WRONG DATA FROM AN OTHER PROCESS (TIMET)
1033	INTERNAL DATA ERROR (TIMET)

☞ Warning about internal software problem in the database. Analysis will stop after requests under analysis are completed. Press START to continue analysis. If the problem persists, restart the workstation. Refer to section 8.4.1.

1041	CANNOT OPEN OR READ %S.INI (TIMET)
1042	CORRUPTED KONELAB.INI (TIMET)

☞ Warning about problem in the configuration, filter or temperature data. Check the data in the Configuration window. Refer to section 3.8. If the problem persists, contact service.

1201	ANALYSING NOT ALLOWED (CHECK WATER, CUVETTES AND COVERS)

☞ To start analysis, check that the distilled water container is full and the wastewater container is empty. Check that covers are closed and check that there are cuvettes. Press START.

1202	ANALYSING NOT ALLOWED (START UP NOT DONE)
1203	ANALYSING NOT ALLOWED (WAIT IDLE-STATE)
1204	ANALYSING NOT ALLOWED (INSTRUMENT WORKING)

☞ To start analysis, perform Start up. Press START.

1206 ANALYSING STOPPED (CHECK MESSAGES)

☞ The actual error messages are seen on the MESSAGES window. Perform remedy procedures and continue analysis.

1207 ANALYSING STOPPED (STOP HAS BEEN PRESSED)

☞ To restart analysis, press START.

1208 START UP NOT ALLOWED (START UP DONE)

☞ Start up is possible to perform after switching on the analyser or after Stand by. Start up is recommended to be done once a day.

1212 START UP NOT ALLOWED (CHECK WATER, CUVETTES AND COVERS)

☞ To perform Start up, check that the distilled water container is full and the wastewater container is empty. Check that covers are closed and check that there are cuvettes.

1213 INSTRUMENT TYPE MISMATCH. SELECT CORRECT TYPE.

☞ Warning that wrong information about the instrument type (20/20XT/30/60) detected. Select the correct instrument type from Start: Programs: Instrument selection.

Concerning Konelab 30 and 30i

1214 EXIT FAILED (%u). REMOVE CUVETTE FROM INCUBATOR - %u MEANS THE INCUBATOR POSITION NUMBER

Cuvette still in the incubator (e.g. the hook has broken) and the analyser has failed to exit it during Stand by or Exit cuvettes (in the Instrument actions) functions.

☞ Wait until analysis is complete. Open the analyser's and incubator's covers and remove the cuvette manually. Refer to section 8.4.2.

Concerning Konelab 60 and 60i

1214 EXIT FAILED (%u). REMOVE CUVETTE FROM INCUBATOR (INSTR. ACTIONS) - %u MEANS THE INCUBATOR POSITION NUMBER

Cuvette still in the incubator (e.g. the hook has broken) and the analyser has failed to exit it during Stand by or Exit cuvettes (in the Instrument actions) functions.

☞ Wait until analysis is complete. Activate F7, Manual cuvette exit in the Instrument actions window. Open the analyser's cover and remove the cuvette manually. Refer to section 8.4.2.

1215 TOO MANY UNUSABLE CUVETTE POSITIONS IN INCUBATOR.

Several cuvettes have remained in the incubator (e.g. the hook has broken) and the analyser has failed to exit them. Analysis will stop after requests under analysis are completed.

☞ Remove cuvettes with Exit cuvettes in the Instrument actions window or perform Stand by. If the error message 1214 appears remove cuvettes manually. Refer to section 8.4.2.

1216 NO USABLE CUVETTE POSITIONS IN INCUBATOR.

All cuvettes in the incubator are unusable (e.g. the hook has broken) and the analyser has failed to exit them. Analysis will stop after requests under analysis are completed.

☞ With Konelab 60, remove cuvettes with Manual cuvette exit in the Instrument actions window (refer to section 8.4.2.) and after that switch the analyzer off and on.

☞ With Konelab 30, 20XT and 20, switch the analyzer off and remove cuvettes manually from the incubator. Refer to section 8.4.2. Switch the analyzer on.

1217 INSTRUMENT TYPE AND TICK LENGTH MISMATCH IN KONELAB.INI

☞ Warning that the instrument type do not match with the tick length. Konelab 20XT, 30 and 60 are using the tick length of 4.5 seconds and Konelab 20 the tick length of 7 seconds. To continue using the Konelab program, first exit from it by selecting F8/F3 in the Management window. Then select the correct instrument type from Start: Programs: Instrument selection. Finally, start the Konelab program again by clicking the konelab -icon. Note that also in the Configuration window the instrument type is selected.

1218 INVALID INTERNAL TICK VALUE

Warning that the instrument's tick length doesn't match with the original one. Analysing continues.

1999 TIMET ERROR MESSAGE (%u)
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.1.3 RESPONSE HANDLER (2 - RH)

2002 FULL MESSAGE QUEUE DETECTED (RH)
2003 MESSAGE QUEUE STAYS FULL (RH)
2004 CANNOT OPEN MESSAGE QUEUE (RH)

☞ Software's internal communication error. Restart the workstation.

2011 CALCULATION ERROR: ZERO DIVIDER (RH)
2012 CALCULATION ERROR: LOG FROM NEGATIVE (RH)
2013 CALCULATION ERROR: TOO HIGH EXPONENT (RH)

Warning that the incorrect initial value for a calculation has been detected. The calculation cannot be done. E.g. calibration is not successful and test's automatic acceptance is changed to manual.

2021 DATABASE LOCK ERROR (RH)

Internal software problem to handle the database. Analysis will stop after requests under analysis are completed. Press START to continue analysis. If the problem persists, restart the workstation. Refer to section 8.4.1.

2022 ERROR WHEN DOING DATABASE OPERATION (RH)
2031 WRONG DATA FROM DATABASE (RH)
2032 WRONG DATA FROM AN OTHER PROCESS (RH)
2033 INTERNAL DATA ERROR (RH)

Warning about internal software problem in the database. Analysis will stop after requests under analysis are completed. Press START to continue analysis. If the problem persists, restart the workstation. Refer to section 8.4.1.

2041 CANNOT OPEN OR READ %S.INI (RH)
2042 CORRUPTED KONELAB.INI (RH)

Warning about problem in the configuration, filter or temperature data. Check the data in the Configuration window. Refer to section 3.8. If the problem persists, call service.

2301 REAGENT REGISTER FULL OF VIALS

To have a new reagent, remove one bottle from the reagent disk in the Reagent disk window when analysis is not in progress.

2302 SAMPLE REGISTER FULL OF SEGMENTS

To add a new segment, remove one segment from the sample disk in the Sample segment window when analysis is not in progress.

2303 NO WATER BLANK DATA (RH)

Perform Start up.

2304 NO TEST DATA (RH)

Software error. If the problem persists, restart the workstation. Refer to section 8.4.1.

2305 CANNOT OPEN OR READ ERDATA.TXT (RH)

Erdata.txt includes error messages.

Restart the workstation. Refer to section 8.4.1. If the problem persists reinstall the software for the workstation.

2306 POOR WATERBLANK MEASUREMENT (%s, SD=mA)
e.g. Poor waterblank measurement 340 nm SD=2.1 mA
i.e. %s means the measured wavelength and
SD=mA means the measured standard deviation

☞ Repeat Start up.

If the problem persists try the following ones:

☞ Possible causes

1. Deteriorated water.
   - Wash the distilled water container at least once a week with spirit and distilled/deionized water. Change water and ensure that it is pure. Repeat water blank in Instrument actions.

2. Dirty cuvettes.
   - Empty the cuvette loader and reload it. Repeat water blank measurement.

3. Photometer error.
   - Check that the lamp is not broken and that it is correctly installed. Refer to section 6.3.2.

If the problem persists call service.

2307 REAGENT VIAL HAD AN UNKNOWN BARCODE (%u)
- %u MEANS THE READ BARCODE NUMBER

The barcode id for the reagent is given in the Reagent definition window. The analyser didn't recognise the barcode.

☞ Open the reagent insert cover and remove the vial. Type the barcode id in the Reagent definition window when analysis is not in progress. Insert the reagent again into the analyser.

2308 NO FREE STAT POSITION

☞ To have a new STAT sample, remove one STAT sample from the sample disk in the Sample entry window when analysis is not in progress.

2309 CORRUPTED ERDATA.TXT (RH)

Erdata.txt includes error messages.

☞ Restart the workstation. Refer to section 8.4.1. If the problem persists reinstall the software for the workstation.

2310 NO VALID CALIBRATION

☞ Ask calibration in the Calibration/ QC selection window. After calibration has been accepted, requests are analysed automatically.

2312 DUPLICATE SEGMENT ID (%u)
-%u MEANS THE SEGMENT'S ID NUMBER

Analyser is removing the last inserted segment.

☞ Insert samples into a new segment.

2313 A NEW SEGMENT DETECTED BY INSTRUMENT (%u) -%u MEANS THE SEGMENT'S ID NUMBER

The user is informed about a new segment. Analysis continues.

2314 UNKNOWN REAGENT VIAL FOUND IN POSITION (%u) -%u MEANS THE REAGENT'S POSITION

Possible causes

E.g. the user has changed a new reagent disk and the analyser couldn't read the barcode or the reagent data has not been given but the analyser detects the presence of a reagent.
- Open the reagent insert cover and take the vial away. Check that the reagent's data is OK in the Reagent definition window. Check the barcode. Insert the reagent again into the analyser.

2315 REMOVE SAMPLE SEGMENTS MANUALLY

Possible causes

E.g. during transportation all segment positions are full and the segment loader is at the higher position.
- Take the red sample cover away and remove segments manually. Perform 'Check sample disk' in the Sample disk window or boot the instrument. Refer to section 8.4.1. After that the segment loader will work.

2316 Na TEST MUST BE IN USE WHEN RUNNING Li (ISE)

When lithium is measured also sodium must be installed because lithium is measuring not only lithium but also sodium. So the Na+ electrode must be measured to reduce the sodium value. Check that Na is installed in the block and that it is marked to be in the block in the ISE Electrodes window. Refer to section 4.3.

2317 LAMP VOLTAGE ADJUSTMENT FAILED (%S) -%S MEANS THE WAVELENGTH

Perform Start up.

2318 ALL SEGMENTS FOR KUSTI SAMPLING ARE FULL
2319 NO SEGMENT FOR KUSTI SAMPLING IN INSTRUMENT
2325 SEGMENTS FOR KUSTI SAMPLING ARE ALMOST FULL

Insert KUSTI segments.

2320 SAMPLE IS ALREADY IN INSTRUMENT, NO DISPENSING FROM KUSTI

- Information to the user. Analysing continues.

2321 NEITHER CONTROL NOR STANDARD SAMPLE DISPENSED FROM KUSTI

- Warning to the user that controls or calibrators cannot be introduced through conveyor.

2322 REFLEX TEST MISSING

- Information to the user. Analysing continues.

To get the reflex test in use, go to the Test definition window and select yes from the 'Test in use' menu.

2323 MISSING KUSTI WASHING SOLUTION

- Warning to the user. Stand by procedures continues. Next time before Stand by procedure, insert Washing solution bottle in KUSTI wash position beside the sample disk. Refer to section 2.5.

2324 INTERNAL DATA ERROR

- This is only for service information.

2998 ERROR MESSAGE FROM UNDEFINED PROCESS
2999 RESPONSE HANDLER ERROR MESSAGE (%u)
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.1.4 USER INTERFACE (3 - UI)

3002 FULL MESSAGE QUEUE DETECTED (UI)
3003 MESSAGE QUEUE STAYS FULL (UI)
3004 CANNOT OPEN MESSAGE QUEUE (UI)

Software's internal communication error. Restart the workstation. Refer to section 8.4.1.

3011 CALCULATION ERROR: ZERO DIVIDER (UI)
3012 CALCULATION ERROR: LOG FROM NEGATIVE (UI)
3013 CALCULATION ERROR: TOO HIGH EXPONENT (UI)

Warning that the incorrect initial value for a calculation has been detected. The calculation cannot be done. E.g. calibration is not successful and test's automatic acceptance is changed to manual.

3021 DATABASE LOCK ERROR (UI)

Internal software problem to handle the database. Restart the workstation. Refer to section 8.4.1.

3022 ERROR WHEN DOING DATABASE OPERATION (UI)

Warning about internal software problem in the database. Analysis continues. If the problem persists restart the workstation. Refer to section 8.4.1.

3027 CANNOT OPEN DATABASE (UI)

Internal software problem to handle the database. Restart the workstation. Refer to section 8.4.1.

3031 WRONG DATA FROM DATABASE (UI)
3032 WRONG DATA FROM AN OTHER PROCESS (UI)
3033 INTERNAL DATA ERROR (UI)
3034 WRONG DATA FROM AN OTHER WINDOW (UI)

Internal software problem in the database. If problem persists restart the workstation. Refer to section 8.4.1.

3502 CANNOT OPEN OR READ FILE (UI)

Warning about problem in the configuration, filter or temperature data. Check the data in the Configuration window. Refer to section 3.8. If the problem persists, contact service.

3503 UNKNOWN MESSAGE STATUS (UI)
3504 UNKNOWN MESSAGE (UI)

Software problem. Restart the workstation. Refer to section 8.4.1.

3041 CANNOT OPEN OR READ %S (UI)
3042 CORRUPTED %S (UI)
3505 FILE CORRUPTED (UI)

Warning about problem in the configuration data (konelab.ini, filter.ini or temperature.ini). Check the data in the Configuration window. Refer to section 3.8.

3506 KONELAB.INI FILE CREATED
3507 KONELAB.INI FILE UPDATED WITH DEFAULT VALUES

The user is informed about the configuration data (konelab.ini) actions.

3508 KONELAB.INI FILE CREATE FAILED
3509 KONELAB.INI FILE UPDATE FAILED

Possible causes
Software problem in the Configuration data (konelab.ini).
- Restart the workstation. Refer to section 8.4.1.

3510 INSTRUMENT TYPE MISMATCH BETWEEN DB AND KONELAB.INI

Select the correct instrument type from Start: Programs: Instrument selection.

3511 NOT ENOUGH FREE SPACE ON HARD DISK

Select Start: Programs: Windows NT Explorer and delete unnecessary files. Free at least 50 Mb.

3512 LANGUAGE MISMATCH BETWEEN UI PROCESS AND KONELAB.INI

To continue using the Konelab program, first exit from it by selecting F8/F3 in the Management window. Then select the correct language from Start: Programs: Language selection. Finally, start the Konelab program again by clicking the konelab –icon.

3513 DB REQUEST COUNT IS APPROACHING 10000. USE CLEAR DAILY FILES.

- Warning the user that Clear daily files should be used. Otherwise the functioning of workstation is slowed down remarkably.

3999 USER INTERFACE ERROR MESSAGE (%u) - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.1.5 LABORATORY INFORMATION MANAGAMENT SYSTEM (4 - LIMS)

4032 WRONG DATA FROM AN OTHER PROCESS (LIMS)

☞ Internal software problem in the database. Restart the workstation. Refer to section 8.4.1.

4401 SERIAL LINE PARAMETER ERROR (LIMS)

☞ Check the serial interface parameters in the Configuration window. Refer to section 3.8.

4402 WRONG SERIAL PORT (LIMS)

☞ Check the serial interface parameters in the Configuration window. Refer to section 3.8.

4403 WRITE ERROR (LIMS)
4407 TRANSMISSION ERROR (LIMS)
4409 MESSAGE BUFFER ERROR (LIMS)

External computer has received the data but transmission has been detected as incorrect.

☞ Possible causes — E.g. electronic malfunction, software error, initialisation error or power failure.
Check the cable connection. If the problem persists call service.

4404 READ ERROR (LIMS)

The analyser has received the data but transmission has been recognised as incorrect.

☞ Possible causes — E.g. electronic malfunction, software error, initialisation error or power failure.
Check the cable connection. If the problem persists call service.

4405 SYNCHRONIZATION ERROR (LIMS)

The analyser received a data record[1] while it was expecting an ACK character or it received ACK/NAK while expecting a data record.

☞ Possible causes	E.g. faulty cable, electronic malfunction, software error. Check the cable connection. If the problem persists call service.

[1] A data record is a string of any characters beginning with ':' and ending with (0D hex) or a string of any characters whose length exceeds the size of input buffer (currently 132).

4406 COMMUNICATION TIMEOUT (LIMS)

External computer did not answer in the allowed time.

☞ Possible causes	E.g. faulty cable, electronic malfunction or wrong initialisation data. Check the cable connection. If the problem persists call service.

4408 ERROR WHEN DOING DATABASE OPERATION (LIMS)

☞ Warning about internal software problem in the database. Analysis continues. If the problem persists restart the workstation. Refer to section 8.4.1.

4410 LIMS TYPE MISMATCH BETWEEN LIMS PROCESS AND KONELAB.INI

☞ To continue using the Konelab program, first exit from it by selecting F8/F3 in the Management window. Then select the correct LIMS process from Start: Programs: lims selection. Finally, start the Konelab program again by clicking the konelab –icon.

4999 LIMS ERROR MESSAGE (%u) - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.2 ERROR MESSAGES COMING FROM THE INSTRUMENT'S PC (5 - INTERNAL PC)

5001 INTERNAL DATA ERROR (INTERNAL PC)

Software error in the internal PC. Another error message details the actual problem, e.g. needle error.

5002 INTERNAL PC ERROR: USED TOO MUCH TIME

The analyser has fallen behind the timetable. It recovers automatically.

5003 INTERNAL PC ERROR: CANNOT SEND CAN-MESSAGE

The internal PC cannot get the message to the board. Analysis will stop.

Possible causes

1. Software problem.
   - Reboot the instrument. Refer to section 8.4.1.
2. Broken PCCAN board or broken recipient board.
   - Call service.

5004 INTERNAL PC ERROR: UNEXPECTED NODE %u BOOT - %u MEANS THE BOARD NUMBER

Possible causes

1. Software problem.
   - Reboot the instrument. Refer to section 8.4.1.
2. Broken board.
   - Call service.

5005 FEEDBACK ERROR WHEN INITIALIZING

Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor, and KUSTI is in ‘not in use’ state.

Possible causes

1. Mechanical obstacle.
   - Check that there are no mechanical obstacles to stop free movement.
2. Too loose cogged belt or broken feedback sensor or damaged motor driving board.
   – Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5006 MIXER NOT RUNNING PROPERLY

This error message is for Konelab 20 and meaning that needle is not mixing properly. Analysing is stopped.

Possible causes

1. An obstacle detected.
   - Remove the obstacle. Press START to continue analysis.
2. Damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5007 MA DISPENSER/ MIXER INITIALIZATION FAILED

Possible causes

1. An obstacle detected.
   - Remove the obstacle. Perform water wash (F6 in the Instrument actions window) before continuing. Water wash must be definitely done when Konelab is connected to the automation conveyor, and KUSTI is in 'not in use' state. Press START to continue analysis.

2. Damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5007 REAGENT/ SAMPLE REGISTER INITIALIZATION FAILED

Possible causes

1. Mechanical obstacle.
   - Open the cover and check if e.g. some reagent vessel/ sample cup is incorrectly attached. Perform water wash (F6 in the Instrument actions window) before continuing. Water wash must be definitely done when Konelab is connected to the automation conveyor, and KUSTI is in 'not in use' state.

2. Reagent/ Sample disk incorrectly located.
   - Check the location of the reagent/ sample disk and reattach. Refer to section 8.4.3. Perform water wash (F6 in the Instrument actions window) before continuing. Water must be definitely done when Konelab is connected to the automation conveyor, and KUSTI is in 'not in use' state.

3. Damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5007 CUVETTE PUSHER INITIALIZATION FAILED

Possible causes

1. Mechanical obstacle.
   - Check if some obstacle can be found. Refer to section 8.4.2. Perform water wash (F6 in the Instrument actions window) before continuing.

2. Damaged opto / opto cable or damaged fuse in the motor driving board or damaged motor driving board.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists, call service.

5007 INCUBATOR INITIALIZATION FAILED

Possible causes

1. Cuvette remained in the cuvette path.
   - Check the incubator. Refer to section 8.4.2. Perform water wash (F6 in the Instrument actions window) before continuing.

2. The cuvette arm cogged belt is broken or damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists, call service.

5007 FILTER DISK INITIALIZATION FAILED

Possible causes

Damaged opto / opto cable/ motor driving board or mechanical obstacles for the movement e.g. loosen filter
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

5008 CAN CARD NOT FOUND

This error message is for Konelab 20XT and 20. Instrument stays 'Not in use' status.

Possible causes

Loose contact in cable/ broken CAN card inside the workstation's PC.
- Call service.

5009 CUVETTE ARM INITIALIZATION FAILED (MEASUREMENT/ SAMPLE/ REAGENT CHANNEL)

Possible causes

1. The cuvette waste compartment is full.
   - Empty the cuvette waste compartment and also the cuvette exit channel.
2. The cuvette arm cogged belt is broken or damaged opto / opto cable or the chord of opto has bent down or damaged motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5010 CAN INITIALIZATION FAILURE

This error message is for Konelab 20XT and 20. Instrument stays 'Not in use' status.

Possible causes

Software problem.
– Restart the workstation. Refer to section 8.4.1.
If problem persists call service.

5011 CANNOT RECEIVE PACKET FROM INSTRUMENT

Communication fault between the workstation and the analyzer. Typically coming when Konelab 20XT or 20 has been switched off. Reboot the instrument. Refer to section 8.4.1.

5014 %S: LIQUID LEVEL DETECTION ERROR

Liquid detected falsely above the surface. Analysis stops. Restart the analyzer. If the problem persists, call service.

Concerning Konelab 30 and 30i

5015 CUVETTE LOADER INITIALIZATION FAILED

Possible causes

1. An obstacle detected.
   - Remove the obstacle if it is seen in the cuvette loader. Press START to continue analysis.
2. The cogged belt is broken or damaged opto / opto cable/ motor driving board
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

Concerning Konelab 60 and 60i

5015 CUVETTE LOADER INITIALIZATION FAILED (LATCH/ CUVETTE MOVER/ CUVETTE PUSHER/ ROTATING UNIT)

Possible causes

1. An obstacle detected.
   - Remove the obstacle if it is seen in the cuvette loader. Press START to continue analysis.
2. The cogged belt is broken or damaged opto / opto cable/ motor driving board
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5016 KUSTI DISPENSER HIT AN OBSTACLE WHILE DISPENSING FROM TRACK

Dispensing continues from the next sample.

Possible causes

Wrong positioning of the tube. The tube is directed to check in the automation line, and the user has to insert it again to the system or to Konelab.

5017 SAMPLE DISPENSER/ SAMPLE MIXER/ REAGENT DISPENSER/ REAGENT MIXER/ ISE DISPENSER/ MA DISPENSER/ MIXER/ KUSTI DISPENSER HIT AN OBSTACLE

Possible causes

1. Probe / Mixer is bent.
   – Check the straightness of the probe / mixer and that it has not fastened into the dispenser's / mixer's cover. To change the probe/ mixer refer to sections 6.3.5. and 6.3.6. Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor.
2. An obstacle detected.
   – Remove the obstacle. Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor. Press START to continue analysis.
3. Programmable adjustments have been changed.
   – Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5018 SEGMENT LOADER DID NOT MOVE CORRECTLY

Possible causes

1. E.g. the user has opened the segment cover while the segment loader has been moving. The segment loader stops.
   - Move the segment loader manually to the lower position and reboot the instrument. Refer to section 8.4.1.

2. An obstacle detected.
   - Remove the obstacle. Move the segment loader manually to the lower position and reboot the instrument. Refer to section 8.4.1.

3. Damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5019 CUVETTE LOADER DID NOT MOVE CORRECTLY

Possible causes

1. An obstacle detected.
   - Remove the obstacle. Press START to continue analysis.

2. Damaged opto / opto cable/ motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5020 CUVETTE CHECK FOUND A DIRTY CUVETTE

The optical quality of every cuvette is checked before use.

Possible causes

Dirty cuvette or bad optical quality of a cuvette.
- Empty the cuvette loader and reload it carefully with clean Konelab cuvettes. Restart analysis.

5021 CUVETTE JAMMED IN LOADER

Possible causes

1. Cuvettes not properly placed in the loader.
   - Open the cover of the cuvette loader. Empty the loader manually. Refill it.

3. Damaged cuvette in the loader.
   - Remove damaged cuvette.

4. Damaged cuvette in the incubator.
   - Remove damaged cuvette. Refer to section 8.4.2.

5022 INSTRUMENT ADJUSTMENT FILE ERROR

Closes connection to the instrument.

Possible causes

Corrupted adjustment file.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

5023 NODE %u SENT WRONG DATA %u MEANS THE BOARD NUMBER

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

5024 INTERNAL PC IS OUT OF MEMORY

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

5025 TEMPERATURE OUT OF RANGE (SAMPLE REGISTER/ REAGENT REGISTER/ MEASUREMENT CHANNEL/ INCUBATOR/ ISE BLOCK/ SAMPLE CHANNEL/ REAGENT CHANNEL)

Possible causes

Broken thermistor / thermal resistor/ thermistor cable.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

5026 NODE %u SENT A WRONG MESSAGE - %u MEANS THE BOARD NUMBER

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

5027 NODE %u DID NOT BOOT - %u MEANS THE BOARD NUMBER

Closes connection to the instrument.

Reboot the instrument. Refer to section 8.4.1. If the problem persists for the same board call service.

5028 SAMPLE DISPENSER/ SAMPLE MIXER/ REAGENT DISPENSER/ REAGENT MIXER/ ISE DISPENSER/ MA DISPENSER/ MIXER/ KUSTI DISPENSER HIT AN OBSTACLE, CORRECTED AUTOMATICALLY

Automatically performed correction. This is seen when ‘Show all messages’ is on in the Messages window.

5029 NODE %u DID NOT RESPOND - %u MEANS THE BOARD NUMBER

Closes connection to the instrument.

Reboot the instrument. Refer to section 8.4.1. If the problem persists for the same board call service.

5035 SAMPLE DISPENSER/ SAMPLE MIXER/ REAGENT DISPENSER/ REAGENT MIXER/ ISE DISPENSER/ KUSTI DISPENSER INITIALIZATION FAILED

Possible causes

1. An obstacle detected.
   - Remove the obstacle. Perform water wash (F6 in the Instrument actions window) before continuing. Water wash must be definitely done when Konelab is connected to the automation conveyor, and KUSTI is in 'not in use' state. Press START to continue analysis.

2. Damaged opto / opto cable/ motor driving board
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5040 SAMPLE DILUTION VOLUME ERROR, DIL.RATIO %S

Test appears in the Main window to the Invalid tests list with the comment invalid parameter. The analyser is not able to perform the dilution defined by the user. Volume goes over the cell limit, 250 µl. Check the dilution ratios and dispensing volumes used in the test in the Test definition and Test flow windows. Refer first to the section 5.1.7. about dispensing.

5044 ISE/ SAMPLE/ REAGENT SYRINGE INIT FAILED

Possible causes

Too stiff mechanics or damaged opto / opto cable / motor driving board
– Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor. Press Start to continue analysis. If problem persists reboot the instrument. Refer to section 8.4.1. If this doesn't help, call service.

5045 INTERNAL SOFTWARE ERROR (INTERNAL PC)
5046 INTERNAL SOFTWARE ERROR (INTERNAL PC)

Software problem. Press Start to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.

Note that in Konelab 20XT and 20 there is no internal PC. This software error in Konelab 20XT and 20 means error in that part of workstation's software, which is controlling instrument.

5047 CUVETTE FETCH FAILED (%s, POS %u)
- %s means measuring, reagent or sample channel
- pos %u means the incubator position

This is seen when 'Show all messages' is on in the Messages window. No action is needed until the error message '1214 Exit failed. Remove cuvette from incubator (%s)' appears.

Possible causes

1. Damaged cuvette.
   - Remove damaged cuvette. Refer to section 8.4.2.

2. Hook in the cuvette arm is not ok.
   - Check the hook. Refer to section 8.4.2.

5048 REAGENT REGISTER/ SAMPLE REGISTER/ INCUBATOR POSITION CORRECTED AUTOMATICALLY

Automatically performed correction. This is seen when 'Show all messages' is on in the Messages window.

5049 REAGENT REGISTER/ SAMPLE REGISTER/ INCUBATOR FEEDBACK ERROR

Perform Start up to continue.

☞ Possible causes

1. Mechanical obstacle.
   - Check that the reagent register/ sample register/ incubator can move freely.
2. Too loose cogged belt or broken feedback sensor or damaged motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5058 ISE DISPENSER/ REAGENT DISPENSER/ SAMPLE DISPENSER/ DISPENSER POSITION CORRECTED AUTOMATICALLY

Automatically performed correction. This is seen when 'Show all messages' is on in the Messages window.

5059 ISE DISPENSER/ REAGENT DISPENSER/ SAMPLE DISPENSER/ DISPENSER FEEDBACK ERROR

☞ Possible causes

1. Mechanical obstacle.
   - Check that the dispenser can move freely.
   Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor.
2. Too loose cogged belt or broken feedback sensor or damaged motor driving board.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

5062 SAMPLE TO AIR BOUNDARY NOT FOUND (ISE)

The liquid detector in the ISE block does not find the liquid-air boundary.

Possible causes

1. Short ISE CAL1.
   - Change a new bag of ISE CAL1. Ask calibration in the Calibration/QC selection window and request 'Add ISE CAL1' in the Reagents window.
2. Loose contact between end slices and liquid detection wires.
   - Open the cover of ISE dispensing arm and ensure that the connections are tight.
3. Leakage or clotting in the needle or in the tube. Refer to section 8.4.4.
   - Locate the leakage or clotting and remove the problem.
4. Liquid detection is not working.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5063 CUVETTE SENSOR CALIBRATION FAILED (REAGENT/ SAMPLE CHANNEL)

Analysis can be continued.

Possible causes

Damaged cuvette in the incubator (in Konelab 60) or in the loader (in Konelab 30) or dirty or broken cuvette sensor.
- Perform Start up. If problem persists call service to check the situation.

5064 FAILED TO FETCH CUVETTE FROM LOADER

Possible causes

1. Cuvettes not properly placed in the loader.
   - Open the cover of cuvette loader. Empty the loader manually. Refill it.
2. Damaged cuvette in the loader.
   - Remove damaged cuvette.
3. Hook in the cuvette arm is not ok.
   - Check the hook. Refer to section 8.4.2.
4. Poor programmable adjustment or the wrong mechanical height of the cuvette feeder or the mechanics of the cuvette arm doesn't work properly.
   - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

5065 SYRINGES SHOULD BE ADJUSTED (ADJUSTMENT PROGRAM)

Select Adjustment program in the Instrument actions window and let the analyser perform 'Syringe zero position'. Adjustment is made automatically.

5066 WORKSTATION SENT WRONG DATA

Software problem. Press Start to continue.

5067	SAMPLE/ REAGENT DILUENT PUMP INIT FAILED
☞ Possible causes	Too stiff mechanics or damaged opto / opto cable / motor driving board. – Perform water wash (F6 in the Instrument actions window) before continuing. This must be definitely done when Konelab is connected to the automation conveyor. Press Start to continue analysis. If problem persists reboot the instrument. Refer to section 8.4.1. If this doesn't help, call service.

Concerning Konelab 60 and 60i

5068	NO CUVETTE FOR WATER BLANK
☞ Possible causes	Damaged cuvette in the incubator. – Perform Start up.

5999	INTERNAL PC ERROR MESSAGE (%u) - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3 ERROR MESSAGES COMING FROM THE INSTRUMENT'S NODES

8.3.3.1 BOOT - 6

%u means the board number

6001	BOOT %u ERROR: ROM CHECKSUM
6002	BOOT %u ERROR: RAM CHECKSUM
6003	BOOT %u ERROR: FILE CHECKSUM
6004	BOOT %u ERROR: UNABLE TO WRITE EEPROM
6005	BOOT %u ERROR: MCACK NOT RECEIVED
6006	BOOT %u ERROR: NOT IN CONNECTED MODE
6007	BOOT %u ERROR: ILLEGAL DOWNLOAD ADDRESS
6008	BOOT %u ERROR: UNEXPECTED START OF APPLICATION
6009	BOOT %u ERROR: UNKNOWN COMMAND

Closes connection to the instrument.

☞ Possible causes	Broken board. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

6999	BOOT NODE ERROR MESSAGE %u - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.2 MOTOR - 7

%u means the board number

7001 MOTOR %u ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

Possible causes: The board is in a wrong position or the board has been configured wrong
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

7002 MOTOR %u ERROR: WRONG ACTION
7003 MOTOR %u ERROR: WRONG COMMAND

Software problem. Press Start to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.

7004 MOTOR %u ERROR: AD CONVERTER

A/D converter is not working.

Possible causes: Broken board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

7005 MOTOR %u FEEDBACK ERROR: WRONG POSITION
7006 MOTOR %u FEEDBACK ERROR: DEVICE HAS BEEN MOVED

The user is warned that the motor has been driven to a wrong position or the device has been moved manually. Analysis continues.

7007 MOTOR %u OVER-CURRENT ERROR

Possible causes: Broken cable/ motor/ board
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

7008 MOTOR %u DECODE ERROR

Software problem. Press Start to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.

7024 MOTOR %u ERROR: ILLEGAL CONFIGURATION

Closes connection to the instrument.

Software problem. Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

7100 MOTOR %u ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

7999 MOTOR ERROR MESSAGE %u
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.3 PHOTO - 8

8001 PHOTOMETER ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

☞ Possible causes

The board is in a wrong position or the board has been configured wrong
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

8002 PHOTOMETER ERROR: WRONG COMMAND
8003 PHOTOMETER ERROR: AD CONVERTER NOT CALIBRATED

☞ Software problem. Perform Start up.

8004 PHOTOMETER ERROR: CHOPPER IS NOT MOVING
8005 PHOTOMETER ERROR: TOO LOW CHOPPER SPEED
8006 PHOTOMETER ERROR: TOO HIGH CHOPPER SPEED

☞ Possible causes

Broken cable in the chopper motor or the chopper motor doesn't work
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

8007 PHOTOMETER ERROR: CHOPPER NOT RUNNING

☞ Software problem. Perform Start up. If the problem persists reboot the instrument. Refer to section 8.4.1.

8008 PHOTOMETER ERROR: MEASUREMENT TIMEOUT

☞ Possible causes

Broken PHOTO board.
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

8009 PHOTOMETER ERROR: ILLEGAL PARAMETER

☞ Software problem. Perform Start up.

8011 PHOTOMETER ERROR: SUSPICIOUS SIGNAL GAIN
8012 PHOTOMETER ERROR: SUSPICIOUS REFERENCE GAIN

The adjustment of lamp voltage cannot be done in a certain wavelength.

☞ Possible causes

1. Wrongly installed lamp.
   - Check the installation. Refer to section 6.3.2.
2. Broken lamp.
   - Replace the lamp. Refer to section 6.3.2.
3. Broken PHOTSIG or PHOTREF or PHOTO boards or cables.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

8013 PHOTOMETER ERROR: ADBUSY-SIGNAL NOT FOUND
8014 PHOTOMETER ERROR: MEASUREMENT SYNC.

Possible causes

Broken PHOTO board.
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

8015 PHOTOMETER ERROR: LAMP IS OFF
8016 PHOTOMETER ERROR: DELAY NOT FOUND
8017 PHOTOMETER ERROR: SOFTWARE ERROR
8018 PHOTOMETER ERROR: CHOPPER CONTROL

Software problem. Reboot the instrument. Refer to section 8.4.1.

8019 PHOTOMETER ERROR: TOO LOW SIGNAL RESULT
8020 PHOTOMETER ERROR: TOO HIGH SIGNAL RESULT
8021 PHOTOMETER ERROR: TOO LOW REFERENCE RESULT
8022 PHOTOMETER ERROR: TOO HIGH REFERENCE RESULT

Possible causes

1. Wrongly installed lamp.
   - Check the installation. Refer to section 6.3.2.
2. Broken lamp.
   - Replace the lamp. Refer to section 6.3.2.
3. Broken PHOTSIG or PHOTREF or PHOTO boards or cables.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

8023 PHOTOMETER WARNING: NO SIGNAL

The warning that no signal detected for some request, e.g. the absorbance is so high. The result is turned to manual acceptance.

8024 PHOTOMETER ERROR: ILLEGAL CONFIGURATION

Software problem. Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

8025 PHOTOMETER ERROR: ILLEGAL COMMAND

Software problem. Perform Start up.

8026 PHOTOMETER ERROR: INNER AD CONVERTER

Possible causes

The PHOTO board is broken.
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

8027 PHOTOMETER LAMP IS BROKEN

Replace the lamp. Refer to section 6.3.2.

8028 PHOTOMETER ERROR: NEGATIVE REFERENCE RESULT

Possible causes

1. Wrongly installed lamp.
   - Check the installation. Refer to section 6.3.2.
2. Broken lamp.
   - Replace the lamp. Refer to section 6.3.2.
3. Broken PHOTSIG or PHOTREF or PHOTO boards or cables.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

8100 PHOTOMETER ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

8999 PHOTOMETER ERROR MESSAGE (%u) - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.4 ISE - 9

9001 ISE-NODE ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

Possible causes

The board is in a wrong position or the board has been configured wrong.
- Reboot the instrument. Refer to section 8.4.1.
  If problem persists call service.

9003 ISE ERROR: TOO LOW DVM DETECTED (%s)
9004 ISE ERROR: TOO HIGH DVM DETECTED (%s)
- %s MEANS THE ELECTRODE'S NAME

Possible causes

1. Loose contact between an electrode pin and an electrode cap.
- Press from the sides of the cap of the signal wire.

2. Dirty electrode.
- Wash with washing solution in Stand by and give ISE Prime solution in Start up.

3. Aged electrode.
- Change the electrode. Refer to section 6.3.8.

4. Poisoned electrode.
- Wash extensively with serum.

5. If all slices give too low or too high DVM most probably filling solution is missing from the reference electrode.
- Fill the reference electrode. Check the electrode pin and change if needed. Refer to section 9.6.2.

6. Damaged reference electrode (all slices give too low or too high DVM).
- Change a new reference electrode. Refer to section 6.3.8.

7. Damaged ISEAMP board or cable.
- Reboot the instrument. Refer to section 8.4.1.
  If problem persists call service.

9005 ISE-NODE ERROR: MEASUREMENT TIMEOUT

Possible causes

Electronic or software problem.
- When 'Running' message has disappeared, press START to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.
In case rebooting is not helping call service.

9006 ISE-NODE ERROR: NO IONS CONFIGURED

Software problem. Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

9007 ISE-NODE ERROR: LIQUID DETECTOR NOT RUNNING

Software problem. Reboot the instrument. Refer to section 8.4.1.

9008 ISE-NODE ERROR: LIQUID DETECTOR TIMEOUT

Possible causes

1. Loose contact between an electrode pin and an electrode cap.
- Press from the sides of the cap of the signal wire.

2. Dirty electrode.
- Wash with washing solution in Stand by and give ISE Prime solution in Start up.

3. Aged electrode.
- Change the electrode. Refer to section 6.3.8.

4. Poisoned electrode.
- Wash extensively with serum.

5. Filling solution is missing from the reference electrode.
- Fill the reference electrode. Check the electrode pin and change if needed. Refer to section 9.6.2.

6. Damaged reference electrode.
- Change a new reference electrode. Refer to section 6.3.8.

7. Damaged ISEAMP/ ISE board or cable.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

9010 ISE-NODE ERROR: MEASUREMENT TIMEOUT

Possible causes

Electronic or software problem.
- When 'Running' message has disappeared, press START to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.
In case rebooting is not helping call service.

9011 ISE-NODE ERROR: WRONG COMMAND
9012 ISE-NODE ERROR: ILLEGAL PARAMETER

Software problem. Perform Start up. If the problem persists reboot the instrument. Refer to section 8.4.1.

9013 ISE-NODE ERROR: SELFTEST; ISE AD GROUND
9014 ISE-NODE ERROR: SELFTEST; ISE AD REFERENCE
9015 ISE-NODE ERROR: SELFTEST; LIQUID DETECTOR
9016 ISE-NODE ERROR: SELFTEST; LIQUID DETECTOR

Possible causes

Damaged ISEAMP/ ISE board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

9024 ISE-NODE ERROR: ILLEGAL CONFIGURATION

Software problem. Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

9100 ISE-NODE ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

9999 ISE-NODE ERROR MESSAGE (%u)
-%u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.5 INOUT - 10

%u means the board number

10 001 IO-NODE %u ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

☞ Possible causes

The board is in a wrong position or the board has been configured wrong
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

10 002 %s COMMUNICATION ERROR
10 003 %s TIMEOUT
10 004 %s COMMUNICATION ERROR

☞ Possible causes

The barcode reader is broken or damaged cable connection or cable or IO board
– Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

10 006 IO-NODE %u ERROR: BARCODE READER CONFIGURATION

☞ Software problem. Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

10 007 IO-NODE %u ERROR: ILLEGAL PARAMETER

☞ Software problem. Press Start to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.

10 008 IO-NODE %u ERROR: SENSOR SELFTEST

Some sensor is giving a poor signal for a moment.

☞ Possible causes

Software problem.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

10 009 IO-NODE %u ERROR: WRONG COMMAND

☞ Software problem. Press Start to continue. If the problem persists reboot the instrument. Refer to section 8.4.1.

10 010 IO-NODE %u ERROR: AD CONVERTER TIMEOUT

☞ Possible causes

1. Software/ electronic problem.
   - Reboot the instrument. Refer to section 8.4.1.
   If problem persists call service.

10 024 IO-NODE %u ERROR: ILLEGAL CONFIGURATION

☞ Software problem. Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

10 100 IO-NODE %u ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

10 999 IO-NODE ERROR MESSAGE (%u)
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.6 TEMP - 11

%u means the board number

11 001 TEMP-NODE %u ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

Possible causes

The board is in a wrong position or the board has been configured wrong.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 002 TEMP-NODE %u ERROR: INNER AD CONVERTER

Possible causes

The TEMP board is broken.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 003 TEMP-NODE %u ERROR: TOO LOW SUPPLY VOLTAGE
11 004 TEMP-NODE %u ERROR: TOO HIGH SUPPLY VOLTAGE

Possible causes

1. A power failure has occurred and the instrument is working with batteries. The voltage of batteries is too low.
   – Wait until the mains have returned. Reboot the instrument. Batteries are charged automatically.

2. An accidental disturbance in the supply voltage of instrument.
   – Reboot the instrument. Refer to section 8.4.1.

11 005 TEMP-NODE %u ERROR: FUSE BROKEN

Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 006 HEATING RESISTOR SHORTCIRCUIT (%s)
11 007 HEATING RESISTOR SHORTCIRCUIT (%s)
- %s MEANS THE POSITION, E.G. INCUBATOR

Possible causes

Broken resistor or cable.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 008 HEATING RESISTOR WIRE BROKEN (%s)
11 009 HEATING RESISTOR WIRE BROKEN (%s)
%s MEANS THE POSITION, E.G. INCUBATOR

Possible causes

Broken resistor or cable.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 010 TEMP-NODE %u ERROR: THERMISTOR VOLTAGES

It is usual that also the error message 11 005 is occurring at the same time.

Possible causes

The thermistor short-circuits.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 011 TEMP-NODE %u ERROR: WRONG COMMAND
11 012 TEMP-NODE %u ERROR: ILLEGAL PARAMETER

Software problem. Perform Start up. If the problem persists reboot the instrument. Refer to section 8.4.1.

11 013 HEATING RESISTOR OVERCURRENT (%s)
11 014 HEATING RESISTOR OVERCURRENT (%s)
- %s MEANS THE POSITION, E.G. INCUBATOR

Possible causes

Broken resistor or cable.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 015 TEMP-NODE %u: UNKNOWN ERROR

- Software problem. Analysis continues.

11 016 THERMISTOR ERROR (%s)
11 017 THERMISTOR ERROR (%s)
11 018 THERMISTOR ERROR (%s)
11 019 THERMISTOR ERROR (%s)
11 020 THERMISTOR ERROR (%s)
11 021 THERMISTOR ERROR (%s)
- %s MEANS THE POSITION, E.G. INCUBATOR

Possible causes

The thermistor wire is broken.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 024 TEMP-NODE %u ERROR: ILLEGAL CONFIGURATION

Software problem. Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 025 TEMP-NODE %u ERROR: AD CONVERTER ERROR
11 026 TEMP-NODE %u ERROR: AD CONVERTER ERROR
11 027 TEMP-NODE %u ERROR: AD CONVERTER ERROR

Possible causes

Damaged TEMP board.
- Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

11 100 TEMP-NODE %u ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

11 999 TEMP-NODE ERROR MESSAGE (%u)
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.3.7 POWCAN - 12

12 001 POWCAN-NODE ERROR: INCORRECT NODE TYPE

Closes connection to the instrument.

Possible causes	The board is in a wrong position or the board has been configured wrong - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 002 POWCAN-NODE ERROR: AD CONVERTER NOT RUNNING
12 003 POWCAN-NODE ERROR: AD CONVERTER TIMEOUT

Possible causes	Software/ electronic problem. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 004 POWCAN-NODE ERROR: 2.5V REF RANGE

Possible causes	The reference voltage of the POWCAN board is damaged. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 005 POWCAN-NODE ERROR: COOLING FUSE BROKEN

Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 006 THERMISTOR SHORTCIRCUIT (%s)
12 007 THERMISTOR WIRE BROKEN (%s)
%s MEANS COOLING OBJECT: SAMPLE OR REAGENT DISK

Possible causes	Broken thermistor or cable. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 008 PELTIER OVERCURRENT (%s)
%s MEANS COOLING OBJECT: SAMPLE OR REAGENT DISK

Possible causes	Broken Peltier or cable. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 009 POWCAN-NODE ERROR: BATTERY LOADING

Possible causes	Damaged cables in the battery or damaged POWCAN board. - Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 011 POWCAN-NODE ERROR: WRONG COMMAND
12 012 POWCAN-NODE ERROR: ILLEGAL PARAMETER

Software problem. Perform Start up. If the problem persists reboot the instrument. Refer to section 8.4.1.

12 013 POWCAN-NODE ERROR: CAN-BUS VOLTAGE
12 014 POWCAN-NODE ERROR: CAN-BUS VOLTAGE

Warning about a voltage error in the CAN bus. Reboot the instrument. Refer to section 8.4.1. If problem persists call service.

12 015 BATTERY VOLTAGE IS TOO LOW

Possible causes

A power failure has occurred and the instrument is working with batteries. The voltage of batteries is too low. Analysis is stopped in a controlled manner.
- Wait until the mains have returned. Reboot the instrument. Refer to section 8.4.1. Batteries are charged automatically.

12 016 PELTIER WIRE BROKEN

Possible causes

Broken Peltier.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 017 POWCAN-NODE ERROR: POWFAIL-SIGNAL IS ACTIVE

Wrong information of power failure.

Possible causes

Loose cable connection/ broken POWCAN board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 018 POWCAN-NODE ERROR: RELAY CONTACT IS BROKEN

Possible causes

Relay contact of battery is broken.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 019 POWCAN-NODE ERROR: BATTERY FUSE OR CABLE IS BROKEN

Possible causes

Battery fuse or cable is broken.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 020 - 12 021 POWCAN-NODE ERROR: BATTERY CHARGING DOESN'T WORK

Possible causes

Batteries are out of condition/ broken POWCAN board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 022 POWCAN-NODE ERROR: BATTERY IS BROKEN

Possible causes

Batteries are out of condition/ broken POWCAN board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 023 POWCAN-NODE ERROR: -5V VOLTAGE IS TOO LOW

Possible causes

Broken cable/ POWCAN board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 024 POWCAN-NODE ERROR: ILLEGAL CONFIGURATION

Software problem. Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 025 POWCAN-NODE ERROR: +12V VOLTAGE IS TOO LOW

Possible causes

Broken cable/ POWCAN board.
- Reboot the instrument. Refer to section 8.4.1.
If problem persists call service.

12 026 POWER FAILURE. BATTERIES ARE SWITCHED ON

- For the user information: Power failure has started and batteries have been switched on.

12 027 POWER FAILURE IS OVER

- For the user information: Power failure is over.

12 100 POWCAN-NODE ERROR: CAN MESSAGE OVERFLOW

Software problem. Press Start to continue. If problem persists reboot the instrument. Refer to section 8.4.1.

12 999 POWCAN-NODE ERROR MESSAGE (%u) - %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.3.4 ERROR MESSAGES COMING FROM REPORTS (13 - Report)

13 032 WRONG DATA FROM AN OTHER PROCESS (REPORT)

☞ Internal software problem in the database. If the problem persists restart the workstation and reboot the instrument. Refer to section 8.4.1.

13 601 ERROR WHEN DOING DATABASE OPERATION (REPORT)

☞ Warning about internal software problem in the database. Analysis continues. If the problem persists restart the workstation and reboot the instrument. Refer to section 8.4.1.

13 602 COMMAND BUFFER ERROR (REPORT)
13 603 SAMPLE BUFFER ERROR (REPORT)
13 604 PATIENT BUFFER ERROR (REPORT)

☞ Software problem. If the problem persists restart the workstation and reboot the instrument. Refer to section 8.4.1.

13 605 ERROR IN REPORT.INI FILE

☞ Some problem in Special report format. Refer to section 3.11. Report formats. Check your own report format, with F1 you can set all to default format and start to format the report again.

13606 NO PRINTER INSTALLED

Warning during switching on, that the printer drivers are missing.

☞ Install the printer when analysing is not going on.

13 999 REPORT ERROR MESSAGE (%u)
- %u MEANS THE ERROR NUMBER

- Software problem. Analysis continues.

8.4 REMEDY PROCEDURES

8.4.1 RESTARTING THE WORKSTATION AND REBOOTING THE INSTRUMENT

8.4.1.1 To restart the workstation

☞ Exit from the Konelab program in the Management window with F8/F3.

☞ Shut down the computer (the button Start: Shut down in the left corner of the window).

☞ Restart the computer.

☞ Start the Konelab program: Start: Programs: click the konelab icon.

8.4.1.2 To reboot the instrument

☞ Switch off the mains by turning the mains key to the OFF position at the rear of the analyser.

☞ Switch on the analyser.

Konelab 60 or KUSTI equipped with the low current switch

Switching off

In case you have Konelab 60 or KUSTI and you cannot reach the main power switch at rear of the analyser, open the left front door and locate the low current switch, turn it in the stand by setting  and unplug the mains cable to turn the power totally off.

When the low current switch is in the stand by setting, only the boards of analyser and the internal PC are powered off.

– If you take the mains cable off when the low current switch is on, the back-up batteries of the instrument are turned on.

WARNING: The low current switch does not turn power totally off.

You can boot the internal PC by turning the low current switch in the stand by setting and waiting at least one minute before turning it on.

Switching on

With Konelab 60 or KUSTI, open the left front door, locate the low current switch, and turn it ON (I). To get the analyser working, both the low current switch and the main power switch at the rear of the analyser must be on.

8.4.2 REMOVING A CUVETTE FROM THE INCUBATOR

Figure 8-2: When removing cuvettes from the incubator in Konelab 60, open the whole top cover and support it with a bearing rod. In Konelab 30, 20XT and 20 is only necessary to open the upper cover.

☞ Wait until analysis is complete. With Konelab 60 and 60i select F7, Manual cuvette exit in the Instrument actions window to remove the cuvette to the hole in incubator's wall. Open the cover of the analyser. Refer to Figure 8-2.

☞ In Konelab 30, 30i, 20XT, 20XTi, 20 and 20i remove the incubator cover screws. Remove a cuvette. There are springs in the separation walls of the incubator slots. Pressing the round end of the spring may help lifting the cuvette from the incubator.

In Konelab 60 and 60i there is no need to open the incubator's covers because the cuvette is directed to the hole in the incubator's wall. Remove a cuvette.

☞ Check the hook of the cuvette arm for visible damage or obstructions.

☞ Reattach the covers of the incubator in Konelab 30, 30i, 20XT, 20XTi, 20 and 20i.

☞ Close the cover of the analyser.

8.4.3 INSTALLING THE SAMPLE / REAGENT DISK

8.4.3.1 Konelab 60 and 30

Be careful the dispenser is moving when you touch the covers! Wait until the dispenser is back in its position.

SAMPLE DISK

To detach the disk:

☞ Take the cal/ctrl sample disk cover away and lift the red segment cover off.

☞ Lift the segment disk up and out.

To attach the disk:

☞ Locate the segment disk into the disk compartment so that the positioning pin aligns with the hole in the middle of the segment disk.

☞ Open the STAT insert cover, attach the segment cover in its position, close the STAT insert cover.

☞ Set the cal/ctrl disk cover in its position.

Be careful the dispenser is moving when you touch the cover! Wait until the dispenser is back in its position.

REAGENT DISK

To detach the disk:

☞ Take the cover away.

☞ Lift the reagent disk up.

To attach the disk:

☞ Attach the reagent disk into the disk compartment so that the positioning pin aligns with the hole in the middle of the reagent disk.

☞ Open the reagent insert cover, attach the reagent cover in its position, close the reagent insert cover.

8.4.3.2 Konelab 20XT and 20

REAGENT DISK

To detach the reagent disk:

☞ Take the yellow cover away.

☞ Lift the reagent disk up with the handle.

To attach the reagent disk:

☞ Locate the reagent disk into the disk compartment so that the positioning pin aligns with the hole in the middle of the reagent disk.

☞ Open the reagent insert cover, attach the reagent cover in its position, close the reagent insert cover.

Figure 8-3: When detaching the sample disk in Konelab 20XT and 20, open the whole dispensing cover. There is a bearing rod to keep the cover up.

SAMPLE DISK

To detach the sample disk:

☞ Open the cover of the analyser. Refer to Figure 8-3. Take the yellow reagent cover off and lift the reagent disk with the handle.

☞ In the middle of the sample disk there are six screws to open.

To attach the sample disk:

☞ Replace the six screws in the middle of the sample disk.

☞ Replace the reagent disk so that the positioning pin aligns with the hole in the middle of the reagent disk. Open the reagent insert cover, attach the reagent cover in its position, close the reagent insert cover.

☞ Replace the analyser cover.

8.4.4 CLOTTING

8.4.4.1 CLOT IN THE NEEDLE

☞ To remove a clot, push a thin piece of metal wire through the needle.

☞ Perform Stand by to wash the needle.

If the problem persists change the needle. The needle packet includes also the needle tube. Refer to section 6.3.5.

8.4.4.2 CLOT IN THE ISE TUBE

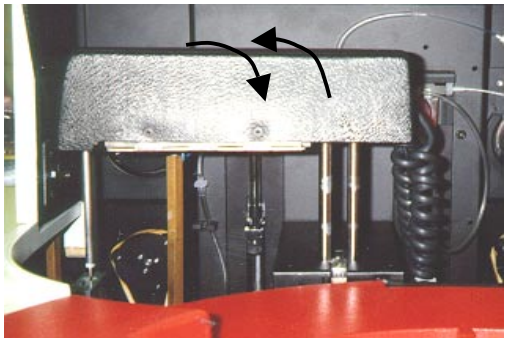


Figure 8-4: Cover of the ISE dispenser arm

☞ Open the cover of the ISE dispenser arm. The cover is hinged, so it is easy to turn open.

☞ Check visually the needle tube. If there is a clot detach the needle tube from the end slice of the ISE block and the other end of the tube from the needle. Rotate the tube in the fingers and press gently. If necessary, squeeze some ISE CAL1 with a syringe into the tube. Check that the clot disappears.

☞ Connect the tube back: the other end of the tube to the end slice of the ISE block and the other end of the tube to the end of the needle.

8.4.5 RECOVERING FROM Konelab DATABASE FAILURE

Symptoms of possible Konelab database failure:

After starting the Konelab program, DB error messages in the main window of Konelab (for example: ”No test data (RH)”).

”DB error” dialogs when entering for example the Test definition window, no data from DB displayed.

Repeating Konelab program crashes or malfunction (this does not always imply a DB failure)

DB backup should be done each time after changing test parameters or calibrating to prevent loss of entered data in case of a DB failure.
DB backups done with previous Konelab software versions are not compatible with the current version. Take a DB backup after software update. (This applies only to major version updates like 4.0x -> 5.0x, 5.0x -> 6.0x)
Konelab DB can NOT be restored by only copying the database file to the correct location. Use restore procedures located in the Konelab Database Management folder. Note that Konelab program must NOT be running while performing these database procedures.

☞ Follow the list until the database works:

1. Restore the latest automatic DB backup. The Konelab DB backup is done automatically every time the user selects ”Clear daily files”. This will mean loss of data changed after previous ”Clear daily files”.
- Exit the Konelab program.
- Select ”Rescue saved DB” from Start – Programs – Konelab Database Management.
- Restart the Konelab program.

2. Restore backup done by ”Save DB” or ”Save DB to CD” or ”Save DB to diskette”.

”Restore saved DB” or ”Restore DB from CD” or ”Restore from diskette” (See previous)

3. Reinstall Konelab DB files and Konelab default database.
- ”Restore Basic DB” (See previous)

If the DB works after this try again to restore some backup (see points 1 and 2).

4. Reinstall the Konelab software from CD.

If you modify the workstation hostname

Hostname of the workstation is included in the DB configuration so it cannot be changed without taking care of the current database.

If you want for some special reason to modify the hostname:

1. Save the DB before any modifications.

2. Modify the hostname.

3. Run "Restore Basic DB".

4. Restore the saved DB.

8.4.6 DISPENSER/ MIXER POSITIONS OF Konelab 20, 20XT, 30 AND 60

The parameter #1 in error messages 'xx dispenser/ mixer hit an obstacle' / 'xx position corrected automatically' / 'xx feedback error' is the dispenser/mixer position as follows:

0. Phi drive level position
1. Resting position
2. Wash position
3. Extra wash position
4. Waste position
5. Wash position on reagent side
6. Extra wash position on reagent side
7. Waste position on reagent side
8. Needle check position
9. Needle manual wash position
10. Outer segment ring, sample cup
11. Inner segment ring, sample cup
12. Stat ring, sample cup
13. Std/ctrl ring
14. Outer segment ring, sample tube
15. Inner segment ring, sample tube
16. Stat ring, sample tube
17. Reagent plate position
18. Cuvette position 1
19. Cuvette position 2
20. Cuvette position 3
21. Cuvette position 4
22. Cuvette position 5
23. Cuvette position 6
24. Cuvette position 7
25. Cuvette position 8
26. Cuvette position 9
27. Cuvette position 10
28. Cuvette position 11
29. Cuvette position 12
30. Cuvette position 1 in reagent dispensing
31. Cuvette position 2 in reagent dispensing
32. Cuvette position 3 in reagent dispensing
33. Cuvette position 4 in reagent dispensing
34. Cuvette position 5 in reagent dispensing
35. Cuvette position 6 in reagent dispensing
36. Cuvette position 7 in reagent dispensing
37. Cuvette position 8 in reagent dispensing
38. Cuvette position 9 in reagent dispensing
39. Cuvette position 10 in reagent dispensing
40. Cuvette position 11 in reagent dispensing
41. Cuvette position 12 in reagent dispensing
42. KUSTI segment ring 1 (outer ring)
43. KUSTI segment ring 2
44. KUSTI segment ring 3
45. KUSTI segment ring 4
46. KUSTI segment ring 5 (inner ring)
47. KUSTI sample transfer line position

9. INSTALLATION INSTRUCTIONS

9.1 UNPACKING

Konelab and its accessories are shipped in two containers; one includes the analyzer, the other PC. Table for the PC must be ordered separately.

⇒ Check the package from the outside for possible damages during transportation. Contact your agent in case there are any damages.

Trained Konelab or Konelab's distributor personnel should unpack the analyzer.

⇒ Check the contents of the package and the shipping list.

⇒ Check the equipment according to the reception reports.

For safe operation, after unpacking:

All electrical equipment is potentially dangerous. Never remove any component, or cover from the analyser, unless directed to do so.

☞ Close the left panel (seen from the front of the analyzer) with a screw so that the user cannot open it. The screw must be fastened from down under (see figure 9-1).

☞ Fix the under front panels with screws. When you open the cuvette waste box you can see the screw positions.

Due to the analyzer packaging, the side and under front panels cannot be attached at the factory.

Figure 9-1: Close the left side of the analyzers for the electricity safe, and fix the under front panels with screws.

9.2 LOCATION

Always disconnect the electrical supply before removing the analyzer panels. Voltage present in the analyzer may produce a severe, perhaps even a fatal electrical shock.

The location of the instrument should satisfy the following criteria:

Dimensions and weight of the analyzer:

	Konelab 60/60i	Konelab 30/30i	Konelab 20XT/20XTi	Konelab 20/20i
Width	150 cm	120 cm	80 cm	80 cm
Depth	79 cm	79 cm	79 cm	79 cm
Height	115 cm	115 cm	115 cm	115 cm
Weight	250 kg	200 kg	142 kg	130 kg

It is necessary to leave a space of 20 cm between the rear of the analyzer and the wall.

Only one power connection and connection to the workstation is needed. Any other connections, e.g. water, draining, air or gas pressure, are unnecessary. Refer to Figure 9-2.

This analyzer is designed to be earthed through the mains electrical lead for safe operation. To ensure continuous safety of operating personnel, the analyzer must be connected to an electrical outlet that has an effective ground connection. If you are in any doubt as to the safety of your electrical supply system, consult a qualified electrician.

Power requirements:

Konelab 60i	Konelab 30i	Konelab 20XTi	Konelab 20i
100 - 240 V ± 10 % 50 - 60 Hz ± 5 % 1200 W	100 - 230 V ± 10 % 50 - 60 Hz ± 5 % 700 W	100 - 240 V ± 10 % 50 - 60 Hz ± 5 % 350 W	100 - 240 V ± 10 % 50 - 60 Hz ± 5 % 350 W

Konelab 60/60i and 30/30i have power failure security (battery back-up facility).

Operating conditions:

- Ambient temperature 15-32 °C

- 40-85% humidity (non condensing)

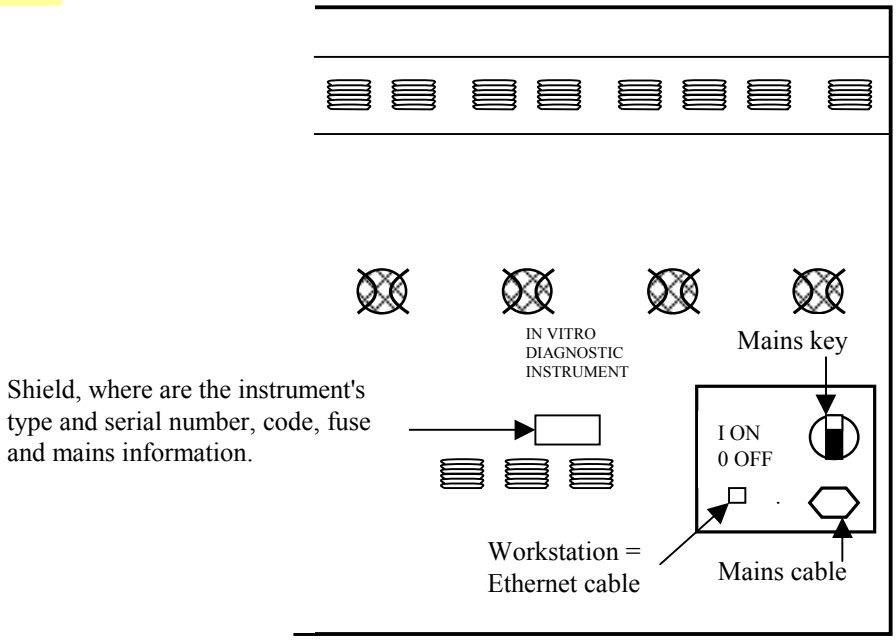


Figure 9-2: The rear of the instrument

9.3 SET UP

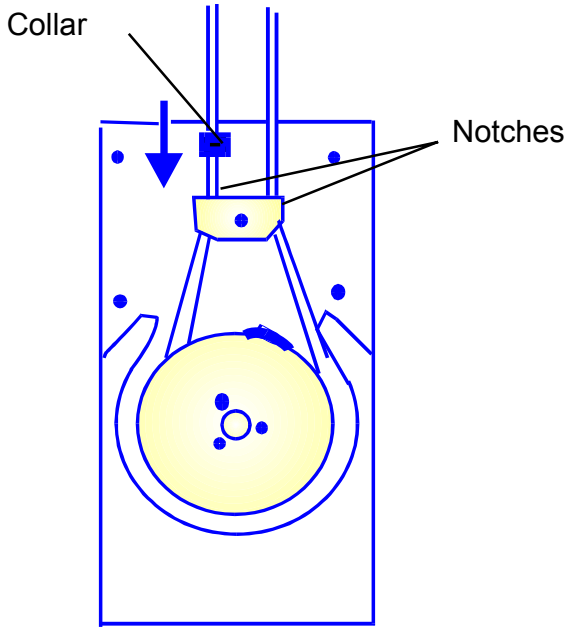
Before connecting the main power plug, do the following:

⇒ Visually inspect the instrument from the outside and inside for shipping damages.

⇒ Study user instructions carefully.

☞ Remove the cushions of foamed plastic placed under dispensers and mixers.

Install pump tubes in Konelab 60 and 30



- Attach the tube to fittings.

- Set the tube to the steering roller and rotate the pump clockwise. Let the rotation of the pump feed the tube, do not stretch it.

- Lift the collar into notches.

- Check that the tube is on every steering roller.

- Rotate the pump to check the water feed.

Figure 9-3: Installation of the pump tube

Install the cuvette waste compartment

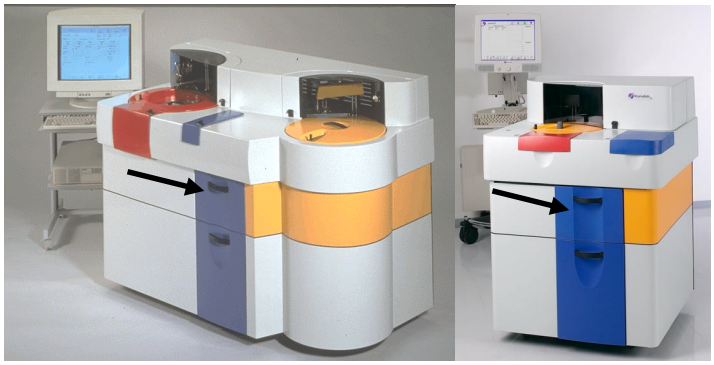
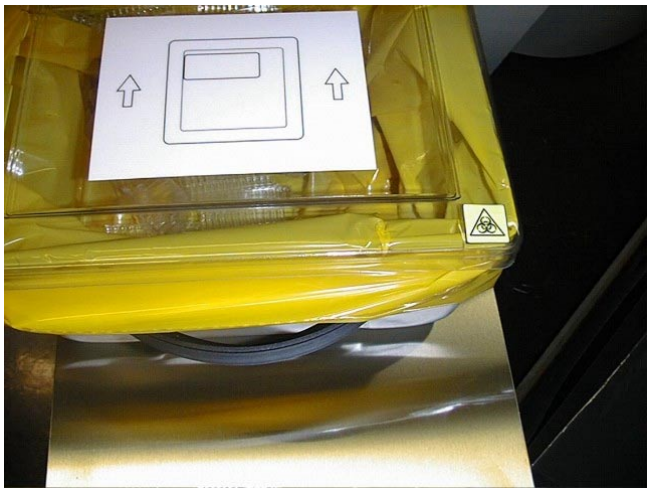


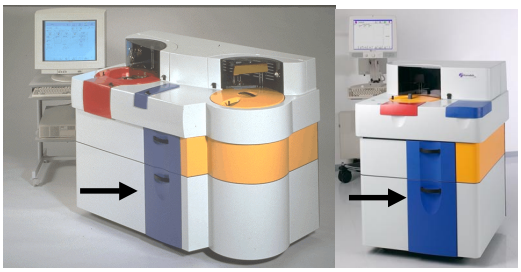
Figure 9-4: The cuvette waste compartment located in the upper drawer of the analyzer stand.

☞ Ensure that there is a plastic bag in the cuvette waste box.

Place the cover of cuvette waste box so that arrows show away from you.



Install distilled water and wastewater containers



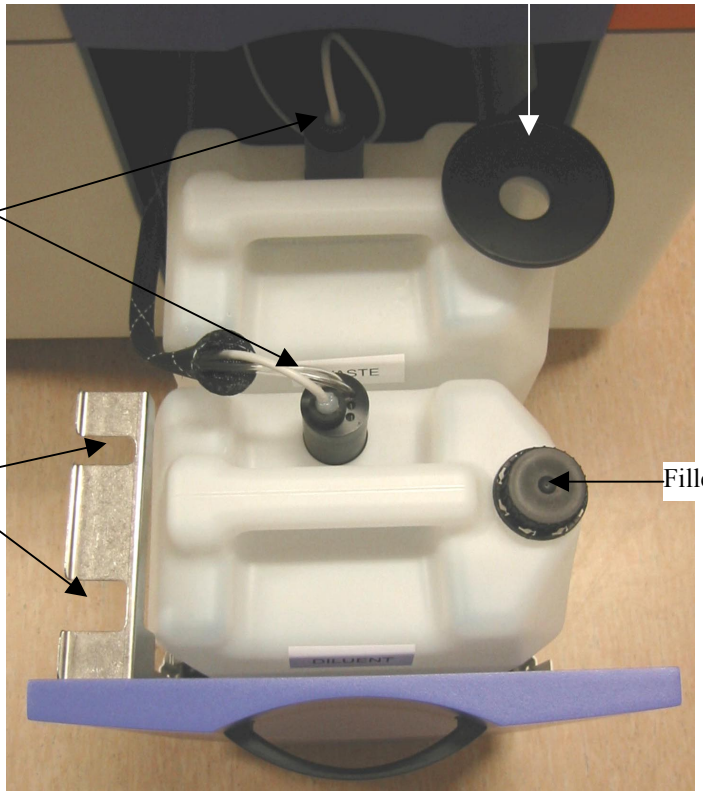


Figure 9-5: The distilled and the wastewater containers are located in the lower drawer of the stand.

☞ Insert the funnel into the wastewater container.

☞ Add distilled water to the distilled water container and install liquid sensors. Purified water, water type 1 is preferred. See requirements under.

☞ Close the drawer slowly and simultaneously check that the funnel is pushing the drop collector to the side under the analyzer, above the drawer.

Requirements of Type 1 water:

>10 MΩcm, 0.2 µm filtering, <170 ppm TDS (=total dissolved solids), <10 cfu/ml

or

Resistivity:	5 – 15 MΩcm (15 MΩcm) setpoint	**TOC**	<50 ppb
Particle-free	>0.22 µm	**TDS**	<50 ppb
Silicates	<10 ppb	**Heavy metals**	<1 ppb
Microorganisms	< 10 cfu/ml		

Assemble your PC

☞ Connect the monitor, keyboard, mouse, printer and the workstation and connect the mains lead to the power supply.

Requirements for PC

Processor	Intel Pentium 4, minimum 2.4 GHz
Chassis	Dell OptiPlex GX260 SD Chassis
Memory	256 Mb (1x256) NON ECC Memory
Monitor	Dell 15” E151FP Flat Panel
Floppy drive	3.5" 1.44 Mb Floppy drive
Keyboard	Dell Slimline 105-key (quiet-key)
Mouse	Microsoft PS/2 IntelliMouse
Hard drive	Minimum 20 Gb (7,200rpm) IDE Hard drive
Cd R/W	48x CD Read/Write drive
Speakers	Internal Dell Business Audio Speaker
Operating system	Windows XP Pro with media, NTFS
Operating System Media Kits	Documentation and Recovery CD
Accessories1	Second Serial Port adapter card
Graphics Card	Integrated graphics

How to format the CD-R disc

1) Insert CD-R disc to the CD-Write drive.
2) Double-click the CD-icon in the right corner of the display beside the time.
   – Next
   – Next
   – Finish, CD is formatted
   – Ok.
3) Press the Eject button locating in the CD drive.
4) Finish, the CD drive opens.

Connect cables, switch mains on (Refer to Figure 9-2)

☞ Connect the Ethernet cable to the rear of the instrument.

☞ Connect the mains cable of the instrument to the power supply.

WARNING: The low current switch does not turn power totally off. When the low current switch is in the stand by setting, only the boards of analyzer and the internal PC are power off. To switch off the analyzer, refer to section 2.6.

☞ Switch on the mains of the PC and monitor and log in (press Ctrl - Alt - Del simultaneously and enter password “Konelab”). Check that the domain name is Konelab. Start the Konelab program: click the icon.

☞ Switch on the mains of Konelab (the mains key is at the rear of the instrument) and wait until the Konelab main window is seen. Refer to section 1.3.

☞ In case you have Konelab 60 or KUSTI, open the left front door where is the low current switch, and turn it ON (I). To get the analyzer working, both the low current switch and the main power switch at the rear of the analyzer must be on.

Fill the cuvette loader

☞ Install one pack of cuvettes. Refer to section 2.2.4.

Contact information

☞ Write the contact information. Refer to section 10.2.6.

Changing maintenance interval

The Maintenance window provides a check table for maintenance procedures. The default intervals are for two preventive maintenance (=PM) per year.

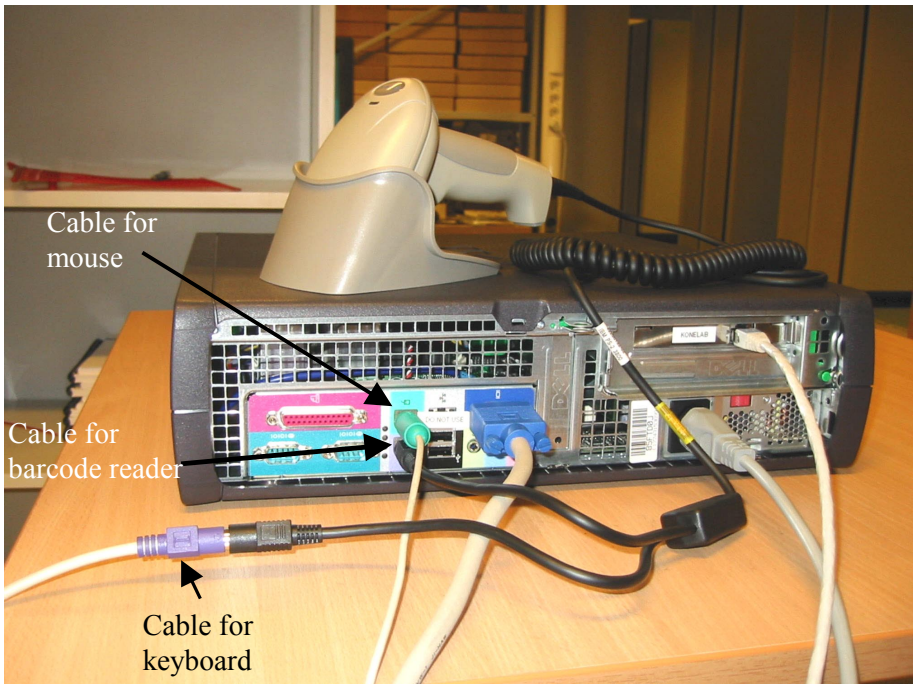
☞ If PM is done one time a year, the interval should be changed as 360 days for all maintenance actions.

☞ If PM is done four times per year, the interval should be halved (i.e. as 90 days and as 180 days) for all maintenance actions.

To change the interval, refer to section 6.1. and to see the recommended preventive maintenance intervals, refer to section 6.3.

9.4 EXTERNAL BARCODE READER AND PRINTER

9.4.1 HOW TO CONNECT AN EXTERNAL BARCODE READER FOR KONELAB 20XT AND 20



9.4.2 MINIMUM REQUIREMENTS FOR A PRINTER

The acceptable type of printer depends on what printer drivers are found in Windows NT PC connected to Konelab. The connection should be a parallel port using the direct RS-232C interface.

9.4.3 HOW TO INSTALL A PRINTER

☞ Select Start: Settings: Control Panel: Printers: Add Printer <next>
My computer (Local printer) <next>
Select a port, e.g. LPT1 <next>
Select the manufacturer and the printer type or copy from Disk, e.g. Epson LX-300 <next> <next>
Not shared <next>
Test page Yes/No
Now the printer has been installed.

☞ Printers –menu is seen. Activate the new printer and select:

File: Document defaults:
- Check Paper size, e.g. for LX-300 fan fold 8.5 x 12 in.
– Check Paper source, e.g. tractor feed

File: Properties:
- Check Device settings
  - e.g. Change Tractor feed setting to fan fold 8.5 x 12 in for LX-300

File: Set As Default.

9.5 CONFIGURATION

To make the configuration of the instrument, refer to section 3.8.

9.6 ISE Set Up

9.6.1 MATERIAL

Konelab micro volume electrodes are ready-to-use. The reference electrode contains filling solution bag, which has to be attached to the side port of the electrode before use.

They are coded with colour spots. The used colours are following:

Na - yellow	**K - red**	**Ca - green**
Cl - blue	**pH - white**	**Li - grey**
Ref – brown		

For sample detection:

End slice - in:	**Grounding wire - black**
End slice - out:	**Impedance - transparent**

The electrode block is built up of 3 (K^+, Na^+ and Cl^-) or alternatively 6 (optional Ca^{2+}, Li^+, pH; in Konelab 20XT and 20 only Li^+ is optional) micro volume ion-selective electrodes, one reference electrode and two additional end slices for grounding and sample detection. The electrodes, as well as the end slices, are connected together using small positioning dowel pins.

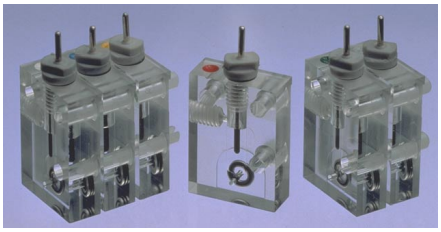


Figure 9-6: Maintenance-free electrode block with 6 ion-selective electrodes

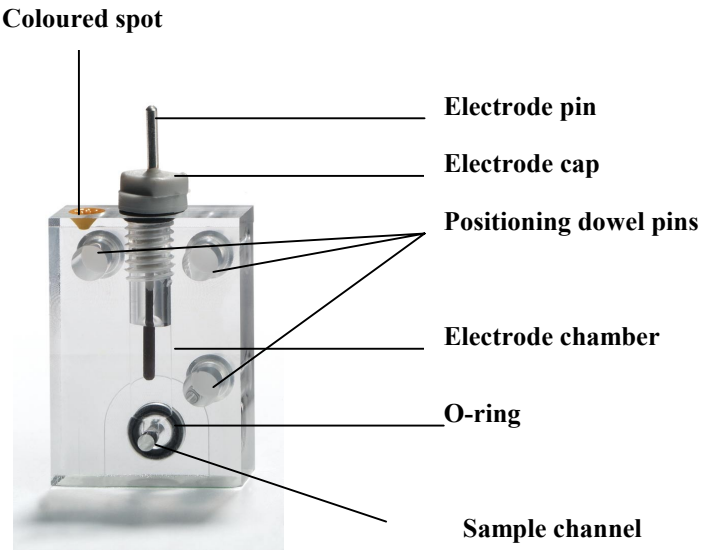


Figure 9-7: A single electrode

9.6.2 INSTALLATION

MAINTENANCE FREE ELECTRODE

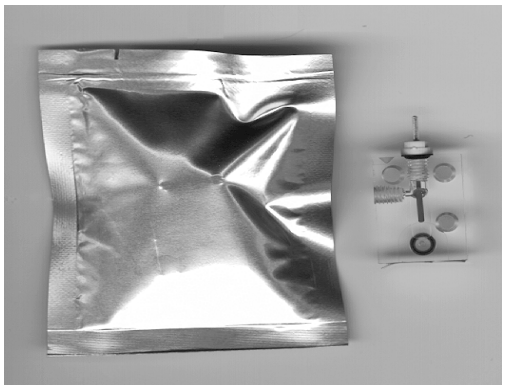


Figure 9-8: Foil bag containing an electrode and the electrode

☞ Remove the foil bag from the electrode box and tear it at the small cut to open.

☞ Check that the inner filling solution is covering the membrane.

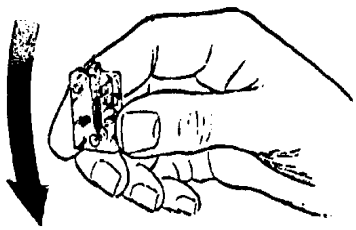


Figure 9-9: Holding the electrode upright, gently force out any trapped air from the membrane surface with a flick of the wrist. Do not tap the electrode on a hard surface!

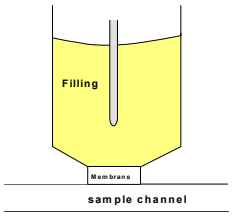


Figure 9-10: An electrode chamber when the electrode is ready for installation into the instrument

The electrode is now ready to be installed.

REFERENCE ELECTRODE

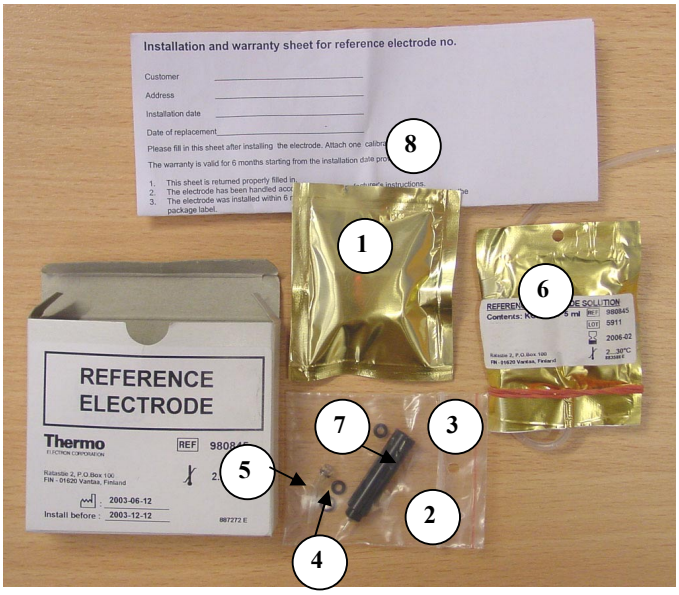


Figure 9-11a: The Reference electrode kit

1. *(1) ref. electrode slice in foil bag*
2. *(1) internal electrode*
3. *(1) large o-ring for internal electrode*
4. *(2) small o-rings, 1 as spare*
5. *(1) PVC tube for filling solution bag attachment*
6. *(1) electrode chamber filling sol. bag*
7. *Tool for tightening the electrode cap*
8. *Warranty sheet*

Check that there is no air in the tubing or chamber.

☞ Remove the reference electrode from the foil bag and rinse the outer surfaces with distilled water. Flick excess liquid out of the chambers and wipe the outer surfaces dry.

☞ Place one large o-ring on the electrode cap, install it loosely into the chamber; refer to Figure 9-11b.

☞ Connect a PVC tube to the side port of the slice so that the metal spring fastens the connection; refer to Figure 9-11b.

☞ Cut the tube of the Filling Solution bag to 5 -7 cm length and attach the PVC tube to open end. Avoid letting air back up into the tubing. Gently squeeze the bag to fill the chamber. Tighten the electrode cap first with fingers then with the tool.

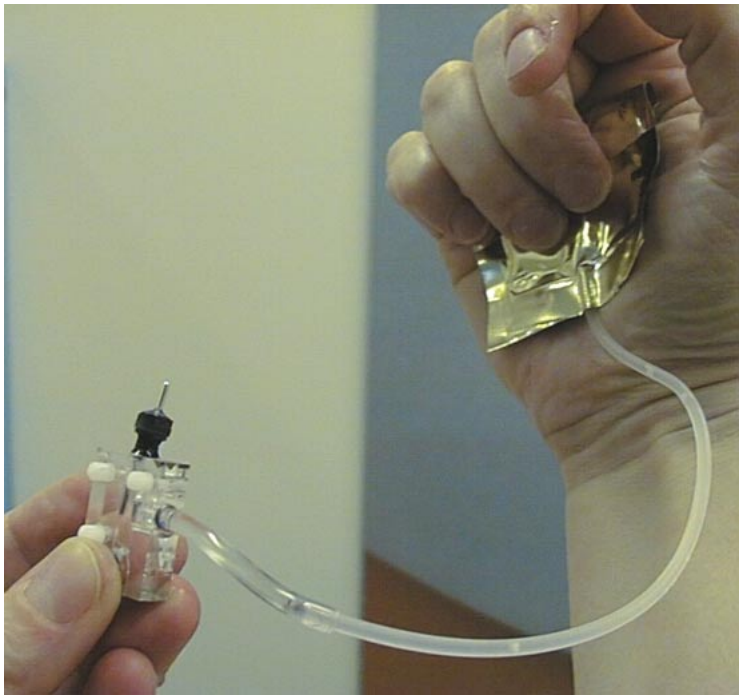


Figure 9-11b: Filling the reference electrode

ASSEMBLING THE ELECTRODES

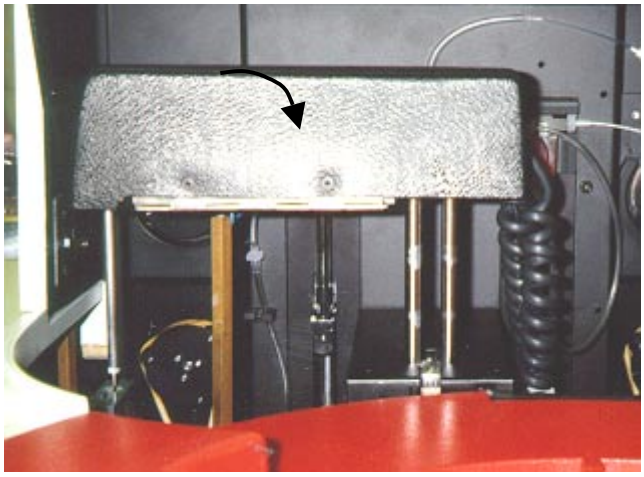


Figure 9-12: The ISE dispensing arm

☞ Turn the cover of the ISE dispensing arm so that you can see the position of the block. The cover is hinged, so it is easy to open.

There must always be an o-ring between two electrodes.

☞ Place electrodes according to the label in the place of the block. Viewed from the front of the block when the ISE needle is to the left, the order of the electrodes is from left to right: end slice with the transparent code, Cl, Ref., K, Na, Li, Ca, pH and end slice with the black code.
Place an o-ring on the left side of the end slice with the black code. Ensure that there is an o-ring between two electrodes before you press the electrodes so that the positioning dowel pins are aligned. Note that the tube of the reference electrode must be towards you.

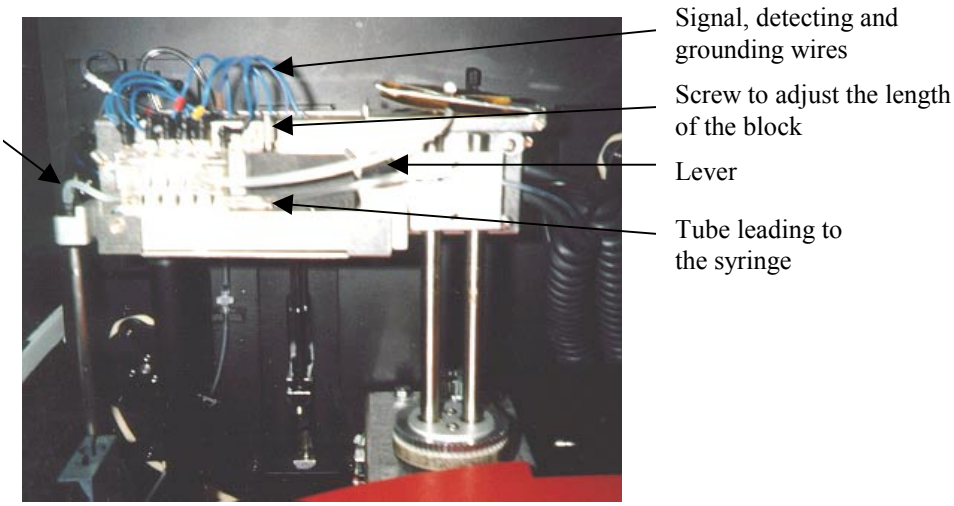


Figure 9-13: The electrode block in the ISE dispensing arm

The block must include the Na electrode when Li is measured and the block must include pH when Ca is measured.

☞ Place the electrode block between end slices. Turn the lever so that the block is firmly in its place. Note that there is a screw with which you can adjust the length of the block.
Attach the filling solution bag of the reference electrode to its place: Place the hole of the bag to the hook and turn the bag under the metal plate.

When removing an electrode block from the instrument, detach it from end slices and leave them intact.

☞ Connect signal, detecting and grounding wires to the pins at the top of the block ensuring that the cap colour corresponds to that of the slice.

☞ Ensure that the tubes are connected: from the left side of the block to the needle and from the right side of the block to the connector of the tube, which leads to the syringe/ to the FMI pump in the Konelab 20XT and 20.

☞ Turn the cover of the ISE dispensing arm back. Check that it is not pressing the tubes.

Define which electrodes are in the block

Open the ISE Electrodes window and select, which electrodes are in the block. Refer to section 4.3. The ISE test has to be defined in the Test definition window. Refer to section 4.1.3.

Install ISE Calibrator 1

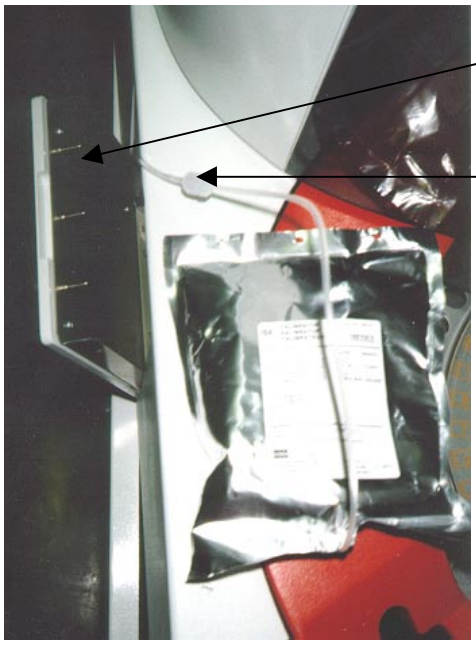


Figure 9-14: ISE Calibrator 1 is in a foil bag, which minimizes evaporation.

☞ Connect the tube of ISE Calibrator solution 1 to the tube coming from the ISE dispensing pump. Connection is made turning the Luer lock to the counterpart.

☞ Hang the bag on the hooks in the gate placed on the left side of the instrument. In case the instrument has the KUSTI module, the gate is in front of the instrument.

☞ After changing the bag, ask calibration in the Calibration/ QC selection window. Refer to section 3.4.1. After that the ISE calibrator 1 can be fetched by Reagents, F4 Add ISE CAL1. Refer to section 3.1.1.

Give ISE requests, check calibration

Never use distilled water as a sample with ISE electrodes.

Once ISE Calibrator solutions are in place (to define the positions of Calibrator solutions 2 and 3 refer to section 4.6) and Start up has been done, give some ISE requests and enter sera as sample. Inspect the detailed calibration results for all electrodes in the Calibration results window, refer to section 3.4.2.

If problems occur, check the connections of electrodes and Calibrator 1. Recalibrate in the Calibration/ QC selection window.

When calibration is successful, a pre run of 10 sera should be analysed with subsequent new calibration before analysing patient samples.

Complete the Warranty and Installation Sheets

Complete the Warranty and Installation Sheets (in the Electrode Kit, one for each electrode). Separate the sheets from each other.

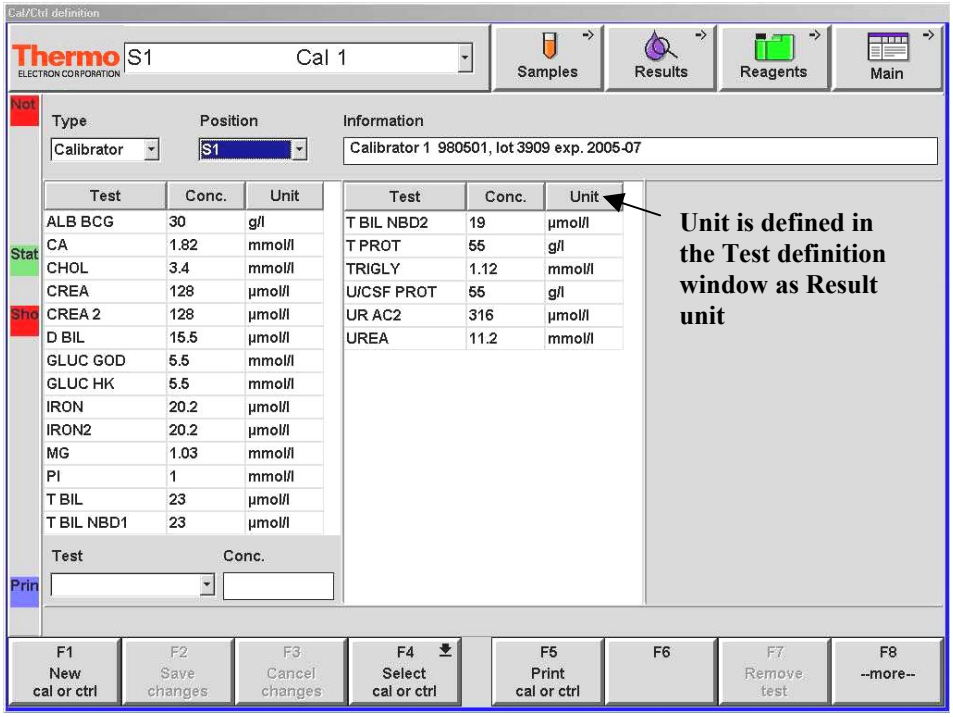
9.7 HOW TO TAILOR TESTS

Refer to General information of Konelab Application Notes. There is, e.g., a conversion table from SI units into conventional units.

Use a point, not a comma as a decimal separator, e.g. 5.6 is right, not 5,6.

For each test customer is using, check the following:

1) CAL/ CTRL DEFINITION

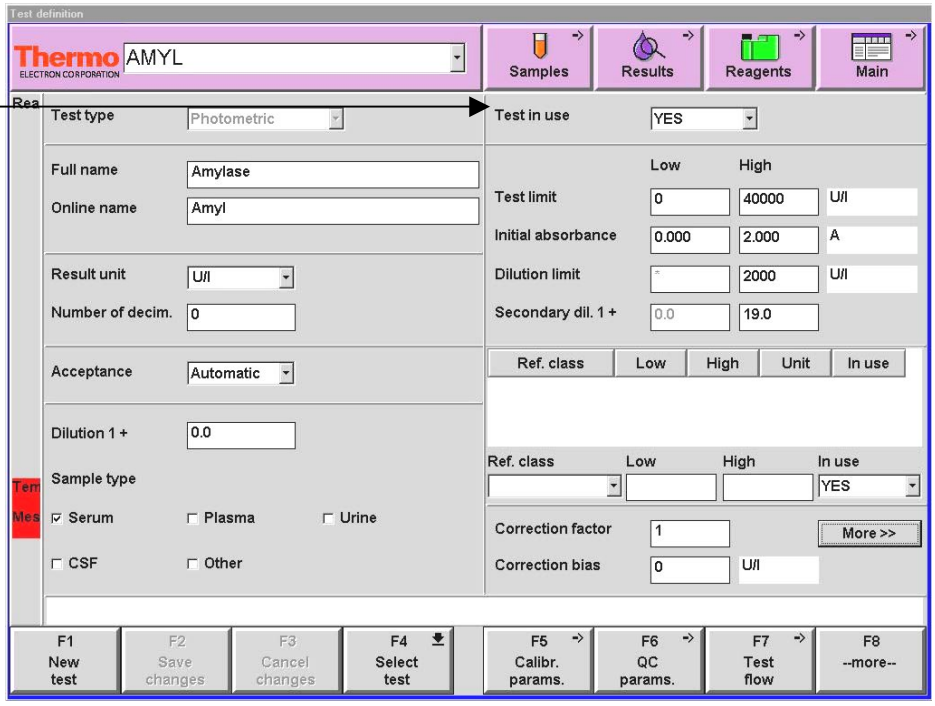


☞ Check values and names of calibrators.

☞ Define names of control samples.

2) TEST DEFINITION

Make sure that the test is selected: Test in use - Yes.



Check and correct:

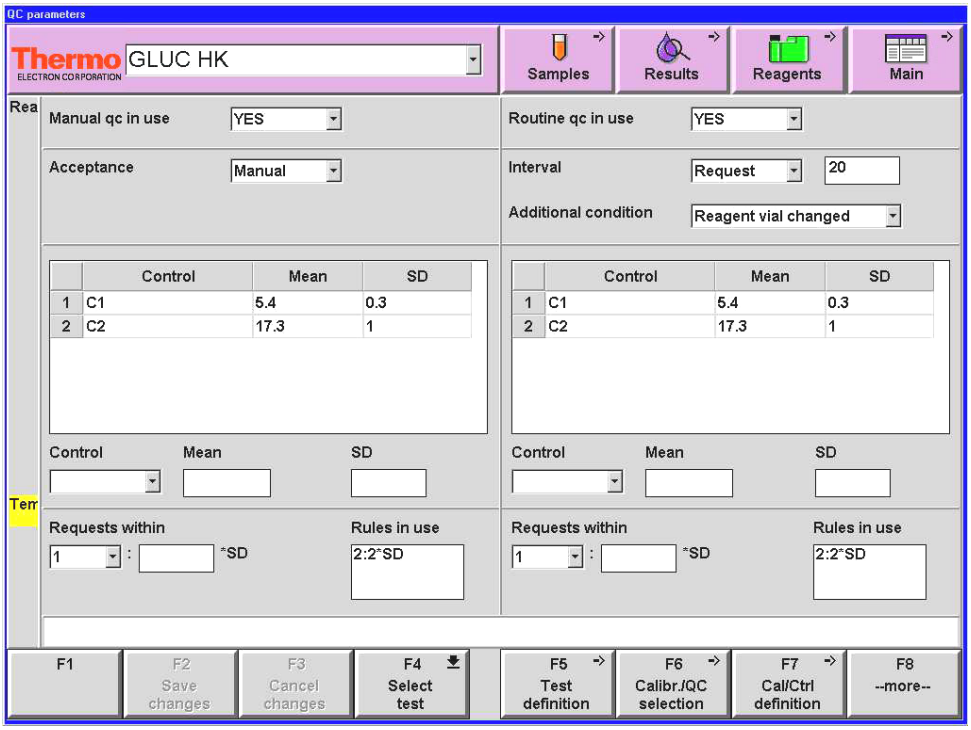
- Result unit.
- Number of decimals.

In case the result unit has been changed, check and correct also:

- Test limit values.
- Dilution limit values.
- Nonlinearity limit value in concentration unit.
- Limit values for antigen excess check sample.

Reference classes should be defined according to the method and usual reference ranges used in the laboratory.

3) QC PARAMETERS



Select Manual qc in use - Yes.

Select Routine qc in use - Yes.

Define Interval as requests or time like 2:00 (2 hours).

Introduce for both quality control types:

- Control name,
- Mean value,
- SD,
- Rules.

4) User levels

The Konelab user interface can be protected in the routine work by using User levels and their passwords.

There are 2 default levels with one default user in each level.

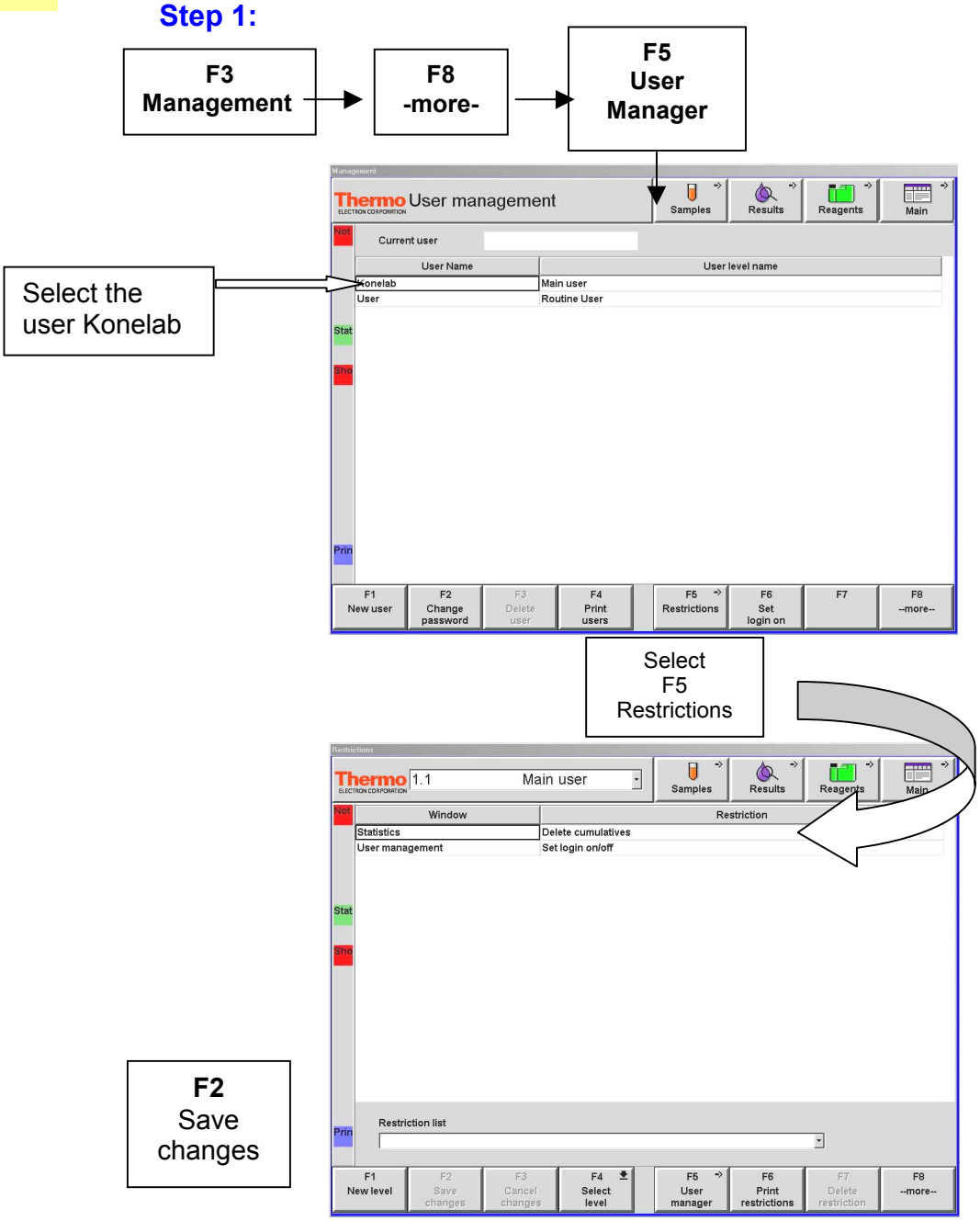
- The highest level with two restrictions is defined to be the user level Main User 1.1, the user name is “Konelab” and the password is “Konelab”
- A lower lever with more restrictions is defined to be the user level Routine user 1.1.1, the user name is “User” and the password is “Konelab”.

The restrictions for user levels are described in the section 4.10. The user level name is editable.

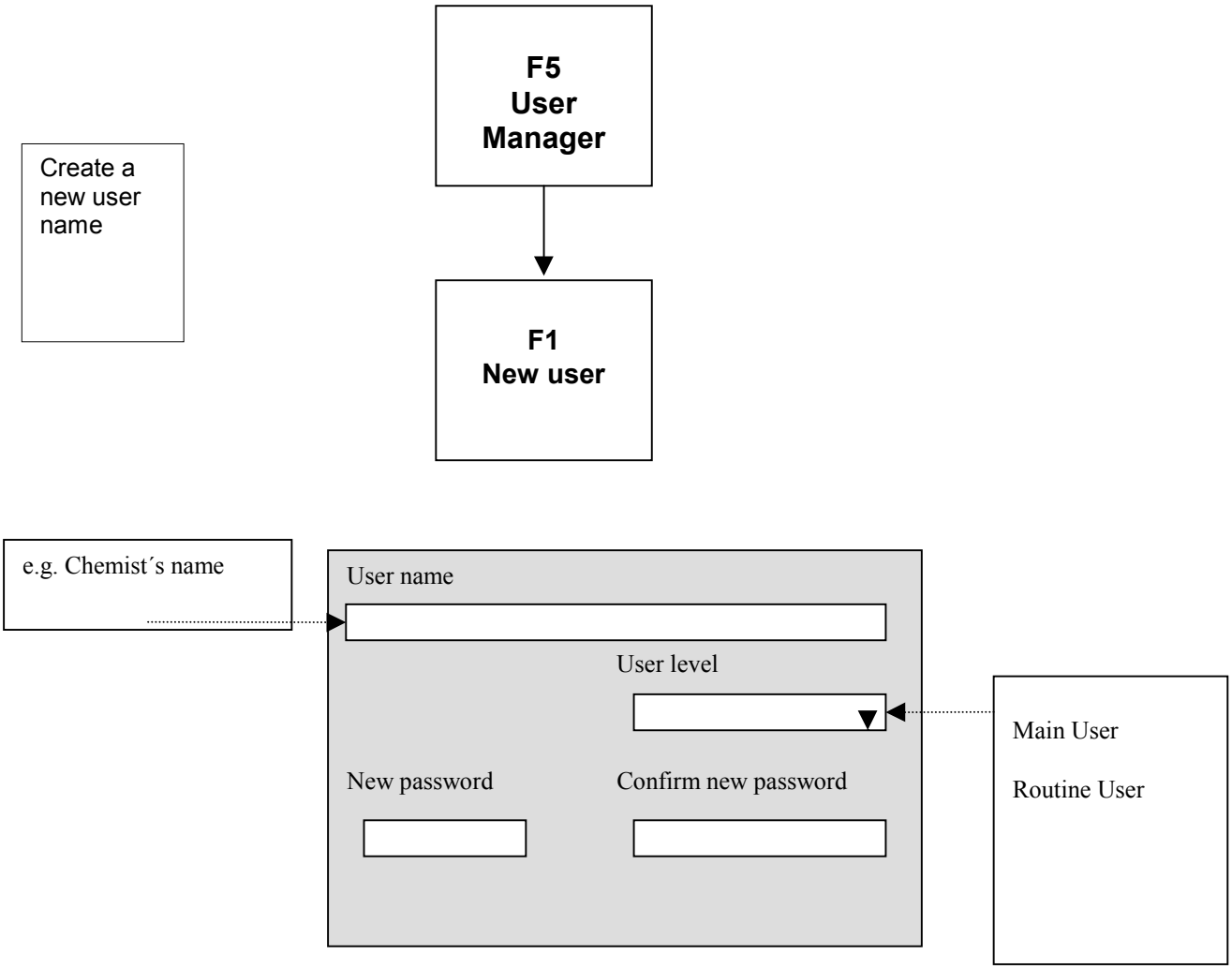
It is recommended to use the two existing levels and tailor the restrictions

☞ At the installation: select and set the users, levels, names and passwords to be set for the laboratory use. Take into use the user levels by selecting F6 Set login on, in the User management window.

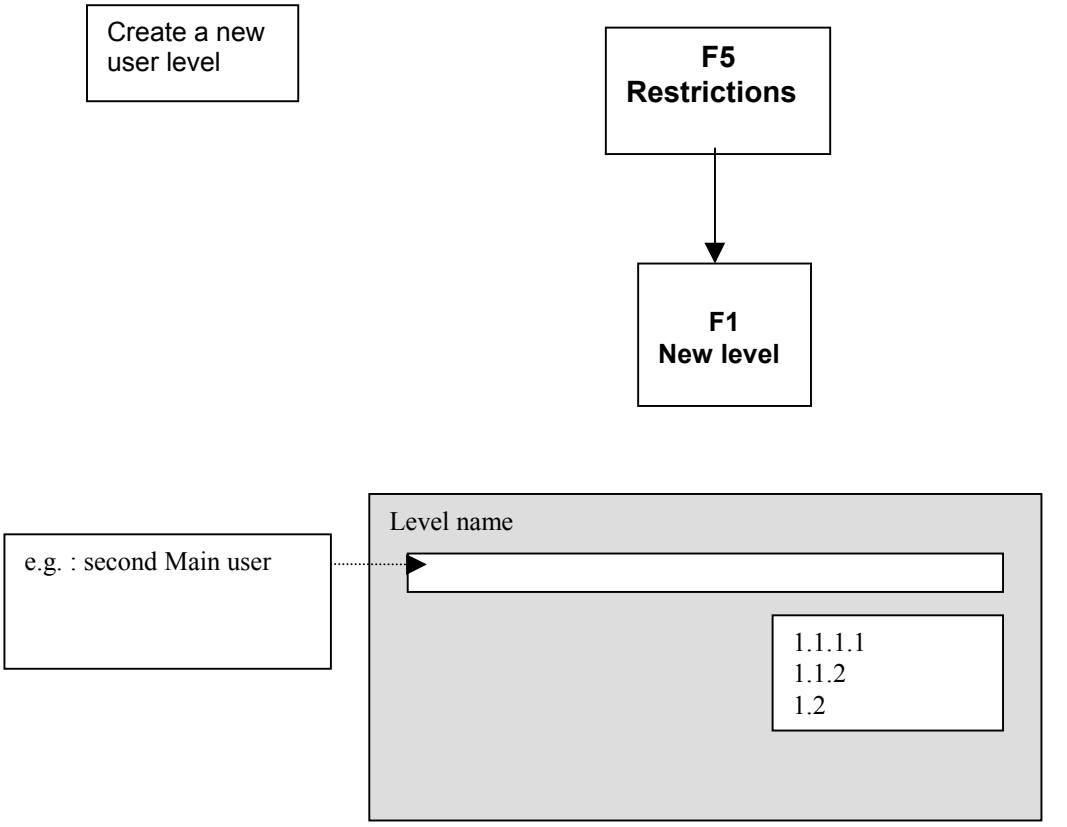
Step 1:



STEP 2:


F5
User
Manager
Create a
new user
name
F1
New user
e.g. Chemist´s name
User name
User level
Main User
Routine User
New password
Confirm new password

STEP 3:

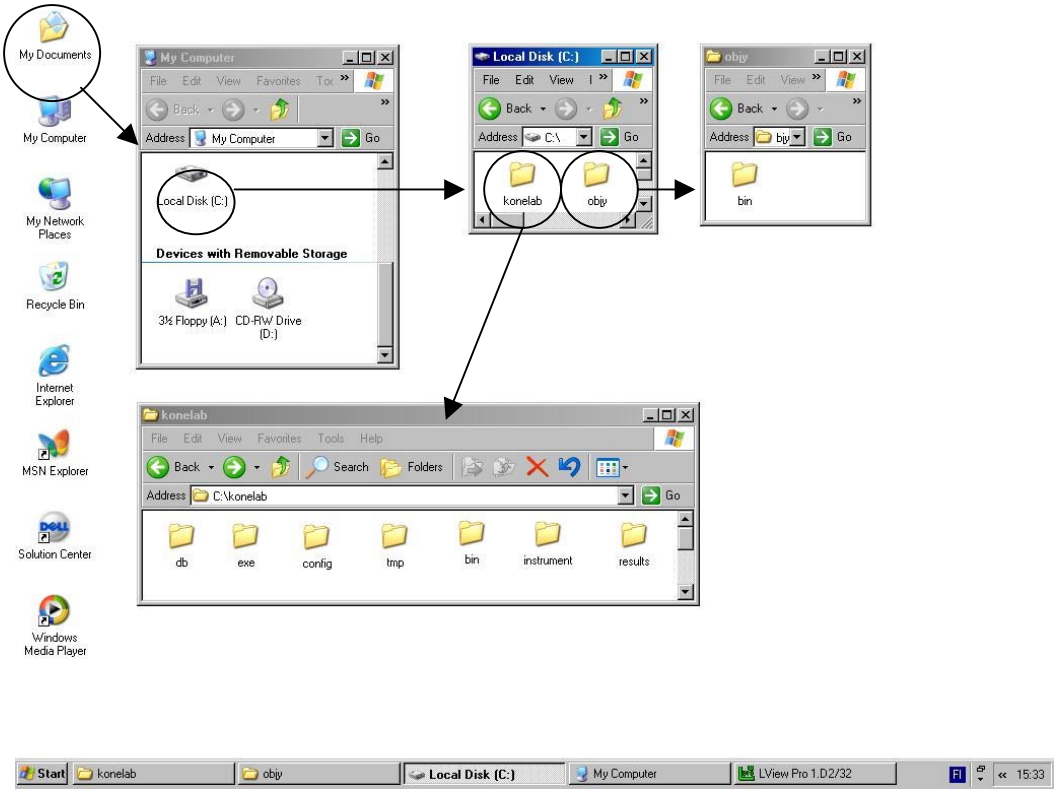


Initially the restrictions for user levels:
1.2. are equivalent to Main user 1.1 restrictions
1.1.2 are equivalent to *routine use*r 1.1.1restrictions
1.1.1.1 are equivalent all possible restrictions

10. WORKSTATION SOFTWARE

Konelab software is on a CD-ROM which is self-starting. In case you have problems take away the CD-ROM from the CD-ROM drive and rerun. If it doesn't help the Konelab software can be opened by the program konelab\setup.exe. Instructions to install the Konelab programs are found from the folder Wrd6 in the CD-ROM. Instructions are in the files klabinst.doc and klwsconf.doc.

10.1 Konelab FOLDERS



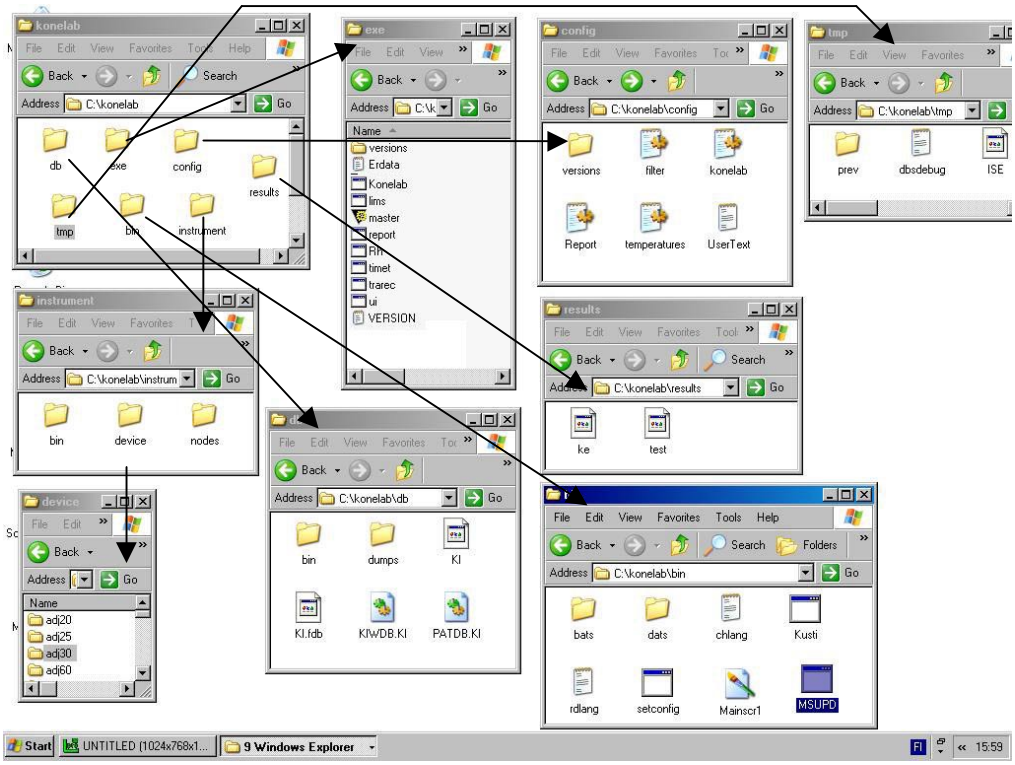
To see the Konelab folders double-click the icon My Computer. Then double-click the drive C icon.

Folders c:\Konelab and c:\objy belong to the Konelab program. The program doesn't work without them.

There may also be a folder c:\konelab\1.5.4.\exe. It contains the files of old Konelab program version. You can keep the older program version for troubleshooting purposes.

Double-click the folder icons Konelab and objy to see the contents of the folders.

10.1.1 CONTENTS OF THE C:\Konelab -FOLDER



The Konelab folder consists of folders db, exe, config, tmp, bin, instrument and results.

C:\Konelab\db -folder

The folder db includes the user database. The folder must include the files: Ki, Ki.fdb and KIWDB.KI.DB. Furthermore there are folders to save and manage the database.

C:\Konelab\exe -folder

The folder includes Konelab exe programs and files version.txt and erdata.txt. The user is not allowed to delete or change any file of the folder.

C:\Konelab\config -folder

The folder includes files konelab.ini, usertext.txt, report.ini, filter.ini and temperatures.ini. The only approved way to change the file konelab.ini is to do it in the Configuration window in the Konelab program. The file usertext.txt consists headers of reports which the user can edit. User texts are edited in the Report formats window in the section General header. Refer to section 3.11. The file report.ini includes the report formats which the user has edited in the Report formats window. The file filter.ini includes list of filters installed.

C:\Konelab\tmp -folder

The folder includes files which are produced during the use of Konelab program. Files are meant for service.

C:\Konelab\bin -folder

The folder includes files for program management, language changing etc. The user is not allowed to delete or change any file of the folder.

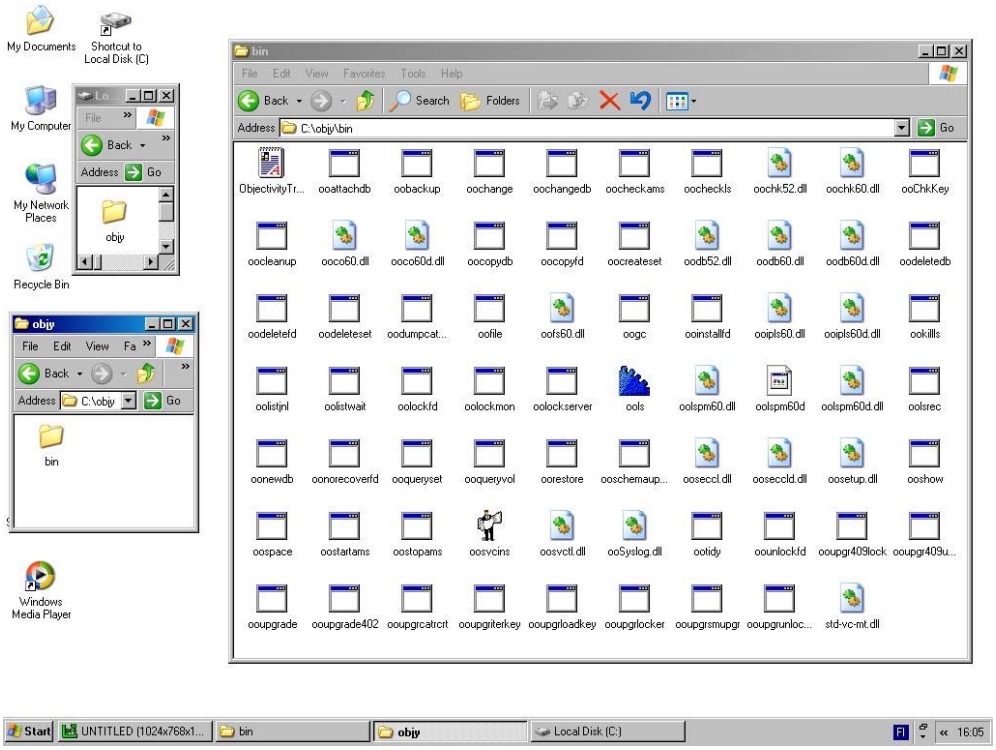
C:\Konelab\instrument -folder

The folder includes folders for instrument management, e.g. adjustment values. The user is not allowed to delete or change any file of the folder.

C:\Konelab\results -folder

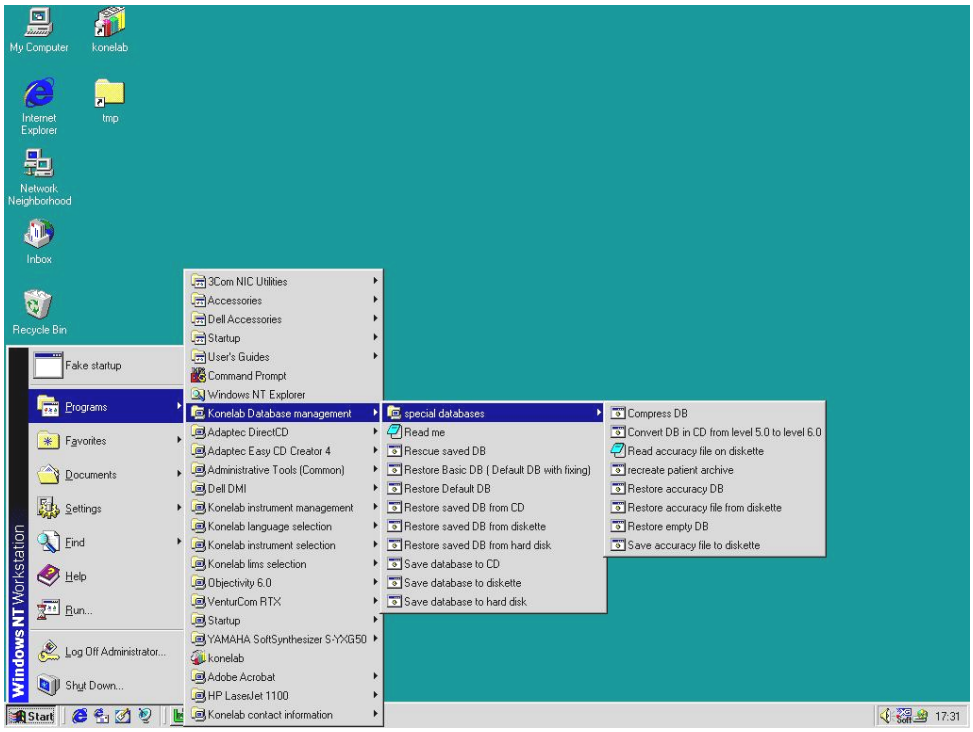
The folder includes result files that are produced when the function Results to file is used in the Reports window. Refer to section 3.5.

10.1.2 CONTENTS OF THE C:\objy\bin -FOLDER



The bin folder includes files which are needed to manage the database. The user is not allowed to delete the files.

10.2 Konelab MENUS



To see Konelab program menus click the Start button in the left corner of the window and select Programs from the list.

konelab

To start Konelab program, click the konelab icon. Wait until the User interface is up. Do not start the program if it is running already. Note that when Konelab 20XT or 20 program is started RTX/RTSS Console application window is seen, DO NOT close it.

10.2.1 Konelab Database management

The menu includes functions to manage the database, it includes different commands for taking a backup of the database and restoring it. **Before any restore the user must EXIT from the Konelab program in the Management window.** The database can be confused if restore is made when the Konelab program is running.

Saving can be done here or in the Management window in the Konelab program. Saving/ restoring means that both routine database (= parameters, samples, reagent list, user levels, controls, calibrators) and patient archive are saved either to hard disk or to CD (refer to section 10.2.1.1). Only routine database without sample results can be saved to/restored from a diskette. It is recommended to clear the daily files before saving the routine database to a disk. Otherwise saving can be very slow and use a lot of memory. For the Management window refer to section 3.6.

The detailed instructions of functions in the Konelab Database management menu are in the 'read me' file.

Save database to hard disk
Takes a backup of the current database and patient archive on hard disk.

Save database to CD
Takes a backup of the current database and patient archive on CD.

Save database to diskette
Takes a backup of the current database to a diskette in drive a:. This overwrites the previous database in diskette if there is one.

Restore saved database from hard disk
Restores the latest database backup taken with "Save database" if there is one.

Restore saved database from CD
Restores the database backup from a CD.

Restore saved database from diskette
Restores the database backup from a diskette in drive a:. Creates automatically a new patient archive. Note that it deletes the old one.

Restore default database
Restores the default database (=factory database) with Konelab parameters. Re-creates patient archive.

Restore Basic database
Restores the basic database system and the default database. Re-creates patient archive. This should be used only, if other restore functions do not work.
Use "Restore saved database" after this to restore the latest backup.

Rescue saved database
Restores the automatic database and patient archive backup taken after last "Clear daily files".

Re-create patient archive
Re-creates patient archive. Note that it deletes the old one, also results. In the Configuration window patient archive is re-created automatically when it has been out of use and it is taken into use again.

Compress database
Compresses and clears up the current database and helps the system work faster. Takes some seconds. This is recommended to be done for the restored databases used before the software level 6.0.5.

10.2.1.1 Saving the Konelab database to CD

We recommend to use one CD for one backup.

If you use re-writable (CD-RW) discs, note that the new backup files replaces the old ones.

If you use write-once (CD-R) discs, once the disc is full, you can only restore backups from it.

How to make database backup using CD-RW drive

NOTE! You must format CD-R(W) discs before you can use them. You can start the formatting by inserting a new, unformatted disc into CD-RW drive. The formatting has to be done only once for each disc.

☞ Insert a disc into CD-RW drive.

Format the disc, if necessary:

1) Select from the appearing menu 'Create a CD using Roxio Easy CD Creator'.
2) Answer 'OK' to the program introduction appearing.
3) Select 'make a data CD'.
4) Select 'directCD'.
5) Select 'format CD'.
6) Write a label to your CD.
7) Select 'Start format'.
8) Answer 'OK' when 'CD Ready' appears.

☞ Select F6 Save DB to CD in the Management window or Save database to CD in the Konelab Database management menu to make a backup.

If problems occur check in the Configuration window that the drive letter of the CD is right.

☞ Eject the disc. When prompted for, select option 'Leave As Is'.

☞ Store the disc in a safe place.

How to restore the backup from CD

NOTE! Databases are named like Save4020.db where first two numbers (40) express the software version and two last ones (20) instrument type.

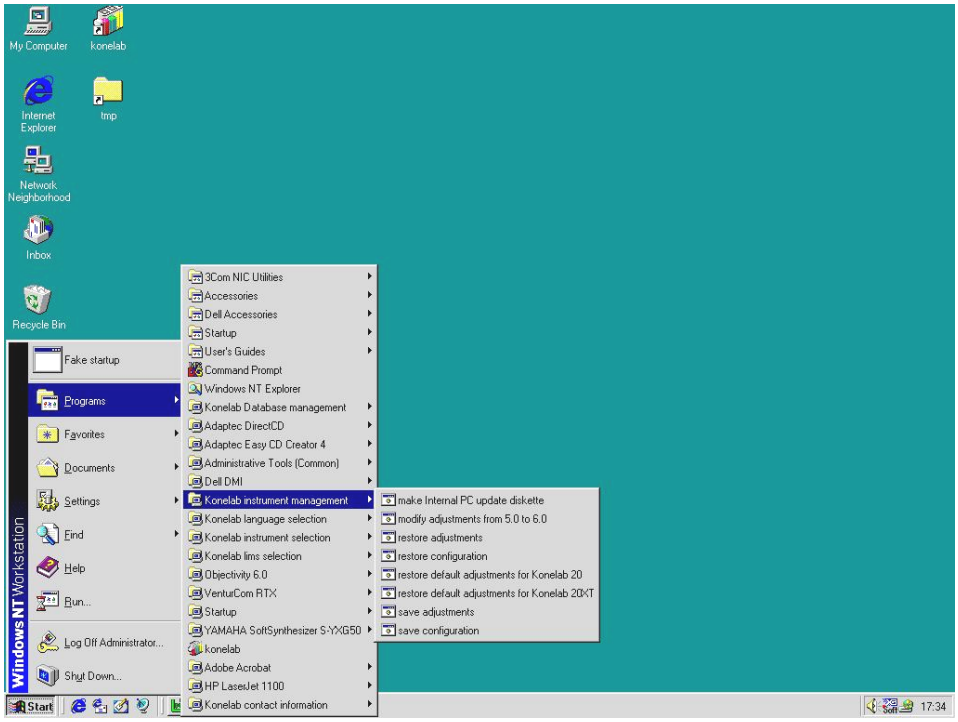
☞ Insert a backup disc into CD drive.

☞ Select Restore DB from CD from the Konelab Database management menu.

10.2.1.2 Results archive - Retrieving data from CD

1) Save database on CD or hard disk.
2) Exit from Konelab software.
3) Restore the previous database from CD.
4) Open Konelab software and go to the Result Archive function to look through the data.
5) Exit from Konelab software.
6) Restore the original database back.

10.2.2 Konelab instrument management

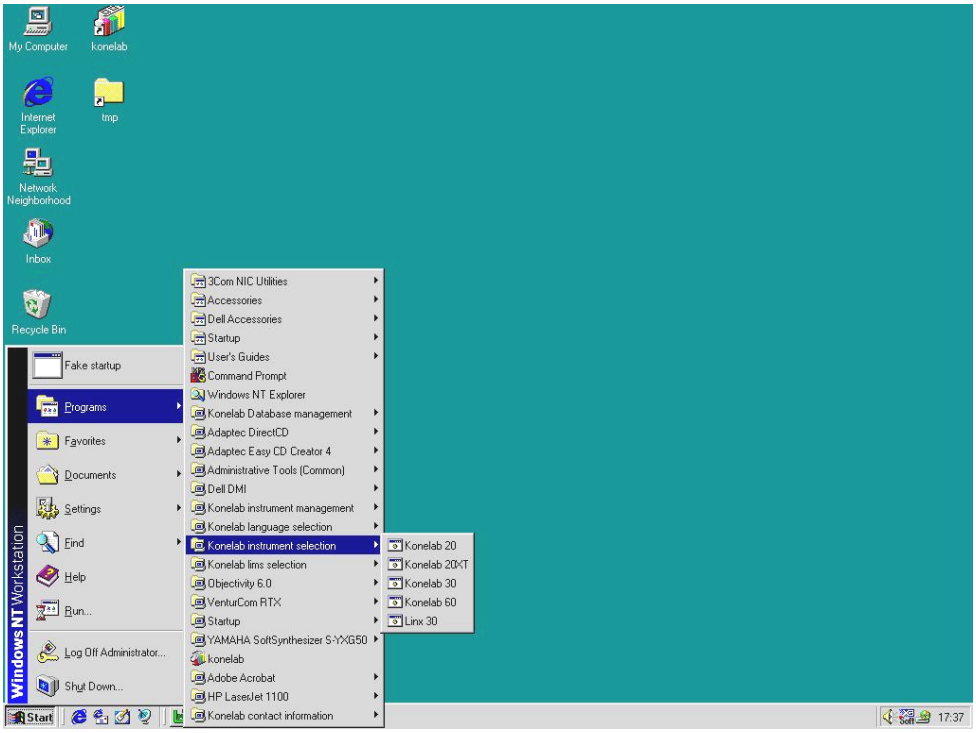


Konelab instrument management menu includes saving and restoring possibilities for configuration. It includes configuration values, user format report, headers of reports which the user has edited and filter wheel configuration. Save configuration saves also accuracy factors and results but they are not restored with restore configuration. Restoring of accuracy results can be done through Start\Programs\Konelab Database management\special databases. See section 10.2.

Saving and restoring possibilities for adjustment values (= analyser specific values) applies only to Konelab 20XT and 20. Default adjustments (= factory adjustments) can be restored in case of problems.

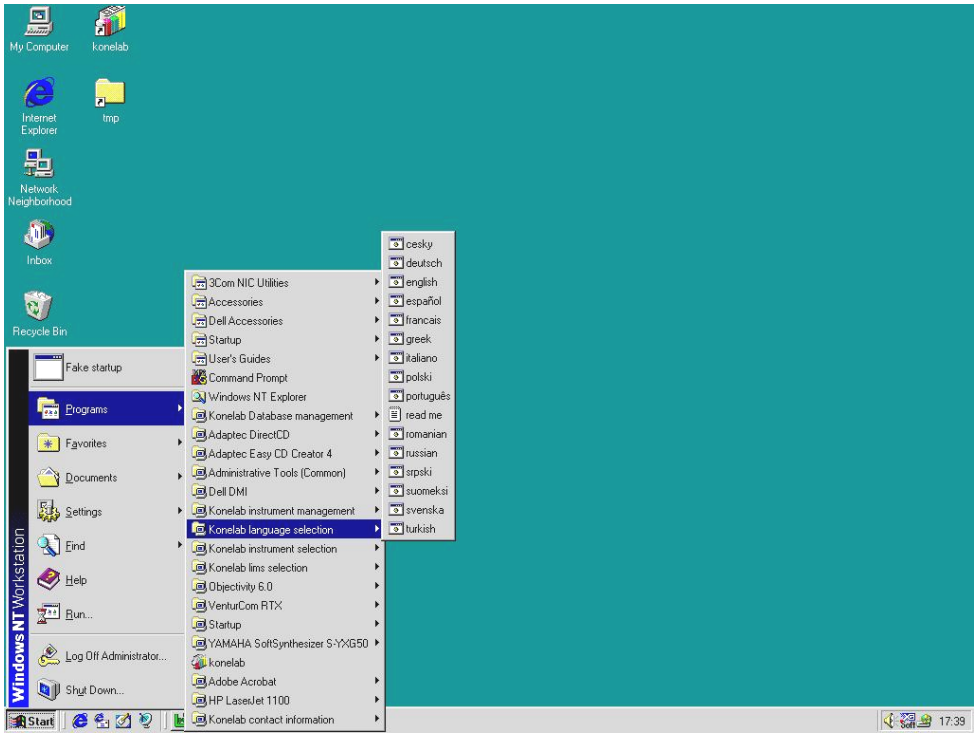
Update diskette for the internal PC for Konelab 60 and 30 can be made here. Put an empty diskette to a disk drive and give a command. The up to date data is loaded. A spare diskette is good to keep for troubleshooting purposes.

10.2.3 Konelab instrument selection



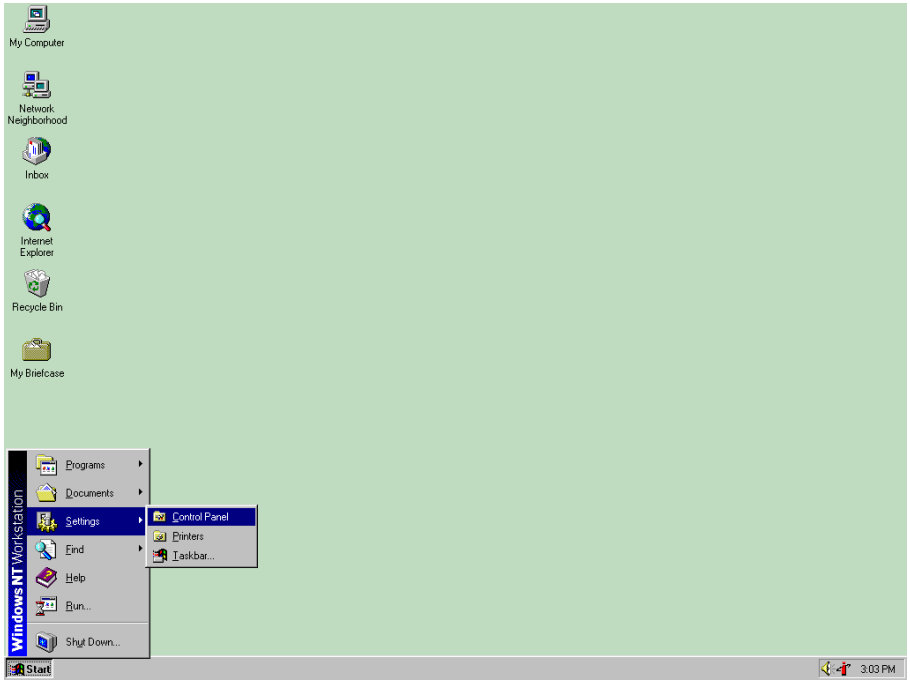
☞ In case of some instrument type mismatch it is necessary to select the correct instrument from this instrument selection menu.

10.2.4 Konelab language selection

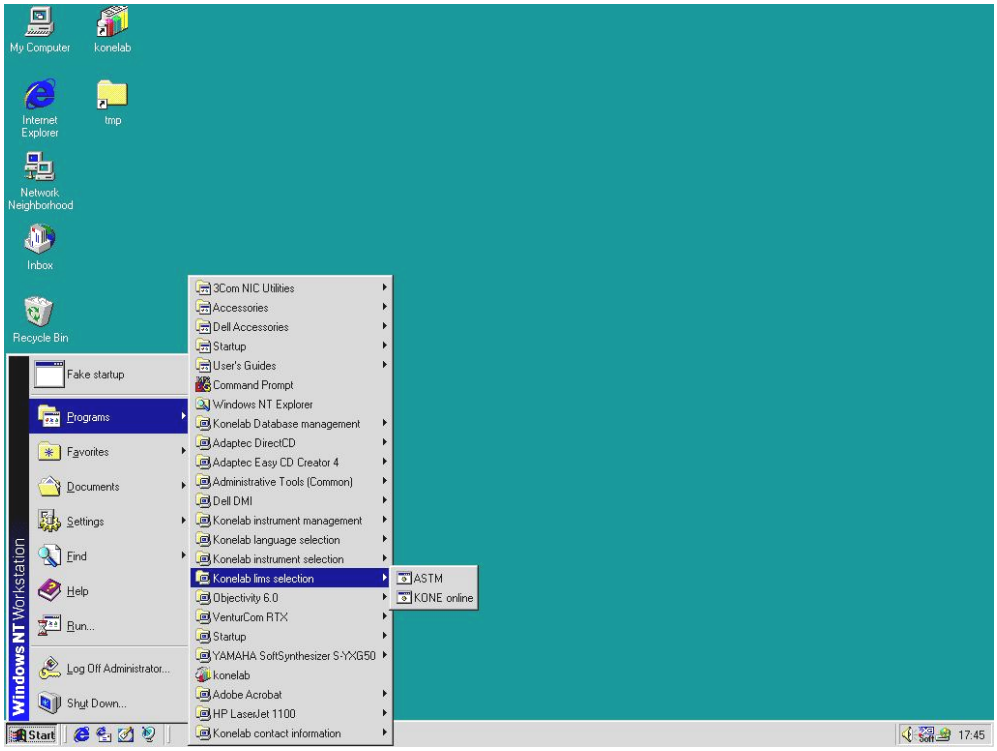


Select the language which the Konelab program is using from the Konelab language selection menu. Do not change the language if the Konelab program is running.

Keyboard, Date/ Time, Regional settings etc. are changed from Start: Settings: Control panel.

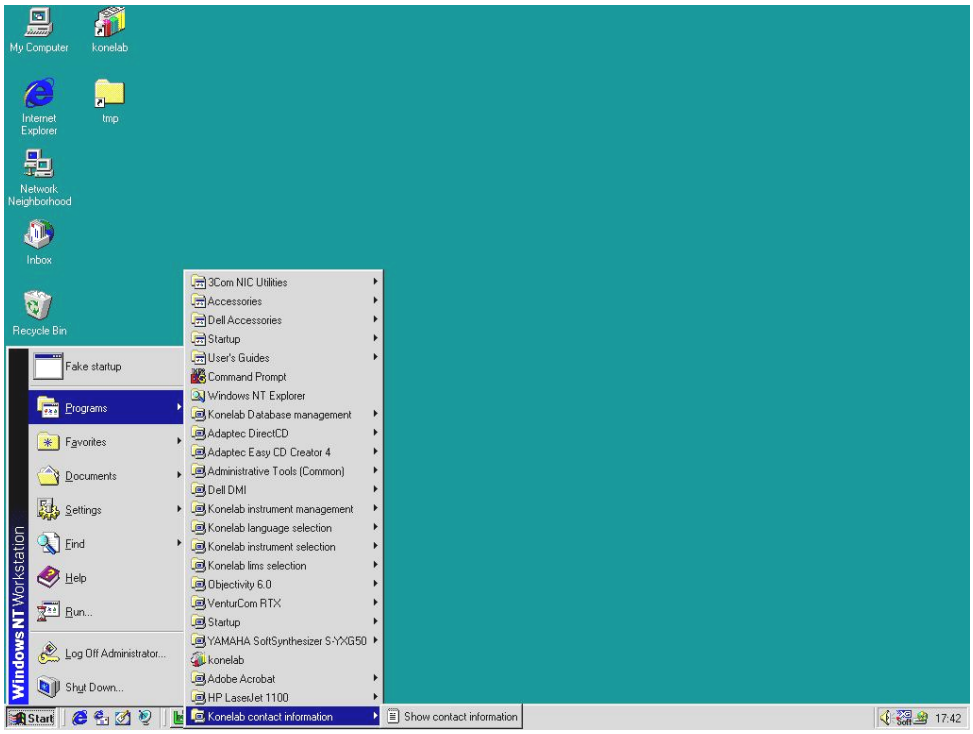


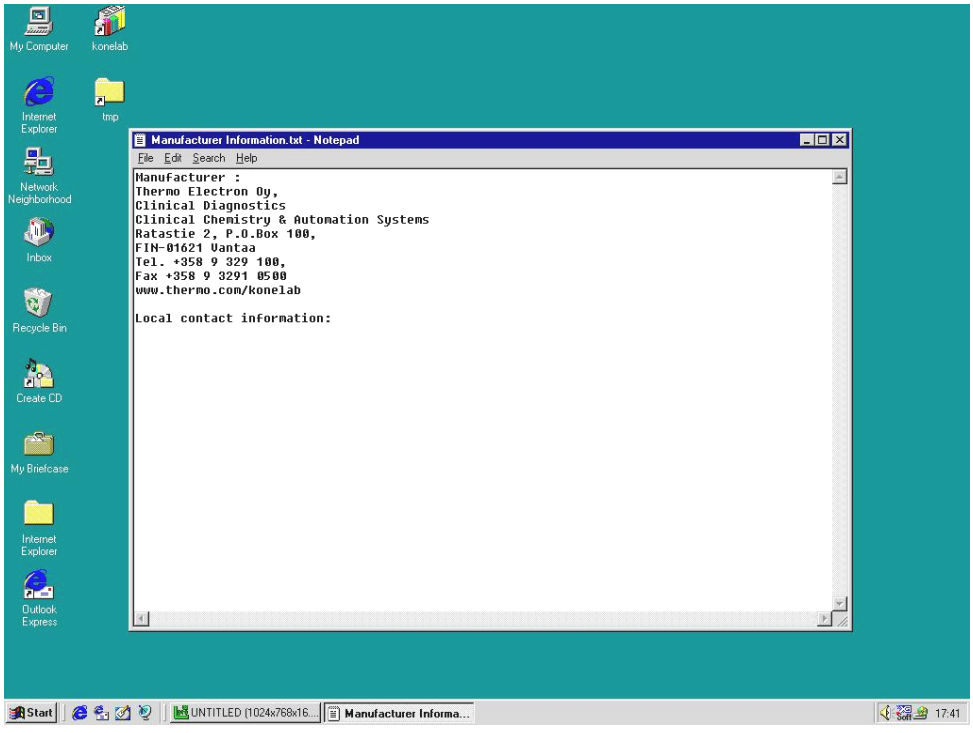
10.2.5 Konelab LIMS selection



Select the LIMS protocol from the Konelab lims selection menu.

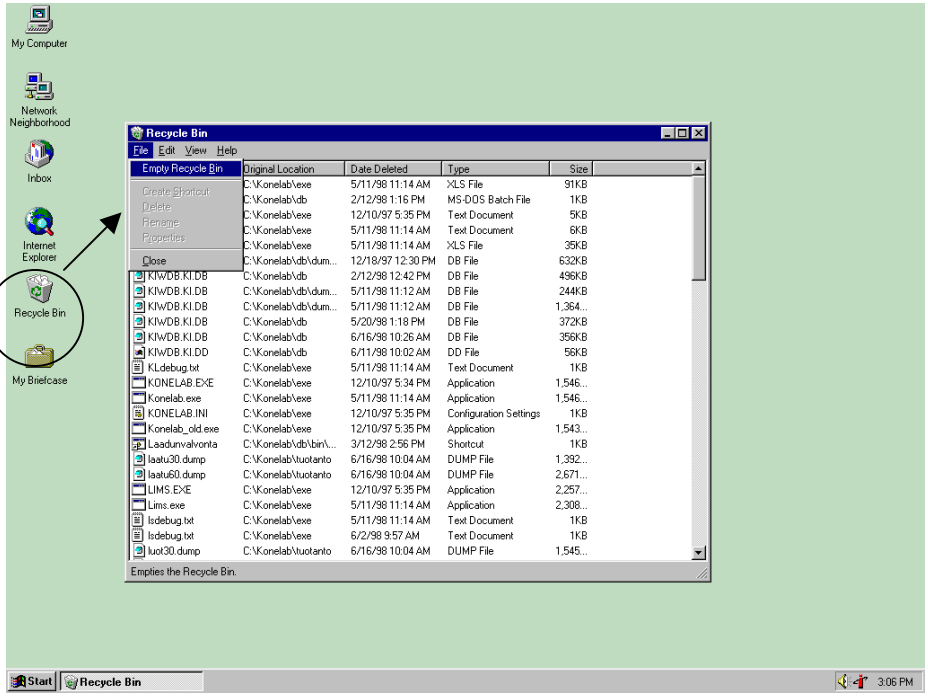
10.2.6 Konelab contact information





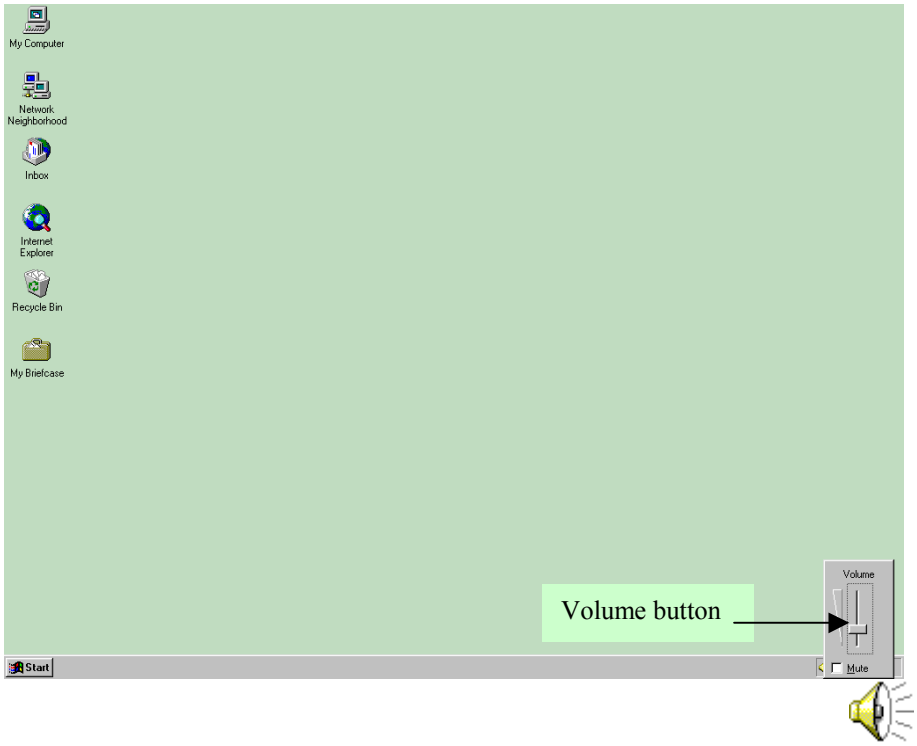
Manufacturer information is seen. The local distributor should write their own contact information there too.

10.3 RECYCLE BIN



All deleted items are gathered to the Recycle Bin. To clean the Recycle Bin double-click the icon, then select File: Empty Recycle Bin. Confirm the selection and close the window.

10.4 VOLUME ADJUSTMENT



To adjust the volume, click the volume icon in the right corner of the window. Activate the volume button by moving the cursor above the button and pressing the mouse's left button down. Move the mouse to adjust the volume. If you want the volume off, click to the square 'Mute'. Close the adjustment by clicking elsewhere in the window.

11. ACCESSORIES AND CONSUMABLES

Konelab is delivered with the reference manual, books for applications as well as for LIMS and LAS interfaces, sample segments (10 pcs with Konelab 60 and 6 pcs with Konelab 30, 20XT and 20) with barcode labels, the keyboard sticker, the power cord, the cable for ethernet and printer, water/ waste containers (3 pcs), set of waste bags for used cuvettes, dust cover, set of tools and the software. When the ISE unit is connected also end slices are installed in the electrode block. When KUSTI unit is connected KUSTI segments (100 pcs), segment holders (6 pcs) and barcode labels for segments are delivered.

11.1 LIST OF ACCESSORIES AND CONSUMABLES

The following codes are used when ordering items:

CODE	START-UP & MAINTENANCE KITS
984001	Start up kit for K60 and 30
984116	Start up kit for K20XT
984002	Start up kit for K20
984003	ISE Start up kit (Na, K, Cl) for K60i and 30i
984009	ISE Start up kit (Na, K, Cl) for K20XTi and 20i
984036	6 Months Maintenance kit for Konelab 20 and 20i
984115	6 Months Maintenance kit for Konelab 20XT and 20XTi
984004	6 Months Maintenance kit for Konelab 30 and 30i
984007	6 Months Maintenance kit for Konelab 60 and 60i
984028	6 Months ISE Complete tubing for K20XTi and 20i
984020	6 Months ISE Complete tubing for K60i and 30i
984097	12 Months Maintenance kit for Konelab 20 and 20i
984114	12 Months Maintenance kit for Konelab 20XT and 20XTi
984096	12 Months Maintenance kit for Konelab 30 and 30i
984098	12 Months Maintenance kit for Konelab 60 and 60i
984029	12 Months ISE Maintenance kit for K20XTi and 20i
984006	12 Months ISE Maintenance kit for K60i and 30i
984076	12 Months KUSTI Maintenance kit
981577	Instrument accuracy testing kit
984016	ISE option kit for K60 and 30
984120	ISE option kit for K20
984118	ISE option kit for K20XT

CODE	CONSUMABLES
984000	Acrylic multicell cuvette (40 x 25 pcs)
984068	FMI Pump tubes
984072	Diluent and wash tubes for Konelab 20
984105	Diluent and wash tubes for Konelab 20XT
984023	Diluent and wash tubes for Konelab 30
984021	Diluent and wash tubes for Konelab 60
984071	Drain/waste tubes for K20
984106	Drain/waste tubes for K20XT
984022	Drain/waste tubes for K60 and 30
981481	Halogen lamp, EMC model
984070	ISE Complete tubing for K20XTi and 20i
984020	ISE Complete tubing for K60i and 30i
984069	KUSTI Complete tubing
984012	Mixing paddle
984093	Dispensing needle (reagent/sample)
984011	Dispensing needle ISE
984073	Dispensing needle KUSTI
981276	Piston for 500 µl syringe
984077	Pump tube for Konelab 20 and 20XT ISE Wash (2 pcs)
980306	Pump tube / PVC/ 2 x grey-grey
981342	Pump tube / ISMAPRENE / 2 x lilac - lilac
984050	Reagent bottle 10 ml (5 pcs)
981456	Reagent vessel 20 ml (14 pcs)
981455	Reagent vessel 60 ml (12 pcs)
989221	Sample cup 2.0 ml (1000 pcs)
989220	Sample cup 0.5 ml (1000 pcs)
984074	Segment holder, KUSTI (1 pc)
984015	Syringe 500 µl grip fix for K20XT and 20
981269	Syringe 500 µl for K60 and 30
980993	Waste / diluent canister (1pc)

CODE	ACCESSORIES
984060	Software for workstation and internal PC
984101	HP Laserjet 1300
984117	Print Cartridge for HP Laserjet 1300
981548	Printer, Epson LX 300
984043	Printer cable (2,5 m)
984044	Online cable (2,5 m)
984040	Reagent disk, 45 pos.
984041	Sample segment for 5 and 7 ml tubes
984051	Sample segment for 10 ml tubes
984100	Sample segment for KUSTI
984052	Sample disk for 10 ml tubes
984042	Barcode labels for sample segments (1-50) and sample disk (0), Konelab 30 and 60
984039	Barcode labels for sample segments (1-50) and sample disk (0), Konelab 20 and 20XT
988018	Tool for tube positioning

CODE	ELECTRODES
980845	Reference electrode
981593	Potassium Micro Volume Electrode
981594	Sodium Micro Volume Electrode
981598	Lithium Micro Volume Electrode
981595	Calcium Micro Volume Electrode
981597	pH Micro Volume Electrode
981596	Chloride Micro Volume Electrode
981602	End slices: in and out

CODE	ISE SOLUTIONS
984031	ISE Calibrator solution 1 (4 x 400 ml)
984035	ISE Calibrator solutions 2 + 3 (2 x 20 ml + 2 x 20 ml)
984034	ISE Calibrator solution 4 (2 x 20 ml)
984030	Washing solution 4.5% (4 x 20 ml)
980314	Reference electrode solution 5 ml

11.2 CONTENTS OF THE KITS

984002	START UP KIT for K20	
984000	Acrylic multicell cuvette (40 x 25 pcs)	1 pc
989221	Sample cup 2.0 ml (1000 pcs)	1 pc
984050	Reagent bottle 10 ml (5 pcs)	1 pc
981481	Halogen lamp	1 pc
984077	Pump tube / ISE Wash (2 pcs)	1 pc
984030	Washing solution (4 x 20 ml)	2 pcs

984116	START UP KIT for K20XT	
984000	Acrylic multicell cuvette (40 x 25 pcs)	1 pc
989221	Sample cup 2.0 ml (1000 pcs)	1 pc
984050	Reagent bottle 10 ml (5 pcs)	1 pc
981481	Halogen lamp	1 pc
984077	Pump tube / ISE Wash (2 pcs)	2 pcs
984030	Washing solution (4 x 20 ml)	2 pcs

984001	START UP KIT for K30/60	
984000	Acrylic multicell cuvette (40 x 25 pcs)	1 pc
989221	Sample cup 2.0 ml (1000 pcs)	1 pc
984050	Reagent bottle 10 ml (5 pcs)	1 pc
981481	Halogen lamp	1 pc
981342	Pump tube / ISMAPRENE / 2 x lilac-lilac	1 pc
984030	Washing solution (4 x 20 ml)	2 pcs

984009	**ISE START UP KIT (Na, K, Cl) for K20i and 20XTi**	
980845	Reference electrode	1 pc
981593	Potassium Micro Volume Electrode	1 pc
981594	Sodium Micro Volume Electrode	1 pc
981596	Chloride Micro Volume Electrode	1 pc
984031	ISE Calibrator solution 1 (4 x 400 ml)	1 pc
984035	ISE Calibrator solutions 2 + 3 (2 x 20 ml + 2 x 20 ml)	1 pc
984077	Pump tube / ISE Wash	2 pcs
984030	Washing solution (4 x 20 ml)	1 pc

984003	**ISE START UP KIT (Na, K, Cl) for K30i and 60i**	
980845	Reference electrode	1 pc
981593	Potassium Micro Volume Electrode	1 pc
981594	Sodium Micro Volume Electrode	1 pc
981596	Chloride Micro Volume Electrode	1 pc
984031	ISE Calibrator solution 1 (4 x 400 ml)	1 pc
984035	ISE Calibrator solutions 2 + 3 (2 x 20 ml + 2 x 20 ml)	1 pc
980306	Pump tube / PVC/ 2 x Grey-Grey	1 pc
981342	Pump tube / ISMAPRENE / 2 x lilac - lilac	1 pc
984030	Washing solution (4 x 20 ml)	1 pc

984036	**6 MONTHS MAINTENANCE KIT FOR KONELAB 20 AND 20i**	
984072	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984115	**6 MONTHS MAINTENANCE KIT FOR KONELAB 20XT AND 20XTi**	
984105	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984004	**6 MONTHS MAINTENANCE KIT FOR KONELAB 30 AND 30i**	
984023	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984007	**6 MONTHS MAINTENANCE KIT FOR KONELAB 60 AND 60i**	
984021	Diluent and wash tubes	1 pc
981481	Halogen lamp	1 pc

984028	**6 MONTHS ISE Complete tubing for Konelab 20i and 20XTi**	
984070	ISE Tubing kit for K20i and 20XTi	

984020	**6 MONTHS ISE Complete tubing for Konelab 30i and 60i**	

984097	**12 MONTHS MAINTENANCE KIT FOR KONELAB 20 AND 20i**	
984015	Syringe 500 µl grip fix	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984072	Diluent and wash tubes	1 pc
984071	Drain/waste tubes	1 pc
981481	Halogen lamp	1 pc
840551	Dispenser ground wire 500	1 pc

984114	**12 MONTHS MAINTENANCE KIT FOR KONELAB 20XT AND 20XTi**	
984122	Syringe 500 µl AD	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984012	Mixing paddle	1 pc
984105	Diluent and wash tubes	1 pc
984106	Drain and waste tubes	1 pc
981481	Halogen lamp	1 pc
840551	Dispenser ground wire 500	1 pc

984096	**12 MONTHS MAINTENANCE KIT FOR KONELAB 30 AND 30i**	
981269	Syringe 500 µl	1 pc
984093	Dispensing needle (reagent & sample)	1 pc
984023	Diluent and wash tubes	1 pc
984022	Drain/waste tubes	1 pc
981481	Halogen lamp	1 pc
984012	Mixing paddle	1 pc
840551	Dispenser ground wire 500	1 pc
570343	Dust filter for the internal PC	1 pc

984098	**12 MONTHS MAINTENANCE KIT FOR KONELAB 60 AND 60i**	
981269	Syringe 500 µl	2 pcs
984093	Dispensing needle (reagent/sample)	2 pcs
984021	Diluent and wash tubes	1 pc
984022	Drain/waste tubes	1 pc
981481	Halogen lamp	1 pc
984012	Mixing paddle	2 pcs
840551	Dispenser ground wire 500	1 pc
570343	Dust filter for the internal PC	1 pc

984029	**12 MONTHS ISE MAINTENANCE KIT for Konelab 20i and 20XTi**	
984070	ISE Complete tubing kit	1 pc
984011	Dispensing needle ISE	1 pc
840551	Ground wire 500	1 pc

984006	**12 MONTHS ISE MAINTENACE KIT for Konelab 30i and 60i**	
984020	ISE Complete tubing	1 pc
984011	Dispensing needle ISE	1 pc
981269	Syringe 500 µl	1 pc
984076	**12 MONTHS KUSTI MAINTENANCE KIT**	
984073	Dispensing needle KUSTI	1 pc
984069	Tubing kit KUSTI	1 pc
981577	**INSTRUMENT ACCURACY TESTING KIT**	
	Accuracy Solution kit	1 pc
841537	Verification protocol	1 pc
841214	Accuracy test procedure –description	1 pc

12. TECHNICAL SPECIFICATIONS

Konelab 60

Operating principle
Random access analyser for routine and special chemistries, including specific proteins, therapeutic drugs, drugs of abuse and user definable applications.
Programmable tests 200.
ISE unit in the model Konelab 60i for Na^+, K^+ and Cl^-.
Li^+, Ca^{2+} and pH are available upon request.

Throughput
Workload dependent being in typical routine use up to 600 tests/hour.
Time to first result is typically 3 to 12 min.

Samples
Samples are placed on continuous loading segments with 14 positions each.
MAX ON-BOARD CAPACITY: 6 segments, 6 additional positions for STAT samples. Integrated barcode reader and cup type recognition.
Optional sample transport interface (KUSTI).
SAMPLE CUPS AND TUBES: 0.5 ml and 2.0 ml cups, 5 ml and 7 ml tubes, 10 ml tubes with tailored segments.
SAMPLE TYPES: Serum, plasma, urine, CSF.
SAMPLE VOLUMES: Possible range 1-120 µl, typically 2-15 µl.
For Na^+, K^+ and Cl^- tests 50 µl.

Reagents
REAGENT VIALS: 10 ml, 20 ml and 60 ml.
ON-BOARD STORAGE: Continuous loading 45 positions in the 4-8 °C refrigerated reagent compartment.
Automated identification by integrated barcode reader. Real time reagent status seen on the workstation window.
REAGENT VOLUMES: 2-250 µl.
Typically 120 - 200 µl.
Up to four reagent additions / test possible.

Cuvettes
Discrete disposable multicell cuvette with 12 reaction positions and measurement cells in a row, light path 7 mm, calculations automatically correspond to 10 mm.
Several blank possibilities programmable.
Continuous loading. On-board capacity of 175 multicell cuvettes (175 x 12 = 2100 positions), typically 4 hours walk-away time.

Dispensing
Externally and internally rinsed single probe dispensers equipped with level detection.
Separate dispensers for samples, reagents and ISE tests.
Dispensing with precision syringes driven by stepping motors.
MIXING: Mixing in the cuvette by externally rinsed mixer.
REACTION END VOLUME: 100-250 µl.
SAMPLE CARRY OVER: <1%.
REPRODUCIBILITY: CV less than 2% for volumes 2- 20 µl.

Dilutions
Automatic sample pre-dilution.
Automatic post-dilution, high and low secondary dilution ratios, of the rerun sample.
Possibility to add the value of manual pre-dilution for the result calculation.
DILUTION RATIOS: up to 1+120

Calibration
Linear, non-linear or bias calibration.
Calibration with separate calibrator samples or with automatically diluted series from a stock calibrator.
Automatically repeated bias correction possibility.
20 positions for calibrator samples in the cooled area of the sample disk. Also possible to load them into segments.

Quality Control
Real time QC with multiple and variable (Westgard) rules.
Programmable control interval.
19 positions for control samples in the cooled area of the sample disk. Also possible to load them into segments.
QC chart printouts, daily and cumulative reports.

Reaction incubation
Reaction incubator for 20 multicell cuvettes (i.e. 240 reaction cells). Measurement compartment and photo detection unit incubated by electronically controlled heating elements.
MEASUREMENT TEMPERATURE: 37°C

Photometric measurement
Single channel interference filter photometer with beam splitting reference. The 12 reaction cells are measured in sequence.
MEASUREMENT PRINCIPLES: Colorimetric, turbidimetric.
MEASUREMENT MODES: Kinetic, end-point.
SPECTRAL RANGE: 340-800 nm.
INTERFERENCE FILTERS: 11 pcs.
5 pcs are available as options.
LIGHT SOURCE: Halogen lamp.
LINEAR ABSORBANCE RANGE: 0-2.5 A.
RESOLUTION: 0.0001 A.
REPRODUCIBILITY: SD ≤0.005 A at 2 A.
KINETIC MEASUREMENT: 15 sec. - 60 min, max 12 points

ISE Measurement in the model Konelab 60i
MEASUREMENT PRINCIPLE: Direct potentiometry. Electrodes for Na^+, K^+ and Cl^-, upon request Li^+,Ca^{2+} and pH.
SAMPLES: Serum, plasma and urine.
USABLE RANGE: (mmol/l)

	serum, plasma	Urine
K^+	2.0-10	20 - 200
Na^+	100 - 200	20 - 200
Cl^-	50 - 150	
Li^+	0.2 - 4.0	
Ca^{2+}	0.5 - 6.0	
pH	6 - 8.5	

PRECISION (CV %):

	serum, plasma	Urine
K^+	1%	5%
Na^+	1%	5%
Cl^-	1%	
Li^+	3%	
Ca^{2+}	2%	
pH	0.02 (SD)	

Data management
INSTRUMENT WORKSTATION: OptiPlex GX260 with Windows® XP.
USER INTERFACE: Graphical user interface. Data input by mouse, by keyboard or online. Different language versions available.
BARCODES IN USE: Code 128, Code 39, USS Codabar, Interleaved 2 of 5.
LIS INTERFACE: ASTM 1394-91 or KONE Online.
HARDWARE INTERFACE: RS-232

RESULT REPORTS: Collated by patient (tests performed by Konelab, off-line results and calculated results) and available in ward or sender order through network or external printer. Automatic or 'on request' printout, automatic STAT reporting. Flagging pathological values and repeats.
OFF-LINE RESULTS: Manual entry of off-line results to Konelab to provide fully collated result reports.
CALCULATED RESULTS: Results are calculated both from measured and off-line results.
DATA STORAGE: Long term storage of patients with demographics including test and QC results and calibrations.

Environmental requirements
SIZE: Instrument width 150 cm, depth 79 cm, height 115 cm, weight 250 kg. Separate workstation table.
POWER REQUIREMENTS: 1.2 kVA, 100 - 240 V ± 10 %, 50 - 60 Hz ± 5%. Power failure security (battery back-up facility).
DISTILLED WATER: Consumption typically <2 l/h. Available on-board, no external connections required.
OPERATING CONDITIONS: Ambient temperature 15-32^{o}C; humidity 40-85% (non condensing).

Regulatory requirements
CONFORMITY WITH:
98/79/EC IVDMD Directive CE

Ordering codes
981700 Konelab 60i
981710 Konelab 60i with KUSTI
981701 Konelab 60
981711 Konelab 60 with KUSTI

NOTE :
Precision is measured with serum based sample material and aqueous calibrator solutions. The information and technical specifications are subject to change without prior notice.

Konelab 30

Operating principle
Random access analyser for routine and special chemistries, including specific proteins, therapeutic drugs, drugs of abuse and user definable applications.
Programmable tests 200.
ISE unit in the model Konelab 30i for Na^+, K^+ and Cl^-. Li^+, Ca^{2+} and pH are available upon request.

Throughput
Workload dependent being in typical routine use up to 300 tests/hour.
Time to first result is typically 3 to 12 minutes.

Samples
Samples are placed on continuous loading segments with 14 positions each.
MAX ON-BOARD CAPACITY:
6 segments, 6 additional positions for STAT samples.
Integrated barcode reader and cup/ tube recognition.
Optional sample transport interface (KUSTI).
SAMPLE CUPS AND TUBES:
0.5 ml and 2.0 ml cups, 5 ml and 7 ml tubes, 10 ml tubes with tailored segments.
SAMPLE TYPES: Serum, plasma, urine, CSF.
SAMPLE VOLUMES: Possible range 1-120 µl ; typically 2-15 µl.
For Na^+, K^+ and Cl^- tests 50 µl.

Reagents
REAGENT VIALS: 10 ml, 20 ml and 60 ml vials.
ON-BOARD STORAGE: Continuous loading 45 positions in the 4-8 °C refrigerated reagent compartment.
Automated identification by integrated barcode reader. Real time reagent status seen on the workstation window.
REAGENT VOLUMES: 2-250 µl; typically 120 - 200 µl. Up to four reagent additions / test possible.

Cuvettes
Discrete disposable multicell cuvette with 12 reaction positions and measurement cells in a row, light path 7 mm, calculations automatically correspond to 10 mm.
Several blank possibilities programmable.
Continuous loading. On-board capacity of 50 multicell cuvettes (50 x 12 = 600 positions), typically 2 hours walk-away time

Calibration
Linear, non-linear or bias calibration.
Calibration with separate calibrator samples or with automatically diluted series from a stock calibrator.
Automatically repeated bias correction possibility.
20 positions for calibrator samples in the cooled area of the sample disk.
Also possible to load them into segments.

Quality Control
Real time QC with multiple and variable (Westgard) rules.
Programmable control interval.
19 positions for control samples in the cooled area of the sample disk. Also possible to load them into segments.
QC chart printouts, daily and cumulative reports.

Dispensing
Externally and internally rinsed single probe dispensers equipped with level sensing.
Dispensing with precision syringes driven by micro-stepping motors.
MIXING: Mixing in the cuvette by externally rinsed mixer.
REACTION END VOLUME:
100-250 µl.
SAMPLE CARRY OVER: <1%.
REPRODUCIBILITY:
CV less than 2% for volumes 2-20 µl.

Dilutions
Automatic sample pre-dilution.
Automatic post-dilution, high and low secondary dilution ratios, of the rerun sample.
Possibility to add the value of manual pre-dilution for the result calculation.
DILUTION RATIOS: up to 1+120

Reaction incubation
Reaction incubator for 6 multicell cuvettes (i.e. 72 reaction cells). Measurement compartment and photo detection unit incubated by electronically controlled heating elements.
MEASUREMENT TEMPERATURE: 37°C

Photometric measurement
Single channel interference filter photometer with beam splitting reference. The 12 reaction cells are measured in sequence.
MEASUREMENT PRINCIPLES:
Colorimetric, turbidimetric.
MEASUREMENT MODES:
Kinetic, end-point.
SPECTRAL RANGE:
340-800 nm.
INTERFERENCE FILTERS:
11 pcs.
5 pcs are available as options.
LIGHT SOURCE: Halogen lamp.
LINEAR ABSORBANCE RANGE: 0-2.5 A.
RESOLUTION: 0.0001 A.
REPRODUCIBILITY:
SD ≤0.005 A at 2 A.
KINETIC MEASUREMENT:
15 sec. - 60 min, max 12 points.

Environmental requirements
SIZE: Instrument width 120 cm, depth 79 cm, height 115 cm, weight 200 kg.
Separate workstation table.
POWER REQUIREMENTS:
0.7 kVA, 100 - 230 V ± 10 %, 50 - 60 Hz ± 5%.
Power failure security (battery back-up facility).
DISTILLED WATER:
Consumption typically <1.5 l/h.
Available on-board, no external connections required.
OPERATING CONDITIONS:
Ambient temperature 15-32°C; humidity 40-85% (non condensing).

ISE Measurement in the model Konelab 30i
MEASUREMENT PRINCIPLE:
Direct potentiometry. Electrodes for Na^+, K^+ and Cl^-; upon request Li^+,Ca^{2+} and pH.
SAMPLES: Serum, plasma and urine.
USABLE RANGE: (mmol/l)

	serum, plasma	urine
K^+	2.0-10	20 - 200
Na^+	100 - 200	20 - 200
Cl^-	50 - 150	
Li^+	0.2 - 4.0	
Ca^{2+}	0.5 - 6.0	
pH	6 - 8.5	

PRECISION (CV %):

	serum, plasma	urine
K^+	1%	5%
Na^+	1%	5%
Cl^-	1%	
Li^+	3%	
Ca^{2+}	2%	
pH	0.02 (SD)	

Data management
INSTRUMENT WORKSTATION: OptiPlex GX 260 with Windows® XP.
USER INTERFACE: Graphical user interface. Data input by mouse, by keyboard or online. Different language versions available.
BARCODES IN USE: Code 128, Code 39, USS Codabar, Interleaved 2 of 5.
LIS INTERFACE:
ASTM 1394-91 or KONE Online.
HARDWARE INTERFACE:
RS-232
RESULT REPORTS: Collated by patient (tests performed by Konelab, off-line results and calculated results) and available in ward or sender order through network or external printer.
Automatic or 'on request' printout, automatic STAT reporting.
Flagging pathological values and repeats.

OFF-LINE RESULTS: Manual entry of off-line results to Konelab to provide fully collated patient reports.
CALCULATED RESULTS: Results are calculated both from measured and off-line results.
DATA STORAGE: Long term storage of patients with demographics including test and QC results and calibrations.

Regulatory requirements
CONFORMITY WITH:
98/79/EC IVDMD Directive CE

Ordering codes
981851 Konelab 30i,
981861 Konelab 30i with KUSTI,
981850 Konelab 30,
981860 Konelab 30 with KUSTI.

NOTE :
Precision is measured with serum based sample material and aqueous calibrator solutions. The information and technical specifications are subject to change without prior notice.

Konelab 20XT

Operating principle
Random access analyser for routine and special chemistries, including specific proteins, therapeutic drugs, drugs of abuse and user definable applications.
Programmable tests 200.
ISE unit in the model Konelab 20XTi for Na^+, K^+ and Cl^-. Li^+ is available upon request.

Throughput
Workload dependent being in typical routine use up to 250 tests/hour.
Time to first result is typically 3 to 12 minutes.

Samples
Samples, calibrators and controls are placed on sample disk in segments with 14 positions each.
MAX ON-BOARD CAPACITY:
6 segments, 5 additional positions for STAT samples.
Integrated barcode reader and cup/ tube recognition.
SAMPLE CUPS AND TUBES:
0.5 ml and 2.0 ml cups, 5 ml and 7 ml tubes, 10 ml tubes with tailored segments
SAMPLE TYPES: Serum, plasma, urine, CSF.
SAMPLE VOLUMES: Possible range 1-120 µl ; typically 2-15 µl.
For Na^+, K^+ and Cl^- tests 50 µl.

Reagents
REAGENT VIALS: 10 ml, 20 ml and 60 ml vials.
ON-BOARD STORAGE: Continuous loading 35 positions in the cooled reagent disk. External barcode reader for identification. Real time reagent status seen on the workstation window.
REAGENT VOLUMES: 2-250 µl; typically 120 - 200 µl.
Up to four reagent additions / test possible.

Cuvettes
Discrete disposable multicell cuvette with 12 reaction measurement cells in a row, light path 7 mm, calculations automatically correspond to 10 mm.
Several blank possibilities programmable.
Continuous loading. On-board capacity of 50 multicell cuvettes (50 x 12 = 600 positions), typically up to 2.5 hours walk-away time

Calibration
Linear, non-linear or bias calibration.
Calibration with separate calibrators or with automatically diluted series from a stock calibrator.
Automatically repeated bias correction possibility.

Quality Control
Real time QC with multiple and variable (Westgard) rules.
Programmable control interval.
QC chart printouts, daily and cumulative reports.

Dispensing
Externally and internally rinsed single probe dispensers equipped with level detection.
Dispensing with precision syringes driven by stepping motors.
MIXING: Mixing in the cuvette by externally rinsed mixer.
REACTION END VOLUME:
100-250 µl.
SAMPLE CARRY OVER: <1%.
REPRODUCIBILITY:
CV less than 2% for volumes 2- 20 µl.

Dilutions
Automatic sample pre-dilution.
Automatic post-dilution, high and low secondary dilution ratios of the rerun sample.
Possibility to add the value of manual pre-dilution for the result calculation.
DILUTION RATIOS: up to 1+120

Reaction incubation
Reaction incubator for 6 multicell cuvettes (i.e. 72 reaction cells). Measurement compartment and photo detection unit incubated by electronically controlled heating elements.
MEASUREMENT
TEMPERATURE: 37°C

Photometric measurement
Single channel interference filter photometer with beam splitting reference. The 12 reaction cells are measured in sequence.
MEASUREMENT PRINCIPLES:
Colorimetric, turbidimetric.
MEASUREMENT MODES:
Kinetic, end-point.
SPECTRAL RANGE:
340-800 nm.
INTERFERENCE FILTERS:
11 pcs.
5 pcs are available as options.
LIGHT SOURCE: Halogen lamp.
LINEAR ABSORBANCE RANGE: 0-2.5 A.
RESOLUTION: 0.0001 A.
REPRODUCIBILITY: SD ≤0.005 A at 2 A.
KINETIC MEASUREMENT:
15 sec. - 60 min, max 12 points.

Environmental requirements
SIZE: Instrument width 80 cm, depth 79 cm, height 115 cm, weight 142 kg.
Separate workstation table.
POWER REQUIREMENTS:
100 - 240 V ± 10 %,
50 - 60 Hz ± 5%,
350 W Konelab 20XTi,
300 W Konelab 20XT.
DISTILLED WATER:
Consumption typically <1 l/h.
Available on-board, no external connections required.
OPERATING CONDITIONS:
Ambient temperature 15-32°C; humidity 40-85% (non condensing).

Regulatory requirements
CONFORMITY WITH:
98/79/EC IVDMD Directive CE

ISE Measurement in the model Konelab 20XTi
MEASUREMENT PRINCIPLE:
Direct potentiometry. Electrodes for Na^+, K^+ and Cl^-;
Li^+ upon request.
SAMPLES: Serum, plasma and urine.
USABLE RANGE: (mmol/l)

	serum, plasma	urine
K^+	2.0-10	20 - 200
Na^+	100 - 200	20 - 200
Cl^-	50 - 150	
Li^+	0.2 - 4.0	

PRECISION (CV %):

	serum, plasma	urine
K^+	1%	5%
Na^+	1%	5%
Cl^-	1%	
Li^+	3%	

Data management
INSTRUMENT WORKSTATION (INCLUDED): Dell OptiPlex GX260 with Windows® XP.
USER INTERFACE: Graphical user interface. Data input online, by mouse, keyboard or barcode reader connected alongside with the keyboard. Different language versions available.
BARCODES IN USE: Code 128, Code 39, USS Codabar, Interleaved 2 of 5.
LIS INTERFACE: ASTM 1394-91 or KONE Online.
HARDWARE INTERFACE:
RS-232
RESULT REPORTS: Collated by patient (tests performed by Konelab, off-line results and calculated results). Automatic or 'on request' printout, automatic STAT reporting.
Flagging pathological values and repeats.
OFF-LINE RESULTS: Manual entry of off-line results to Konelab to provide fully collated result reports.
CALCULATED RESULTS: Results can be calculated both from measured and off-line results.
DATA STORAGE: Long term storage of patients with demographics including test and QC results and calibrations.

Ordering codes
984141 Konelab 20XTi,
984140 Konelab 20XT.

NOTE :
Precision is measured with serum based sample material and aqueous calibrator solutions. The information and technical specifications are subject to change without prior notice.

Konelab 20

Operating principle
Random access analyser for routine chemistries and specific proteins, as well as for user definable applications.
Programmable tests 200.
ISE unit in the model Konelab 20i for Na^+, K^+ and Cl^-. Li^+ is available upon request.

Throughput
Workload dependent being in typical routine use up to 200 tests/hour.
Time to first result is typically 3 to 12 minutes.

Samples
Samples, calibrators and controls are placed on sample disk in segments with 14 positions each.
MAX ON-BOARD CAPACITY:
6 segments, 5 additional positions for STAT samples.
Integrated barcode reader and cup type recognition.
SAMPLE CUPS AND TUBES:
0.5 ml and 2.0 ml cups, 5 ml and 7 ml tubes, 10 ml tubes with tailored segments
SAMPLE TYPES: Serum, plasma, urine, CSF.
SAMPLE VOLUMES: Possible range 1-120 µl ; typically 2-15 µl.
For Na^+, K^+ and Cl^- tests 50 µl.

Reagents
REAGENT VIALS: 10 ml, 20 ml and 60 ml vials.
ON-BOARD STORAGE:
Continuous loading 35 positions in the cooled reagent disk. External barcode reader for identification.
Real time reagent status seen on the workstation window.
REAGENT VOLUMES: 2-250 µl; typically 120 - 200 µl. Up to four reagent additions / test possible.

Cuvettes
Discrete disposable multicell cuvette with 12 reaction positions and measurement cells in a row, light path 7 mm, calculations automatically correspond to 10 mm.
Several blank possibilities programmable.
Continuous loading. On-board capacity of 50 multicell cuvettes (50 x 12 = 600 positions), typically 3 hours walk-away time

Calibration
Linear, non-linear or bias calibration.
Calibration with separate calibrator samples or with automatically diluted series from a stock calibrator.
Automatically repeated bias correction possibility.

Quality Control
Real time QC with multiple and variable (Westgard) rules.
Programmable control interval.
QC chart printouts, daily and cumulative reports.

Dispensing
Externally and internally rinsed single probe dispensers equipped with level sensing.
Dispensing with precision syringes driven by stepping motors.
REACTION END VOLUME:
100-250 µl.
SAMPLE CARRY OVER: <1%.
REPRODUCIBILITY:
CV less than 2% for volumes 2- 20 µl.

Dilutions
Automatic sample pre-dilution.
Automatic post-dilution, high and low secondary dilution ratios, of the rerun sample.
Possibility to add the value of manual pre-dilution for the result calculation.
DILUTION RATIOS: up to 1+120

Reaction incubation
Reaction incubator for 6 multicell cuvettes (i.e. 72 reaction cells).
Measurement compartment and photo detection unit incubated by electronically controlled heating elements.
MEASUREMENT TEMPERATURE: 37°C

Photometric measurement
Single channel interference filter photometer with beam splitting reference. The 12 reaction cells are measured in sequence.
MEASUREMENT PRINCIPLES:
Colorimetric, turbidimetric.
MEASUREMENT MODES:
Kinetic, end-point.
SPECTRAL RANGE:
340-800 nm.
INTERFERENCE FILTERS:
11 pcs.
5 pcs are available as options.
LIGHT SOURCE: Halogen lamp.
LINEAR ABSORBANCE RANGE:
0-2.5 A.
RESOLUTION: 0.0001 A.
REPRODUCIBILITY:
SD ≤0.005 A at 2 A.
KINETIC MEASUREMENT:
15 sec. - 60 min, max 12 points.

Environmental requirements
SIZE: Instrument width 80 cm, depth 79 cm, height 115 cm, weight 130 kg.
Separate workstation table.

POWER REQUIREMENTS:
100 - 240 V ± 10 %,
50 - 60 Hz ± 5%, 350 W Konelab 20i, 300 W Konelab 20.
DISTILLED WATER:
Consumption typically <0.5 l/h.
Available on-board, no external connections required.
OPERATING CONDITIONS:
Ambient temperature 15-32°C; humidity 40-85% (non condensing).

Regulatory requirements
CONFORMITY WITH:
98/79/EC IVDMD Directive CE

ISE Measurement in the model Konelab 20i
MEASUREMENT PRINCIPLE:
Direct potentiometry. Electrodes for Na^+, K^+ and Cl^-;
Li^+ upon request.
SAMPLES: Serum, plasma and urine.
USABLE RANGE: (mmol/l)

	serum, plasma	urine
K^+	2.0-10	20 - 200
Na^+	100 - 200	20 - 200
Cl^-	50 - 150	
Li^+	0.2 - 4.0	

PRECISION (CV %):

	serum, plasma	urine
K^+	1%	5%
Na^+	1%	5%
Cl^-	1%	
Li^+	3%	

Data management
INSTRUMENT WORKSTATION (INCLUDED): Dell OptiPlex GX260 with Windows® XP.
USER INTERFACE: Graphical user interface. Data input online, by mouse, keyboard or barcode reader connected alongside with the keyboard. Different language versions available.
BARCODES IN USE: Code 128, Code 39, USS Codabar, Interleaved 2 of 5.
LIS INTERFACE: ASTM 1394-91 or KONE Online.
HARDWARE INTERFACE:
RS-232
RESULT REPORTS: Collated by patient (tests performed by Konelab, off-line results and calculated results) and available in ward or sender order through network or external printer.
Automatic or 'on request' printout, automatic STAT reporting.
Flagging pathological values and repeats.
OFF-LINE RESULTS: Manual entry of off-line results to Konelab to provide fully collated patient reports.
CALCULATED RESULTS:
Results are calculated both from measured and off-line results.

DATA STORAGE: Long term storage of patients with demographics including test and QC results and calibrations.

Ordering codes
981800 Konelab 20i,
981801 Konelab 20.

NOTE :
Precision is measured with serum based sample material and aqueous calibrator solutions.
The information and technical specifications are subject to change without prior notice.