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Manufacturer according to 93/42/EEC

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Technology upgrade is a continuous process at KONTRON MEDICAL. Hence, the
specifications mentioned in this manual are subject to change without any prior
notice. The contents in this manual are strictly not to be reproduced in any form,
by any method, for any purpose.
REGULATORY REQUIREMENT

This product complies with regulatory requirements of the following European directive 93/42/CEE concerning medical devices.

CE
0459
PREFACE

To use the unit correctly and ensure a long operation life of the unit, it is most important to understand well the instructions, operation as well as its necessary maintenance. Please read the operator manual carefully before using it.

Even though the system is designed and manufactured with the safety of its operators and patients emphasized, be sure to read the following instructions to ensure a safe and reliable operation of the system:

a. The system should be operated by a qualified person, or let other person operate the unit under his guidance.

b. This unit belongs to Type B, Class 1 of the IEC Standard. Be sure to use it correctly and safely according to the safety instruction specified in Section 1.5 Safety of the Operator Manual.

c. Never try to remodel the unit. If remodeling is necessary, let us or our appointed agents do the work.

d. The unit has been completely adjusted before delivery. Do not touch any adjustable parts that have been well fixed.

e. Should any abnormality occur during operation, immediately shut off the power supply and contact our appointed contactor or us.

f. The power cord of the unit should be connected to a power socket with ground terminal. The grounding wire should not be moved away.

g. In case of connecting the unit with other manufacturer’s device either electrically or mechanically, make sure the device conform to IEC60601-1 standard and re-check the safety of electrical leakage of the system to avoid any possible hazard caused.

h. The system is running with safety, however according to specialist’s promote, the working probe cannot be placed on an organ of a patient particularly the
fetus for a long time.

i. The ultrasound gel applied on the patient should be a qualified one.

This Operator manual may be different from that of your equipment due to the updated software for SONEO.
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1. GENERAL INFORMATION

1.1 The characteristic of the products

SONEO is an electronic linear/convex ultrasound scanner with an advanced built-in digital scan converter (DSC) and a full range of multi-frequency probes from 2.5MHz to 10MHz. Take the C2-5S4 probe as an example. The center frequency of C2-5S4 is 3.5MHz and it can be converted to 2.5MHz, 3.0MHz and 5.0MHz.

SONEO consists of a 10" non-interlaced monitor with larger ultrasound imaging and a backlit keyboard. The backlit keyboard allows the operator to view clearly the character on the keyboard even in a dark room. Besides, some keys will become brighter when activated. It is compatible with a video printer and equipped with a RS-232 interface for storage and handling of the image via a computer.

SONEO is a full-featured and easy-operated ultrasound scanner.

1.2 Application and Warning

With a varied selection of probes, SONEO can be used for examination of abdominal organs, OBS/GYN (including vagina), cardiac and thyroid gland etc. in a polymorphous hospital.

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SONEO is not applicable for ophthalmology or any examination that ultrasound beam would penetrate through eye.</td>
</tr>
</tbody>
</table>

1.3 Ambient Conditions

- This unit must be used on the following environmental conditions to ensure a safe and correct operation:
Operation condition | Storage condition
---|---
Ambient Temperature: | 5～40℃ | -40℃～55℃
Relative Humidity: | ≤80% | ≤95%
Atmospheric Pressure: | 700~1600hPa | 700~1600hPa

If the operation temperature and humidity are beyond the ranges above, no correct ultrasonic images are ensured.

**NOTE**

In case of storing the unit for a long time, the ventilation of the storage place must be considered.

- Strong radiation sources or electromagnetic waves, from broadcast & TV station for instance, may cause the unit to display an image overlapped or noise. Keep the unit away from the disturbance sources.
- Do not place anything on the top of main unit.
- After use of the unit, be sure to turn off the power switch and protect the unit with the accessory dust proof cover. Whenever the unit is not used, keep the cover on since the unit is sensitive to dust.

### 1.4 Power Requirements

The power requirements for the unit are as specified as below. Never use this unit when power supply does not meet the requirements, or the unit may possibly be damaged.

- **Power Voltage for the Main Unit**

  The power voltage for the main unit should be in accordance with the specification on the rear panel of the unit. The voltage fluctuation of power supply to the unit should be within the limits of ±10%. Otherwise, the unit is likely to be damaged.
• Power voltage: 110V~/220V~
• Frequency of the Power Supply: 50Hz/60Hz
• Apparent Impedance of Power Supply: 0.5Ω or less
• Grounding
  Connect the power supply after the additional protective ground connector is connected to the special ground device.

**WARNING**
The user should wait for at least 20 seconds before switching the unit on again after power off.

1.5 Safety Classification

a. This system is designed and manufactured in accordance with the Safety Requirements of IEC. To operate the unit correctly and safely, observe the following instructions:
• The safety protection of electronic shock is classified in I class Type B.
• The safety protection of deleterious fluid is classified in IPX0.
• The unit should not be used in a flammable atmosphere.
• The unit can be operating continuously more than 8 hours.
• This unit needs a protective grounding device. When using it, be sure to earth it with the additional grounding device. Do not use the unit where no ground terminal is available.

b. Data of Acoustic Output:

<table>
<thead>
<tr>
<th>5-2MHz, C2-5S4 Convex Array</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
</tr>
<tr>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10-5MHz, L5-10S5 Linear Array</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
</tr>
<tr>
<td>X</td>
</tr>
</tbody>
</table>
c. Adverse Effects and Precautions

The SONEO, same as other diagnostic ultrasound system in the market, should be used only for clinically appropriate reasons, for the shortest period of time and at power settings as low as reasonably achievable (ALARA).

The American Institute of Ultrasound in Medicine (AIUM) principle of As Low As Reasonably Achievable (ALARA) is recommended during selection of the output of ultrasound power. Try not to aim probe at the same spot in tissue for a long period of time unless it is really necessary for diagnostic purpose. This system generates acoustic power that is below pre-enactment level, which is generally considered to be safe for the respective applications.

- The value of $I_{SPTA,3}$ under M-mode and B/M-Mode is larger than the $I_{SPTA,3}$ under B-mode.

- The value of $I_{SPTA,3}$ is the maximum when only focus M is selected. However the difference between the values of $I_{SPTA,3}$ for each focus is no so much.

- Multi-frequency
  Each probe has three frequencies, including the center frequency, high frequency and low frequency. The acoustic output is decreasing from low frequency, center frequency to high frequency.
1.6 Safety Mark

The user should observe the operating procedure in this Operator Manual and the relative warning message to ensure the safety of the unit. Following is the interpretation of the mark on the unit:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![ Equalization potential terminal ]</td>
<td>Equalization potential terminal</td>
<td>To eliminate the phasic mistake, the terminal linking to the unit cover should connect to the corresponding terminal of other equipment.</td>
</tr>
<tr>
<td>![ Caution ]</td>
<td>Caution</td>
<td>Please refer to the relative explanation in the Operator Manual when you find this label on the unit or any document. It is labeled for the safety assurance of the unit.</td>
</tr>
<tr>
<td>![ Type B ]</td>
<td>Type B</td>
<td>Type B equipment (IEC 60601-1)</td>
</tr>
<tr>
<td>![ Damage for electric shock ]</td>
<td>Damage for electric shock</td>
<td>Terminals at the High voltage</td>
</tr>
</tbody>
</table>
2. STRUCTURE OF THE UNIT

2.1 Main Unit Operation principle

The block diagram of SONEO is shown in Fig. 2-1.

Following the main unit operation principle:

a. The CPU (Central Processing Unit) in the main CPU module reads the instruction from the key operation on the keyboard and issue control commands to the ultrasonic transmitter/receiver according to the instructions.

b. The ultrasonic transmitter/receiver sends ultrasonic transmitting signal to the ultrasonic probe.

c. The electrical signals are converted into ultrasonic signals by the transducer in ultrasonic probe, and are able to propagate in a patient’s body.

d. The ultrasonic waves reflected from a patient’s body are then converted into the electrical signal by the transducer.

e. The echo signals are sent to the ultrasonic transmitter/receiver, where the signals are amplified, compressed and detected.

f. The detected signals are analog signals. The digital scan converter (DSC) converts them to digital signals, and further writes into a frame memory. The signals in the frame memory are read by means of television timing signals and then are converted into analog signals once again and displayed as an ultrasonic image on the monitor screen. Some image processing function, such as freezing, frame averaging, interpolation and gray scale mapping, is also realized by DSC.

g. The 10” monitor receives the non-interlaced compounded video signal and display on the CRT.
2.2 The front panel of main unit

Fig 2-2 shows you the scheme of the front panel. The numbers on the front panel represent:

1. 10" monitor
2. Nameplate
3. Brightness Control knob
   The brightness of the monitor will increase when the knob is turned clockwise.
4. Contrast Control Knob
   The contrast will increase when the knob is turned clockwise.
5. Power Switch
   Turn on and off the power supply of the unit.
2.3 The rear panel

Fig 2-3 shows you the scheme of rear panel.
1. Probe Connector A  
2. Probe Connector B  
3. Video output interface for non-interlaced signal  
4. Video output interface for interlaced signal  
5. Video printer Connector  
6. Connector for Foot Switch (Freeze and unfreeze)  
7. RS-232 Port  
8. Fan for heat-sinking  
9. Power connector  
10. Grounding terminal  
11. Fuse  
12. Warning label  
13. Label  

2.4 Keyboard  

Fig 2-4 shows you the picture of keyboard.

- **B-mode Selection keys**  
  a) B-mode full screen image will be displayed by pressing the key.  
  b) The active B mode image of dual B mode will be displayed on the left half of the screen by pressing the key. Press the key, the active B mode image is displayed on the right half of the screen and the image on the left side will freeze.

- **M-mode Selection keys**  
  Press the key to display M-mode and B-mode images simultaneously. The left part on the screen is B-mode image. The sampling beam position, which can be changed by operating the trackball, decides the sampling position of M-mode image on the right part of the screen.
Press \[ \textbf{M} \] key to display the full M-mode image.

- **M-mode Sweep Speed Selection key** \[ \textbf{M SPEED} \]

Press \[ \textbf{M SPEED} \] key repeatedly, and you can select four sweep speeds: 8s/f, 4s/f, 2s/f and 1s/f.

- **Image Magnification Selection keys** ▲▼

(a) Magnification factor increases by pressing ▲ key.

Magnification factor decreases by pressing ▼ key.

(b) Press ▲ key repeating, the magnification factor will be changed from \( \times 0.8 \rightarrow \times 1.0 \rightarrow \times 1.2 \rightarrow \times 1.5 \rightarrow \times 1.7 \rightarrow \times 2.0 \).

- **Image Vertical shift keys** \[ \textbf{C} \] \[ \textbf{V} \]

The image will be shifted up or down vertically about 2 mm by each press when the image is in B mode and the magnification factor is >1.0.

- **Focus Selection keys**  N M F1 F2

\[ \begin{array}{c}
\text{Fig 2-4 Keyboard}
\end{array} \]
The focus is corresponding to a required position in the depth direction, which can be selected by the following operation. The focus selected is displayed on the right side of the screen.

- **N**: Select the focus in near field, i.e., focus in less-depth portion.
- **M**: Select the focus in middle field, i.e., focus in intermediate portion.
- **F1**: Select the focus in far field, i.e., focus in deep portion.
- **F2**: Select the focus in extra-far field, i.e., focus in deeper portion.

### NOTE

- Only one focus can be selected in M or B/M mode.
- Multi-step focusing can be selected in B-mode and adjacent focus should be selected simultaneously, **N**, **M**, and **F1**, for instance, or else the image may have horizontal straps with discontinuous darkness.

### Image Processing key

Press key to enter into Image Processing Menu

1. **CORRM**: Change correlated coefficient
   
   To select an extent of frame correlation, there are four correlation factors for selection. When you select a correlation factor form CORR0 to CORR3, a corresponding indication is displayed on the left side of screen.

2. **ENHCM**: Image Edge Enhancement
   
   By pressing the key, four kinds of edge enhancement can be selected.

3. **GREYM**: Grayscale Curve Selection key
   
   There are 4 grayscale curves (γ correction) for selection. A corresponding indication is shown on the screen.

4. **P/N M**: Image Positive-Negative Reverse Key
   
   To reverse the display of image between positive and negative. The key is initially set for negative image display (black background and white characters).
(5) L/R M  Image Left-Right Reverse key
Pressing the key can change scanning direction of ultrasonic beam to reverse the image between left and right.

(6) U/D M  Image Upside/downside Reverse Key
The image can be upside-down by pressing this key. The near field is initially set on the upside when power on. This function is subject to trans-vaginal probe only.

The Item can be selected by pressing down the corresponding number key or by moving the trackball to highlight the item. To activate the function, pressing key or key. Press key repeatedly to alter the parameter of the item after selected. Press key to retreat from the alteration.

● Frequency selection key
Press Key to convert the working frequency of the probe. There are four frequencies available for selection for each probe. The working frequency will correspondingly be display on the right side of the monitor.

● Probe Selection key
Press key to select the desired probe. The model and the frequency of the probe will be displayed on the left side of the screen. Message “NO PROBE” will appear on the screen and the image will be frozen when no probe connects to the selected probe connector.

<table>
<thead>
<tr>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probe A will be automatically selected when SONEO power on.</td>
</tr>
<tr>
<td>Probe B will be initially selected if no probe connects to Probe A when the system turn on.</td>
</tr>
</tbody>
</table>
• **Freeze key**

Freeze key is to freeze or unfreeze the image. The character inputted and image acquired will remain unchanged when frozen. The screen will be renewed after unfrozen.

• **Cine loop Control key**

To playback the single frame, please press down the CINE key when the image is frozen. Under single B-mode, press the CINE key to Cine loop the frame continuously. Under M-mode continuous Cine loop is not available.

Press “U” to change the speed of Cine loop. Four different kinds of speed are available.

In single frame loop under B-mode, the number of frame can be selected by moving the trackball.

In M-mode, single frame can be selected by choosing different time slice with trackball.

The CINE key will be unable when one of PROCESS, OB, MEAS or BODY key is activated.

• **Body Mark Control Key**

Press the BODY key to enter into the Body Mark Menu shown as below:

- **BODY**  Enter the selection of Body Mark
- **MOROP**  Move and turn over the Probe Mark
- **OFFBY**  Remove the Body Mark
### NOTE

a. Press to enter into the table of Body Mark. And then move the trackball to select the corresponding body mark and press key to activate.

b. Press key to move and turn over the Probe Make. Press to select the Probe Mark and move it to the desired position by the trackball. Press key to exit.

#### Distance Measurement key

Under frozen state, press key to activate the distance measurement.

#### Function keys for measurement

<table>
<thead>
<tr>
<th>Key</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEAS</td>
<td>AREAE (measure the area with ellipse method)</td>
</tr>
<tr>
<td>MEAS</td>
<td>AREAT (measure the area with trackball)</td>
</tr>
<tr>
<td>MEAS</td>
<td>VOL-E (measure the volume with ellipse method)</td>
</tr>
<tr>
<td>MEAS</td>
<td>VOL-B (measure the volume with biplane method)</td>
</tr>
<tr>
<td>MEAS</td>
<td>ANGL (measure the angle)</td>
</tr>
</tbody>
</table>

### NOTE

The measurement of one angle with ANGLE in this menu is different from that of two angles with ANGLE in the OB menu.
b. To display the following menu in M-mode:

- **HR**  
  (measure the heart rate)
- **MV**  
  (measure the Mitral Valve)
- **LV**  
  (measure the Left Ventricle)
- **AO**  
  (measure the Aortic Valve)
- **TIME**  
  (measure the time)
- **SLOPE**  
  (measure the slope)

NOTE

The item indicated with "*" must be measured for OB report.

By pressing down the **OB** key, the measurement function menu will display immediately under unfrozen.

In B or B.B mode, to display items 1-9 of the measuring function menu.

- **BPD**  
  (Biparietal Diameter)
- **GS**  
  (Gestational Sac)
- **CRL**  
  (Crown-Rump Length)
- **FL**  
  (Femur Length)
- **AC**  
  (Abdominal Circumference)
- **HC**  
  (Head Circumference)
- **VOL-B**  
  (Volume) (Bi-plane method)
- **ANGLE**  
  (Angle)
- **OBRPT**  
  (Obstetric Patient Report)
NOTE

Item indicated with “*” must be measured for OB Report.

key: Confirm key

key: Exit key

● ID key

Press this key to input the patient’s ID. Press ID key again to exit.

● COMMENT key

A cursor “_” will appear at the center of the screen by pressing down this key. Use the trackball to move the cursor to the desired position to comment on the image. Press the COMMENT key again to withdraw.

● SET key

Press this key to alter the preset menu. There are five items.

a. For inputting the detailed information of the patient including Name, ID, AGE and LMP). Press “EDIT” to enter edit operation.

NOTE

The data inputted here is equivalent to that inputted after pressing the ID key. When the new information of patient ID is inputted, the system will automatically renewed the ID on left side of the screen.

b. Move the cursor to “[ ]” for inputting the hospital name.

c. For setting the system time. Follow the prompt and input date and time in the “[ ]”. During inputting, the system will execute a validity test.
d. For modifying the reference list of OB/GYN measurement, including the TOTAL PERIODS and six other measurement tables.

e. For setting the communication baud rates between the main unite and the PC. 115K and 57K are selectable.

Note: When the setting is finished, move the cursor to “EXIT” and press down the key to save and exit the Preset Menu.

● Biopsy Guide Line

Biopsy Guide Line will appear on the screen by pressing down key first (it will become brighter) and then press key under active state. Biopsy Guide Line is available to all probes for SONEO. Among the biopsy guide line of the ER5-9SB probe is movable. To move the biopsy guide line of ER5-9SB probe, please press down key. The biopsy guide line will shift down 2mm. The biopsy guide line of ER5-9SB will continuously shift down to the deepest 5 cm.

● Numeral/Character keys

Press the group of keys on the keyboard to input date, annotation, etc. Among those there are some special keys:

key: To clear the annotation and measured diagram, etc. Press down key while annotating, only the cursor will be cleared. This function is equivalent to press key at the second time.

key: To select the upper or lower part of the Number/Character key. When this key is highlighted, the upper part of the Number/Character is effective.
● **PRINT** key

To start the video printer linked to the main unit to print the image. This key is equivalent to the Print Knob on panel of the printer.

● **STORE** key

This key is effective only when storage device is available. Press down this key, “STORE NO??” will be displayed at right side of screen. Press 01-16 (two digit) to identify the storing ultrasound image, for example press 12. The displayed ultrasound image and No. 12 will be stored into the non-volatile memory.

**NOTE**

Please wait for 15 seconds to press the STORE or RECALL key again. However it will not affect the other operation.

● **RECALL** key

This key can be activated when storage device is available. “RECALL NO.??” will appear on the right side of screen by pressing down RECALL key. Select No. 01 to 16 to recall the stored ultrasound image. Press 12, the No. 12 ultrasound frame will be recalled. On the analogy of this, press 13 to recall the No. 13 ultrasound frame. Press ESC key to exit.

● **Gain Control knob**

The whole gain will be increased when the knob is turned clockwise.

● **7-steps TGC Control**

There are 7 TGC sliding control on the keyboard. To adjust the gain of Near
field, please slide the TGC control near the monitor. For changing the gain of Far field, just slide the TGC control near the Gain Control Knob. Move the TGC sliding to the left to increase the gain of the corresponding field and vice versa.

2.5 Probe

C2-5S6 3.5MHz R60 Convex high density multi-frequency probe.

2.6 Accessories

- Ultrasound gel one Bottle
- Power Cable one piece
- Ground wire one piece
- Fuse 50T-T1.6AL 250V two pieces

2.7 Options

- Probe (Please refer to 3.2 probe.)
- Video Printer
- Foot Switch
- RS-232C communication line
- Component for Memory
3. SPECIFICATIONS

3.1 Specifications of main unit

- **Scanning Mode**: electronic convex and linear
- **Display Mode**: B, B/B, B/M, M
- **Grey scale**: 256
- **Frequency of probe**: From 2.5MHz to 10MHz
- **Image Display Multiple**: $\times 0.8, \times 1.0, \times 1.2, \times 1.5, \times 1.7, \times 2.0$, Shift about 2mm step
- **Focusing method**: Variable aperture 1-4 focal zone electronic focusing
- **Display range (max)**:
  - Convex probe: Depth 200mm, Angle 80°
  - Linear probe: Depth 140mm, width 65mm
- **Image adjustment**:
  - General Gain Control Knob
  - 7 steps TGC Control
  - Grey map curve: 4 types
  - Frame correlation: 4 steps
  - Edge Enhance: 4 steps
- **Sweep Speed in M mode**: 1, 2, 4, 8 sec/frame
- **Image display**: left/right, positive/negative, up/down
- **Cine loop**: up to 64 frames under B-mode, continual/single,
  up to 256 sec under M-mode
- **Image storage**: 16 frames of image with related characters and diagram (Optional)
- **DSC Memory capacity**: $512 \times 512 \times 8$ bit
- **Monitor**: 10 inch B/W non-interlaced monitor
- **Backlit keyboard**: All the keys have background light. Some keys will become brighter when activated.
- Character Display:
  
  Patient ID
  Hospital Name
  Comment
  
  Automatically Display Item: Date & time, Frequency probe, Gain and operating parameters, and various measured values

- **Body marks:** 25 types

- **Measuring function:**
  
  Basic measurement: Distance, Circumference, area, volume, angle, HR, time
  Obstetrics measurement: BPD, CRL, FL, AC, HC, GS, VOL, ANG
  Other measurement: MV, LV, AO, Slope

- **Input/output port:**
  
  RS-232C port for transmitting image to PC (optional)
  One active convex or linear array port

- **Video system:**
  
  Video I: non-interlaced 50 frame/sec
  Video II: 625 lines/frame, 50 field/sec (PAL format)

- **Dimension:**  417 × 310 × 260 (mm)

- **Net weight:** 12Kg approx.

- **Power consumption:**
  
  ~110V  60Hz  120VA
  ~220V  50Hz  120VA

- **Environmental requirement:**

<table>
<thead>
<tr>
<th>Operation condition</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature:</td>
<td>5～40℃</td>
</tr>
<tr>
<td>Relative Humidity:</td>
<td>≤80%</td>
</tr>
<tr>
<td>Atmospheric Pressure:</td>
<td>700～1600hPa</td>
</tr>
<tr>
<td></td>
<td>-40℃～55℃</td>
</tr>
<tr>
<td></td>
<td>≤95%</td>
</tr>
<tr>
<td></td>
<td>700～1600hPa</td>
</tr>
</tbody>
</table>
## Order references:

<table>
<thead>
<tr>
<th>PN</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>171078</td>
<td>SONEO B/W ultrasound system (~220V)</td>
</tr>
<tr>
<td></td>
<td>W/ one convex probe of C2-5S6</td>
</tr>
<tr>
<td>171078-01</td>
<td>SONEO B/W ultrasound system (~110V)</td>
</tr>
<tr>
<td></td>
<td>W/ one convex probe of C2-5S6</td>
</tr>
<tr>
<td>171190</td>
<td>SONEO B/W ultrasound system (~220V)</td>
</tr>
<tr>
<td></td>
<td>W/ one microconvex probe of MC3-7S2</td>
</tr>
<tr>
<td>171190-01</td>
<td>SONEO B/W ultrasound system (~110V)</td>
</tr>
<tr>
<td></td>
<td>W/ one microconvex probe of MC3-7S2</td>
</tr>
</tbody>
</table>
### 3.2 Probe Specifications

The following probes are optional except C2-5S6 probe.

<table>
<thead>
<tr>
<th>PN*</th>
<th>Model</th>
<th>Frequency</th>
<th>Angle/Width</th>
<th>Depth</th>
<th>Transverse resolution</th>
<th>Longitudinal resolution</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>171093</td>
<td>C2-5S4</td>
<td>2.5/3.0/3.5/5.0</td>
<td>80°</td>
<td>220mm</td>
<td>4mm</td>
<td>2mm</td>
<td>Abdominal, OB/GYN</td>
</tr>
<tr>
<td></td>
<td>Convex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;80mm)</td>
<td>(depth&lt;80mm)</td>
<td></td>
</tr>
<tr>
<td>171115</td>
<td>L5-10S5</td>
<td>5.0/6.0/7.5/10.0</td>
<td>50mm</td>
<td>90mm</td>
<td>1mm</td>
<td>1mm</td>
<td>Small Part</td>
</tr>
<tr>
<td></td>
<td>Linear</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td></td>
</tr>
<tr>
<td>171069</td>
<td>EV3-7S1</td>
<td>3.5/4.0/5.0/6.5</td>
<td>135°</td>
<td>120mm</td>
<td>3mm</td>
<td>1mm</td>
<td>Gynecology</td>
</tr>
<tr>
<td></td>
<td>Endovaginal</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td></td>
</tr>
<tr>
<td>171050</td>
<td>MC3-7S1</td>
<td>3.5/4.0/5.0/6.5</td>
<td>130°</td>
<td>120mm</td>
<td>3mm</td>
<td>1mm</td>
<td>Pediatrics</td>
</tr>
<tr>
<td></td>
<td>Microconvex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td></td>
</tr>
<tr>
<td>171026</td>
<td>C2-5S6</td>
<td>2.5/3.0/3.5/5.0</td>
<td>70°</td>
<td>220mm</td>
<td>4mm</td>
<td>2mm</td>
<td>Abdominal, OB/GYN</td>
</tr>
<tr>
<td></td>
<td>Convex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;80mm)</td>
<td>(depth&lt;80mm)</td>
<td></td>
</tr>
<tr>
<td>171166</td>
<td>MC2-5S2</td>
<td>2.5/3.0/3.5/5.0</td>
<td>110°</td>
<td>170mm</td>
<td>4mm</td>
<td>2mm</td>
<td>Cardiology</td>
</tr>
<tr>
<td></td>
<td>Microconvex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;80mm)</td>
<td>(depth&lt;80mm)</td>
<td></td>
</tr>
<tr>
<td>171174</td>
<td>MC3-7S2</td>
<td>3.5/4.0/5.0/6.5</td>
<td>110°</td>
<td>120mm</td>
<td>3mm</td>
<td>1mm</td>
<td>Pediatric cardiology</td>
</tr>
<tr>
<td></td>
<td>Microconvex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td></td>
</tr>
<tr>
<td>171107</td>
<td>C3-7S4</td>
<td>3.5/4.0/5.0/6.5</td>
<td>90°</td>
<td>140mm</td>
<td>3mm</td>
<td>1mm</td>
<td>Pediatrics/Abdominal</td>
</tr>
<tr>
<td></td>
<td>Convex</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td></td>
</tr>
<tr>
<td>171131</td>
<td>ER5-9SB</td>
<td>5.0/6.5/7.5/9.0</td>
<td>60mm</td>
<td>110mm</td>
<td>1mm</td>
<td>1mm</td>
<td>Transrectal</td>
</tr>
<tr>
<td></td>
<td>Biplane</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;40mm)</td>
<td>(depth&lt;40mm)</td>
<td></td>
</tr>
<tr>
<td>171042</td>
<td>L3-7S5</td>
<td>3.5/4.0/5.0/6.5</td>
<td>50mm</td>
<td>110mm</td>
<td>3mm</td>
<td>1mm</td>
<td>Pediatric</td>
</tr>
<tr>
<td></td>
<td>Linear</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;60mm)</td>
<td>(depth&lt;60mm)</td>
<td>Small parts</td>
</tr>
<tr>
<td>171123</td>
<td>LO5-12S1</td>
<td>5.0/7.5/10.0/12.0</td>
<td>28mm</td>
<td>90mm</td>
<td>1mm</td>
<td>1mm</td>
<td>Intra-operative</td>
</tr>
<tr>
<td></td>
<td>Linear</td>
<td></td>
<td></td>
<td></td>
<td>(depth&lt;40mm)</td>
<td>(depth&lt;40mm)</td>
<td></td>
</tr>
</tbody>
</table>
4. INSTALLATION AND VERIFICATION

4.1 Preparations before turning on the system

Please refer to 5.1.

4.2 Inspection after power on

a. The keys on the front panel light up within three seconds after the system switches on.
b. Make sure that the fan on the rear panel is running correctly.

4.3 Performance verification

The performance verification can be done by a professional doctor or service engineer. The verification includes:

a. Display model: B-mode, duplex B-mode (left and right real-time image), B/M-mode and M-mode
b. Focus: N, M, F1, F2, image display multiple, shift up/down under ZOOM
c. To check up if the numeral/character key is working by inputting ID or press COMMENT key etc.
d. Confirm the measurement of distance and area, etc working properly.
5. OPERATION

5.1 Preparation before turning on the system

● Cord connection
  a. Connect one end of the additional ground connector to the ground terminal on the real panel of the main unit and the other end to a reliable grounding device.
  b. Connect the probe to the probe socket on the rear panel and lock it securely. (Please refer to Fig 5-1.)
  c. Please confirm that the power switch is off.
  d. Connect the Power Cord (refer to Fig. 5-2).

● Grounding wire and power cord check-up
  Make sure the grounding wire grounded properly and there is no any abnormality or shedding of isolation cover of both wires. In order to avoid danger, special attention should be paid to these wires each time before use.

● Consumables
  a. Ultrasound Jelly
     For applying to the region of a patient’s body to be examined.
  b. Tissue Paper
     For removing and cleaning ultrasound jelly away from the patient and the probe head after examination.
  c. Recorder (Option)
Fig. 5-1 Connect of Probe

Fig. 5-2 Connect of power cord
5.2 Operation Procedures after installation of the equipment

● Turn on Power Supply

Turn on the power switch on the front panel, the backlit keyboard lights up within 3 seconds. The monitor starts to work after 30 seconds. Automatically the system is initially set to frozen state after power on, press key or footswitch to unfreeze the screen.

● Initial setting upon turning on the power supply is as follows:

<table>
<thead>
<tr>
<th>Item</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze</td>
<td>Image is set to frozen state.</td>
</tr>
<tr>
<td>Examination Mode</td>
<td>B-mode</td>
</tr>
<tr>
<td>ZOOM</td>
<td>×1.0</td>
</tr>
<tr>
<td>FOCUS</td>
<td>M, F1</td>
</tr>
<tr>
<td>Enhance</td>
<td>1</td>
</tr>
<tr>
<td>Grey scale calibration γ</td>
<td>0</td>
</tr>
<tr>
<td>Frame correlation CCOR</td>
<td>2</td>
</tr>
<tr>
<td>Orientation of Probe</td>
<td></td>
</tr>
</tbody>
</table>

● Unfreeze the state

Press key or footswitch to unfreeze the screen to begin scanning.

● Preliminary setting of GAIN control

Set the GAIN, TGC controls nearly at the middle of the respective tuning ranges.

5.3 Image Depiction

● Image Depiction

a. Apply sufficient amount of ultrasonic jelly to the patient’s body region to be examined and the front probe surface.
NOTE
If air enters between the patient body surface and the transducer place during examination, a dark spot will appear in the image. In this case, re-apply the ultrasound gel.

b. When the probe is placed on the examination region, a real-time image will immediately appear on the TV monitor screen. The orientation of the probe and the corresponding image on the screen change according to the “left/right reverse” as shown in Fig. 5-3.

c. When a satisfied image is acquired on the TV monitor, press key or footswitch to freeze it.

● Fine adjustment of GAIN and TGC

It is necessary to adjust the gain setting according to the shape of the patient and different organ to be examined. When adjusting, please refer to the following instructions.

<table>
<thead>
<tr>
<th>The upper portion of an image depicting the region near the body surface is too white. (near gain is too high)</th>
<th>Move the near field TGC sliding to the left.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The lower portion of an image depicting the inner body is too dark. (far gain is low)</td>
<td>Move the far field TGC sliding to the right.</td>
</tr>
<tr>
<td>Too many fine echoes on the image (the full image shows white)</td>
<td>Anti-clockwise turn the GAIN control</td>
</tr>
</tbody>
</table>

● Split the screen
a. Press key in unfrozen B-mode state. The B-mode image is now displayed on the left half of the screen, and the right half of the screen is blacked. A mark “▲” (real-time mark) also appear under the real-time B-mode image. Press down key. The real time B-mode image appears on the right half screen with the mark “▲”, and the image on the left side will freeze.

Both image on the left and right sides will be frozen when key is pressed. And a freeze mark “F” will be displayed on the lower left side of the screen.

b. Setting a Body Mark

A body mark can be set in the image with a “▲” mark.

c. Freeze Release

The freeze state can be released only for the image with a “▲” mark.

● Description of M-mode and B/M-mode Image

a. Depiction of M-mode Image

Under unfrozen state, M-mode measurement can be done by pressing the key and entered the M-mode image. (Fig. 5-4)
b. B/M-mode image display

Under unfrozen state, press down $\text{B|M}$ key to enter into B/M-mode image. The real-time B-mode image is displayed on the left half of the screen while a M-mode image on the right half. The position of the sampling line of M-mode can be moved with trackball.

c. A Sweep Speed Selected for M-mode Image

Four sweep speed ranges including 1s/f, 2s/f, 4s/f and 8s/f can be selected by pressing $\text{M SPEED}$ key.

When $\text{FREEZE}$ key or foot switch is pressed, the freeze mark “F” is displayed, but the M-mode image will not freeze until the last frame is swept. (See Fig.5-5)
● Zooming Operation

The image display magnification can be changed by pressing ⬆️ ⬇️ key in the unfrozen state.

● Scroll of an Image

In an unfrozen single B-mode and magnification factor is >1.0, by pressing ⬆️ ⬇️ key, the display depth can be changed. The image is vertically shifted up or down 2mm by each press. (See Fig. 5-6).

● To change over the enhancement extent, γ calibration curve, Frame Correlation,
Left/right, positive/negative, up/down reverse, press down \( \text{PROCESS} \) to select the item desired and modify it by pressing \( \text{MODIFY} \).

### 5.4 Character input and measurement operation

- There are two ways for inputting the patient’s information.

1) Input a patient’s detail information (NAME, ID, Age and so on).
   a. Press \( \text{SET} \) key and move the cursor to “EDIT” in the first item of “PATIENT INFO”. And then press \( \text{key} \) to enter into the submenu “PATIENT INFORMATION”.

b. New patient Input:
   To decide whether to clear the current gestation measurement data (BPD, HC, FL, AC), move the cursor to “YES” or “NO”, then press \( \text{key} \). Select “YES” to delete the data, “NO” is to keep the data. Usually select “YES”. Select “NO” only when correcting AGE and LMP (see c and d) but not gestation data.

   c. Name and ID Input:
   In the input box “[  ]”, press letter key, numeral key to input maximum of 9 characters of NAME and 8 characters of ID.

   d. Age Input:
   In the input box “[  ]”, maximum of 3 numbers can be inputted at Age.

   e. LMP Input:
   Input the first day of the last menstrual period (year, month and day) in the input box “[  ]” by numeral keys. Any number should be inputted in two digits like “01” for January.

   **NOTE**
   The cursor will remain at the same place if the inputted date is invalid.

   f. Move the cursor to “OK” and press \( \text{key} \) key to save the inputted information.
and exit. Move the cursor to “CLEAR” and press $\Rightarrow$ to clear the patient’s information and be ready for re-input. Move the cursor to “CANC” and press $\Rightarrow$ to abort the inputted information and exit.

2) Input the brief information of the patient (ID)

a. Press $\text{ID}$ key and move the cursor. Press $\Rightarrow$ key after inputting the character at the position of cursor.

b. Press $\text{ID}$ key to confirm and exit after finishing inputting.

● Date Input

a. Press $\text{SET}$ key to enter the SET interface and move the cursor to Edit box $[ / / ]$ of the third item “D/T”. Input the date and time as the format YYYY/MM/DD HH in the prompt box.

b. Move the cursor to “EXIT” and press $\Rightarrow$ key to confirm and exit the SET interface.

● Annotation Input

a. Press $\text{COM}$ key. A cursor will appear at the center of the screen. Move the cursor to a desired place by trackball to input character or number.

b. Press $\text{COM}$ key again to exit. The cursor will disappear but the comment will remain on the screen. (See Fig. 5-7)
Fig. 5-7  Annotation Input

● Hospital name input
  a. Press \textcolor{olive}{SET} key to enter the main SET interface. Move the cursor to the prompt box “[ ]” of the second item “HOSPITAL NAME” to input hospital name.
  b. Move the cursor to “EXIT” and press down \textcolor{olive}{↓} key to exit SET interface.

● Distance Measurement \textcolor{olive}{DIST}
  To measure the distance between any two points in the image.
  a. Press \textcolor{olive}{DIST} key. A cursor of “+” appear at the center of screen, simultaneously “D” and “MM” appear at the region of character. By operating the trackball, move the cross mark “+” to a desired place.
  b. Press \textcolor{olive}{ENTER} key to set the cross mark “+” at the first measuring point desired. Operate the trackball to move the cursor “+” to the second point while the distance between these two points appears at the DIST region.
  c. Press \textcolor{olive}{ENTER} key to fix the “+”. In case of a distance measurement in a B-mode image, the distance between the two points is displayed in the
image. (See Fig. 5-8)

After completion of the operation c, the distance measurement can be repeatedly done by repeating the above operations.

![Fig. 5-8 Distance Measurement](image)

**Area and Circumference Measurement (AREA)**

The area and circumference of a selected portion of a tomographic image displayed can be measured in the frozen state.

a. Press MEAS key, a menu will display. Select AREAT (tracing the edge of the measured area with trackball) or AREAE (measuring the area with ellipse method) and press down ENTER key to confirm. A cross mark “+” display at the center of the image while “C MM” appear at the character region. Move the cross mark “+” with trackball to a portion where measurement is going to be done.

b. When AREAT is selected. Press ENTER key to set the initial point. By operating the trackball, the trace of “+” mark having been moved is displayed as a solid line. The length of this trace is the circumference.
c. Press ENTER key, and an area will be displayed. If an object area has not yet been traced, there will be a line between the start and stop points, and an area and circumference are displayed.

After completion of the operation of (c) above, it can be started again as described in (a). By repeating the above operation, measurement can be repeated as desired. And the measured value will be renewed.

**NOTE**
If the traces intersect each other, no correct area and circumference is measured.

![Fig. 5-9 Area and Circumference measurement](image)

Fig. 5-9 shows you the area and circumference measurement with the ellipse method (AREAE).

Ellipse method is to measure the object area or circumference with an approximate ellipse.

Move the first “+” to the top point of major axis or minor axis of the measured ellipse, press ENTER key to confirm. Operate the trackball to draw out the second point and then press ENTER again to confirm the major or minor axis. Moving the trackball again can change the length of the other axis.
DL: Diameter of Major axis
DS: Diameter of Minor axis
C: Circumference \[ C = \frac{\pi}{4}(2DL + DS + \sqrt{\frac{1}{2}(DL^2 + DS^2)}) \]
A: Area \[ A = \frac{\pi}{4}(DL \cdot DS) \]

- Measurement of Heart Rate (HR)

Heart rate can be measured in frozen state of M-mode or B/M-mode.

a. Press \( \text{MEAS} \) key. Highlight “HR” and press \( \text{ENTER} \) key. A small “+” mark is displayed at the center of an image, and “BEAT NUM: 2HR” appears beneath the image. By operating the trackball, set the “+” mark at the point of heartbeats desired to measure.

b. Press \( \text{ENTER} \) key. The large “+” is fixed, and by operating the trackball, move the small “+” mark to make the interval be two heartbeats.

c. Press \( \text{ENTER} \) key. The heart rate between the interval of two heartbeats is obtained and displayed in the heart rate displayed region. (See Fig. 5-10) Measurement can be repeated. However, the previously measured value will be replaced by a new value.

- NOTE

The numeral key 1~9 can be pressed to change the number of cardiac cycles while measuring.
**Measurement of Time (TIME)**

Time between any two points in the image can be measured in frozen state under M or B/-mode.

a. Press \[ \text{MEAS} \] key. Highlight “TIME” in the menu and press \[ \text{ENTER} \] key. A small “+” mark will appear at the center of the image and “T: SEC” in the character area. By operating the trackball, move the “+” to the first measured point. (See Fig. 5-11)

<table>
<thead>
<tr>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>T represents the time span between two points.</td>
</tr>
</tbody>
</table>

b. Press \[ \text{ENTER} \] key to fix the “+” mark on the image. By operating the trackball, move the “+” mark to another point to be measured. The time between two points are displayed in time display area.

c. Press \[ \text{ENTER} \] key to fix the “+” mark. Time between two points is displayed in time display area. (See Fig. 5-11)

Repeat the above operation after (c) is finished. Measurement can be taken.
repeatedly, but the previous value will be replaced by a new measure value.

![Image](image.png)

**Fig. 5-11  Time Measurement**

- **Measurement of Slope (SLOPE)**

  Speed between any two points in the image can be measured in frozen state under M or B/M-mode.

  a. Press \( \text{MEAS} \) key. Highlight “SLOPE” in the menu and press \( \text{ENTER} \) key. A small “+” mark will appear at the center of the image and “H: MM  S: MM/S” is in the character area. By operating the trackball, set the “+” at the point to be measured.

  **NOTE**

<table>
<thead>
<tr>
<th>H: The depth difference between two points</th>
</tr>
</thead>
<tbody>
<tr>
<td>S: The slope of two points</td>
</tr>
</tbody>
</table>

  b. Press \( \text{ENTER} \) key to fix the “+” mark in the image. By operating the trackball, move the “+” to another point to be measured. Speed between two points is displayed in speed display area.

c. Press \( \text{ENTER} \) key to fix the “+” mark. Speed between two points is displayed
in time display area. (See Fig. 5-12)

Repeat above operation after (c) is finished. Measurement can be taken repeatedly, but previous value will be replaced by new measured value.

![Fig. 5-12  Slope Measurement](image)

### Measurement of Mitral Valve (MV)

In M-mode or B/M-mode frozen state, the following items can be measured and calculated based on the coordinates of each of the points A to F (except B) in the image.

<table>
<thead>
<tr>
<th>Item</th>
<th>Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-wave amplitude</td>
<td>CE</td>
</tr>
<tr>
<td>Distance DE</td>
<td>DE</td>
</tr>
<tr>
<td>A-wave amplitude</td>
<td>CA</td>
</tr>
<tr>
<td>DE gradient</td>
<td>DE</td>
</tr>
<tr>
<td>EF gradient</td>
<td>EF</td>
</tr>
<tr>
<td>A wave/E wave</td>
<td>A/E</td>
</tr>
</tbody>
</table>

a. Press **MEAS** key. Highlight “MV” and press **ENTER** key. MV measurement schema will be displayed at the low part of left side of image while “+” mark at
the center of the image. By operating the trackball, move the cursor to the corresponding point A.

![Image](image_url)

**Fig. 5-13 MV Measurement**

b. Press key to confirm A point. The “+” mark will be fixed on the image, and point B and C will be displayed. By operating the trackball, move the “+” mark to points C, D, E and F on the M-mode image in the same way. The measurement and calculation result of mitral valve are displayed. (See Fig. 5-13)

- The measurement of Left Ventricle and Aorta can be carried out with the following prompt schema.

- **Measurement of Volume-Biplane method**

![Diagram](diagram_url)

**Fig. 5-14**
Volume measurement can be conducted in a duplex B-mode frozen image. Volume can be calculated and displayed according to perpendicular D1, D2 and D3 value calculated in a solid as shown in Fig. 5-14.

Volume can be calculated by the following equation:

\[ \text{Volume} = \frac{\pi}{6} \times D1 \times D2 \times D3 \]

a. Display two images on the screen and determine a biggest plane (L plane) of the solid, and freeze it.

b. Obtain a plane perpendicular to L plane and freeze it. (Shown as R plane in Fig. 5-15).

c. Press \( \text{MEAS} \) key. Highlight “VOL—B” and press \( \text{ENTER} \) key. A mark “+” will display at the center of the image and “D1 MM”, “D2 MM”, “D3 MM” and “VOL—CC” be displayed in the character area. Move trackball and set the “+” mark at the beginning point of major axis of L (R) plane.

d. Press \( \text{ENTER} \) key to fix the beginning point. Operating the trackball, move the cursor to the terminal point of major axis.
e. Press \( \text{ENTER} \) key to fix mark “+”. The distance of long axis D1 is achieved.

f. The distance of perpendicular D2 and D3 in the R plane can be obtained by the same way of measuring D1.

g. The value of volume will be display in “VOL CC” column after pressing \( \text{ENTER} \) key to finish D3 measurement.

● Measurement of area- Ellipse method

a. Press \( \text{MEAS} \) key. Highlight “VOL-E” and press \( \text{ENTER} \) key. A “+” will be displayed at the center of image and “DL MM DS MM VOL CC” simultaneously in the character area.

\[
V = \frac{\pi}{6} \times DL \times DS^2
\]

b. The rest of measurement is the same as the measurement of area method.

● Measurement of Angle

For gynecology, the measurement of angle is mainly for fetal hip-joint angle. It is available in the frozen state of B or B/M mode.

a. Press \( \text{O8} \) key. Select “ANGLE” in the menu and press \( \text{ENTER} \) key. A small “+” appear at the center of the image.

At the same time “\( \alpha : \circ \); \( \beta : \circ \)” is displayed in the status bar.

b. Move the “+” to the initial point of basic line “B” and press down \( \text{ENTER} \) key.

Then move the “+” mark to the end point of basic line “A”. Press \( \text{ENTER} \) key. A baseline section BA will be displayed on the screen.

c. Fix the initial point and the end point in the same way to determine the first
top-line of hipbone OA. The angle between top-line OA and baseline BA will be calculated automatically.

d. Fix the initial point and the end point in the same way to determine the second top-line of hipbone OB. The angle between top-line OB and baseline BA will be calculated automatically.

● Measurement of BPD

This measurement can be done in B-mode or B/M-mode frozen state. The gestation week and its error (unit: day) can be figured out basic on the pre-set data table and the distance measured. Simultaneously, the date of delivery and its error (unit: day) will be displayed according to the confinement data previously inputted.

a. Press key. Highlight “(1) BPD” and press key. A small mark “+” will display at the center of image while “BPD W±D” and “EDD / / ±D” in character area. Move the “+” to the first point will be measured by trackball.

b. Press key to fix the first point. And then move to the second point with trackball.

c. After pressing key to fix the mark “+” at the second point, the gestation weeks and its error (in day) will be displayed as calculated through linear interpolation on a distance between two points. A calculated date of confinement and its error (in days) will be displayed as well.

● Measurement of Crown Rump Length (CRL) (7~12 weeks)

CRL measurement can be conducted in B-mode or B/M-mode under frozen state. Gestation week, its error (in days) and a date of delivery are displayed in accordance to measured distance and data table previously inputted.
Press **OB** key. Highlight “(3) CRL” and press down **ENTER** key. A small mark “+” will be displayed at the center of image and “CRL W±D” and “EDD // ±D” in the character area. Other operations are the same as the measurement of biparietal diameter (BPD).

- **Measurement of Femur length (FL) (14~22 weeks)**

  The FL measurement can be performed in B-mode or B/M-mode under frozen state. Gestation week, its error (in days) and a date of childbirth are displayed based on the measured distance and data table previously inputted.

  Press **OB** key. Highlight “(4) FL” and press down **ENTER** key. A small mark “+” will be displayed at the center and “FL W±D” and “EDD // ±D” in the character area. Other operations are the same as in the BPD measurement.

- **Measurement of Gestational Sac (GS) (5~7 weeks)**

  This measurement can be conducted in B-mode or B/M-mode under frozen state. Gestation week, its error (in days) and a date of confinement are displayed based on the measured distance and data table previously inputted.

  Press **OB** key. Highlight “(2) GS” and press down **ENTER** key. A small mark “+” will be at the center of image and “GS W±D” and “EDD // ±D” displayed in the character area. Other operations will be the same as BPD.

- **Measurement of Fetal Abdominal Circumference (AC)**

  This measurement can be conducted in B-mode under frozen state. Gestation week, its error (in days) and a date of confinement are displayed based on the measured distance and data table previously inputted.
a. Press \textit{OB} key. Highlight “(5) AC” and press down \textit{ENTER} key. A small mark “+” will be displayed at the center of the image.

b. Move the “+” to the initial point of measurement and press \textit{ENTER} key. A small ellipse will be displayed on the screen. Move the “+” to the other end of measurement.

c. Press \textit{MEAS} key and operate the trackball to change the length of minor axis of ellipse to the fitness.

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{NOTE} & \\
\hline
When moving the trackball, circumference C and confinement date EDD will be calculated automatically.) & \\
\hline
\end{tabular}
\end{table}

d. Press \textit{ENTER} key to complete the measurement. A calculated date of confinement will be displayed in the character area.

\textbf{● Measurement of HC}

It is the same as the measurement of AC.

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{NOTE} & \\
\hline
If the measurement menu displays when the \textit{OB} or \textit{MEAS} key is pressed, since there is a number before every menu item, press the numeral key on the keyboard to enter measurement of the corresponding item. & \\
\hline
\end{tabular}
\end{table}

\textbf{● Input of GYN table (BPD, GS, FL, CRL, AC, HC)}

The data can be modified as following:

Press \textit{SET} key. Move the cursor to the fourth item. The total pregnant
weeks can be modified in the table of TOTAL PERIODS. Move the cursor to the table and press key to enter into the menu.

Take HC as an example.

Highlight “HC TABLE ►” and press key. The table will display as follows:

a. In the title column “TABLE OF HC: (1/2), “1/2” means the table is displayed in 2 screens. Highlight “NEXT” and press key to display the next screen.

b. The middle of the screen is for the display of data area. Only the pregnant weeks can be modified. For example: In “85MM: 13W5±11D 98MM: 14W0±11D”, only the underlined characters can be modified. The cursor automatically jumps to the next position to be inputted when inputting the characters.

c. The functions for every virtual key are as follows:

“SAVE”: After inputting, save the inputted data and exit the entry of GYN table.

“NEXT”: If the GYN table cannot be fully displayed in on screen, it is pressed to display the next screen.

“LOAD”: To load the preset data.

“CLEAR”: To clear the items of data in the table and the unit is available for reentry of data.

“CANC”: Do not save the modification to the GYN table and exit the entry of GYN table.

● OB/GYN measurement data report

a. Input requirement and contents

Input patient data in detail including LMP data.

A maximum of 4 groups of BPD, FL, AC and HC measurement results can
be stored.

Report display function:
The screen can display 1) each latest stored measurement data and its average; 2) all data measured and their averages; and 3) estimated fetus weight.

b. Operation steps:
Use OB/GYN report function as follows:

1. **Input patients’ data**
Enter patient’s data and clear all stored measuring data before measurement.

2. **GYN measurement**
Measurement of BPD, CRL, AC and HC, and store the measured results automatically.

3. **Report display**
Stored data is displayed in the report table on the screen.

c. Input patients’ data:
See the operation of (1D).

d. Storage of OB/GYN measurement results
Measuring the BPD, CRL, AC and HC as mentioned above, the results will be stored automatically. The results can be displayed immediately by using report display function OBRPT.
Each of 4 measurement functions can store up to 4 groups of measured data.

When measured more than 4 times repeatedly, the old data will be cleared on by one.

To modify the stored data as follows:
Select “YES” for “New” in the detailed information of the patient. Then
highlight “OK” and press \( \text{ENTER} \) key to save the data.

e. Report display Function
Display all OB/GYN measured results. The averages and fetus weight calculated based on the measured results will be displayed in frozen state.

**Display:**
A column displays:
The patient’s information (HP, NAME, AGE, ID and LMP) is displayed on the first to the third rows.

**GA:** Estimated Data of Delivery, obtained by adding 40 weeks to the LMP.

**EDD1:** Expected Data of Delivery obtained from the calculation based on LMP.

**AUA:** The average fetal age obtained from various measurements of OB.

**EDD2:** The average EDD obtained from various measurements of OB.

B column displays:
Displayed BPD, HC, AC, FL of OB and the last 4 corresponding measurements and mean values.

C column displays:

**FETAL WEIGHT:** Fetus weight obtained from BPD, AC and FL. The estimated fetus weight is calculated based on the equation of HADLOCK FP (1985):

\[
\log_{10} WT = 1.335 - 0.0034 \times AC \times FL + 0.00316 \times BPD + 0.00457 \times AC + 0.01623 \times FL
\]

**HEART HR:** Fetal Heart Rate

**HC/AC:** The result is the mean ratio between HC and AC.

**CONTROL METHOD**

Display report: Press \( \text{O8} \) key, Highlight “(9) OBRPT” and press \( \text{ENTER} \) key.

FINISH REPORT
Press the key to resume to the examination state.

5.5 Relocation of the equipment

When moving the system with the transportation trolley, please be sure:

- Not to tilt the equipment more than 10°.
- To place a space under the casters, if a step is higher than 2cm, so as to make the step height less than 2cm.
- Fix the power cable, ground cord and probe cable tightly so that they will not be caught by the casters.
- To make sure that the main unit has been well fixed on the trolley.
- To unlock the caster stoppers before moving the cart.

Transportation of the main unit, please be sure:

- First disconnect the wires connected in the rear panel of the main unit (except the power cord, ground cord and probe cord).
- Put the probe tightly into the probe holder.
- Disconnect the main unit from the trolley and transport it with the power cords, ground cords and probe cable held together.
6. MAINTENANCE AND SERVICE

6.1 Maintenance and service of probe

a. Fig 6-1 shows you the structure of standard Linear and convex probe.
b. Even a minor attack will damage the probe. Carefully handle the probe and make sure not to hit any hard objects.
c. Make sure that the system is under the state of frozen or shut off before connect or disconnect the probe.
d. Pay special attention to the surface of scanhead (lens) and make sure not to scratch it.
e. After use, clear the probe with sponge immersed with water or soft cloth. Solution like alcohol or other organic solvent for example thinner should not be used for cleaning.
f. If the probe were immersed in the water, abnormality will probably occur. In this case, please contact our service engineer.
g. Electric shock would happen if the cable is scratched. Please get contact with our service engineer immediately.
h. Rotate the handle of probe as indicated in order not to broken the connector, while connecting the probe.

![Fig. 6-1]

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6.2 Cleaning and disinfection

(1) Cleaning

● Clear the scanhead with soft cloth wetted with water.
● If the probe is heavily tainted, please clean it with suds and soft cloth.

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol or solution with alcohol should not be used for cleaning.</td>
</tr>
</tbody>
</table>

(2) Disinfection

● Disinfect the probe with the liquid chemical disinfecter reasoning by FDA, such as CIDEX. The liquid chemical disinfecter used for clean should be blended, store and use according to the instruction of producer.
● The scanhead of probe can soaked in the disinfecter for not less than 20 minutes but no more than 1 hour.
● Clean the probe with clear water after disinfection and swab it with dry soft cloth.

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>The probe cannot contact with high-pressure steam or ethylene oxide.</td>
</tr>
</tbody>
</table>

Please refer to the Operator Manual of probe for more warning.

6.3 Maintenance

Do the routine check-up (normally within half year) according to the procedure in “4. Installation and verification”.
6.4 Service

When any abnormality occurs, shut off the power supply and inform our appointed contractor. Our service engineer will visit you. More detail report of the abnormal phenomena, more help to our service. It will shorten the service time. If it is caused by the fuse problem, the fuse 50T-T1.6AL 250V can be replaced under the instruction of service engineer. Two fuses are shipped with the unit as accessories. The same fuses can be purchased from the local market.

6.5 Service responsibility

The portable diagnostic ultrasound scanner SONEO is a complicated electronic system. Except simple failure, for field service usually our authorized service contractor or we will replace the defective parts. We are not responsible for any failure caused by the service conducted by others.

6.6 Service information

Call for service, please contact with:

KONTRON MEDICAL S.A.S
Zone d'Activités les Gâtines
52, rue Pierre Curie
Boîte Postale 97
F – 78373 PLAISIR – FRANCE
Phone : +33 (0) 1 30 07 60 00
Telefax : +33 (0) 1 30 07 55 82
Internet : www.kontronmedical.com
E-mail : infos@kontronmedical.com
## APPENDIX A

### The means of the warning mark

<table>
<thead>
<tr>
<th>Warning Signs</th>
<th>Name of Warning Signs</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Attention</td>
<td>Please refer to the Operator Manual attached to the unit if you see this Warning Mark on the unit for safety.</td>
</tr>
<tr>
<td>⬇️</td>
<td>Equalization potential terminal</td>
<td>To eliminate the phasic difference, the terminal linking to the unit cover should connect to the corresponding terminal of other equipment.</td>
</tr>
<tr>
<td>⬇️</td>
<td>Ground</td>
<td>Protective earth (ground)</td>
</tr>
<tr>
<td>🔴</td>
<td>Type CF</td>
<td>Type CF, isolated input (IEC 60601-1) Grounding isolation, maximal leakage current: Normal $\leq 10\mu$A, Single failure: $\leq 50\mu$A</td>
</tr>
<tr>
<td>⬆️</td>
<td>Type BF</td>
<td>Type BF, isolated input (IEC 60601-1) Grounding isolation, maximal leakage current: Normal $\leq 100\mu$A, Single failure: $\leq 500\mu$A</td>
</tr>
<tr>
<td>⬆️</td>
<td>Type BF</td>
<td>Type BF, isolated input, defibrillator proof (IEC 60601-1)</td>
</tr>
<tr>
<td>⬆️</td>
<td>Type B</td>
<td>Type B equipment (IEC 60601-1) Maximal leakage on patient: Normal $\leq 100\mu$A, Single failure: $\leq 500\mu$A</td>
</tr>
<tr>
<td>IP</td>
<td>Airproof</td>
<td>Conform to the requirement of IEC60529 for dust proof and immersion</td>
</tr>
<tr>
<td>⬌</td>
<td>Off/On</td>
<td>Main power switch</td>
</tr>
<tr>
<td>📣</td>
<td>Non-ionizing radiation</td>
<td>Sound wave generated by the ultrasound system</td>
</tr>
<tr>
<td>🍀</td>
<td>Sterilization</td>
<td>Under sterilization</td>
</tr>
</tbody>
</table>