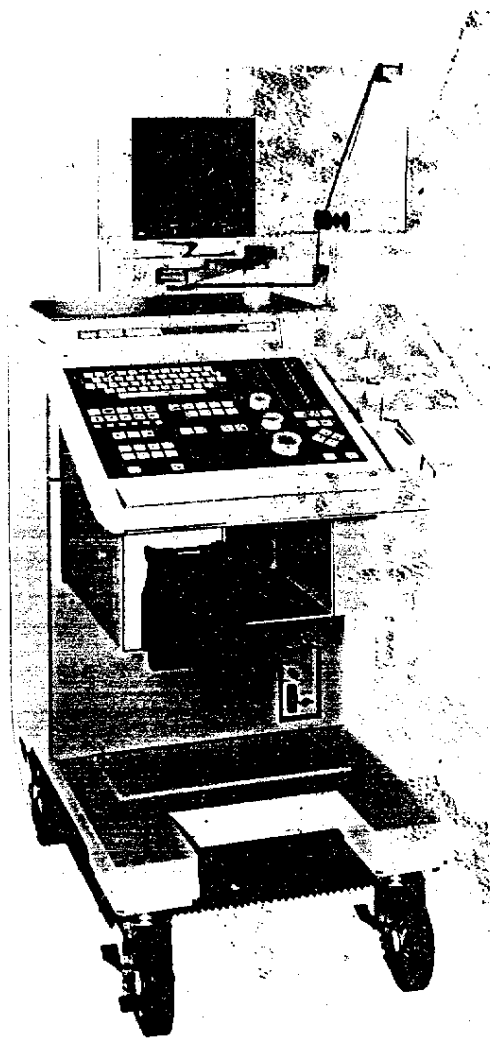
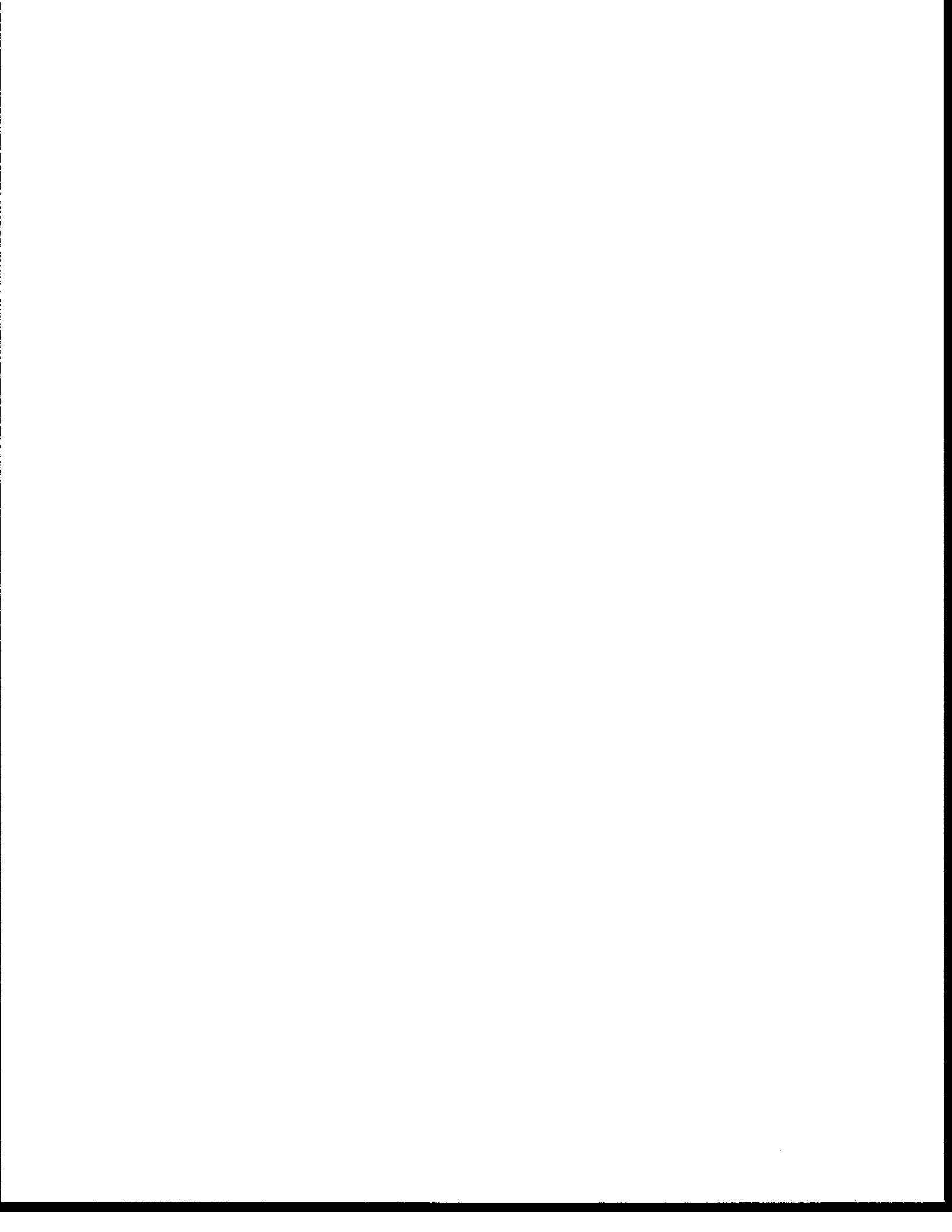


OPERATOR'S MANUAL

SSD-650



Manual No. MN1-0493
Version: 9.0 (91M5011 ~)
Issued on June 7, 1991



MANUAL CONSTITUTION

This operation manual is divided into two volumes.

Volume I is "System Description and Imaging".

Volume II is "Measurement and Analysis".

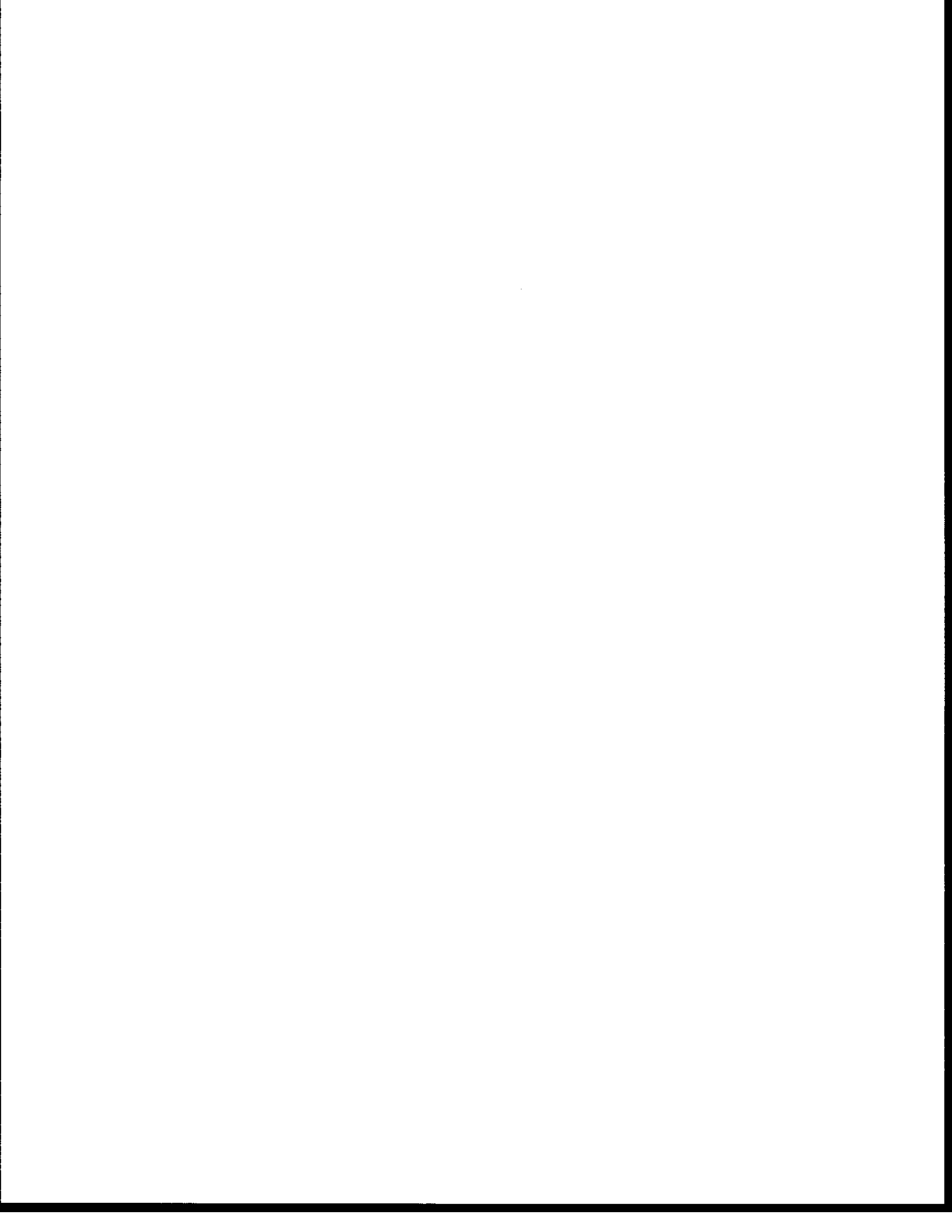
First, read Volume I and acquire knowledge of the equipment. Volume I describes the functions of the switches and controls, imaging procedures and cautions.

Volume II describes procedures for measurements and calculating functions.

Keep manual at hand with the equipment.

This operation manual describes only the main unit. For detailed operation of optional units, read the manuals attached to them.

MODEL SSD-650



Volume I System Description and Imaging

DESCRIPTION OF THE SYSTEM

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1. GENERAL

This equipment is a multi-purpose ultrasonic diagnostic equipment equipped not only with the linear scan and convex sector scan capabilities for abdominal and obstetric diagnoses, but also with the mechanical sector scan mechanism (option) that provides broad diagnostic fields of view through a narrow echo window such as an intercostal space for the diagnosis of circulatory organs.

It permits multiple types of probes to be connected to suit the diagnostic objective or area, and enables a broad range of examinations under optimized conditions.

In addition, the use of its trackball function facilitates distance, area, and other measurements with easy operation.

Backed by its optional Doppler unit, a great variety of optional probes, and its enriched measurement as well as computation capabilities, the Aloka-650 assures reliable diagnostic achievements in Doppler analysis.

Before operating this equipment, read this operation manual carefully for the equipment capabilities to be maximally utilized through its correct handling.

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CAUTIONS

2.CAUTIONS

This section describes safety precautions.

- (1) The SSD-650 is ultrasonic diagnostic equipment. Do not use it for other purposes than specified.
- (2) The SSD-650 is medical equipment which is to be operated only by qualified medical personnel. Operate the equipment only after becoming sufficiently familiar with its handling and operation. Use of minimum practical acoustic exposure is prudent.
- (3) KEEP THE EQUIPMENT AWAY FROM:
 - a. Water splashing
 - b. High humidity
 - c. Bad ventilation
 - d. Direct sunlight
 - e. Dust
 - f. Salty or sulphurous air
 - g. Chemical drugs or gases
 - h. Strong vibration or shock
- (4) BEFORE USE, CHECK THAT:
 - a. The capacity and voltage of the power source are suited to the equipment.
 - b. The voltage does not fluctuate abruptly.
 - c. The equipment is normal and operates safely.
 - d. The equipment is connected to a Hospital Grade power receptacle.

Also, note that:

- e. Noise may occur on the image if the equipment is operated near a power generator, X-ray equipment, broadcasting stations or underneath power transmission lines because of radio interference.
- f. Using other ultrasound equipment near this equipment may cause an abnormal image.

CAUTIONS

(5) OPERATING THE EQUIPMENT

- a. Read this manual and completely understand the operations and functions of the equipment.
- b. Do not turn the power on and off repeatedly in a short time period.
Wait 5 seconds or more to turn the power on again.
- c. Turn the power off prior to any cable and probe connection or disconnection.
- d. In case of improper conditions or equipment malfunctions, turn the system power off immediately and disconnect the power cord.
Put an adequate indication on the equipment, such as "Under repair. Do not use". Contact Corometrics Service for repair.

(6) OTHERS

- a. Some points within the system could pose an electrical shock hazard.
Do not open doors or remove secured covers and panels.
- b. Be very careful of the probes while the equipment is being moved.
- c. Perform periodic checks of the equipment and the probe.
- d. Do not modify the unit.

(7) Battery charge

The backed-up function (hospital name and date/time display) is supported by a battery in the equipment.

To charge the battery, apply power to the unit for at least eight hours a week, even when the equipment has not been operated for a long time. A fully charged battery is functionable for about one month.

When the battery has run down, charge it by continuous running of the equipment for 15 hours or so.

- (8) When the mechanical sector probe has operated continuously for 20 minutes, it will stop automatically (the FREEZE switch lights) to prevent mechanical exhaustion.

This is not a failure. To restart examination, press the FREEZE switch.

CAUTIONS

179112J 1HP DYTANIKO (B)

179112J 1HP DYTANIKO (B)

CAUTIONS WHEN USING THE PROBE:

- (1) The probe is easily affected by shocks. In particular, its connector and probe patient contact area are easily damaged by bumps, so use extreme care.
- (2) Do not immerse the whole probe in water or other liquids.
- (3) Avoid rough bending or pulling of the cable as this may cause it to break.
- (4) After using the probe, wipe off the ultrasound gel. To clean the probe, use a neutral detergent or alcohol. Use a clean probe at all times.
- (5) To clean the intra-operative probe, wash its tip with water then wipe it with a soft material such as gauze or a sponge, or wash it in running water. Avoid using a hard brush.

Note 1: Avoid sterilizing or disinfecting and decompressing or pressurizing the probe by autoclave or boiling. These will cause a failure.

Note 2: Do not apply medical liquid to the connector for cleaning and other purposes. (The connector is not waterproof.)

Note.3: For detailed cleaning instructions, consult the probe's Operator's Manual.

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SPECIFICATIONS

3. SPECIFICATIONS

3.1 Technical Specifications

(1) General

Scanning Method:	Electronic Linear Scanning Electronic Convex Sector Scanning Mechanical Sector Scanning
Display Mode	B mode (1,2,3 or 4-image display is possible) B and M simultaneous mode (B/M mode) M mode Doppler mode (option)
Sensitivity Control	
GAIN:	Maximum 90 dB, continuously variable
STC:	11-point sliding controls
Contrast	7 steps switchable, independent for B and M modes
Gray Shades:	64
Image Memory Capacity:	512 x 512 x 6 bits
Image Processing	
AGC	B and M modes, continuously variable
FTC:	ON/OFF for M mode
Edge Enhance:	3-step switchable
Post-Processing:	5 kinds of curves selectable
Image Direction:	Possible to change laterally and longitudinally (B-mode only)
Character Display:	With full alphanumeric keyboard
Automatic Displays:	Date and Time, Probe data (Main Frequency), Gain setting, Display range, Focal areas, Measurement and calculation data, etc. Gray scale bar, Scale marks, Acoustic power
Other Displays:	Body mark (20 patterns), Puncture guideline, M-mode cursor
Measuring Functions:	Distance, Area, Circumference, Volume, Velocity, Time interval, Dimension
Calculating functions:	Left-ventricle Function Analysis, Obstetrical Calculations (Gestational Age, Fetal Weight Estimation), Doppler Analysis (option), Ratio, Percent Stenosis, Histogram
Viewing Monitor:	9-inch diagonal
Power Requirement:	115/120/220/240 V \pm 10 %, 50/60 Hz, 390W
Dimensions	Approx. 21,3 (W) x 33,5 (D) x 52,8(H) inch
Weight	Approx. 397 bl
Safety Regulation:	Complies with IEC 601-1, Class I, Type B

SPECIFICATIONS

(2) Linear Scanning

Scanning Method:	Electronic linear scanning
Frame Rate:	Max. 30 frames/sec
Magnification :	x 0.7, x 1, x 1.5 and x 2, four-step selectable
Focusing Method:	4-point dynamic focusing with acoustic lens in transmission Full Range real-time dynamic focusing with acoustic lens in reception

(3) Convex Sector Scanning

Scanning Method:	Electronic convex sector scanning
Frame Rate:	Max. 30 frames/sec
Magnification :	x 0.7, x 1, x 1.5 and x 2, four-step selectable
Focusing Method:	4-point dynamic focusing with acoustic lens in transmission Full Range real-time dynamic focusing with acoustic lens in reception

(4) Mechanical Sector Scanning (optional)

Main Frequency:	2 to 7.5 MHz (depends on probe)
Scanning Angle:	Max. 80 degrees
Display Range:	4, 6, 9, 12, 15, 18, 21, and 24, eight-step selectable (except W type probes)
Frame Rate:	Max. 30 frames/sec

(5) Environmental conditions

In operation

Temperature:	+50 F ~ +104 F
Relative humidity:	30 ~ 85 % (noncondensing)
Atmospheric pressure:	700 ~ 1060 mb

In storage

Temperature:	+14 F ~ +140 F
Relative humidity:	30 ~ 92 % (noncondensing)
Atmospheric pressure:	700 ~ 1060 mb

* The specifications may be subject to change without notice for improvement.

SPECIFICATIONS

3.2 Standard Components

	<u>Model</u>	<u>Quantity</u>
Imaging Console (Main Unit)	USI-106	1
Viewing Monitor	IP-0920B-TH	1
Grounding Wire	NCC-0850	1
Cable Hanger		1
Operation Manual		2 copies
Installation Instruction Sheet		1 copy

* The specifications may be subject to change without notice.



INSTALLATION

4. INSTALLATION

This section provides information on installation for trouble-free operation.

An installation instruction sheet is attached separately. Read the instructions for assembling the unit. It is recommended that installation be performed by a qualified service representative.

4.1 Equipment Setting

(1) Site Requirements

a. Environmental Condition

The system should be operated in an ambient environment with temperatures between 50 F and 104 F, and relative humidity between 30% and 85% (noncondensing).

Avoid operation near flammable agents.

b. Power Requirements

Voltage: 115/120/220/240 V \pm 10%

Wattage: Approx. 390 W (with standard components)

WARNING

If the voltage fluctuations are more than the above values, use an auto voltage regulator having a capacity of 1 kW or more.

c. Space Requirements

The size of main console is approx. 21.3 (W) x 33.5 (D) x 52.8 (H) inch.

(2) Equipment Transfer

The equipment can be moved to suit the operating location.

Before moving the equipment, unlock the caster lock. Be careful not to bump the equipment against anything or subject it to shock during the moving.

After moving the equipment, be sure to lock the caster lock. (See Fig. 4-1.)



Fig. 4-1

INSTALLATION

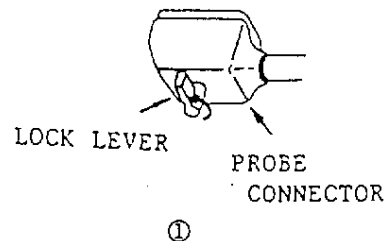
4.2 Probe Connections

Probe connector sockets are provided on the equipment's right side panel, to accommodate two linear (or convex), two mechanical sector and one independent probes. The connector sockets individually correspond to the PROBE switches on the operation panel. Connect probes as illustrated in Fig. 4-2 and 4-3.

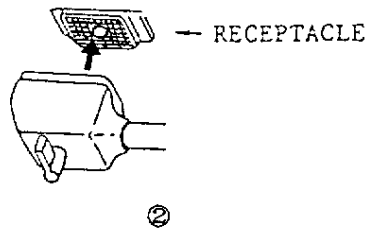
(1) Linear/convex Probe

Turn off the power whenever a probe is to be connected or disconnected.

- a. Turn the lock lever of the probe connector fully counterclockwise. ①



- b. Plug the connector into the receptacle completely. ②



- c. Turn the lock lever clockwise by hand as far as it will go. ③

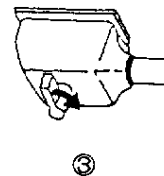


Fig. 4-2

- d. Confirm that probe connector does not come off.

To disconnect the probe, turn the lock lever counter-clockwise.

(2) Sector Probe

- a. Plug in the multi-pin connector into the receptacle ... ①
- b. Turn the fixing ring clockwise as far as it will go ... ②
- c. Plug in the BNC connector into the receptacle ③
- d. Turn the head of the connector clockwise ... ④

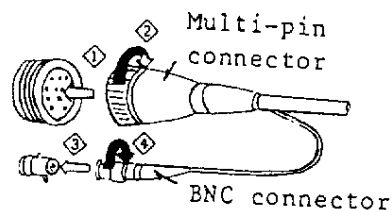


Fig. 4-3

DESCRIPTION OF SWITCHES AND CONTROLS

5. DESCRIPTION OF SWITCHES AND CONTROLS

5.1 External View

The number shows the subsection containing each description.

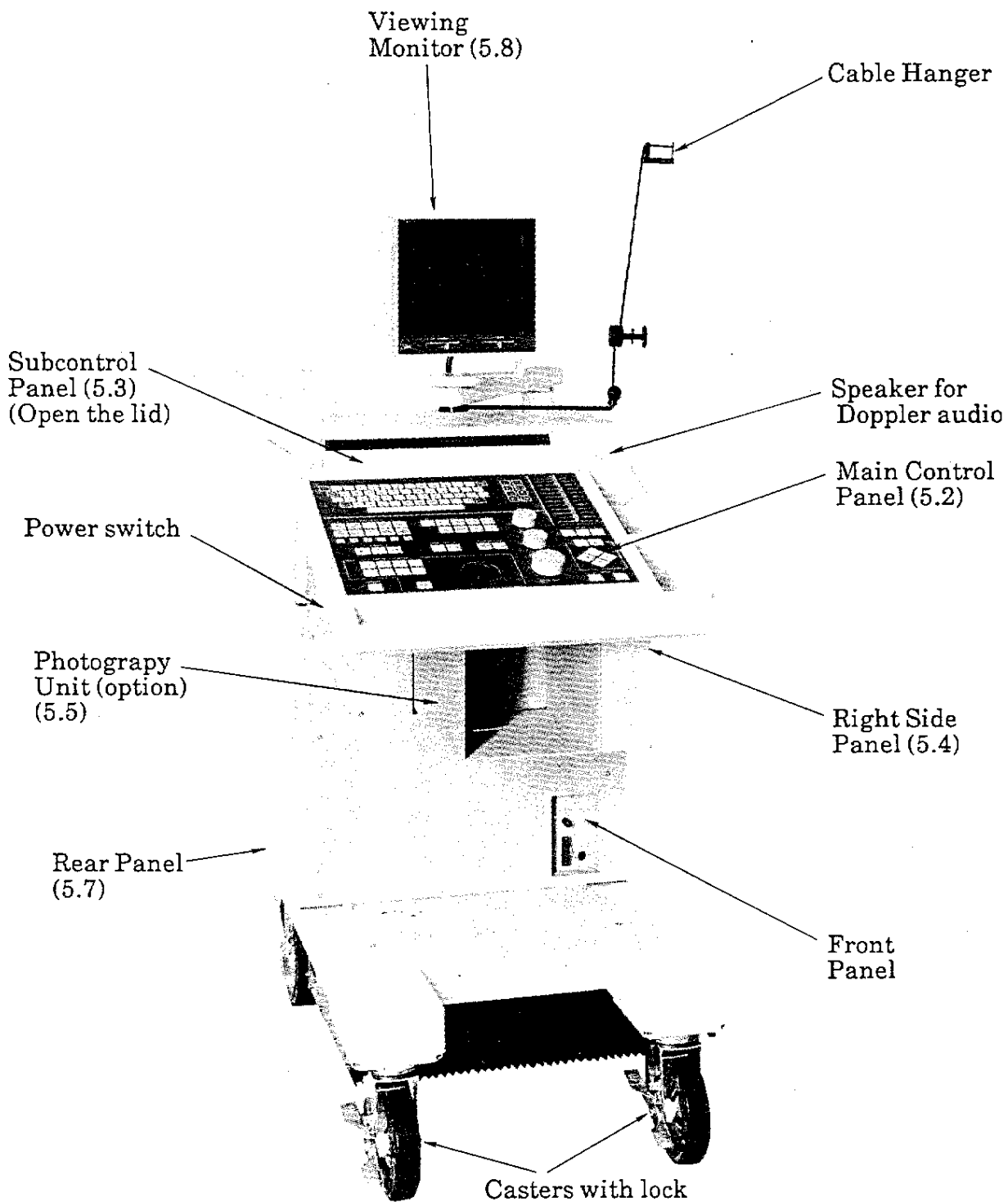


Fig. 5-1

DESCRIPTION OF SWITCHES AND CONTROLS

5.2 Main Control Panel

See page 5-11 for the figure of the panel.

(1) POWER lamp

Indicates that the POWER switch (33) on the left side panel is on. When the power is turned on, this lamp lights green. In about 10 seconds, an image will be displayed on the viewing monitor screen.

NOTE: If power cannot be applied by turning on the switch, check to see if the power cord is plugged into a power outlet.

(2) PROBE switch

To select a probe for examination.

Any of the probes (including optional probes) connected may be selected with one of these switches, as required. (See page 5-15 for the figure of the connectors.)



: Displays the image acquired by a probe connected to electronic scan probe socket (29). Also, pressing this switch alternates the probe for imaging between connectors **1** and **2**. (**1** is selected first.)



: Displays the image acquired by a mechanical sector probe (option) connected to mechanical sector probe socket (30). Also, pressing this switch alternates the probe for imaging between connectors **SINGLE** and **DUAL**. (**SINGLE** is selected first.)



: Enables the display acquired by the Independent Probe (option) which is for exclusive use in Doppler (CW mode).

(3) MODE switch

To select a display mode.

B:	Displays B-mode image.
M:	Displays M-mode image.
B/M:	Displays B-mode and M-mode images.
M/PW:	Displays M-mode image and PW Doppler pattern.
B/M.PW:	Displays B-mode and M-mode image and PW Doppler pattern.
PW:	Displays PW Doppler pattern.
B/PW:	Displays B-mode image and PW Doppler pattern.
CW:	Displays CW Doppler pattern.
B/CW:	Displays B-mode image and CW Doppler pattern.

* After the image is frozen, MODE switch cannot be switched.

NOTE: Doppler function (PW and CW modes) are operable when optional Doppler Module is installed.

DESCRIPTION OF SWITCHES AND CONTROLS

(4) POSITION switch

When an image via an electronic scanning probe (linear or convex sector) is displayed, this switch shifts the image display range. In a multi-image display mode, it shifts only the one being observed in real time (indicated by the active mark "▼").

For example:

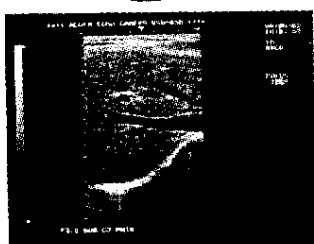
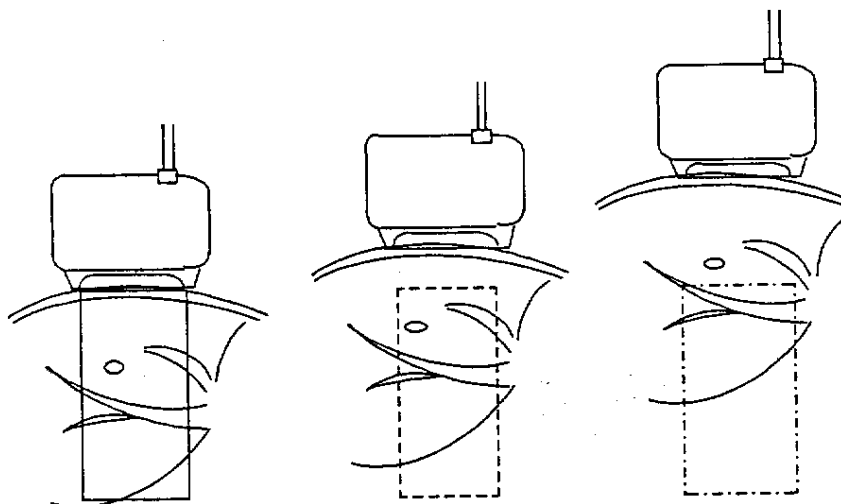


Fig. 5-2

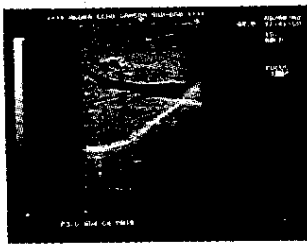


Fig. 5-3

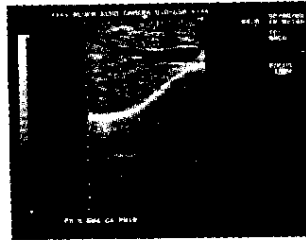


Fig. 5-4

The shift (positional) distance is numerically displayed in the upper right corner of the image display area.

When the arrow key "↕" under the POSITION key is pressed, the image is scrolled up.

When the "↕" key is pressed again, the range can be shifted, as shown in Fig. 5-4. Conversely, by pressing the "↕" key, the image is scrolled down.

NOTE: Positional shifting is impossible under the following conditions:

- While the image is frozen
- The image is acquired by mechanical sector probe
- The image is magnified by the ZOOM function.

* In the Doppler mode, the POSITION switch works for shifting the base line.

* Position shifting range is probe dependent.

DESCRIPTION OF SWITCHES AND CONTROLS

(5) MULTI IMAGE switch

Selects one of two-, three- and four-image displays. Operable in B-mode. Each time this switch is pressed, the display rotates in sequence between two-image, three-image, four-image, then returns to two-image display. To return to one-image display, press the B of the MODE switch. The image observed in real-time is switched by the arrow switches. The image indicated by the active mark "▼" can be observed in real-time.

(Two-image display)

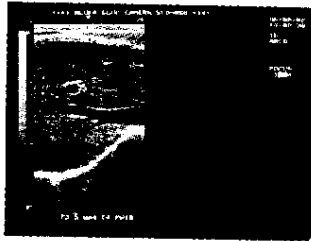


Fig. 5-5

(Three-image display)

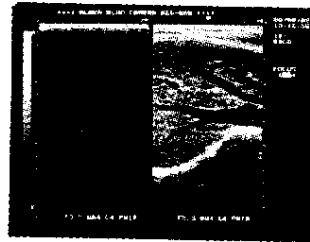


Fig. 5-6

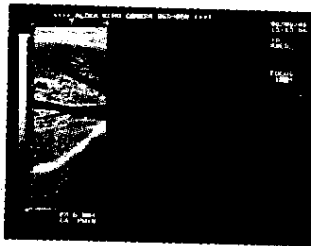


Fig. 5-7

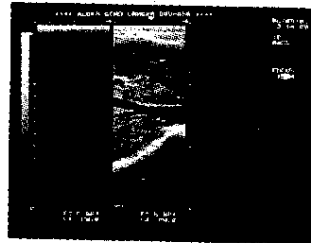


Fig. 5-8

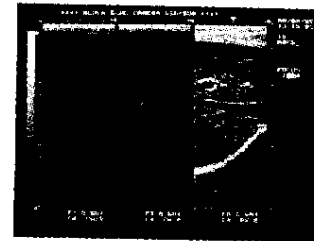


Fig. 5-9

(Four-image display)

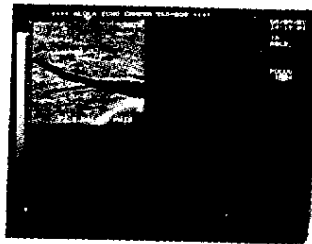


Fig. 5-10

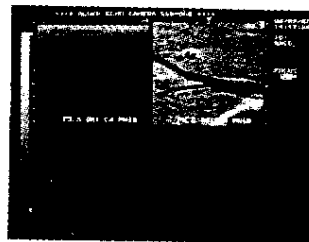


Fig. 5-11

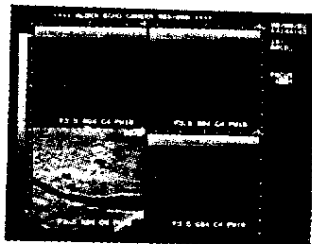


Fig. 5-12

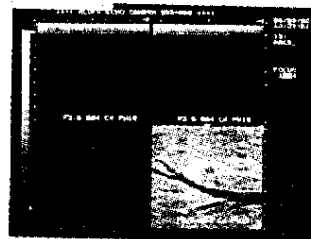


Fig. 5-13

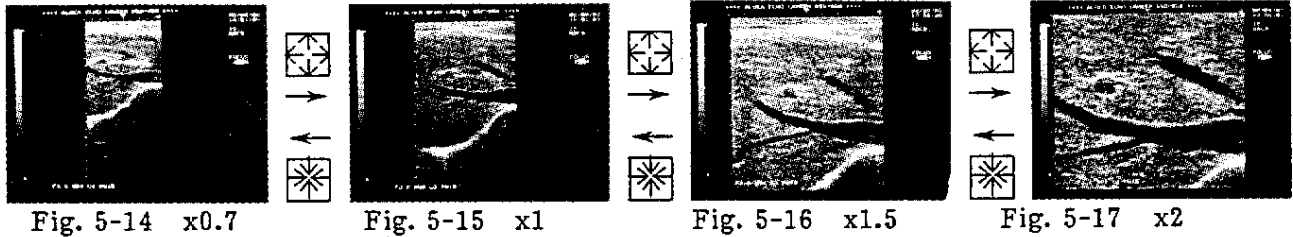
DESCRIPTION OF SWITCHES AND CONTROLS

(6) MAGNIFICATION switch

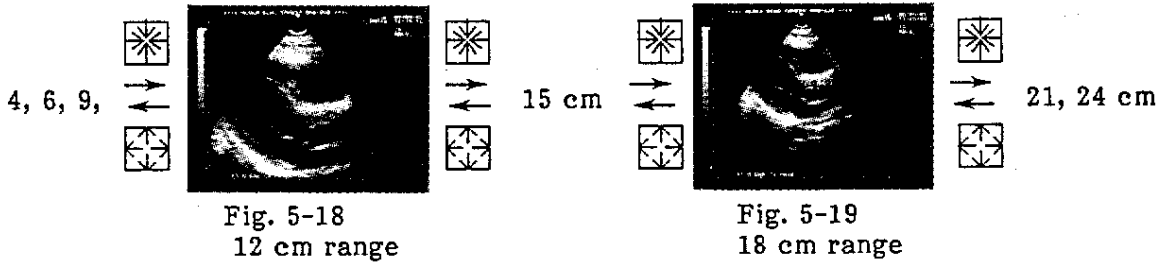
Changes the display magnification factor of the electronically scanned image (either linear or convex), and also the display distance (the depth range) of the mechanically scanned sector image.

NOTE; After an image is frozen, its magnification cannot be changed.

In the case of an electronically scanned image (linear or convex);
The display magnification is switched in four steps.




In the case of mechanically scanned sector image;
The display distance (the depth range) is switched in eight steps.



* In Doppler mode, the MAGNIFICATION changes the Doppler velocity range.

(7) IMAGE DIRECTION switch

To change the direction (right/left) of a B-mode image.

 :Inverts up-down direction of B-mode image.

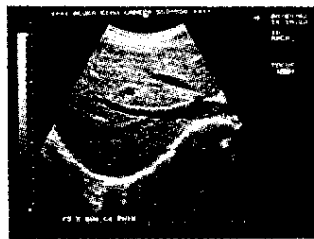



Fig. 5-20



Fig. 5-21

 :Inverts left-right direction of B-mode image.

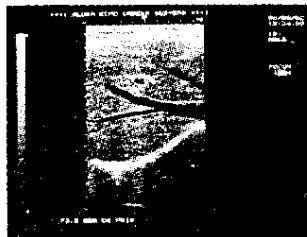


Fig. 5-22

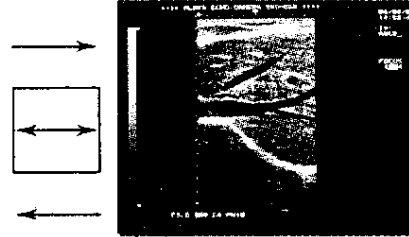


Fig. 5-23

NOTE: After an image is frozen, the image direction can not be changed.

DESCRIPTION OF SWITCHES AND CONTROLS

(8) B GAIN control

Adjusts the sensitivity (brightness) of the B-mode image.

Turning this control clockwise increases the brightness of the B-mode image. Turning this control counterclockwise decreases the brightness.

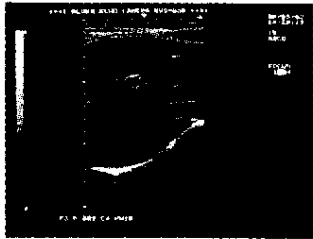


Fig. 5-24 Too low

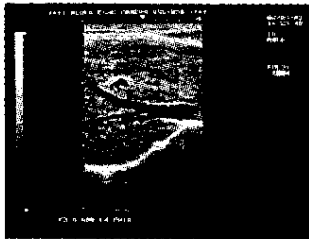


Fig. 5-25 Good



Fig. 5-26 Too high

(9) M GAIN control

Adjusts the sensitivity (brightness) of the M-mode image.

Turning this control clockwise increases the brightness of the M-mode image. Turning this control counterclockwise decreases the brightness.

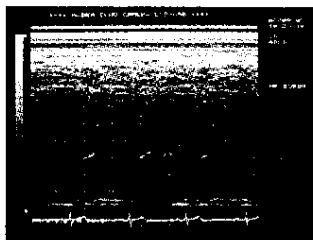


Fig. 5-27 Too low

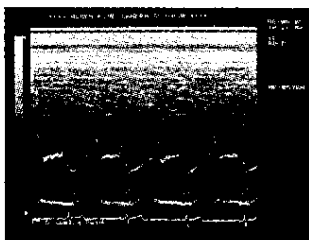


Fig. 5-28 Good

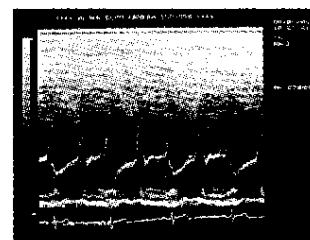


Fig. 5-29 Too high

(10) D GAIN control

Adjusts the sensitivity (brightness) of the Doppler pattern. Signals higher than a certain level do not change with this control. (See the figure to the right.)

This control works when optional Doppler Module is installed.

NOTE: This control does not change overall sensitivity.

Output

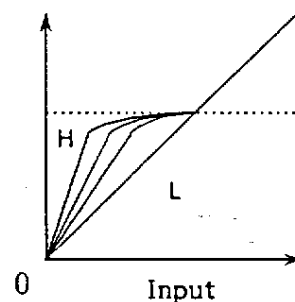


Fig. 5-30

(11) FREEZE switch

To obtain a still ultrasound image. Pressing the switch freezes the image.

B: Freezes B-mode image.

M/D: Freezes M-mode image and/or Doppler pattern.

The B and M/D freeze switches operated independently.

NOTE: While the image is frozen, the MODE, MAGNIFICATION, and PROBE switches are inoperable. Before operating these switches, release freezing.

DESCRIPTION OF SWITCHES AND CONTROLS

(12) STC (Sensitivity Time Compensation) knobs

The STC control consists of 11 sliding knobs.

The sensitivity for an ultrasound echo at a specified depth can be adjusted independently with each knob.

As each knob is moved to the right, the echo display becomes brighter. As the knob is moved to the left, the echo display becomes darker.

Generally, near field echos being more intense appear brighter and far field echos being more faint appear darker.

With the knob positioned nearly in the center, a good image is obtained. However, if the image is too bright or very noisy, move the STC knob corresponding to the depth to the left. If the image is too dark, move the STC knob to the right.

NOTE: When the image is too bright or too dark as a whole, correct it using the GAIN control.

(13) TRACKBALL FUNCTION group

Selects the function to be controlled by the TRACKBALL.

ZOOM Displays a box cursor to indicate the area where the image is to be enlarged. (Zoom function)

To move the box cursor, use the TRACKBALL.

ANGLE Displays angle compensation mark for correction of Doppler frequency depending on incident angle. By pressing the MARK REF switch, the mark rotates counterclockwise. This works when optional Doppler module is installed.

CURSOR Displays a cursor mark on the B-mode image to show M-mode sampling position. (When Doppler mode is on, sampling cursor for Doppler is displayed.) The cursor position may be shifted by rolling the TRACKBALL. (See Fig 5-31.) The cursor mark shifting direction will directly correlate with the TRACKBALL rolling direction, even when the vertical or horizontal reversal of a B-mode image is made with IMAGE DIRECTION switch.

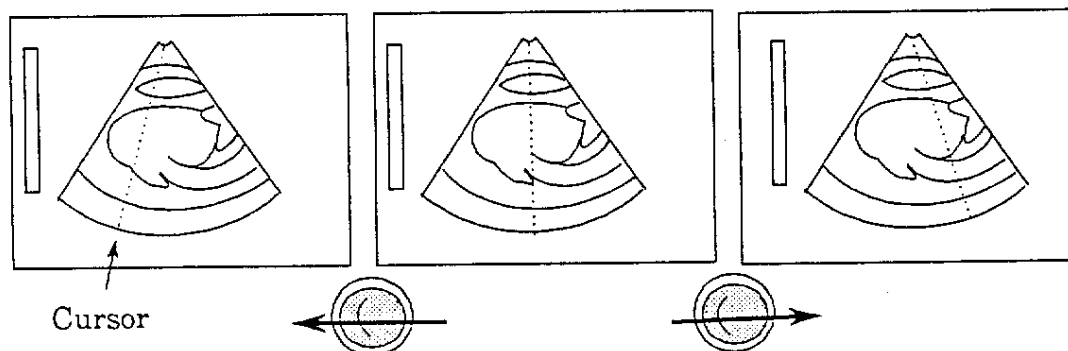


Fig. 5-31

DESCRIPTION OF SWITCHES AND CONTROLS



Displays a body mark on the screen. The probe mark is to indicate the probe location. It may be shifted by rolling the TRACKBALL. Relative to the body mark display, refer to Section 7.1 BODY MARK DISPLAY on pages 7-1 onward for further instructions.

+, x, ·:· and ::

Caliper switches: Displays each caliper mark for measurement. With this switch pressed, you can start a B-mode distance measurement or M-mode velocity measurement. Up to four of the same kind of measurements are possible at the same time.



Press this switch to use the + caliper mark.



Press this switch to use the x caliper mark.



Press this switch to use the :: caliper mark.



Press this switch to use the ·:· caliper mark.

For measurement procedure, see Vol. II "MEASUREMENT AND ANALYSIS".

MARK REF

: Switches the functions of the TRACKBALL.

- Switching the caliper marks (large and small +, x, :: and ·:· marks) that can be shifted by the TRACKBALL.
- Rotating the probe mark on the body mark.
- Switching in ZOOM mode.

(14) TRACKBALL

Performs functions selected by the TRACKBALL FUNCTION group such as shifting M-mode cursor, and shifting caliper mark/probe mark.

(15) CAMERA switch

Shutter switch of the incorporated Polaroid camera (option).

Take a photograph after freezing the image.
The CAMERA switch will not operate unless the image is frozen.

DESCRIPTION OF SWITCHES AND CONTROLS

(16) FUNCTION group

Selects the menu to be displayed.

When a menu display switch (such as MENU, MEASUREMENT, FOCUS, PRE PROCESS, etc.) is pressed, the menu for each function is displayed in the lower part of the screen.

The function can be set with the function setting numeral switches (1 to 6) below the menu display switch.

MENU:

Menu item	Menu Name	Contents
M-WIN	M-MODE WINDOW	Setting M-mode image magnification within the diagnostic range of B-mode image
A-DSP	A-MODE/STC DISPLAY	Displays A-mode image and STC curve (option)
PRESET	PANEL PRESET	Panel preset function
LINE-D	LINE DENSITY	Setting mechanical sector probe scanning line density
D-SELEC	DOPPLER TRANSDUCER	
PUNC	PUNCTURE GUIDE LINE	Setting puncture guideline display.
D-TRAC	DOPPLER TRACE	Setting Doppler trace display
D-DSP	DOPPLER DISPLAY	Setting Doppler pattern display
M-SELEC	M-MODE TRANSDUCER	Setting main frequency of independent M-mode probe
CH-DSP	CHARACTER DISPLAY	Setting image information display
DATE	DATE TIME	Setting calendar/timer
HOSPIT	HOSPITAL NAME	Setting backup comment area message
CALIP	CALIPER SIZE	Setting measurement caliper mark size
GAMMA	GAMMA	Gamma curve setting for photography monitor
VTR-MEM	VTR-MEMORY	Setting storage method for VTR playback

DESCRIPTION OF SWITCHES AND CONTROLS

MEASUREMENT:	Displays measurement menu. For detailed instructions, see Volume II, "Measurement and Analysis".
FOCUS:	Setting transmit focal area
PRE PROCESS:	Setting the degree of image contour enhancement
POST PROCESS:	Setting the display brightness characteristic of an ultrasound image on the monitor
DOP PRE COMP:	To change precompression curve.
DOP REJECT:	To eliminate weak Doppler echoes.
DOP FILTER:	To set wall filter
SAMPLE VOLUME:	To select sample volume size for obtaining PW Doppler information.
BODY MARK:	Setting the body mark group to be displayed by the body mark switch " "

1 6

Press one of these switches to select a function listed in the above menus. Enables an ECG-synchronized B-mode image.

(17) R DELAY switches

This switch can operate only when the ECG switch in the physiological signal unit (option) is on.

ECG SYNC : Freezes the B-mode image of the cardiac time phase set by the "←" and "→" switches and it is kept displayed until the B-mode image of the next cardiac time phase appears.

"←": Decreases the delay time.

"→": Increases the delay time.

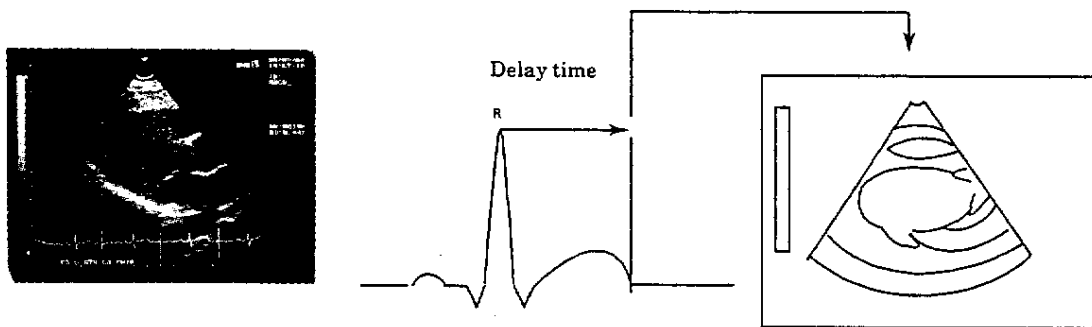


Fig. 5-32

(18) Alphanumeric keyboard

To move the character cursor (_) to an arbitrary position on the screen and write characters at that position.

When the LOCK KEY has been pressed and its red lamp lit, the keyboard will not operate.

Before operating the keyboard, be sure to release the LOCK key. For detailed instructions, see "CHARACTER DISPLAY" on P. 8-1 through P. 8-9.

(19) Probe holder

A case for holding unused probes and the gel bottle.

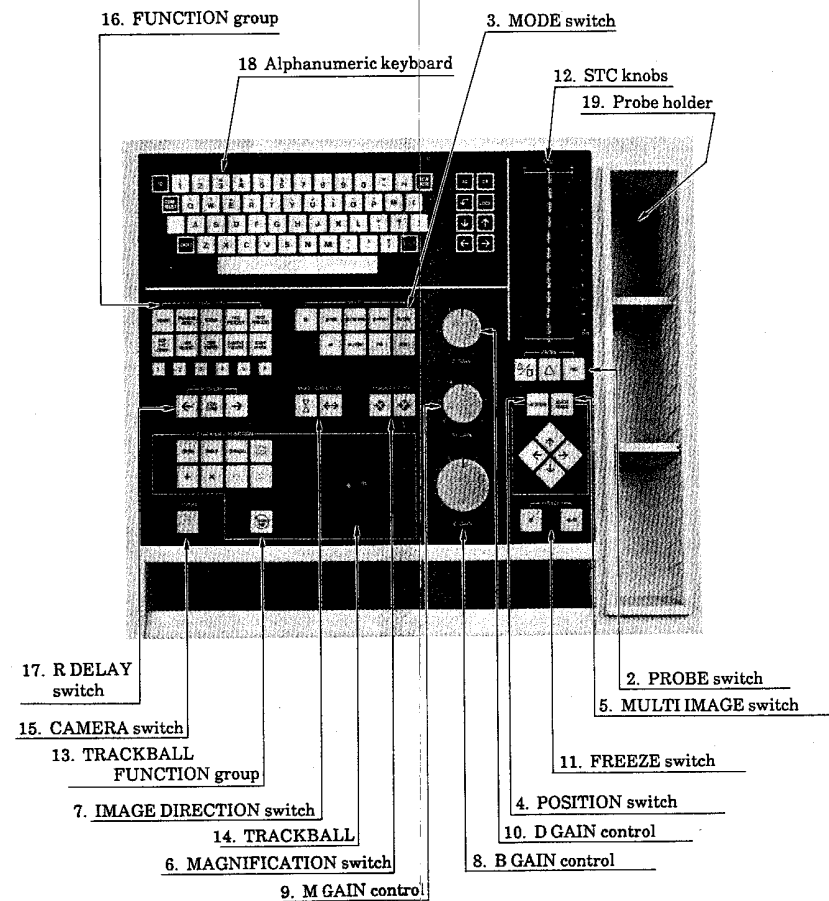


Fig. 5-33 Main Control Panel

NOTE: The switches related with Doppler are operable only when the optional Doppler module is installed.

DESCRIPTION OF SWITCHES AND CONTROLS

5.3 Subcontrol Panel

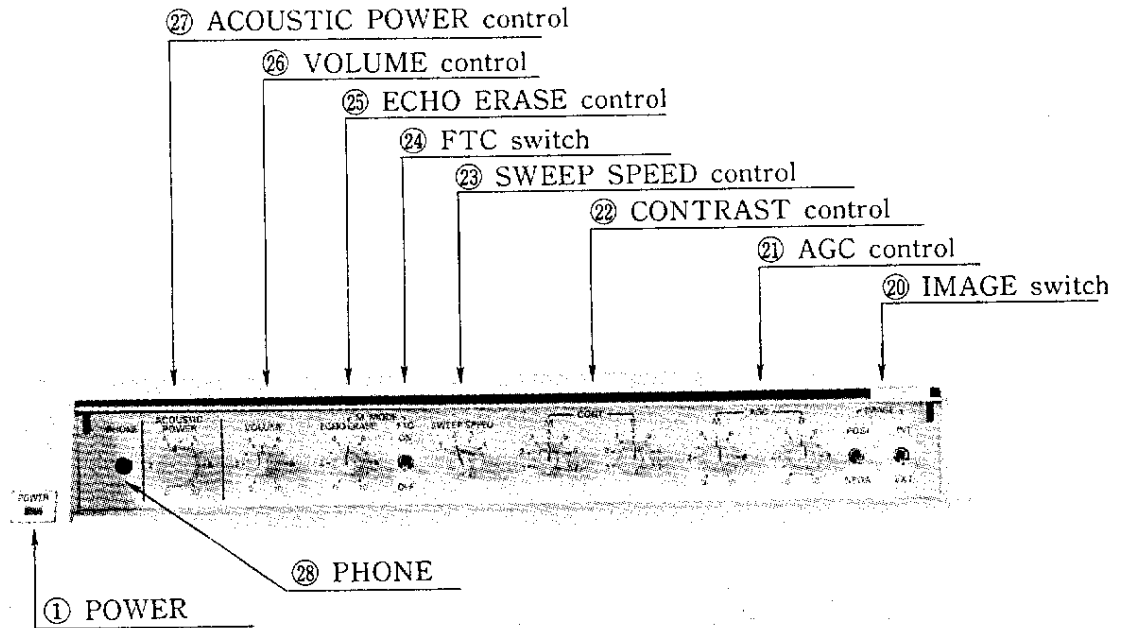


Fig. 5-34

(20) IMAGE switch

POSI/NEGA : To change white and black of the whole image on the screen.

POSI : White-on-black image is displayed. (See Fig. 5-32)
NEGA : Black-on-white image is displayed. (See Fig. 5-33)

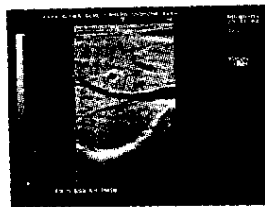


Fig. 5-35 POSI

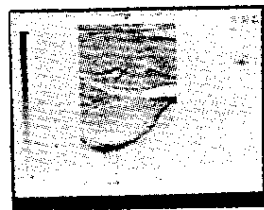


Fig. 5-36 NEGA

INT/EXT : To change video signal source to be displayed on the monitor screen. Set the switch to INT for normal usage.

INT : Displays internal signals (from imaging console).
 Image scanned by the unit is displayed.

EXT : Used to display external video signals from video tape recorder. Set the switch to EXT for observing a played back image.

DESCRIPTION OF SWITCHES AND CONTROLS

(21) AGC control

To separate the adjacent strong echoes by giving gradation to them before displaying them. As the control number increases, the degree of strong echo separation becomes higher.

B mode

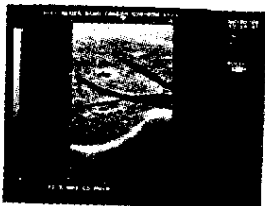


Fig. 5-37 AGC: 0

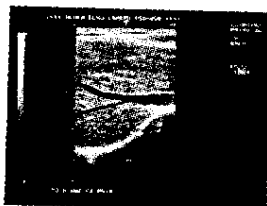


Fig. 5-38 AGC: 2

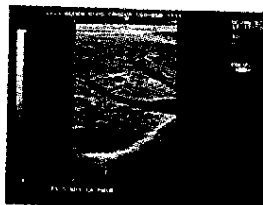


Fig. 5-39 AGC: 5

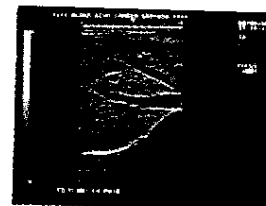


Fig. 5-40 AGC: 8

M mode

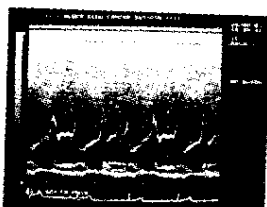


Fig. 5-41 AGC: 0

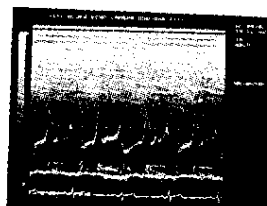


Fig. 5-42 AGC: 2

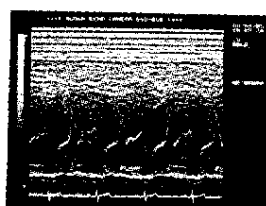


Fig. 5-43 AGC: 55

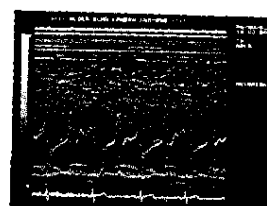


Fig. 5-44 AGC: 8

AGC can be used in combination with PRE PROCESS.

(22) CONTRAST control

Adjusts the contrast of an ultrasound image. As the control number increases, the contrast increases.

B mode

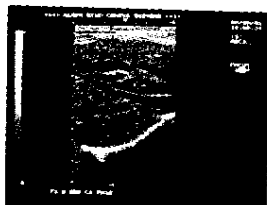


Fig. 5-45
CONTRAST: 1

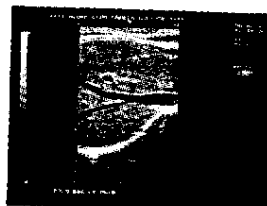


Fig. 5-46
CONTRAST: 3

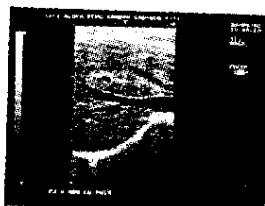


Fig. 5-47
CONTRAST: 5

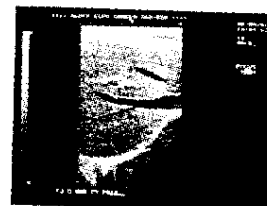


Fig. 5-48
CONTRAST: 7

M mode

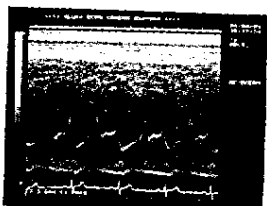


Fig. 5-49
CONTRAST: 1

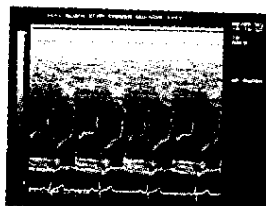


Fig. 5-50
CONTRAST: 3

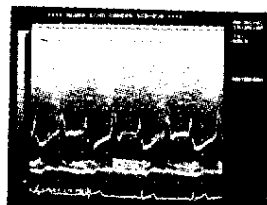


Fig. 5-51
CONTRAST: 5

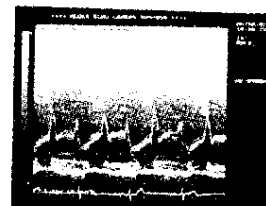


Fig. 5-52
CONTRAST: 7

DESCRIPTION OF SWITCHES AND CONTROLS

(23) SWEEP SPEED control

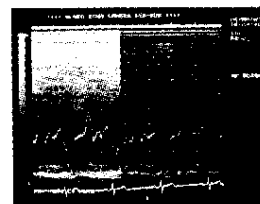
Switches the speed of the M-mode image in four steps.

- 1 ... It takes about 16 seconds for the image to move from one end of the screen to the other.
- 2 ... It takes about 8 seconds for the image to move from one end of the screen to the other.
- 3 ... It takes about 4 seconds for the image to move from one end of the screen to the other.
- 4 ... It takes about 2 seconds for the image to move from one end of the screen to the other.

The time mark is displayed at 0.5-second intervals.

(24) FTC control

Displays the M-mode image in a line drawing display.



FTC OFF → ON
Fig. 5-53

(25) ECHO ERASE control

Partly erases the lower area of the M-mode image to make it easier to see a simultaneously displayed physiological signal on the M-mode image.

If the area of the M-mode image does not need to be erased, set the control to 0.

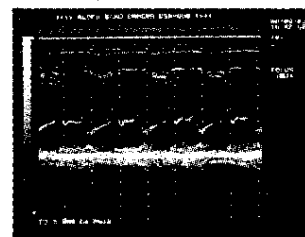


Fig. 5-54

(26) VOLUME control

Controls volume of Doppler audio.

(27) ACOUSTIC POWER control

Controls the transmitted ultrasound power.

- 10 : Maximum transmittig power
- 0 : No less than 10% amplitude.

Note: Use of minimum practical acoustic exposure is prudent.

(28) PHONE connector

Doppler audio can be heard by connecting optional headset to this connector.

DESCRIPTION OF SWITCHES AND CONTROLS

5.4 Right Side Panel

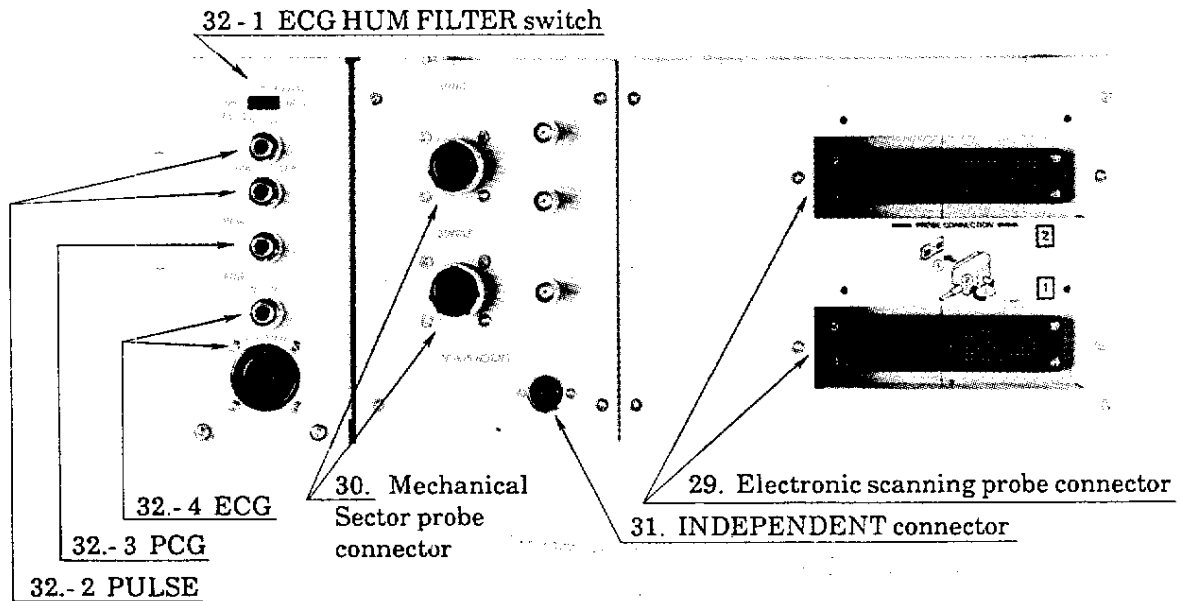


Fig. 5-55 Right Side Panel

(29) Electronic scanning probe connectors

Accepts the electronic scanning probe (either linear or convex).

Either connector will accept a linear or convex probe.

(30) Mechanical sector probe connectors

(30)-1 SINGLE connector,

Accepts single-element mechanical sector probe.

(30)-2 DUAL connector

Accepts dual-element mechanical sector probe.

(31) INDEPENDENT connector

Accepts Independent Doppler Probe.

(32) Physiological signal unit (option)

(32)-1 ECG HUM FILTER switch

Removes AC ripple in the power source.

DESCRIPTION OF SWITCHES AND CONTROLS

(32)-2 PULSE connector

Connection for the pulse wave transducer. (Option)

DC IN : Connector for preamplified physiological signal obtained from another unit used with it (e.g., the monitoring unit).

TRANSDUCER: Accepts the signal directly taken from the human body with the pulse wave transducer (option).

(32)-3 PCG connector

Connects the PCG microphone. (option)

(32)-4 ECG connector

Connects the ECG signal lead cord.

DC IN : Connector for preamplified ECG signal obtained from another unit used with it (e.g., the monitoring unit).

ISOLATED: Accepts the ECG signal directly taken from the human body. This connects the ECG lead cord.

DESCRIPTION OF SWITCHES AND CONTROLS

5.5 Left Side Panel

* The photography unit is optional.

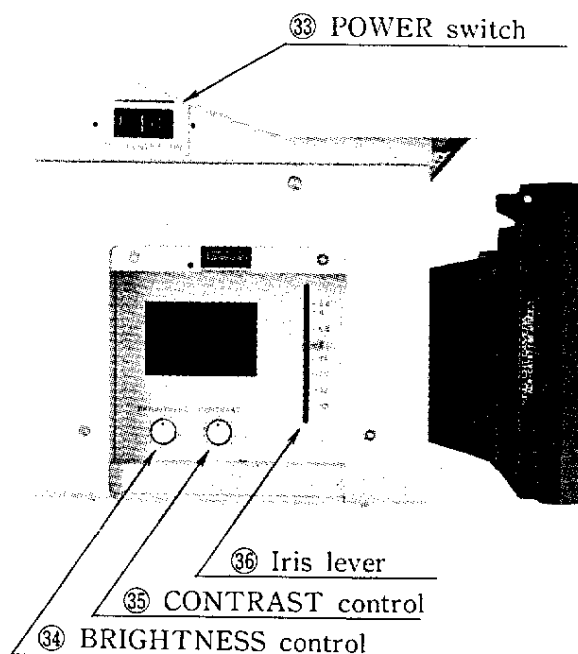


Fig. 5-56 Left Side Panel

(33) POWER switch

Turns on the equipment power supply. With this switch on, the POWER lamp (1) on the control panel lights to indicate that power is applied to the equipment.

(34) BRIGHTNESS control

Adjusts the screen base brightness of the photography monitor. When this control is turned clockwise, the base becomes brighter.

(35) CONTRAST control

Adjusts the contrast of the photography monitor. When this control is turned clockwise, the contrast increases.

(36) Iris lever

Adjusts the exposure time. As the lever is moved upward, the iris expands and the exposure increases. As the lever is moved downward, the iris contracts and the exposure is reduced.

DESCRIPTION OF SWITCHES AND CONTROLS

5.6

Front Panel

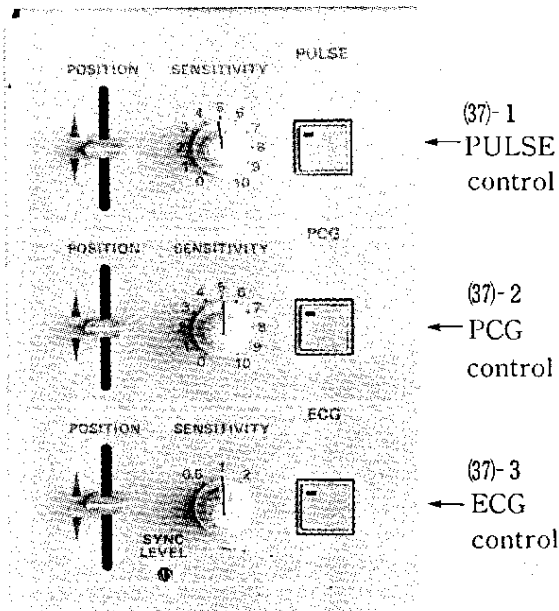


Fig. 5-57 Front Panel (upper part)

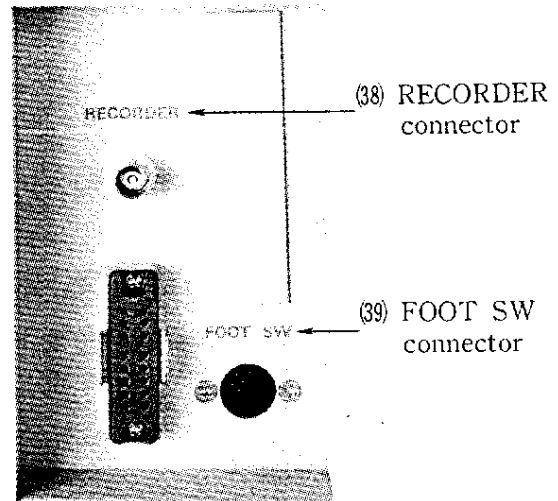


Fig. 5-58 Front Panel (lower part)

(37) Physiological signal unit (option)

(37)-1 PULSE control

Controls the physiological signal of the pulse wave displayed on the screen.

POSITION : Adjusts the display position of PULSE signal.

SENSITIVITY : Adjusts the sensitivity (amplitude) of the pulse wave signal.

PULSE switch: Turns the PCG signal display on or off.

(37)-2 PCG control

Controls the PCG signal displayed on the monitor.

POSITION : Adjusts the display position of the PCG signal.

SENSITIVITY : Adjusts the sensitivity (amplitude) of the DCG signal.

PCG switch : Turns the PCG signal display on or off.

(37)-3 ECG control

POSITION : Adjusts the display position of the ECG signal.

SENSITIVITY : Adjusts the sensitivity (amplitude) of the ECG signal in three steps.

ECG switch : Turns the ECG signal display on or off.

DESCRIPTION OF SWITCHES AND CONTROLS

(38) RECORDER connector

Connects the strip chart recorder model SSZ-95 (option).

(Connection)

<u>SSD-650 side</u>		<u>SSZ-95 side</u>
SIGNAL OUT	-----	SIGNAL
VIDEO OUT	-----	TV IN

(39) FOOT SW connector

Connects the footswitch model MP-2614 (option).

The use of the footswitch permits freezing the image and operating the shutter of the photography unit. The footswitch can be used instead of the **FREEZE B** switch, **FREEZE M/D** switch, and **CAMERA** switch.

DESCRIPTION OF SWITCHES AND CONTROLS

5.7 Rear Panel

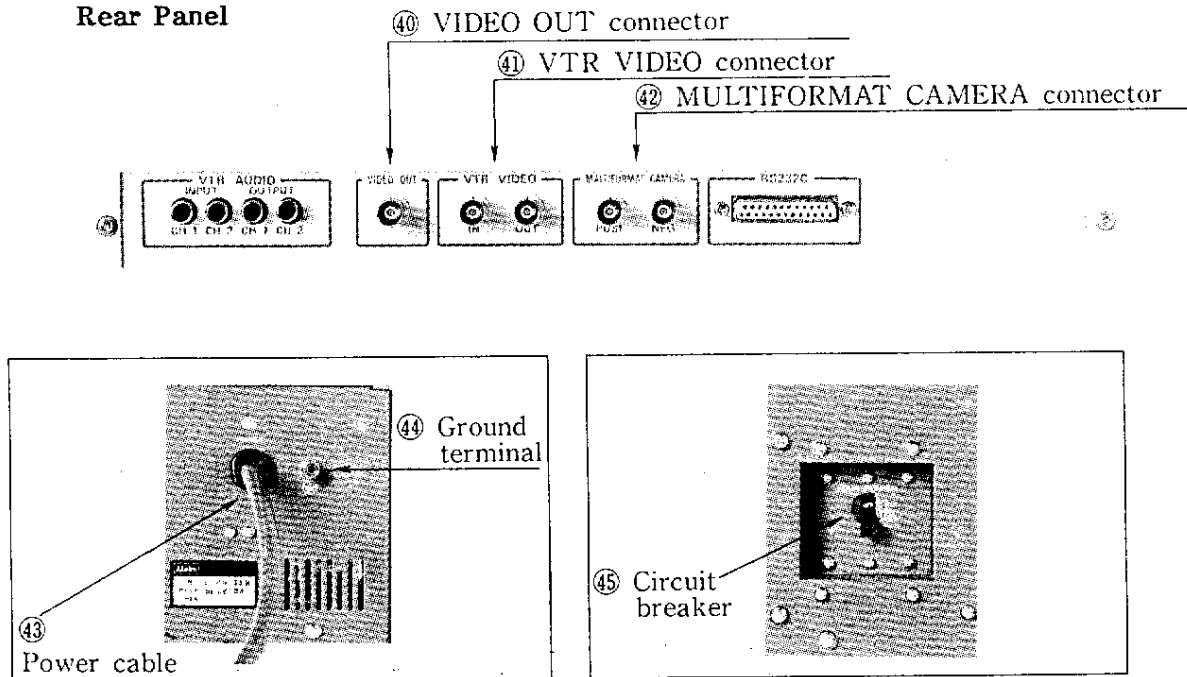


Fig. 5-59 Rear Panel

(40) VIDEO OUT connector

Outputs the same video signal as that displayed on the viewing monitor. Connect it to the VIDEO input connector of the optional video printer.

(41) VTR VIDEO connector

IN : Accepts the video signal output from the VTR.

OUT : Outputs the same video signal as that displayed on the viewing monitor.
Connect it to the VIDEO input connector of the VTR.

(42) MULTIFORMAT CAMERA connector

Connector an optional multi-format camera.

There are two signal outputs available according to the kind of image to be recorded (NEGA/POSI).

NEGA (white on black)
POSI (Black on white)

(Connection)

<u>SSD-650 side</u>	<u>Camera side</u>
POSI -----	VIDEO IN
NEGA -----	(VIDEO IN)

* Connect the POSI or NEGA signal to VIDEO IN.

DESCRIPTION OF SWITCHES AND CONTROLS

(43) Power cable

Inputs the power to this equipment. Connect it to a Hospital Grade outlet. The equipment consumes about 390W. Check the capacity and voltage of the outlet before making the connection.

(44) Ground terminal

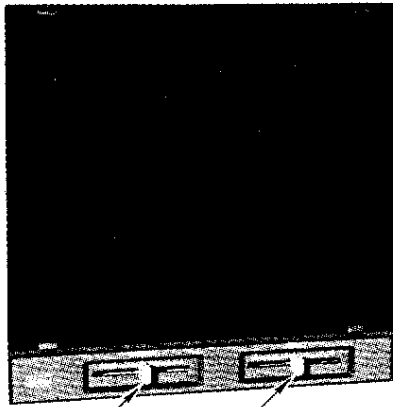
Connects to the grounding conductor.

(45) Circuit Breaker

Normally set it to ON position.

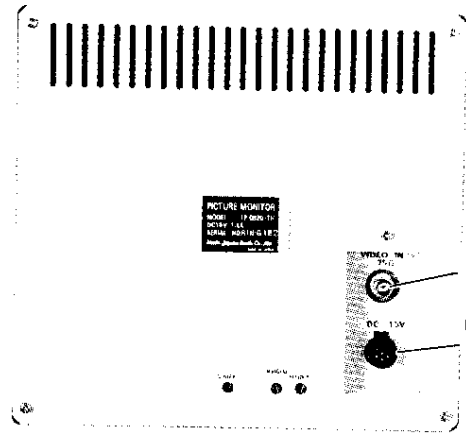
DESCRIPTION OF SWITCHES AND CONTROLS

5.8 Viewing Monitor



(46) CONTRAST control
(47) BRIGHTNESS control

Fig. 5-60 Monitor (front panel)



(48) VIDEO connector
(49) POWER connector

Fig. 5-61 Monitor (rear panel)

(46) CONTRAST control

Adjusts the contrast of the image on the viewing monitor.

(47) BRIGHTNESS control

Adjusts the brightness of the screen base of the viewing monitor.

(48) VIDEO IN connector

Inputs the VIDEO signal output from the main unit.

(49) POWER connector

Connects the power cable of the viewing monitor.



BASIC IMAGING PROCEDURE

6. BASIC IMAGING PROCEDURE

6.1 Turning Power on and Initial Setting

Before turning on the system power, note the following points:

- The unit has been installed in an appropriate environment. (See section 4 for the information.)
- The power cable has been plugged in an appropriate wall outlet.
- Grounding is complete.

CAUTION

For the patient's and operator's safety, be sure to ground the equipment chassis.

- a. Turn on the POWER switch (33) on the left side panel.

The green POWER lamp (1) lights. In about 10 seconds, an image appears on the viewing monitor screen.

The display shown in Fig. 6-1-1 appears on both observation monitor and photography monitor (option).

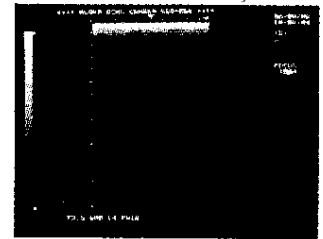


Fig. 6-1-1

NOTE When no probe is connected, or the probe cable plug is not locked correctly, or the INT/EXT selector switch (22) is set at EXT, no image is displayed.

Brightly lit switches are now operable. Those lighting faintly are not operating, however become active when pressed.

NOTE: When the POWER switch is turned on, all the lamps light for about 2 seconds. This has no connection with the operation of the equipment.

When the POWER switch is turned on, the lamps shown below light to show initial state.

(Switches light when power is turned on)

POWER Lamp

PROBE

MODE B

The above mode is the standard setting with a probe connected on the electronic probe connector 1. When the Preset Function (See subsection 7.8.) has been employed, the equipment will start in a mode that conforms with the presetting.

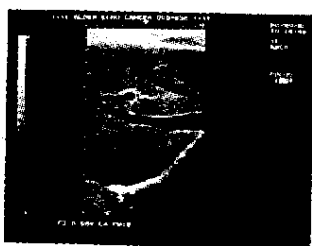
BASIC IMAGING PROCEDURE

b. Set other switches and controls as follows;

B GAIN: 6 - 7
M GAIN: 6 - 7
CONTRAST: 4 - 5
STC mark: The position marked " ▼ " (at the center)

c. Then, follow the procedure for each display mode described from the next page onward.

(Image display items)



86/09/02	Date
16:10:40	Time
ID:		
ABCD	Patient number
FOCUS		
1234	Focal area display

Fig. 6-1-2

"Measurement/calculation
result display"

F 3.5	Nominal frequency of the probe used to create a displayed image (MHz).
G 80	Value of gain setting
C 4	Value of image contrast setting
PW 10	Value of ultrasound transmitting power (Maximum value is 10.)
→	Indicates the direction of the probe front mark.
05.9	Indicates the distance of image shift. Distance between the ultrasound transmitting/receiving position (probe surface) and the tomographic display position (top end of displayed image). It is displayed in the upper right corner of the image display when position of image display range is shifted.
RNG 12	Indicates the display distance (depth range) of sector image.
▼	Indicates the real-time ultrasound image that can be controlled from the panel.
┌	Gray scale bar (echo level display) and post process setting level marks.

BASIC IMAGING PROCEDURE

6.2 B-mode Imaging

(1) Using Electronic Probe (either linear or convex)

a. Check that the date display is correct, then key in the patient identification (ID) number

For the entry procedure, refer to section 8 "CHARACTER DISPLAY"

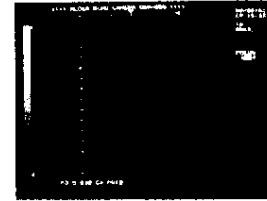


Fig. 6-2-1

b. Select a probe to be used for examination with the PROBE switch (2).

c. Apply a sufficient amount of ultrasound gel to the entire scan region of the patient and the probe.

NOTE: Insufficient ultrasound gel generates air gaps between the skin and probe, blocking the formation of a good image. Apply additional gel to dispel such gaps.

d. Apply the probe to the scan region of the patient's body. A tomographic image will be displayed on the screen.

The positional relationship between the probe front mark and the B-mode image on the screen is shown in Fig. 6-2-2 and Fig. 6-2-3.

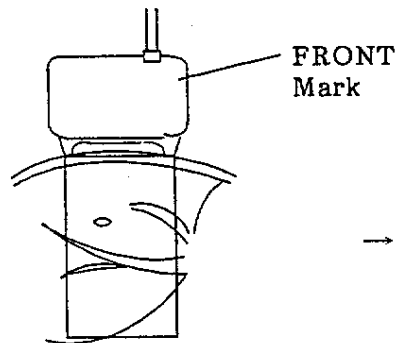


Fig. 6-2-2

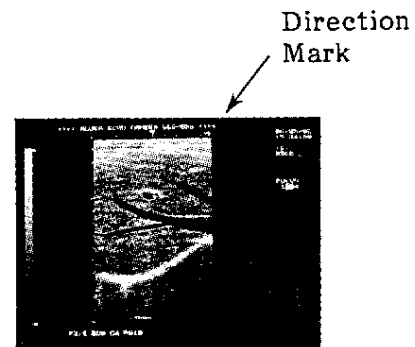


Fig. 6-2-3

e. To change lateral direction (left/right) of the image, press the IMAGE DIRECTION switch "←→".

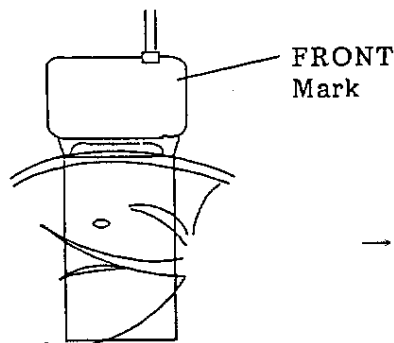


Fig. 6-2-4

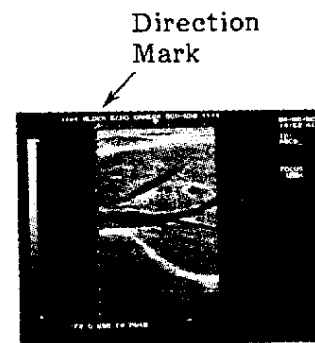


Fig. 6-2-5

BASIC IMAGING PROCEDURE

- f. While observing the image on the screen, adjust the B GAIN control (8) and STC knobs (11) so that a uniform echo brightness is observed.

In addition, make additional adjustments with the AGC, CONTRAST and other controls to display an easy-to-diagnose image. For more detailed instructions, see "6.4 B-mode and M-mode Images Adjustment".

- g. To change the image magnification, press the MAGNIFICATION switch.

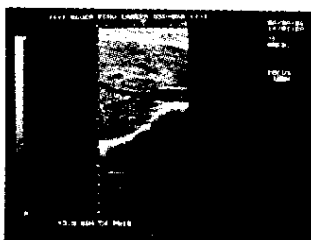


Fig. 6-2-6 x 0.7

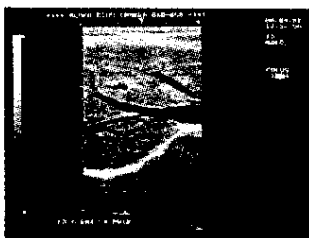


Fig. 6-2-7 x 1



Fig. 6-2-8 x 1.5

The image display magnification can be set in four steps.

The display range can be moved up or down by the arrow switches " \diamond " and " \blacktriangledown " after turning on the POSITION switch.

- h. When performing a multi-image display, turn on the MULTI IMAGE switch (5) and select an image to be controlled by the arrow switches.

For each image, it is possible to perform operations in the same way as in B-mode single image display.

- i. After obtaining an optimal image, freeze it with the FREEZE switch (10).

When freezing the image, ask the patient to hold his/her breath to obtain a less blurred image.

- j. Display a body mark to indicate the scan region (tomographic image position).

For more detailed instructions, refer to "OPERATION AIDS (Body Mark Display)" on P. 7-1 and P. 7-4.

- k. Images can be recorded with an optional photography unit, VTR, thermal printer, etc. To take a photo, press the CAMERA switch (14).

- l. After the examination, wipe the ultrasound gel off the patient and probe and put the probe back in the probe holder.

(2) Using the Mechanical Sector Probe

Steps "a." through "c." are the same as those for the electronic probe.

- d. Apply the probe to the scan region.

B-mode image appears on the monitor.

The positional relationship between the probe front mark and the B-mode image on the monitor is shown in Fig. 6-2-9 and Fig. 6-2-10.

BASIC IMAGING PROCEDURE

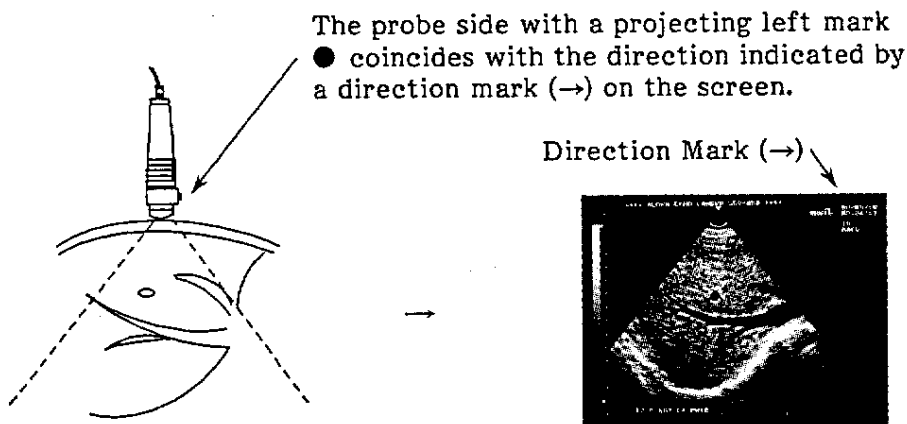


Fig. 6-2-9

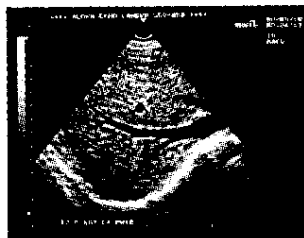


Fig. 6-2-10

- e. To reverse the lateral direction (left/right) of the image, press **IMAGE DIRECTION** switch "↔". To invert the direction (up/down) of the image, press **IMAGE DIRECTION** switch "⊗".

Figure 6-5 and Fig. 6-12 show an image with a left and right reversal.

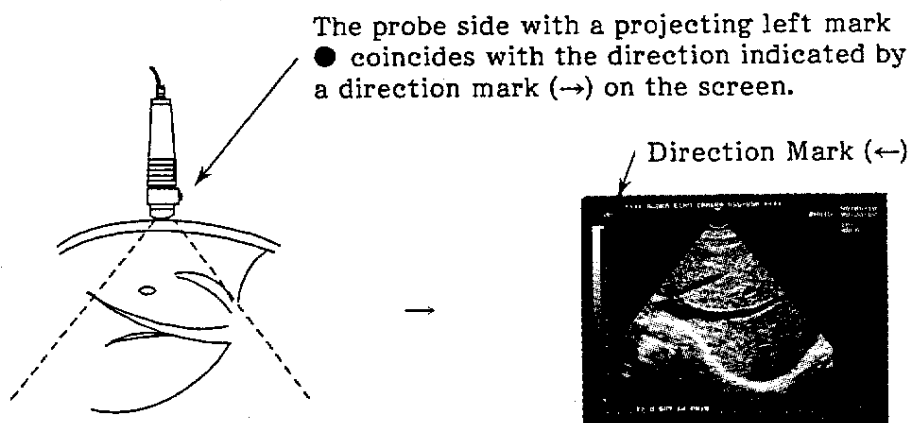


Fig. 6-2-11



Fig. 6-2-12

- f. Set the **MAGNIFICATION** switch (6) according to the depth of the image to be observed.

The range of the sector image consists of eight steps from 4 to 24 cm corresponding to diagnostic distances. Each time the "⊞" switch is pressed, the diagnostic range is reduced. Each time the "⊚" switch is pressed, it increases.

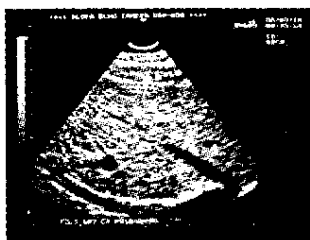


Fig. 6-2-13
RANGE 9 cm

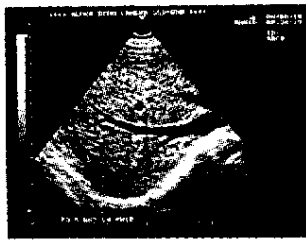


Fig. 6-2-14
RANGE 15 cm

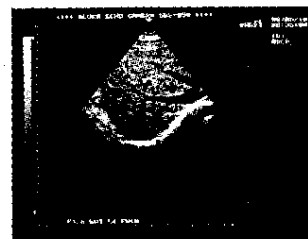


Fig. 6-2-15
RANGE 21 cm

BASIC IMAGING PROCEDURE

- g. While observing the image, adjust the GAIN, STC, and other controls in the same way as when using the linear probe.
- h. After obtaining an optimal image, freeze it with the FREEZE switch (10).
After displaying a scan region with a body mark, record the image.
Operations for a multi-image display can be performed in the same way as the linear probe.
- i. After the examination, wipe the ultrasound gel off the patient and probe and put the probe back in the probe holder. This completes the examination.

BASIC IMAGING PROCEDURE

6.3 M-mode Imaging

To obtain a M-mode image in an arbitrary direction on the B-mode image, perform the following operations.

- a. Press the B/M of the MODE switch (3).

B-mode image with M-mode sample cursor and an M-mode image are displayed on the screen.

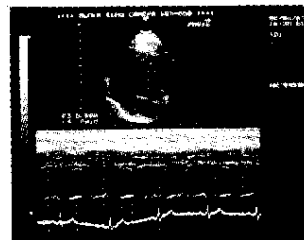


Fig. 6-3-1

- b. Press the CURSOR switch then shift the cursor using the TRACKBALL to the position where an M-mode image is to be obtained.

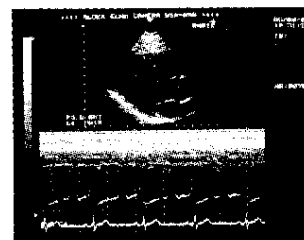


Fig. 6-3-2

- c. Adjust the brightness of the image using the M GAIN control (9). Make adjustments with the M CONTRAST (22), and other controls so that the display is optimized.

To convert the M-mode image to a line drawing, turn on the FTC switch. To make its contour distinct, adjust the M AGC control (21).

To display physiological signals using the optional unit, erase the lower part of the image with the ECHO ERASE knob (25).

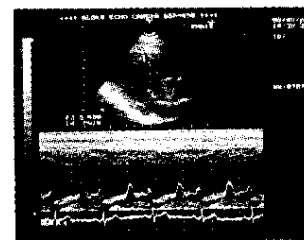


Fig. 6-3-4

- d. The M-mode image sweep speed can be set with the SWEEP SPEED control (23).

The M-mode time mark is always displayed at 0.5-second intervals.

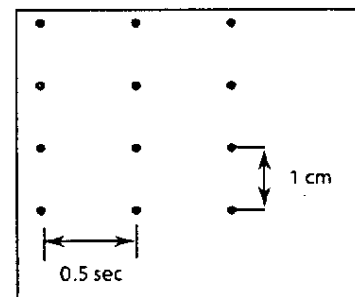


Fig. 6-3-3

- e. To display a full screen M-mode image, set the MODE switch (3) to " M ".

The image can be recorded with an optional photography unit, VTR, thermal recorder, etc. To record on instant film, freeze the image using the FREEZE switch (11), then press CAMERA switch (15).

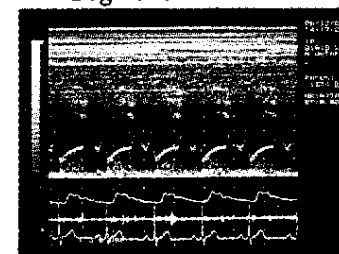


Fig. 6-3-5

BASIC IMAGING PROCEDURE

6.4 B mode and M-mode Image Adjustments

(1) Image adjustment by GAIN and STC

Normally, set GAIN and STC as shown in Fig. 6-4-1 before starting an examination.

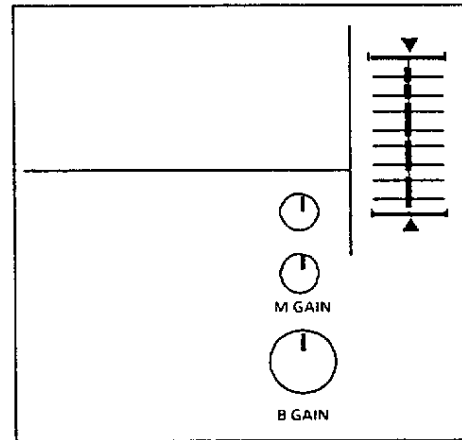


Fig. 6-4-1

Adjust the gain (brightness) of the ultrasound image using the GAIN controls and STC knobs. When the GAIN knob is turned clockwise, the image becomes brighter. When the knob is turned counterclockwise, the image becomes darker.

Adjust the GAIN controls so that each STC knob may come as close to the reference line ("▼" mark) as possible.

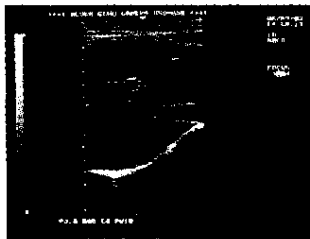


Fig. 6-4-2
Under Gain

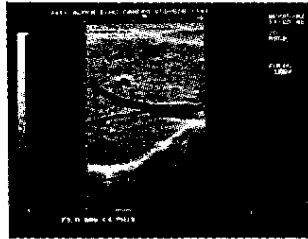


Fig. 6-4-3
Adequate Gain



Fig. 6-4-4
Over Gain

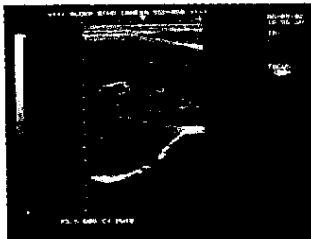


Fig. 6-4-5
STC on the "▼" Mark

Make the adjustments so that the region of interest may be clearly observed.

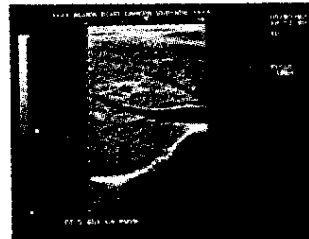


Fig. 6-4-6
After STC Adjustment

Note that if the gain is too high, the echoes will become saturated and anatomic detail obscured.

BASIC IMAGING PROCEDURE

(2) Image adjustment using CONTRAST controls

The B-mode image and M-mode image are independently adjusted so that the contrast levels may be optimized.

B-mode

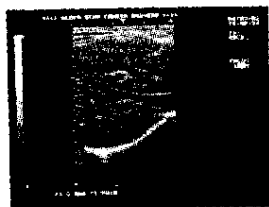


Fig. 6-4-7
CONTRAST 1

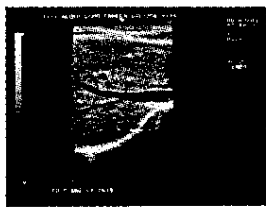


Fig. 6-4-8
CONTRAST 3

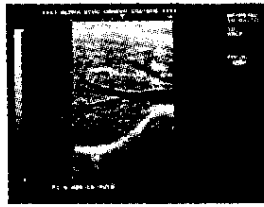


Fig. 6-4-9
CONTRAST 5

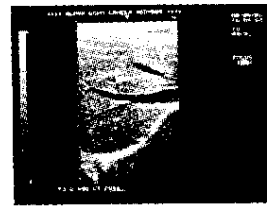


Fig. 6-4-10
CONTRAST 7

M-mode

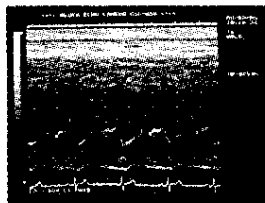


Fig. 6-4-11
CONTRAST 1

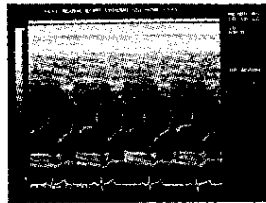


Fig. 6-4-12
CONTRAST 3

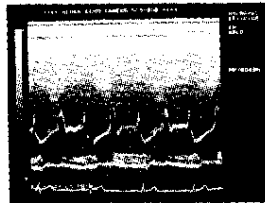


Fig. 6-4-13
CONTRAST 5

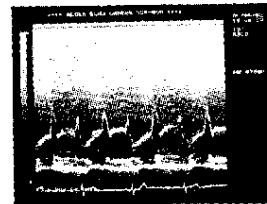


Fig. 6-4-14
CONTRAST 7

(3) Image adjustment using AGC

The AGC is normally set to 0. If there are many weak echoes which are hidden by strong echoes and the desired image is hard to observe, the AGC control can enhance the contour of the image for a clearer display. This control can be used together with the PRE PROCESS function.

B-mode

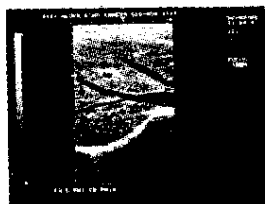


Fig. 6-4-15
AGC 0

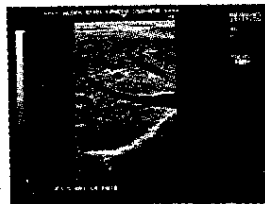


Fig. 6-4-16
Medium AGC



Fig. 6-4-17
High AGC

M-mode

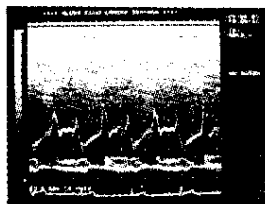


Fig. 6-4-18
AGC 0

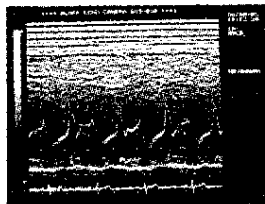


Fig. 6-4-19
Medium AGC

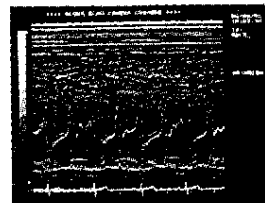


Fig. 6-4-20
High AGC

BASIC IMAGING PROCEDURE

(4) Image adjustment by FOCUS

Normally, when the electronic scanning probe is used, two or three focal distances (focal points) are set according regions of interest. Set the FOCUS menu according to the diagnostic purpose.

When a real-time characteristic is especially required, one-point focus is used for the region of interest. When a high-resolution image throughout the diagnostic distance is required, multi-point focus is used.

Press the FOCUS of the FUNCTION switch to display FOCUS menu.

In B mode, focus setting is performed on the first page of FOCUS menu. In B/M or M mode, it is performed on the second page of FOCUS menu.



Fig. 6-4-21 One-point Focus



Fig. 6-4-22 Multi-point Focus

(5) Image adjustment by PRE PROCESS

This function, enhances the contour of the B-mode or M-mode image for a clearer display. It can be used together with the AGC.

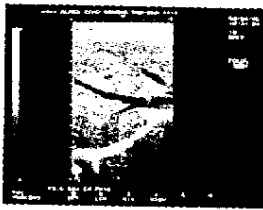


Fig. 6-4-23
OFF

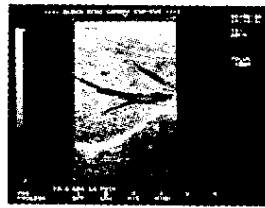


Fig. 6-4-24
LOW

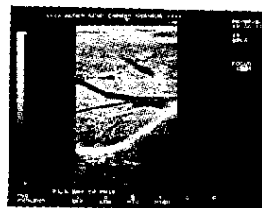


Fig. 6-4-25
MID



Fig. 6-4-26
HIGH

BASIC IMAGING PROCEDURE

(6) Image adjustment by POST PROCESS

The display brightness characteristic for each echo intensity can be changed by the POST PROCESS function. Press the POST PROCESS of the FUNCTION switch to display the menu.

LINEAR

Images are normally made in this state.

All echoes are displayed with the brightness corresponding to their individual intensity.

This condition is created by selecting LINEAR from POST PROCESS and expanding LOW and HIGH from the LEVEL menu maximally. That is, all 64 shades are used.

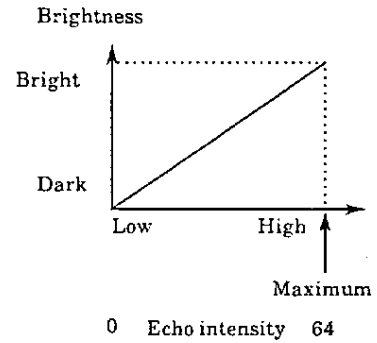


Fig. 6-4-27

SLOPE 1

Lower level echoes than the area where the brightness is to be expanded are displayed with the minimum brightness and higher echoes are displayed with the maximum brightness.

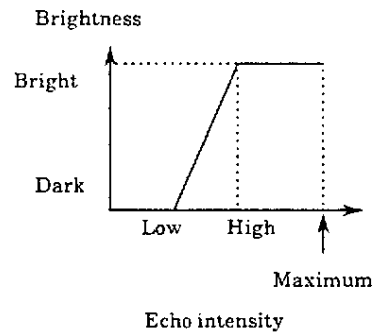


Fig. 6-4-28

- a. Using LOW and HIGH from the LEVEL menu, set an echo level.

Echoes stronger than the level set are displayed with the set high level. Weaker echoes are displayed with the set low level.

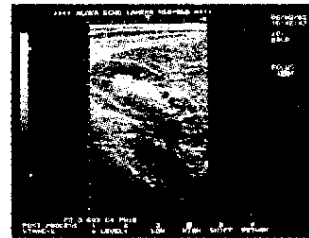


Fig. 6-4-29

- b. When the range is shifted downward using SHIFT from the LEVEL menu, the display becomes as shown in Fig. 6-4-30.

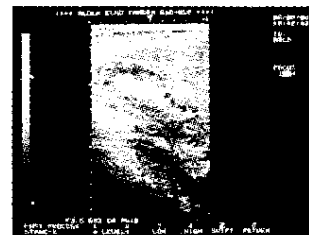


Fig. 6-4-30

BASIC IMAGING PROCEDURE

- c. When the range is shifted upward using SHIFT from the LEVEL menu, the display becomes as shown in Fig. 6-4-31.

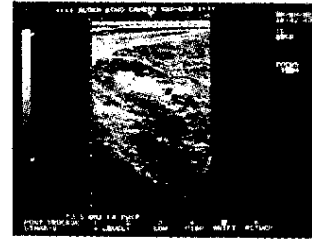


Fig. 6-4-31

SLOPE 2

Echoes both weaker and stronger than the area where the brightness is to be expanded are not displayed.

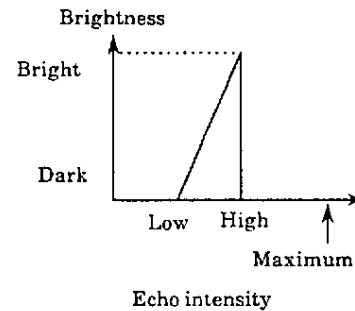


Fig. 6-4-32

- a. Using LOW and HIGH from the LEVEL menu, set an echo level.

Echoes both stronger and weaker than the set level are not displayed.

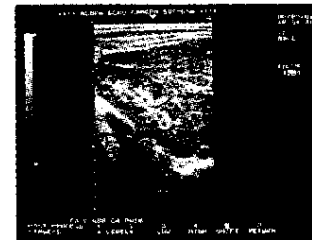


Fig. 6-4-33

- b. When the range is shifted downward using SHIFT from the LEVEL menu, the display becomes as shown in Fig. 6-4-34.

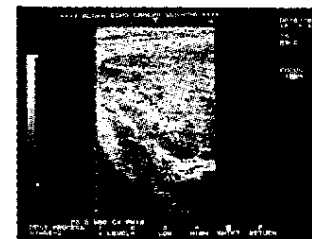


Fig. 6-4-34

- c. When the range is shifted upward using SHIFT from the LEVEL menu, the display becomes as shown in Fig. 6-4-25.

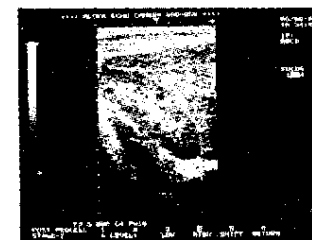


Fig. 6-4-35

BASIC IMAGING PROCEDURE

SLOPE 3

Echoes lower and higher than the area where the brightness is to be expanded are displayed with the change in brightness reduced to 1/4.

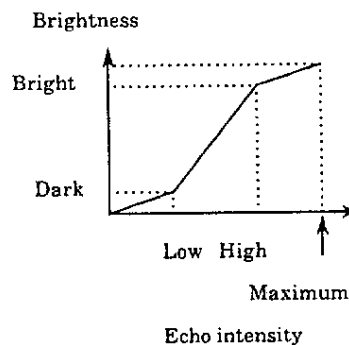


Fig. 6-4-36

Using HIGH from the LEVEL menu, set an echo level.

Echoes both stronger and weaker than the set level are displayed with the change in brightness reduced to 1/4.

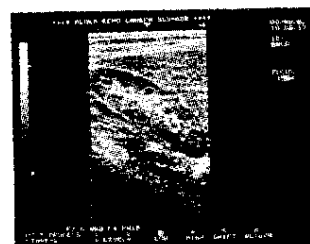


Fig. 6-4-37

REJECT

Using the LEVEL menu, set an echo level.

All the echo signals lower than the set level are cut and displayed with level 0 (zero).

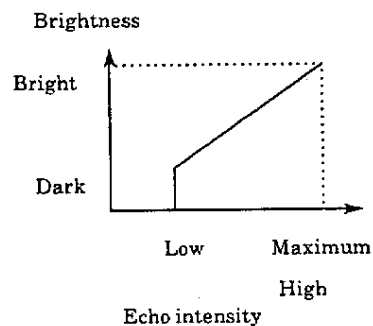


Fig. 6-4-38

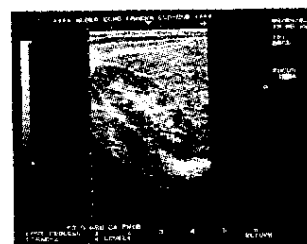


Fig. 6-4-39

BASIC IMAGING PROCEDURE

6.5 Doppler Pattern Display Procedure

6.5.1 Introduction

There are two ways to obtain Doppler information, one is Pulsed Wave (PW) and the other Continuous Wave (CW).

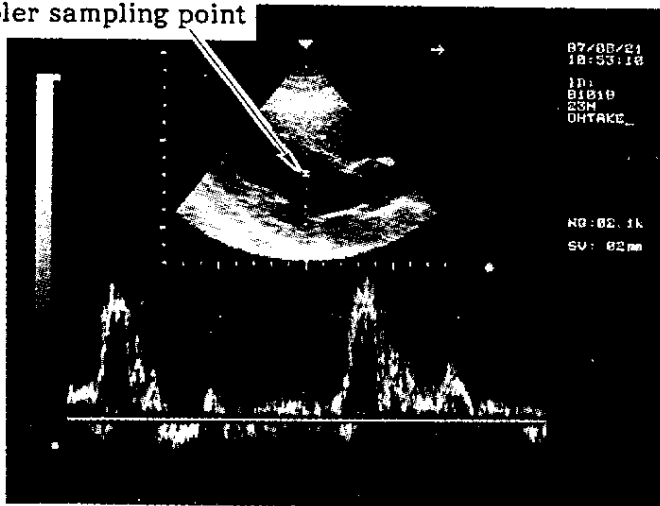
The PW method can set a sampling volume to an arbitrary position, however maximum detectable velocity is lower than CW method. So the PW method is used for localized analysis. For example, it is used for obtaining Doppler pattern of portal vein and hepatic vessels.

On the contrary, the CW method picks up all the information on an specified line, however, maximum detectable velocity is much higher than the PW method. So it is used, for example, to detect maximum velocity for judging seriousness of stenosis or regurgitation at mitral valve or aortic valve.

One more method which is included in the PW method is High Pulse Repetition Frequency (HPRF) PW method. The HPRF-PW method uses multiple sample volumes on a line for picking up Doppler information. So information from several points are mixed, and maximum detectable velocity is between the PW and CW methods. The HPRF-PW method is automatically available by increasing the velocity range of PW Doppler pattern.

(1) Display Format

Doppler sampling point



↑ Toward flow
BASE LINE
↓ Away flow

Fig. 6-5-1

Information Display:

NQ: Nyquist rate (in kHz). Half of the pulse repetition frequency.

SV: Sample volume size (in mm).

(2) Switches that work differently in Doppler mode

MAGNIFICATION:

When Doppler power spectrum is displayed, this switch changes the maximum detectable velocity. PRF (Pulse repetition frequency) changes as the maximum detectable velocity changes.

: Raises the maximum detectable velocity. The Doppler pattern reduces.

BASIC IMAGING PROCEDURE

- : Lowers the maximum detectable velocity. The Doppler pattern expands.

POSITION:

When Doppler power spectrum is displayed, this switch shifts the baseline.

- : Raises the base line.
- : Lowers the base line.

BASIC IMAGING PROCEDURE

6.5.2. PW Doppler Analysis

- (1) Using a mechanical sector probe.
 - a. Display an real-time B-mode image to find out the area of interest.
 - b. Press the B/PW (or B/M, PW) switch.

B-mode image is displayed in the upper area and nothing is displayed in the lower area.

- c. Press the B of the FREEZE switch.

The B-mode image is frozen and Doppler pattern appears in the lower area.

To obtain a clean Doppler pattern, see subsection "3 Adjustment of Doppler Pattern."

- d. Press the **CURSOR** switch to display the Doppler cursor with the sample volume.

Using the trackball, position the sample volume ("I" mark) to the point where Doppler information is to be sampled.

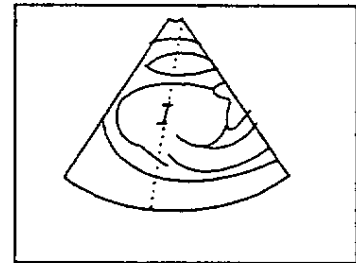


Fig. 6-5-2

When it is necessary to change the sample volume size, press the **SAMPLE VOLUME** switch to display the menu.

SAMPLE	1	2	3	4	5	6
VOLUME	2 mm	3 mm	5 mm	10 mm		

Select a sample volume size with the **FUNCTION** numeral switch.

- e. Press the **ANGLE** switch. Angle mark is displayed on the sample volume.
 - f. Press and hold the **MARK REF** switch. The angle mark rotates counter-clockwise. When the angle mark is parallel to the blood flow, let your finger go.

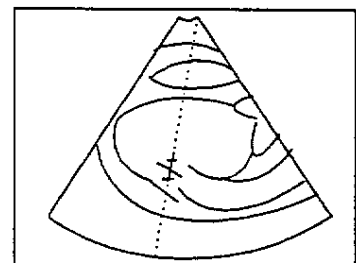



Fig. 6-5-3


NOTE: The angle mark rotates only counterclockwise.

BASIC IMAGING PROCEDURE

(2) HPRF Doppler

In PW mode, pressing the  switch raises the velocity range to observe high velocity blood flow. When the velocity range is extended, additional sample volume marks, "-" sampling mark(s) will appear. This shows the multiple sampling points that are available. This is called HPRF (High Pulse Repetition Frequency) Doppler.

Step:

- a. Press the B/PW of the MODE switch. When the area of interest is displayed, press the FREEZE B switch.
- b. Pressing the  switch to expand the velocity range and HPRF Doppler is automatically executed.

At this time multiple "-" sample volume marks are displayed. All the information at the "-" sample mark including the main sample volume mark is displayed as Doppler information.

BASIC IMAGING PROCEDURE

6.5.3 CW Doppler Analysis

- a. Display a real-time B-mode image to find out the area of interest.
- b. Press the **CURSOR** switch to display the sampling cursor.

Using the trackball, position the sampling cursor to the point where Doppler information is to be obtained.

- c. Press the **B/CW** switch.

B-mode image is displayed in the upper area. Nothing is displayed in the lower area.

- d. Press the **B** of **FREEZE** switch.

B-mode image is frozen and Doppler pattern appears.

To obtain a clean Doppler pattern, see subsection "3 Adjustment of Doppler Pattern."

BASIC IMAGING PROCEDURE

6.5.4 Adjustment of Doppler Pattern

(1) FUNCTION Switches

DOP PRE COMP:

To change the pre-compression curve. (See the figure to the right.) When the curve is set to HIGH, low level signals are displayed brightly. When the curve is set to LOW, low level signals are displayed.

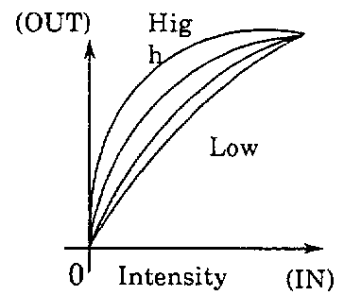


Fig. 6-5-4

DOPPLER	1	2	3	4	5	6
COMPRESSION	LOW	MID-1	MID-2	HIGH		

DOP REJECT:

To change the rejection level to eliminate low level signals. It is possible to eliminate weak Doppler signals.

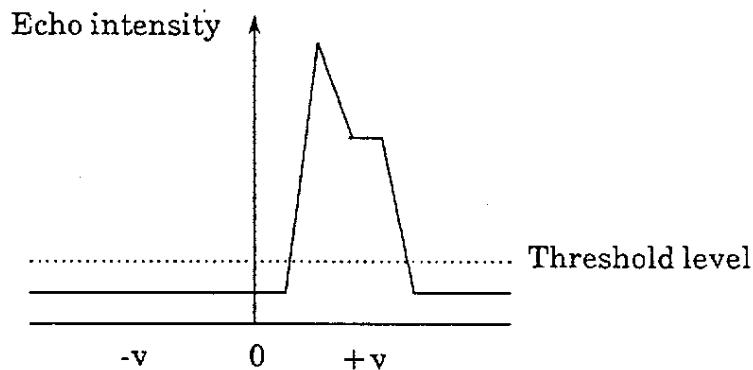


Fig. 6-5-5

DOPPLER	1	2	3	4	5	6
REJECT	↓	LEVEL ↑				RESET

- ↑ : Raises the threshold level.
- ↓ : Lowers the threshold level.
- RESET: The level returns to the lowest position.

DOP FILTER:

To change cut-off frequency of the low-cut filter. Low frequency components caused by wall motion can be eliminated.

BASIC IMAGING PROCEDURE

DOPPLER	1	2	3	4	5	6
FILTER	100	200	400	600	800	1000(Hz)

- (2) When there is excessive background noise:

See the attached table (on next page) and understand the function of each Doppler signal processing.

Perform the following steps in order until background noise is eliminated.

- a. Using DOP PRE COMP menu, select LOW.
- b. Using the DOP REJECT menu, raise the rejection level.
- c. Using the D GAIN control, reduce the gain of low level signal.

NOTE: When no strong Doppler information is inputted, only weak signals are displayed brightly in whole image area. When a strong Doppler signal is inputted, those weak signals will disappear. If noise remains, perform the above steps.

- (3) When there is excessive wall motion signal:

Using the DOP FILTER menu, raise the cut-off frequency of the wall motion filter.

OPERATION AIDS

7. OPERATION AIDS

7.1 Body Mark Display


When the TRACKBALL FUNCTION switch marked  is pressed, a body mark and a probe mark are displayed in a lower left corner of the image.



Fig. 7-1 Body Mark


(1) Body Mark Pattern Changes

20 types of body marks have been prepared that may be classified into four groups according to clinical applications.

Press the BODY MARK switch of the FUNCTION group. The following menu is displayed:

BODY MARK	1	2	3	4	5	6
GROUP	ABDOM	OBST	HEAD	OTHER		AL OFF

- 1 ABDOM : Body marks which suit abdominal imaging are displayed.
- 2 OBST : Body marks which suit obstetrical imaging are displayed.
- 3 HEAD : Body marks which suit neck and head imaging are displayed.
- 4 OTHER : Body marks which suit ophthalmological and cardiac imaging are displayed.
- 5 AL OFF : Erases all the body marks displayed.

The body marks belonging to a group selected from the BDY-MK menu may be changed cyclically by pressing the  switch, as follows:

(ABDOM)



Fig. 7-2
Supine



Fig. 7-3
Left lateral



Fig. 7-4
Right lateral

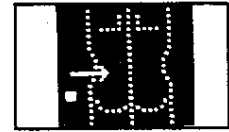


Fig. 7-5
Prone



Fig. 7-6
Chest



NO DISPLAY



OPERATION AIDS

(OBST)



Fig. 7-7
Supine

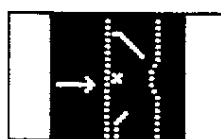


Fig. 7-8
Left lateral

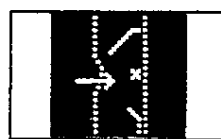


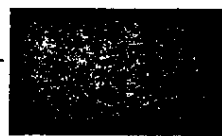
Fig. 7-9
Right lateral



Fig. 7-10
Fetus 1



Fig. 7-11
Fetus 2



NO DISPLAY



(HEAD)



Fig. 7-12
Neck



Fig. 7-13
Right Side Head



Fig. 7-14
Left Side Head



Fig. 7-15
Vertex



NO DISPLAY



(OTHER)



Fig. 7-16
Left eye



Fig. 7-17
Right eye



Fig. 7-18
Heart 1



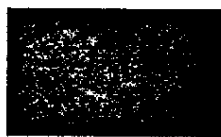
Fig. 7-19
Heart 2



Fig. 7-20
Heart 3



Fig. 7-21
Heart 4



NO DISPLAY



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(2) Probe Mark Shifts

After defining a body mark pattern, the TRACKBALL and MARK REF switches may be operated to positionally shift a probe mark on the body mark, to display probe position.

- a. By operating the TRACKBALL, shift the probe mark to a position that corresponds to the actual probe location.
- b. Press the MARK-REF switch. By rolling the TRACKBALL to the right or left, rotate the probe mark.
A rightward rolling of the TRACKBALL rotates the probe mark clockwise, and a leftward rolling rotates it counterclockwise.
- c. Operate the TRACKBALL and MARK REF switches to have the probe mark closely approximate the actually applied location.
Each time the MARK REF switch is pressed, the TRACKBALL will alternately set either shifting or rotation of the probe mark.

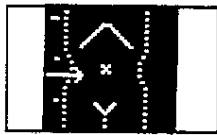


Fig. 7-22



Fig. 7-23



Fig. 7-24

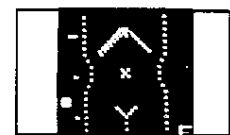


Fig. 7-25

(3) Body Mark in Multi-Image Display Mode

In a (two, three or four) multi-image display mode, the body mark may be displayed individually for each of the images.

By operating the arrow switches, select the image in which to have a body mark displayed, and manipulate the body mark and a probe mark there in the same manner as in the case of a single image.

It is in an image marked with ▼ at the top that the body mark may be changed.

Body marks may be displayed with or without the freeze enabled.

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7.2 ZOOM Function

This function enlarges the part specified by box cursor ("□") to the next larger magnification.

Images scanned by linear and convex probes can be enlarged. The zoom function is not operable with mechanical sector probes.

- a. Display a real-time B-mode image.
- b. Press the **ZOOM** switch. A box cursor is displayed on the screen.
- c. Shift the box cursor to the part to be enlarged on the ultrasound image with the **TRACKBALL**.

The size of the box cursor can be changed by pressing the **MAGNIFICATION** switch.

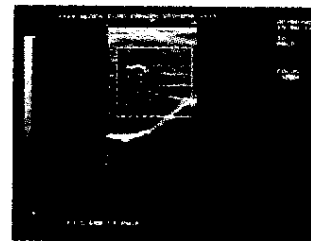


Fig. 7-26

- d. Press the **MARK REF** switch. The area specified by the box cursor is enlarged.

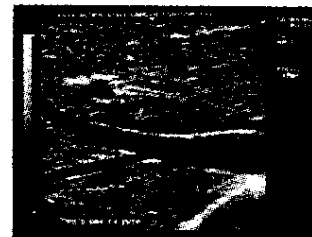


Fig. 7-27

- e. To change the position of the part to be enlarged, press the **MARK REF** switch again.

The image reduces and the box cursor is displayed again.

Perform the same operations as c. to d..

- f. To terminate the **ZOOM** function, press the **ZOOM** switch.

NOTE:

It is impossible to perform zooming during a multi-image display and at maximum magnification.

Also zooming is impossible when the image is frozen.

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7.3 M-WINDOW Function "MENU" function.(Pg.1, #1)

For a B/M-mode or M-mode display, this function enlarges only the window area of the M-mode image without changing the B-mode image.

NOTE: When the B-mode image is displayed in the maximum magnification, the M- WINDOW function cannot be performed.

Press the MENU Switch to display the menu. Then select "M-WIN" in the menu. The menu changes as follows;

M-MODE	1	2	3	4	5	6
WINDOW	EXIT	NARROW	WIDE	↓ POSITION ↑	↑	RESET

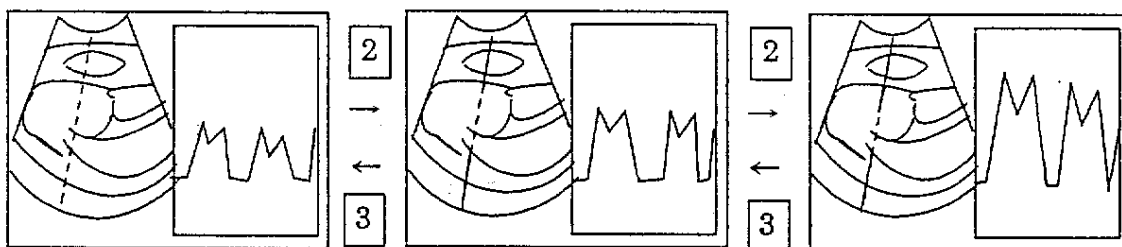


Fig. 7-28

Fig. 7-29

Fig. 7-30

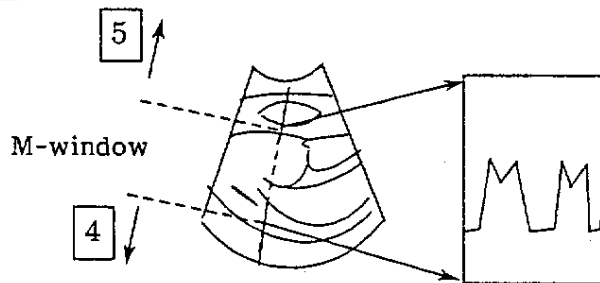
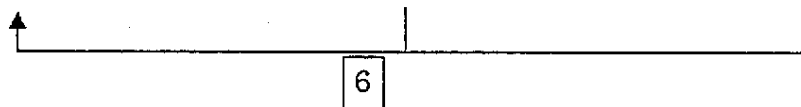


Fig. 7-31

- 1 EXIT: Returns to the previous menu.
- 2 NARROW: M-window cursor is displayed and magnified M-mode image is displayed. Each time the 2 switch is pressed, the M-Window becomes narrower.
- 3 WIDE: Each time the 3 switch is pressed, the M-Window becomes wide and M-mode image is reduced.
- 4 ↓: Moves the M-window down.
- 5 ↑: Moves the M-window up.
- 6 RESET Returns to the initial state.

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7.4 LINE DENSITY Function (LIN-D) "MENU" function. (Pg.1, #4)

When the mechanical sector probe is used, this function changes the scanning line density of the B-mode image.

LINE	1	2	3	4	5	6
DENSITY	EXIT	LOW-1	HIGH-1	LOW-2	HIGH-2	RESET

LOW : Line density of the ultrasound image is low, however, frame rate is high. This position is used to observe fast moving organs (such as the heart).

HIGH : Line density of the ultrasound image is high, however, frame rate is low. This position is used to observe slowly moving organs (such as abdominal organs).

NOTE:

LOW-1, HIGH-2..... Switches the line density of the probe connected to the SINGLE connector.

LOW-2, HIGH-2..... Switches the line density of the probe connected to the DUAL connector.

After setting, select "1 EXIT" to return to the previous menu.

7.5 CALIPER SIZE Function (CALIP) "MENU" function. (Pg 2, #3)

This function sets the size of the measurement caliper marks.

CALIPER	1	2	3	4	5	6
SIZE	EXIT	NORMAL	SMALL			

2 NORMAL: Large and small marks (moving mark is large, fixed mark is small)

3 SMALL: Both moving mark and fixed mark are small.

After setting, selecting "1 EXIT" returns to the previous menu.

7.6 CHARACTER DISPLAY Function(CH-DSP) "MENU" function. (Pg.2, #5)

This function turns the automatic information displays (frequency, gain, ultrasound transmitting power, range, etc.) on and off.

CHARACTER	1	2	3	4	5	6
DISPLAY	EXIT	OFF	ON			

2 OFF: The automatic displays are erased.

3 ON : The automatic displays are displayed.

After setting, selecting "1 EXIT" returns to the previous menu.

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7.7 PRESET Function

By presetting the panel condition, the unit powers up in the preset condition. Also during operation, it is possible to reset the panel conditions by selecting the number in the PANEL PRESET menu.

This function can store 4 different pre-set programs.

PANEL	1	2	3	4	5	6
PRESET	EXIT	-----	-----	-----	-----	SET UP

2 ~ 5 ---- : Title of the preset panel condition is displayed. (The title is displayed as "----" when a built-in condition has been preset.) When one of these items is selected, panel conditions change as programmed.

6 SET UP : To program preset conditions by the user.

Procedure for setting panel switch conditions:

There are two ways to preset the switch condition.

- INITIALIZE: Built-in condition already stored in the system is set for initial condition.
- PROGRAM: User can program a new condition.

(1) To preset the built-in conditions:

a. Select "6 SET UP" in the above menu. The menu changes as follows.

PANEL	1	2	3	4	5	6
SET UP	EXIT	↑	↓	PREV[]	NEXT[]	SET

- 1 EXIT: Returns to the previous menu.
- 2 ↑: The highlighted part returns to the previous item.
- 3 ↓: The highlighted part proceeds to the next item.
- 4 PREV[]: The previous item of the sequence is indicated in parentheses.
- 5 NEXT[]: The next item of the sequence is indicated in parentheses.
- 6 SET: To store individual condition of the item. The highlighted part proceeds to the next item.

NOTE: "2 ↑" and "3 ↓" just shifts the highlighted item, and does not store the revised condition. After revising the condition of an item, be sure to select "5 SET" to store the condition, or the original condition remains unchanged.

At the same time, a list of the preset conditions is displayed on the screen.

b. Assign a number to the presetting you undertake. This number may be selected among 2, 3, 4 and 5. To change the number, select "5 NEXT()" to increase its numeric value or "4 PREV()" to decrease its numeric value.

PANEL PRESET NO. = 3 [INITIALIZE] TITLE [-----]
--

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- c. Select "6 SET", and the highlighted part proceeds to "INITIALIZE" item. Select "6 set".

PANEL PRESET NO. = 3 [INITIALIZE] TITLE [-----]
--

- d. The highlighted part proceeds to "PANEL SET UP" (at the last item).
By selecting "3 ↓" or "6 SET", the panel switch presetting is completed.

(2) For the user to program initial conditions:

- a. Follow the same procedure as in step "a." of "(1) To preset the built-in conditions.

Assign a number to the presetting you undertake.

- b. The highlighted part proceeds to the INITIALIZE item. Select "5 NEXT[]". The item changes to "PROGRAM". Then select "6 SET" to set it. The highlighted part proceeds to the next item, which is "TITLE".

- c. Enter the program name into the "TITLE" item by using the keyboard. A maximum of 6 characters can be entered. Then, select "6 SET" to set it. The contents to be programmed will be described individually in the text below. Use the "PANEL SETUP" menu to proceed to each operation.

- PROBE ... Selection of probe selector switch.

Select from 3 possible choices: [LINEAR & CONVEX] [SECTOR] [IND]

- MODE ... Selection of display mode and number of multi-display.

Select from 12 choices: [B] [M] [B/M] [PW] [M.PW] [B/M.PW] [CW] [B/CW] [MULTI-2] [MULTI-3] [MULTI-4]

Note: The Doppler (PW or CW) is selectable when optional Doppler module is installed.

- IMAGE DIRECTION... Selection of image display direction.

LINEAR/CONVEX [→] [△]

SECTOR RANGE [→] [△]

Select from 2 choices: [→] [←]

Select from 2 choices: [△] [▽]

- MAGNIFICATION ... Selection of magnification or display range

LINEAR & CONVEX [x0.7] [x1] [x1.5] [x2]

SECTOR [12] [4] [6] [9] [12] [15] [18] [21] [24]

- FOCUS F1 F2 F3 F4 ... Selection of focal point and number of steps

B-MODE [ON] [ON] [ON] [--]

B/M, M [ON -- -- --]

Select from 2 choices: [ON] [--]

- PRE PROCESS ... Selection of preprocess on/off.

Select from 2 choices: [ON] [OFF]

- POST PROCESS ... Selection of POST PROCESS

LEVEL DATA SET [--] [two choices: [ON] [--]]

Select from 4 choices: [SLOPE 1] [SLOPE 2] [SLOPE 3] [REJECT]

SLOPE 1 [0,63]

SLOPE 2 [0,63]

SLOPE 3 [0,63]

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REJECT [0]

The POST PROCESS value that was previously set is automatically used again.

To change the value, reset the image to POST PROCESS. Then, preset it again [after adjustment].

- **GAMMA** ... Selection of gamma for photographing
Select from 3 choices: [A] [B] [C]
- **ECG [OFF] PCG [OFF] PULSE [OFF]** ... Selection of physiological signal display
Select from 2 choices: [ON] [OFF]
- **ECG SYNC** ... Selection of ECG sync display
Select from 2 choices: [ON] [OFF] [This item cannot be set when ECG is OFF.]
R-DELAY ... Setting of ECG sync delay time
Changeable [0.00] - [2.55] sec
- **DOP RANGE** ... Selection of velocity range of Doppler pattern
Select from 6 choices: [1] - [6]
- **DOP RANGE PRE COMP** ... Selection of Doppler Precompression Curve
Select from 4 choices: [LOW] [MID1] [MID2] [HIGH]
- **DOP FILTER** ... Selection of Doppler filter
Select from 6 choices: [100] [200] [400] [600] [800] [1300]
- **DOP REJECT** ... Selection of threshold level eliminating weak echoes
Select from 11 choices: [00] - [11]
- **DOP TRACE** ... Selection of Doppler trace
Select from 8 choices: [OFF] [MAX] [MIN] [MEAN]
[fMAX] [fMIN] [fMEAN] [AMP]
- **DOP TRANSDUCER** ... Not available at present.
- **SAMPLE VOLUME SIZE mm** ... Selection of Doppler sample size
Select from 5 choices: [1] [2] [3] [5] [10]
- **CALIPER SIZE** ... Selection of caliper mark size
Select from 2 choices: [LARGE-SMALL] [SMALL-SMALL]
- **PUNCTURE GUIDE LINE** ... Selection of puncture guide line display
Select from 2 choices: [ON] [OFF]
- **BODY MARK** ... Selection of body mark group
Select from 4 choices: [ABDOM] [OBST] [HEAD] [OTHER]
- **CHARACTER DISPLAY** ... Selection of ON/OFF of automatic display
Select from 2 choices: [ON] [OFF]
- **A-MODE, STC** ... Selection of display ON/OFF of A-mode image and STC display
Select from 2 choices: [ON] [OFF]
SIZE ... Selection of magnification

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- ACOUSTIC POWER ... Selection of transmitting power LINEAR/
CONVEX [54] SECTOR [40]
Select a value in the range from [0] to [54]
Select a value in the range from [0] to [49]
- DATA ON/OFF ... Selection of information display on the screen
ON/OFF
Select from 2 choices: [ON] [OFF]
- VTR MEMORY ... Selection of VTR playback measurement storage
method
Select from 2 choices: [FRAME] [FIELD]

NOTE: During the setting process, it is possible to finish the setting and return to the image display (without changing the set contents) by selecting 1 EXIT..

If you log-on again, the preset function will execute the program that was last selected before powering off.

To select different initial conditions during the examination, display the "PANEL PRESET" menu. Then press the program number corresponding to each desired condition.

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7.8 A-MODE/STC Display Function (optional)

To display A-mode image and STC setting curve at the position specified by the A-mode cursor on B-mode image.

- a. Press the **MENU** switch of **FUNCTION** group to display **FUNCTION** menu. Then select "A-DSP" in the menu. The menu changes as follows;

A-MODE/STC	1	2	3	4	5	6
DISPLAY	EXIT	A-OFF	A-ON	S-OFF	S-ON	SIZE

- b. To display A-mode image, select "3 A-ON" in the menu.

A-mode cursor is displayed and A-mode image is displayed at the left end.

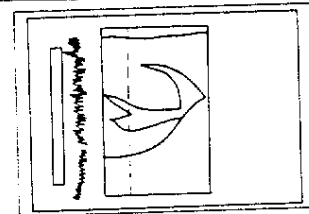


Fig. 7-32

- c. To display STC curve, select "5 S-ON" in the menu.

- d. Turn on the **CURSOR** switch. Using the **TRACKBALL** to move the cursor to the position where A-mode image is to be displayed.

- e. To enlarge the A-mode image, select "6 SIZE". To return to the original magnification, select "6 SIZE" once again.

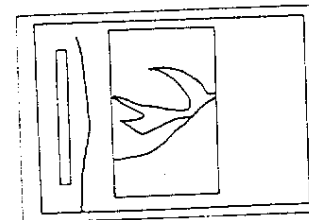


Fig. 7-33

- f. To turn off the A-mode display, select "2 A-OFF".

To turn off the STC curve display, select "4 S-OFF".

- g. Selecting "1 EXIT" returns the menu to the original one.

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7.9 Gamma Adjustment

A characteristic of photo sensitive film is called gamma. Adjust the gamma suitable for the unit or film used.

- a. Press the **ENHANCE** of the **FUNCTION** switch, then select "GAMMA" in the menu. The menu changes as follows;

	1	2	3	4	5	6
GAMMA	EXIT	A	B	C		

- 2 A: This is adapted for optional SSZ-600-35 and SSZ-300.
- 3 B This is adapted for Polaroid TYPE667 and Fuji FP-3000B films.
- 4 C: This is adapted for Polaroid TYPE611 and Fuji FP-400B films.
- b. Select one of the above items according to the photographing unit or film in use.
- c. After setting, selecting "1 EXIT" to return to the original menu.

7.10 Puncture Marker Display

Some convex probes and linear array probes can perform puncturing with optional puncture adapters. When an image is displayed, a puncture guide line may be displayed.

Further, a guide line for mechanical sector probe may be displayed. Mount the optional puncture adapter on the probe.

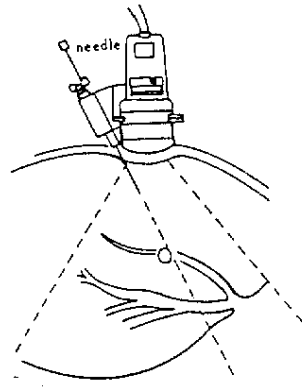


Fig. 7-34

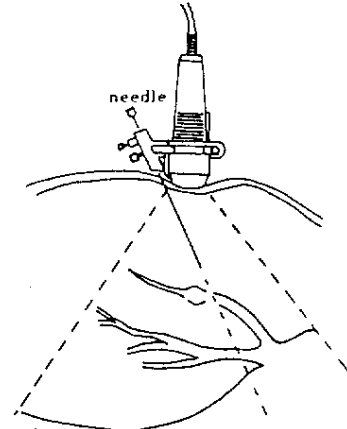


Fig. 7-35

Step for displaying puncture marker

- a. Display a single-frame B-mode image. Press the MENU switch of FUNCTION group. A menu is displayed. Select "PUNC" in the menu. The menu changes as follows;

PUNCTURE	1	2	3	4	5	6
GUIDE LINE	EXIT	OFF	ON			SELECT

- b. To display a puncture marker, select "3 ON". To erase the marker, select "2 OFF".

NOTE: When there are some puncture markers for a probe, select "6 SELECT" till a suitable marker is displayed.

OPERATION AIDS

c. To terminate the puncture marker display, select "1 EXIT".

NOTE:

- (1) While the puncture marker display is ON, setting of the PROBE switch (2) automatically changes the marker according to the selected probe.
- (2) When B/M mode and multi-frame B-mode are displayed, the puncture markers do not appear.
- (3) The lateral direction (left/right) of the puncture markers change according to the IMAGE DIRECTION switch.

For the detailed operational procedures and other information, refer to each manual attached to the probe or puncture adapter.

7.11 M-Mode Transducer (M-SELC)

When the M-mode static probe is being used, this function sets the appropriate frequency.

- a. Press the MENU switch of the FUNCTION group. Then select "M-SELC" in the menu. The menu changes as follows;

M-MODE	1	2	3	4	5	6
TRANSDUCER	EXIT	OFF	S-2.0M	S-2.5M	S-3.0M	S-5.0M

- 3 S-2.0M: For using the 2.0 MHz probe.
- 4 S-2.5M: For using the 2.5 MHz probe.
- 5 S-3.0M: For using the 3.0 MHz probe.
- 6 S-5.0M: For using the 5.0 MHz probe.

- b. Select the numeral switch corresponding to the frequency of the probe to be used.
A M-mode image will be displayed.
- c. To terminate the setting, select "2 OFF" then "1 EXIT". The menu returns to the original one.

OPERATION AIDS

7.12 Doppler Trace (D-TRAC)

When the Doppler module is installed, this function is operative.
The Doppler spectrum waveform is displayed by 7 sorts of processing.

- a. Press the MENU switch of the FUNCTION group, then select "D-TRAC" in the MENU. The menu changes as follows;

DOPPLER	1	2	3	4	5	6
TRACE-1	EXIT	MIN-V	MAX-V	MEAN-V	AMP	NEXT

DOPPLER	1	2	3	4	5	6
TRACE-2	EXIT	fMIN	fMAX	fMEAN		NEXT

- b. Select the numeral switch.

(1) DOPPLER TRACE-1

- 2 MIN-V: Displays only the maximum value of the Doppler spectrum waveform on the AWAY FLOW side.
- 3 MAX-V: Displays only the maximum value of the Doppler spectrum waveform on the TOWARD FLOW side.
- 4 MEAN-V: Displays the mean value of the Doppler spectrum waveform by averaging the values on both the TOWARD FLOW and AWAY FLOW sides.
- 2 AMP: Displays the intensity of the Doppler spectrum waveform output.

(2) DOPPLER TRACE-2

- 2 fMIN: Displays the integrated value of the maximum value of the Doppler spectrum waveform on the AWAY FLOW side. This waveform is automatically reset to zero when an ECG signal R wave is input.
- 3 fMAX: Displays the integrated value of the maximum value of the Doppler spectrum waveform on the TOWARD FLOW side. This waveform is automatically reset to zero when an ECG signal R wave is input.
- 4 fMEAN: Displays the integrated value of the mean value of the Doppler spectrum waveform (averages both TOWARD FLOW and AWAY FLOW sides). This waveform is automatically reset to zero when an ECG signal R wave is input.

- c. To terminate the Doppler trace function, press the same numeral switch as the selected one at present, then select "1 EXIT".

NOTE: The fMIN, fMAX and fMEAN are operable only when optional physiological signal display unit is connected and ECG signal is detected. However, when a R wave is not inputted, the trace does not return to zero.

OPERATION AIDS

7.13 DOPPLER DISPLAY function (D-DSP)

It is possible to invert the Doppler pattern upside down.

- a. Press the MENU switch of the FUNCTION group, then select "D-DSP" in the MENU. The menu changes as follows;

DOPPLER	1	2	3	4	5	6
DISPLAY	EXIT	SP-INV				

- b. Select "2 SP-INV". The Doppler pattern is inverted.
- c. To reset select "2 SP-INV" again.
- d. To terminate the function, select "1 EXIT". The menu returns to the original one.

OPERATION AIDS

7.14 VTR MEMORY function (VTR-MEM)

To enable VTR playback measurement (option), use this function to select an image storage method.

- a. Press the MENU switch of the FUNCTION group, then select "VTR-MEM" in the MENU. The menu changes as follows;

VTR	1	2	3	4	5	6
MEMORY	EXIT	FIELD	FRAME			

- b. Select the method.

2 FIELD: Suitable for the playback measurement of a fast moving image, such as an M-mode image or B/M-mode image (D and B/D are also possible) or B-mode image of the heart. Set the VTR in playback or pause mode beforehand.

3 FRAME: Suitable for storing an slowly moving image or frozen image. This kind of image can be stored most clearly. Set the VTR in playback mode beforehand.

- c. To display original menu, select "1 EXIT".

CHARACTER DISPLAY

8. CHARACTER DISPLAY

8.1 Display Area Selection

The screen displays various information as shown in Fig. 8-1.

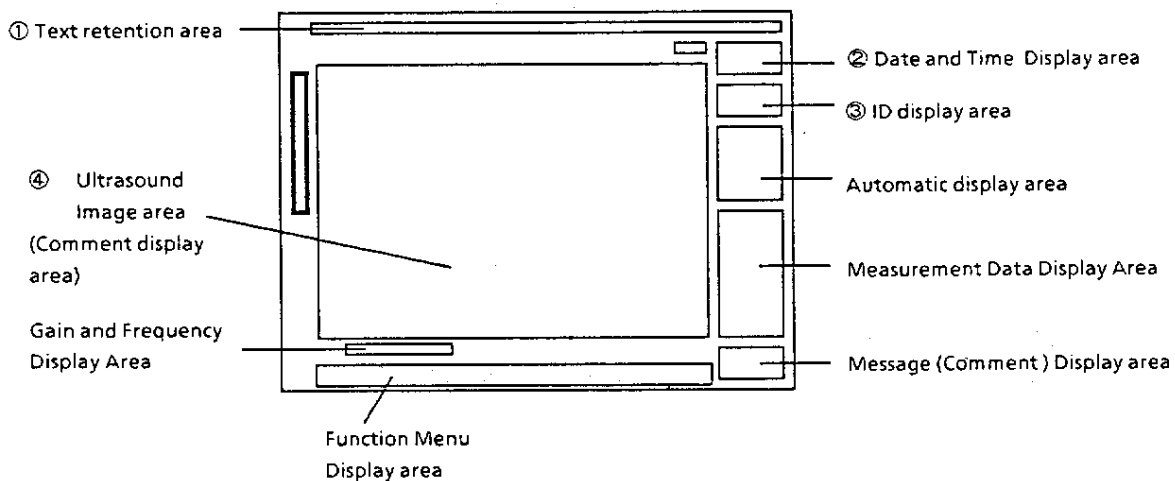


Fig. 8-1

(1) Shift of character cursor (_) to each display area:

As shown in Fig. 8-1, characters (alphanumerics, digits and symbols) can be displayed in each display area.

The character cursor (_) which indicates where characters can be displayed is displayed in the ID display area when the power is turned on.

To shift the area for character display, perform the following keyboard operations or FUNCTION switch operations:

- ① Text retention area:
Select "HOSPIT " from the menu displayed by pressing the MENU switch of FUNCTION group.
- ② Date/time display area:
Select "DATE" from the menu displayed by pressing the MENU switch of FUNCTION group.
- ③ ID display area:
Press the "ID" key on the keyboard.
- ④ Ultrasound image display area (comment display area):
Press the "COMMENT" key on the keyboard.

In each display area, the cursor is moved by the arrow keys on the keyboard. Shift the cursor (_) to an arbitrary position to display characters.

CHARACTER DISPLAY

(2) Message display area

In the following cases, a message is displayed.

NO.	Message	Operation	Measures
1	Inv. Probe	A probe that can not be accepted by SSD-650 is connected.	Connect a probe which is listed in the catalog.
2	No ECG	In ECG synchronized display, ECG waveform is not displayed.	Connect the ECG lead cord correctly.
3	FRZ Req.	You attempted to operate histogram measurement while FREEZE is off.	Turn on the FREEZE switch before measurement.
4	Over Rng	You attempted to make another measurement when there is no space in measurement display area.	Erase measurement display(s) which is (are) not necessary.
5	Over Rng	In the process of fetal growth table setting (PROG-D), a number other than 1 - 6 is entered.	Enter a valid number.
6	Inv. Date	In the process of gestational age calculation by date calculation method (G-CALC), invalid data is entered in month and day.	Enter a valid value.
7	Inv. Mode	In the process of calculation, where keyboard operation is to be done, ID, COMMENT or NEW PATIE key is pressed.	Enter a valid character.
8	Inv. Mode	In the process of AREA-T measurement, after selecting additional measurement marker you attempted to return to an already completed measurement mark.	Start the measurement over again.
9	Inv. Mode	While no measurement result is displayed, RATIO is selected.	Select RATIO calculation after measurement results are displayed. .
10	Inv. Mode	In the process of Fetal growth table setting (PROG-D), "USER", "INT", "CLEAR" and "SET" is selected when it is invalid.	Enter a valid value.
11	Inv. Mode	In a measurement process, "SET" is selected when it is invalid.	Enter a valid value.

CHARACTER DISPLAY

8.2 Character Display

(1) Character input

After shifting the character cursor in a preferred display area, characters may be entered from the keyboard.

By consecutively pressing alphanumerical keys, the corresponding characters may be written consecutively in the assigned display area.

With regard to keys marked with two characters, such as

%
5

, keying it in as is will have its lower case symbol, such as 5 in the example cited, displayed, and keying it in with the SHIFT key held down at the same time will have its upper case symbol, such as %, displayed instead.

NOTE: Displayed characters are always capitals. The SHIFT key works for displaying symbols.

o Tomographic Image (or ID) Display area

- a. Press the **COMMENT** or **ID** key of the keyboard to have the character cursor (_) shifted in the ultrasound image display (comment display) area or ID display area.
- b. Move the character cursor (_) with arrow keys and enter characters from the keyboard for display.

o Text Retention Area

- a. Select "**HOSPIT**" from among the menu displayed by pressing the **MENU** switch of **FUNCTION** group to relocate the character cursor (_) in the text retention display area.
- b. Move the character cursor (_) with arrow keys and have characters displayed with the keyboard.
- c. After the character input in the text retention area is completed, select "**6 SET**", to have the input characters registered. All such registered characters will hence-forth be displayed in the text retention display area at every power on.
- d. To terminate the character input in text retention area, select "**1 EXIT**" in the menu or press the **MENU** switch.

NOTE:

The text retention area is powered by a battery in the equipment. Apply power to the equipment about eight hours a week, even when the equipment has not been operated for a long time.

A fully charged battery supports operation for about one month.

If the retained text has disappeared, the battery may have been discharged. If so, apply power continuously for 15 hours or so.

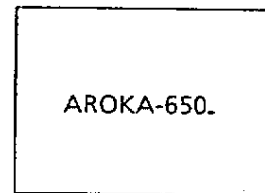
CHARACTER DISPLAY

8.3 Correction

- (1) To revise all the characters displayed in an area:
 - a. Shift the character cursor () to an area that contains the characters requiring a revision.
 - b. Press the AC key. All the characters displayed in the area are erased.
 - c. Freshly input characters from the keyboard.

- (2) To revise only some of the displayed characters:

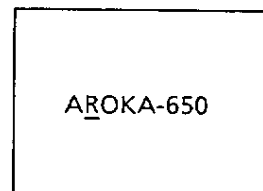
(Example: "R" to be revised to "L".)



AROKA-650.

Fig. 8-2

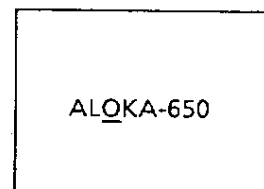
- a. Move the character cursor () with arrow keys to the location where R is displayed.



AROKA-650

Fig. 8-3

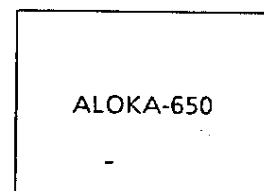
- b. From the keyboard, key in L, and R will be altered to L while the character-cursor () shifts to the next character.



ALOKA-650

Fig. 8-4

- c. By operating the arrow keys, move the character cursor () to a location for the next key input.



ALOKA-650

Fig. 8-5

- d. When CR Key is pressed, the character cursor () will move to the left by one space per pressing, erasing the characters displayed. When SPACE key is pressed, it will move to the right by one space per pressing, again erasing the characters displayed.

NOTE:

When a new patient is to be examined, press the NEW PATIE (NEW PATIENT) key. The data input in the comment and ID area is erased and the cursor shifts to the ID area.

CHARACTER DISPLAY

8.4 Date and Time sStting

- a. Press the MENU switch of FUNCTION group. Function menu is displayed.

Selecting "DATE" can correct date, "TIME" can correct time, and "FORMAT" can change display format of date (Refer to (3).)

(1) Date Setting

- b. Select "DATE" from the menu to shift the cursor (_) to the date display area.

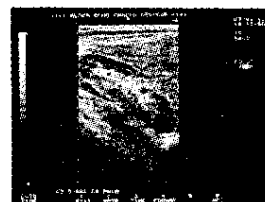


Fig. 8-6

- c. Enter a new date from the keyboard as follows.

Example: January 13, 1987 87/01/13

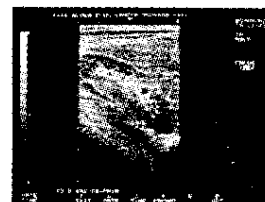


Fig. 8-7

- d. After entering the date, select "6 SET" from the menu to register the input date.

(2) Time setting

- e. Select "TIME" from the menu. The cursor (_) is displayed in the time display area.

Enter the time as follows.

Example:

When the present time is 7:16 and 8 seconds p.m., enter 19:17:00 (Just enter "19 17 00" from the keyboard, ":" is displayed automatically).

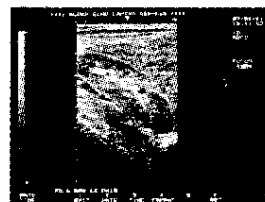


Fig. 8-8

- f. Press the 6 switch for selecting "SET" from the menu at the moment your watch reads 17 minutes 00 seconds to register the time. The clock starts at the same time.

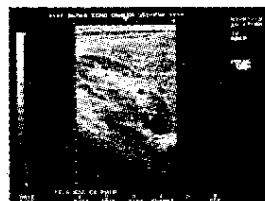


Fig. 8-9

CHARACTER DISPLAY

To correct a part of the displayed date, use the CR key or space bar.

The AC key is used to erase the character (date area or time area) above the cursor (_).

(3) Date display format setting:

The following three date display formats are available.

Example: May 22, 1987

1. 87/05/22 (Japanese style)
2. 05. 22. 87 (American style)
3. 22-05-87 (European style)

To change the display format, press the 4 switch for "FORMAT" of the FUNCTION menu. Each time this key is pressed, the style changes in the sequence of 1, 2, 3, and 1.

Enter numbers in two digits.

Example: 1 01
 9 09
 12 12

NOTE:

The date/time is displayed using the clock operated by the internal battery. Charge the battery about eight hours a week, even when the equipment has not been operated for a long time. A fully charged battery will maintain the functions for about one month.

If the clock is not running, the battery may be fully discharged. If so, charge the battery continuously for 15 hours or so.

PHOTOGRAPHY

9. PHOTOGRAPHING (OPTION)

9.1 Adjustment of Gamma

A characteristic of photo sensitive film is called gamma. Adjust the gamma to suite the unit or film used.

- a. Press the **ENHANCE** switch of **FUNCTION** group, then select "**GAMMA**" in the menu. The menu changes as follows;

	1	2	3	4	5	6
GAMMA	EXIT	A	B	C		

2 A: This is adapted for optional SSZ-600-35 and SSZ-300.

3 B: This is adapted for Polaroid TYPE667 and Fuji FP-3000B films.

4 C: This is adapted for Polaroid TYPE611 and Fuji FP-400B films.

- b. Select one of the above items according to the photographing unit or film for use. In case of SSZ-600P, select "3" or "4" according to the film used.
- c. After the setting, selecting "1 EXIT" to return to the ENHANCE menu.

9.2 Photographing Procedure

(1) Film Loading:

- a. Open the cover of Polaroid camera back, and insert a film pack (Fig. 9-1).
- b. Close the Polaroid back cover, while exercising care not to catch the white tab between the film pack and the Polaroid camera (Fig. 9-2).
- c. Pull the black tab off the camera back (Fig. 9-3).

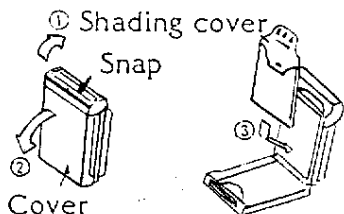


Fig. 9-1

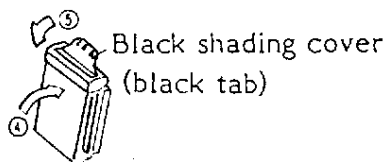


Fig. 9-2

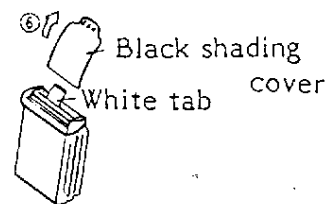


Fig. 9-3

(2) Picture Taking:

- a. Have an ultrasound image displayed on the monitor screen.
- b. Freeze the image with the **FREEZE** switch.
- c. Open the blind panel, and check to assure the photography monitor is displaying the same ultrasound image as that on the viewing monitor, as well as no missing characters or any other required display.
- d. Close the blind panel, and operate the shutter (by pressing **CAMERA** switch).

PHOTOGRAPHY

(3) Development

- a. After taking a picture, pull the white tab straight out (Fig. 9-4).

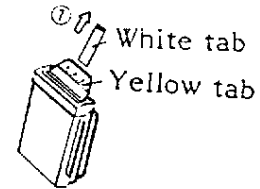


Fig. 9-4

- b. After the white tab is pulled out, a yellow tab will appear. Slowly pull the yellow tab straight out in a single sweeping motion without stopping midway (Fig. 9-5).

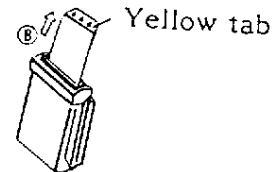


Fig. 9-5

(Development Start)

- c. Wait the specified developing time to have the film fully developed (Fig. 9-6).

Time (sec.)	Temp	
	(F)	(C)
30	75+	24+
45	70	21
60	65	18
75	60	16
90	50	10

Fig. 9-6

- d. After the specified developing time has elapsed, swiftly peel the print off the negative film (Fig. 9-7).

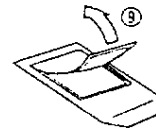


Fig. 9-7

An insufficient developing time provides an unevenly developed print lacking in clarity that will exhibit diffused blacks, while an excessive developing time makes dark areas of the printed image low in definition.

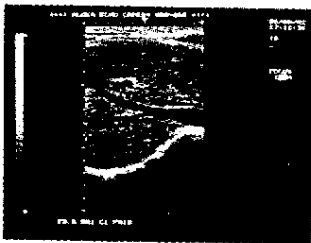


Fig. 9-8 Developing Time too long

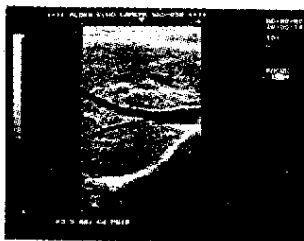


Fig. 9-9 Optimum

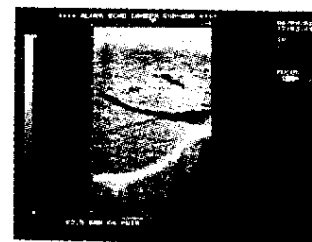


Fig. 9-10 Developing Time too short

Immediately after development, the print surface is highly vulnerable to finger marks. Exercise utmost care against touching it with bare hands until the print thoroughly dries.

PHOTOGRAPHY

9.3 Troubleshooting and Maintenance

(1) Jammed Film:

When no yellow tab emerges after pulling out of the white tab, the film has become jammed inside the camera.

Follow the steps below to remove jammed film:

- a. Open the camera back cover.
At this point in time, do not remove the film pack.
- b. Pull the yellow tab of the jammed film out.
- c. Dismount and examine the film pressure roller mounted on the back cover.
If paper or excessive developer fluid is found adhered to the roller, clean the roller.
The developer fluid may be removed with hot water (Fig. 9-11).
- d. Using a dry cloth, thoroughly wipe water off the roller, and set it back on the camera back.
- e. Set the next white tab, and close the back cover.

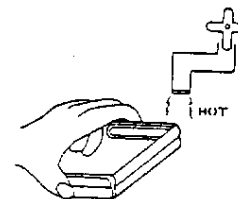


Fig. 9-11

(2) Developer Roller Maintenance:

The developer roller is very easily soiled by the developer fluid, and if left in such a state for long, the below listed nonconformities will develop.

It is important to maintain a clean roller at all times.

- A white tab has been pulled out, but no yellow tab will emerge.
- Evenly spaced spots will appear on the prints.
- The developer fluid will adhere to the back of the prints.

Upon detecting any of these symptoms, dismount and clean the roller. In addition to the above, development is sometimes impeded by the roller catching a claw at the tip end of a yellow tab that has just been pulled out. If this occurs, dismount the roller and remove the caught claw.

PHOTOGRAPHY

(3) Troubles and Precautions

Inadequate handling may cause any of the following defects to develop on the print:

a. Corner Eclipse (Fig. 9-12)

(Cause)

The yellow tab was pulled out at an angle.

(Precaution)

Gripping the yellow tab at its center and slowly pull it straight out from the camera back without stopping midway.



Fig. 9-12

b. Mottles (brown with Type 667) all over Print (Fig. 9-13)

(Cause)

The film brushed against the camera back opening edge when pulled.

(Precaution)

Pull the yellow tab out straight.

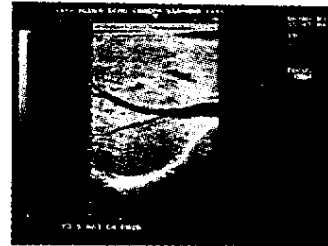


Fig. 9-13

c. Evenly spaced White Spots (Fig. 9-14)

(Cause)

Foreign matter on the roller.

(Precaution)

Keep the roller clean by following the developer roller maintenance procedure.



Fig. 9-14

d. Marks on Image (Fig. 9-15)

(Cause)

Pressure applied to the print during its development.

(Precaution)

During development, do not apply undue pressure on prints, bend them, or peel them off negative films.

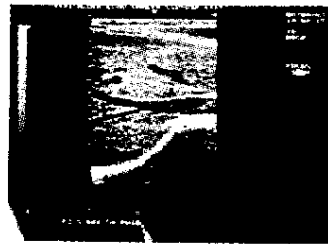


Fig. 9-15

e. Numerous White Spots (Fig. 9-16)

(Cause)

The yellow tab was pulled out too fast.

(Precaution)

Slowly pull the yellow tab out at a steady speed, without stopping midway.

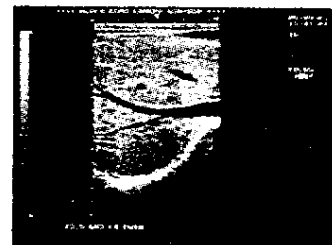


Fig. 9-16

PHOTOGRAPHY

(4) Photography Set Up:

Picture taking parameters of the camera are adjusted at shipment from the factory to accommodate Polaroid Type 667 films (for positive images). When readjustments are required follow the steps outlined below:

- a. Open the blind panel on the left cover of the camera.
- b. Set the Polaroid camera iris stop at F11 to F16.
- c. Turn the brightness control knob to have the ultrasound image background (echo-free dark areas) photographed barely lighter than total black.
- d. Turn the contrast control knob to have only the brightest level of the gray scale bar photographed brightly.

Repeat taking pictures and making adjustments until an optimum picture results.

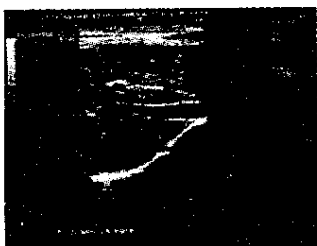


Fig. 9-17
BRIGHT too low



Fig. 9-20
CONTRAST too low

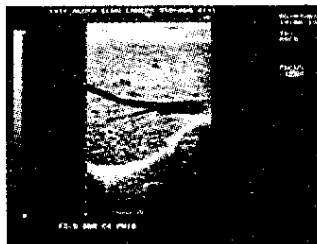


Fig. 9-19 Optimum

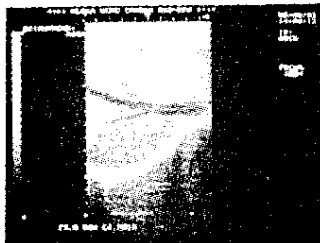


Fig. 9-18
BRIGHT too high

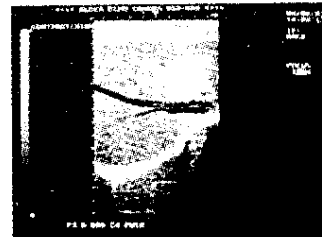


Fig. 9-21
CONTRAST too high

- e. When using other Polaroid films (Type 611), set the camera iris stop as follows:
Type 611: F5.6 to 8 35 mm Single Lens Reflex Camera
with ISO 100: F4 to 8
35 mm Single Lens Reflex Camera
with ISO 400: F8 to 16
- f. When using negative images, adjust the BRIGHT and CONTRAST of the photography monitor to provide equivalent quality Polaroid pictures to images on the observational monitor.



TROUBLESHOOTING

10. TROUBLESHOOTING

1. The power switch is pressed, but the power lamp (green) does not light and no image appears on the screen.

- (1) Is the power cable connected correctly?

Confirm again that the power cable from the rear panel is correctly plugged into the outlet.

2. The power lamp lights but no image appears.

(A gray scale bar and characters are displayed.)

- (1) Is the GAIN knob turned to the maximum counterclockwise position?

Adjust the gain with the GAIN knob.

- (2) Is the probe cable firmly connected?

Connect it securely.

- (3) Turn the power switch off then on again.

3. The power switch lamp lights but nothing appears on the screen.

- (1) Are the CONTRAST and BRIGHTNESS controls on the viewing monitor turned to the maximum counterclockwise position?

Adjust these controls.

- (2) Is the VIDEO switch set to EXT?

Set it to INT except when a VTR is played back.

- (3) Are the power and VIDEO signal cables on the TV monitor connected properly?

Reconfirm that the cable connections on the rear panel of the monitor are correct.

4. Photography fails or good photos cannot be taken.

Refer to "Photography" on P. 9-1 through P. 9-5.

5. The quality of the image on the viewing monitor is poor.

- (1) Are ENHANCE, AGC, PRE PROCESS and FOCUS set normally?

Set them normally or turn them off.

Volume II Measurement and Analysis



CONTENTS

Volume II MEASUREMENT AND ANALYSIS

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DESCRIPTION OF MEASUREMENT MENU

1. DESCRIPTION OF MEASUREMENT MENU

1.1 List of Measurement and Calculation Functions

Measurement/ calculation function	MEMU display	Full spelling and description
Distance measurement	DIST	Distance
Area and circumference measurement	AREA-E	Area: Ellipse method
	AREA-T	Area: Trace method
Volume measurement	VOLUME	Volume
Velocity, dimension and time interval measurements	VEL	Velocity
Heart rate measurement	H-RATE	Heart rate
Acceleration, velocity and time interval measurements	ACCEL	Acceleration
Histogram measurement	HIST-B	Histogram: Box method
	HIST-T	Histogram: Trace-Area method
Obstetrical (fetal growth) calculations	Setting of optional names such as BPD, CRL, etc.	Title display for the data used as indexes for gestational age and estimated delivery date calculation (Table name display in setting a data table)
	FETL-W	Fetal Weight
	G-CALC	Gestational week calculation
Cardiac function (left ventricular function) calculations	LV-B	Left Ventricular function: Area-Length method (B-mode image)
	POMBO	Uses Pombo's equation (M-mode image)
	TEICH	Uses Teichholz's equation (M-mode image)
Average flow velocity measurement	AVE	Average Velocity
Valve orifice area measurement	CARDIO	
Stroke volume and cardiac output measurement	SV/CO	Stroke volume and cardiac output
Peripheral vascular measurement	PV	Peripheral Vascular Pulsatility index and Pourcelot index
Ratio calculation	RATIO	Ratio
Stenosis percentage calculation	% STENO	Percent stenosis
Scale calibration for image playback measurement	CAL-B, M or D, S-650	Calibration for B, M and Doppler mode

Note: Measurements using the Doppler mode can be made when the optional Doppler unit is connected.

DESCRIPTION OF MEASUREMENT MENU

1.2 Selection of measurement function

The contents of each measurement function are programmed according to the frequency of use (according to the image display mode) so that a complete function may be readily called up.

Usable measurement functions differ with the display modes. When the MEASUREMENT switch is pressed or the TRACKBALL FUNCTION caliper switch (+ or x) is pressed, the relationship between the image mode displayed on the screen and the measurement menu is as follows.

Display mode	Measurement menu display sequence					
	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT
	CLEAR	*	*	*	*	NEXT
	CLEAR	*	*	RATIO	FETL-W	NEXT
	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT
	CLEAR	OB-PRO				NEXT
B/M	1	2	3	4	5	6
	CLEAR	VEL	H-RATE	POMBO	TEICH	NEXT
	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT
	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT
M	1	2	3	4	5	6
	CLEAR	VEL	H-RATE	POMBO	TEICH	NEXT

- * At the part indicated by the asterisk (*), title of a growth table programmed by the user is displayed.
- a. When the MEASUREMENT switch is pressed, the measurement menu corresponding to the mode is displayed in the function menu display area on the screen.
- b. Select a desired number in the measurement menu by pressing a FUNCTION numeral switch. The information on the measurement function selected by the numeral switch is displayed in the measurement information display area. For individual measurement functions, refer to the "Measurement procedure".

DESCRIPTION OF MEASUREMENT MENU

When the optional Doppler unit is connected, the following measurement functions are added.

Note: In the Table, "D" denotes Doppler, meaning both PW (Pulse Wave) Doppler and CW (Continuous Wave) Doppler.

Display mode	Measurement menu display sequence					
B/D	1	2	3	4	5	6
	CLEAR	VEL	ACCEL	AVE		NEXT
	CLEAR	CARDIO	SV/CO	PV	V.UNIT	NEXT
	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT
	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT
	CLEAR	OB-PRO				NEXT
D	1	2	3	4	5	6
	CLEAR	VEL	ACCEL	AVE		NEXT
	CLEAR	CARDIO	SV/CO	PV	V.UNIT	NEXT

(Before starting an optional VTR playback measurement, calibration is required. For calibration, the following menu is displayed.)

Note: This menu is displayed when a VCR is connected to the system.

Display mode	Measurement menu display sequence					
	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

DESCRIPTION OF MEASUREMENT MENU

Menu display	Mode used	Contents of measurement
DIST	B	
AREA-E	B	The circumference of the displayed ellipse and the area enclosed with it are found and displayed.
AREA-T	B	The length of the moving path of the caliper mark and the area enclosed by it are found and displayed.
VOLUME	B	The volume is calculated by regarding the long axis of the ellipse (obtained in the same way as the area measurement by ellipse) as the axis of revolution of an ellipsoid of revolution. By measuring the 3rd axis after an ellipse measurement, a higher-accuracy value can be obtained.
BPD, CRL, GS, F, LV etc. (Obstetrical measurement)	B	Using caliper measurement values as parameters, the gestational age and estimated delivery date are calculated and displayed.
G-CALC	B	By entering the starting date of the last menstruation from the keyboard, the gestational age and estimated delivery date are calculated and displayed.
FETL-W	B	With measurement values such as BPD (Biparietal Diameter), FL (Femur Length) and AC (Abdominal Circumference), the fetal weight is calculated by 3 expressions and then displayed.
LV-B	B	With a B-mode image, 12 parameters are calculated as left ventricular functions (such as left ventricular volume, cardiac output and ejection fraction) and then displayed. The left ventricular cavity volume is calculated by regarding the long axis of the left ventricular cavity as the axis of revolution of an ellipsoid of revolution. (Area-Length method)
HIST-B HIST-T	B	The echo information in the area enclosed by the box cursor or trace optionally set on the B-mode image is displayed as a histogram.
RATIO	B	On a B-mode image, the distance, area and circumference are compared.
% STENO	B	By using the distance, area and circumference on a B-mode image, the stenosis percentage is found and displayed.
VEL	M	By obtaining a distance component and time component between two caliper marks (i.e., "+ ... +" or "X ... x"), the change velocity of the same region (e.g., valve) is displayed.

BASIC MEASUREMENTS

2. BASIC MEASUREMENTS

2.1 Distance

- a. Select B mode (B/M or B/D mode are also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.
Press the MEASUREMENT switch to display the following menu;

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Select "2 DIST" in the menu.

NOTE: Distance measurements may also be engaged merely by displaying a B-mode image and pressing one of the "+", "x", "∴", and "∴∴" switch of the TRACKBALL FUNCTION group.

A "+" caliper mark appears at the center of the screen. The "+" TRACKBALL FUNCTION switch lights.

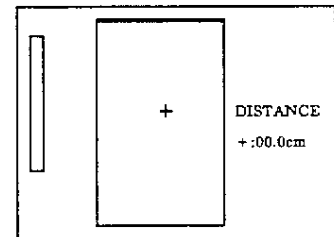


Fig. 2-1-1

- b. Operate the TRACKBALL to position the mark to the starting point for a distance measurement.

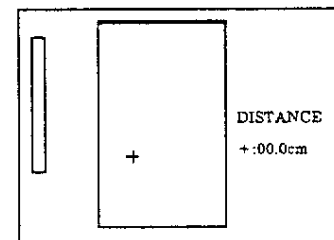


Fig. 2-1-2

- c. Press the MARK REF switch, and operate the TRACKBALL to move the mark to an end point.

NOTE: Pressing the MARK REF switch and operating the TRACKBALL will split the mark in two, one large and the other small.

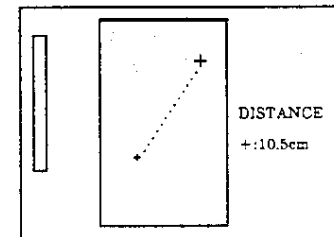


Fig. 2-1-3

The distance between the two marks will be displayed in the measurement data display area.

NOTE: The large mark may be moved with the TRACKBALL initially. The positions of the large and small marks may be interchanged by pressing the MARK REF switch.

BASIC MEASUREMENTS

- d. The " x ", " :. ", and " :: " caliper marks may be displayed by pressing each switch. The "x", " :. ", and " :: " caliper marks also serve the same purposes as the "+" mark, and may be manipulated in the same manner.
- e. To terminate the measurement, select "1 CLEAR" in the menu. All the measurement marks and results will be erased.

NOTE: After measurements using the "+" and "x" marks, if only one of the marks and relevant measurement results are to be erased, turn on the switch corresponding to the mark (the switch lights) and repress the switch for that mark.

"DIST" Measurement Data Display Example:

DISTANCE	
+ :07.2 cm	The distance between "+" marks.
x :03.1 cm	The distance between "X" marks.
:. :4,6 cm	The distance between " :. " marks.
:: :5.5 cm	The distance between " :: " marks.

BASIC MEASUREMENTS

2.2 Area and Circumference

Area and circumference measurements may be performed by either of two methods. One is "AREA-E" method which encloses the target with an elliptical measurement mark, and the other "AREA-T" method which traces the outline of the target.

2.2.1 AREA-E (Ellipse method)

- a. Select B mode (B/M or B/D mode is also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.

Press the MEASUREMENT switch to display the following menu:

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Select "3 AREA-E" from the menu. The area measurement mark "⊕" will appear at the center of the screen. And the "⊕" TRACKBALL FUNCTION switch lights.

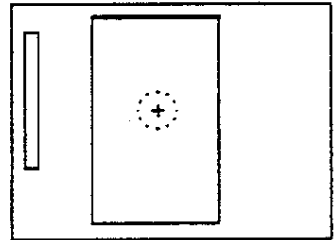


Fig. 2-2-1

- b. Use the TRACKBALL to position the mark to the center of a target.

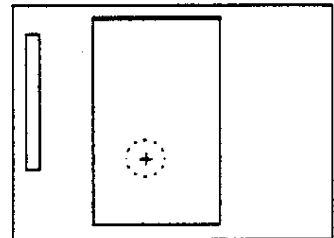


Fig. 2-2-2

- c. Press the MARK REF switch. The TRACKBALL works to lengthen or shorten the long and short axes of the mark. (See Fig. 2-2-3.)

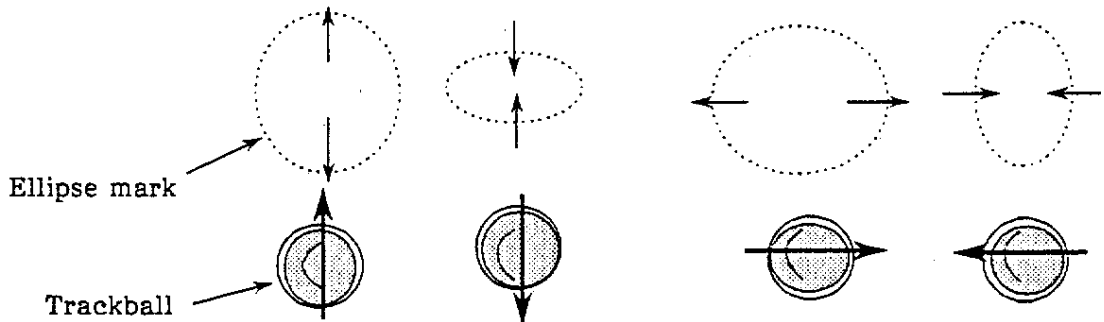


Fig. 2-2-3

- ↑ : Upward rolling lengthens the vertical axial length
- ↓ : Downward rolling shortens the vertical axial length
- : Rightward rolling lengthens the horizontal axial length
- ← : Leftward rolling shortens the horizontal axis length

BASIC MEASUREMENTS

Operate the **TRACKBALL** to make the shape and size of the ellipse the same as those of the target.

- d. Press the **MARK REF** switch.

The trackball changes its function to rotation of the axis.

The axis of the ellipse mark may be rotated counterclockwise by a rightward rolling of the **TRACKBALL**, or clockwise by a leftward rolling. (See Fig. 2-2-4.)

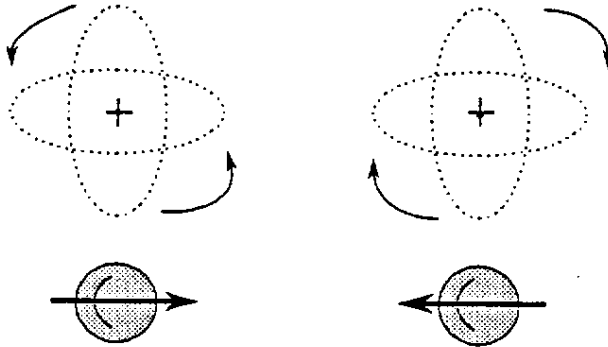


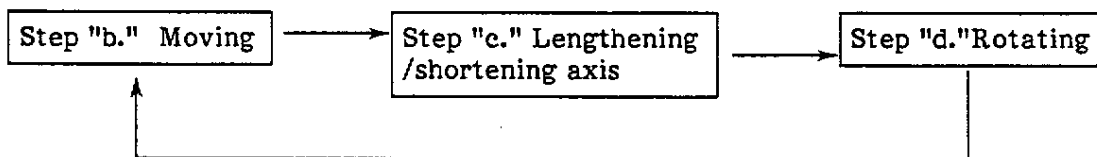
Fig. 2-2-4

Set the axial dimensions (long and short axes) of the ellipse by operating the **TRACKBALL**.

When the mark has ceased to move, the area, circumference (C), short axis (S), and long axis (L), of the ellipse thus set will be computed and displayed.

- e. By repressing the **MARK REF** switch, the ellipse may be repositioned with the **TRACKBALL** rollings.

Then steps "b." through "d." may be repeatedly carried out by pressing the **MARK REF**.



- f. By pressing the "x", " :- ", or " :: " **TRACKBALL FUNCTION** switch, another area measurement is possible by the "x", " :- ", or " :: " mark.
- g. To terminate the measurement, select "1 CLEAR" in the menu. All the measurement marks and results will be erased.

NOTE: After the measurements using the "+" and "x" marks, if only one of the marks and relevant measurement results are to be erased, turn on the switch corresponding the mark (the switch lights) and repress the switch for that mark.

BASIC MEASUREMENTS

2.2.2 AREA-T (Tracing method)

- a. Select B mode (B/M or B/D mode is also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.
Press the MEASUREMENT switch to display the following menu:

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Select "4 AREA-T" from the menu. The "+" mark will appear at the center of the screen. And the "+" TRACKBALL FUNCTION switch lights.

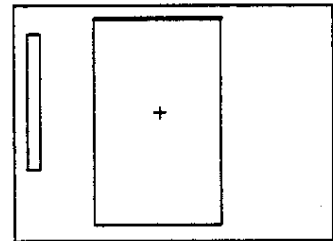


Fig. 2-2-5

- b. Use the TRACKBALL to position the mark to the trace starting point on the target outline.

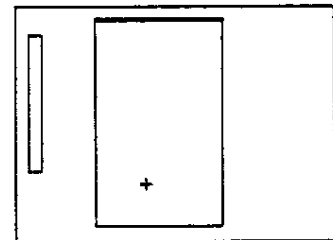


Fig. 2-2-6

- c. Press the MARK REF switch. Operate the TRACKBALL to trace the outline of the target. The tracing movement will leave a line behind. Circumference length starts to be displayed.

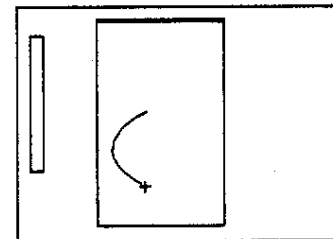


Fig. 2-2-7

NOTE: To turn back the tracing on the way, press and hold down the MARK REF switch for a length of time. The traced line will be erased backwards starting at its end point. When the line is erased for the desired length, release the MARK REF switch. Retracing is possible from the end of the line. If you press and immediately release the MARK REF switch, step "d." below occurs.

- d. Press the MARK REF switch
Area of the enclosed area by the line is displayed in cm^2 .

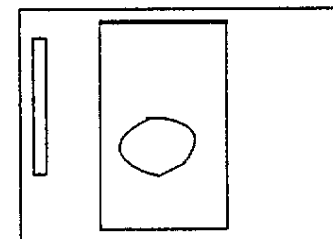


Fig. 2-2-8

BASIC MEASUREMENTS

NOTE: The starting and end points of a tracing are automatically connected together with a straight line. The circumference display may slightly vary when the MARK REF switch is pressed.

- e. To restart the measurements, press the MARK REF switch and follow steps "b." onward.
- f. To measure another area and circumference, press the "x", "∴", or "∴∴" switch. The "x", "∴", and "∴∴" marks are also operated in the same manner as the "+" mark.
- g. To terminate the measurement, select "1 CLEAR" in the menu. All the measurement marks and results will be erased.

NOTE:

When there are a number of areas enclosed by tracing, the total area enclosed in the outermost trace line is computed.

The areas A and B in Fig. 2-2-9 are computed respectively as the shaded area A' and B'.

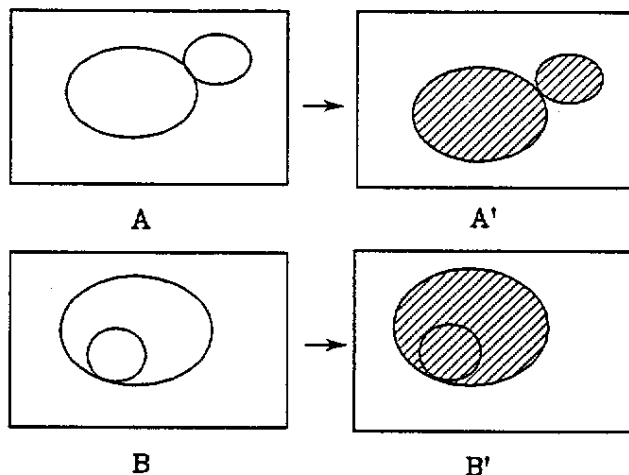


Fig. 2-2-9

NOTES: The circumference display covers the overall length of the displayed trace.

Pressing the MARK REF switch twice in succession disables the TRACKBALL operation. To make it operable, repress the MARK REF switch.

Area Measurement Data Display Examples:

AREA-E Method

ELLIPSE

+:028.6 cm²

C:20.6 cm

S:04.0 cm

L:09.1 cm

(The measurement data of "x" mark is displayed under the measurement data of "+" mark.)

The area enclosed in a "+" mark ellipse.

The circumference of a "+" mark ellipse.

The short axis length of a "+" mark ellipse.

The long axis length of a "+" mark ellipse.

AREA-T Method

TRACE

+:016.8 cm²

C:16.5 cm

x:000.0 cm²

C:00.0 cm

The area enclosed in a "+" mark trace.

The length traveled by a "+" mark.

The area enclosed in a "x" mark trace.

The length traveled by a "x" mark.

BASIC MEASUREMENTS

2.3 Ratio

Two measurement values are compared and their ratio is calculated. For example, ratio between BPD (Biparietal Diameter) and FL (Femur Length) is used for checking fetal growth balance. Any measurements among distance, circumference and area are possible for comparison. Further, the circumference and area measurement values do not depend on the methods used, either ellipse or trace. The ratio is calculated by the following expression;

$$\text{Ratio} = N (\text{Numerator}) \div D (\text{Denominator}) \times 100 (\%)$$

NOTE: Though it is possible to calculate two measurements of different units (e.g. distance and area), there is no clinical application for this type of comparison.

Steps:

- a. First, make measurements of the part where the ratio is to be calculated. Without erasing the menu displayed at present, select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR			RATIO	FETAL-W	NEXT

- b. Select "4 RATIO" in the menu. The menu changes as follows;

RATIO	1	2	3	4	5	6
	EXIT					SET

- c. The measurement value at the top is highlighted. The highlighted value is entered into the position of "D :". When the value is suitable for the denominator, select "6 SET" to set the value. If the value is not suitable, press the MARK REF switch to lower the highlighting downward till a suitable value is highlighted, then select "6 SET".
- d. The measurement value at the top of the measurement value display area is highlighted. The highlighted value is entered into the position of "N :". When the value is suitable for the numerator, select "6 SET" to set the value. If the value is not suitable, press the MARK REF switch to lower the highlighting downward till a suitable value is highlighted, then select "6 SET".
- e. After completing steps c and d, the ratio is automatically calculated and displayed on the screen.

RATIO
N/D %
D: 03.8
N:

RATIO
N/D137 %
D: 03.8
N: 05.2

To terminate the calculation, select "1 EXIT". The calculated value is erased.

BASIC MEASUREMENTS

2.4 Volume

Measurement and calculating method:

There are two ways to measure a volume, one is the ellipse (two-axis) method and the other the three-axis method. The ellipse method requires only a vertical sectional image. The three-axis method requires a vertical sectional image and a transverse sectional image.

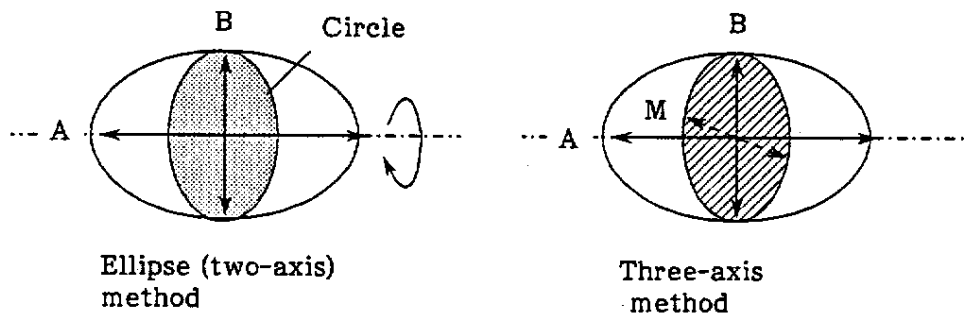


Fig. 2-4-1

The equation for the ellipse measurement is:

$$\text{Volume} = (\pi/6) \times A \times B^2 \quad (\text{A is long axis, B is short axis.})$$

The equation of three-axis measurement is:

$$\text{Volume} = (\pi/6) \times A \times B \times M \quad (\text{M is the third axis length.})$$

Steps:

- a. Select B mode (B/M or B/D mode is also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.

In the three-axis method, it is convenient that the user displays two images using Dual-B mode.

Press the MEASUREMENT switch to display the MEASUREMENT menu.

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Select "5 VOLUME" from the menu. The area measurement mark " ⊕ " will appear at the center of the screen. And the " ⊕ " TRACKBALL FUNCTION switch lights.

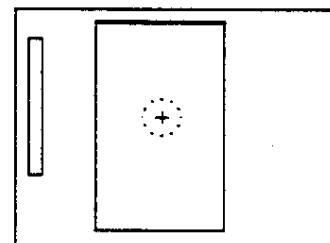


Fig. 2-4-2

BASIC MEASUREMENTS

- b. Use the **TRACKBALL** to position the mark to the center of a target.

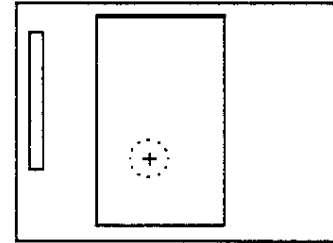


Fig. 2-4-3

- c. Press the **MARK REF** switch. Operate the **TRACKBALL** in the same manner as the "AREA-E" measurement, step "c." (page 2-3) to adjust the long and short axes size.
- d. Press the **MARK REF** switch.

The **TRACKBALL** function changes to the axis rotating function.

Operate the **TRACKBALL** similarly to the case of area measurements, and set an elliptic cross-section. The volume of a spheroid with its rotary axis coinciding with the long axis of the ellipse will be computed and displayed.

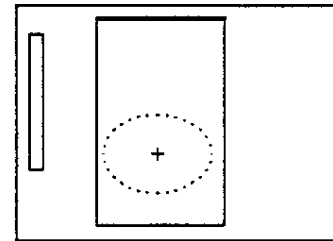
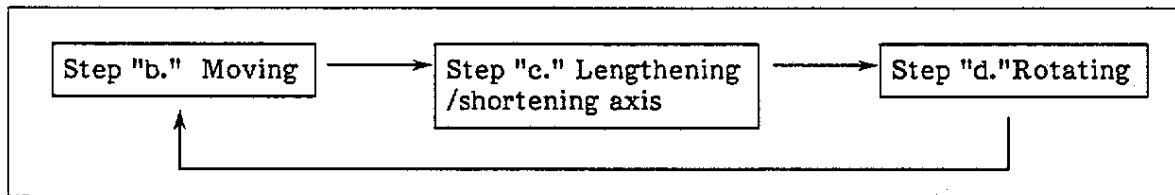


Fig. 2-4-4

- e. By pressing the **MARK REF** switch again, the ellipse set by the above steps may be positioned with the **TRACKBALL**.

Steps "b." through "d." may be repeated for any number of times by pressing the **MARK REF** switch.



* At this stage, the two-axis measurement method is complete, and the three-axis measurement method follows from the next step.

- f. Rescan the B-mode image for an orthogonal cross-section of the initially set spheroid, passing through the latter's short axis.

- g. Press the " + " **TRACKBALL FUNCTION** switch. The "+" mark appears at the center of the screen.

NOTE: In the case of **MULTI-IMAGE** display, the + mark for third axis measurement is displayed in the image indicated by the active mark ▼ which shows the image displayed in real time.

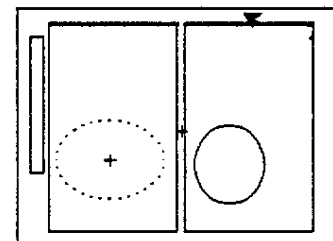


Fig. 2-4-5

BASIC MEASUREMENTS

- h. Measure the third axis by the distance measuring process. When the third axis is measured, the volume is newly computed, and displayed.

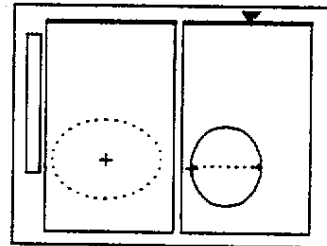


Fig. 2-4-6

- i. To restart the measurement repress the "+" TRACKBALL FUNCTION switch twice. The volume measurement data generated thus far may be reset, and the parameters again made resettable. Then follow steps "b." onward.
- j. To measure another volume, press the " x ", " ∴ ", or " :: " TRACKBALL FUNCTION switch. The "x", " ∴ ", and " :: " marks are operated in the same manner as the "+" mark.
- k. To terminate the volume measurement, select "1 CLEAR" in the MEASUREMENT FUNCTION Menu.

All the measurement marks and results will be erased.

Volume Measurement Data Display Examples:

VOLUME

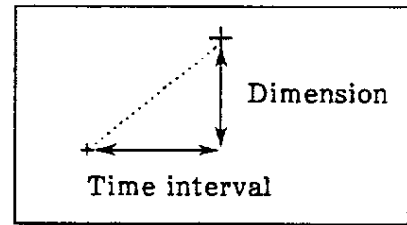
+:111.8 cm ³	The volume enclosed in a "+" mark spheroid.
S:04.0 cm	The short axis length of a "+" mark ellipse.
M:05.8 cm	The distance of the third axis. (When a two-axis measurement, it is displayed as "M:---- cm".)
L:09.2 cm	The long axis length of a "+" mark ellipse.

BASIC MEASUREMENTS

2.5 Velocity (M-slope) Measurement

The velocity is calculated by the following equation:

$$\text{Velocity (cm/s)} = \text{Dimension (cm)} / \text{Time interval (sec)}$$



- a. Select **M** mode (B/M mode is also possible) with the **MODE** switch. When a desired image is displayed, freeze the image with the **FREEZE** switch. Press the **MEASUREMENT** switch to display the following menu:

MEASURE	1	2	3	4	5	6
M	CLEAR	VEL	H-RATE	POMBO	TEICH	NEXT

Select "**2 VEL**" in the menu.

- NOTE:** Velocity measurements may also be engaged merely by having an M-mode image displayed and pressing either the "+" or "x" of the **TRACKBALL FUNCTION** switch.

A "+" caliper mark will appear at the center of the screen and the "+" **TRACKBALL FUNCTION** switch lights.

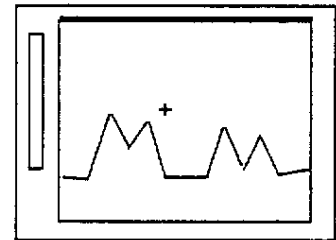


Fig. 2-5-1

- b. Operate the **TRACKBALL** to position the mark to the starting point for a velocity measurement .

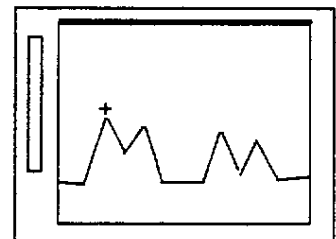


Fig. 2-5-2

- c. Press the **MARK REF** switch. Operate the **TRACKBALL** to move the mark to an end point.

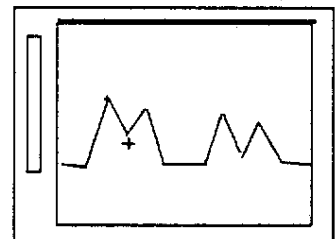


Fig. 2-5-3

BASIC MEASUREMENTS

NOTE: Pressing of the MARK REF switch and operating the TRACKBALL splits the mark in two, one large and the other small.

The velocity, dimension and time interval between the two marks will be displayed in the measurement data display area.

NOTE: Only one of the two split marks may be moved with the TRACKBALL at a time. Two marks are switched by pressing the MARK REF switch.

The "x" mark may be displayed by pressing the "x" switch. The "x" mark also serves the same purpose as the "+" mark, and may be manipulated in the same manner.

- d. Another velocity may be measured by the "x", " ∴ ", or " :: " mark. Press the " x ", " ∴ ", or " :: " switch and operate the mark in the same manner as the "+" mark.
- e. To terminate the velocity measurement, select "1 CLEAR" in the MEASUREMENT FUNCTION Menu.
All the measurement marks and results will be erased.

NOTE: After measurements using the "+" and "x" marks, if only one of the marks and its measurement results are to be erased, phase in an operative mode of that mark, and repress the switch for that mark.

VEL Measurement Data Display Examples:

VELOCITY

+:02.0 cm/s	The velocity between the " + " and "+" marks.
D:01.1 cm	The distance between the " + " and "+" marks.
T:0.53s	The time interval between the " + " and "+" marks.
X:12.5 cm/s	The velocity between the "X" and "x" marks.
D:02.0 cm	The distance between the "X" and "x" marks.
T:0.16s	The time interval between the "X" and "x" marks.

BASIC MEASUREMENTS

2.6 Heart Rate

This measurement is made by measuring the time interval of two cardiac cycles (heartbeats). The heart rate is automatically computed based on the time measurement result.

The heart rate is calculated by the following equation:

$$\text{Heart Rate (beats/min)} = 120/T \text{ (sec)}$$

(T: Time Duration of Two Heartbeats)

- a. Select **M** mode (B/M mode is also possible) with the **MODE** switch. When a desired image is displayed, freeze the image with the **FREEZE** switch. Press the **MEASUREMENT** switch to display the measurement menu as follows:

MEASURE	1	2	3	4	5	6
M	CLEAR	VEL	H-RATE	POMBO	TEICH	NEXT

Select "**3 H-RATE**" in the menu.

A "+" caliper mark will be displayed on the screen as shown in Fig. 2-5-1, and the "+" TRACKBALL FUNCTION switch lights.

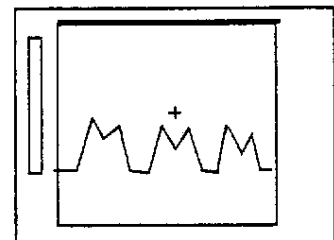


Fig. 2-6-1

- b. Operate the **TRACKBALL** to position the mark to the starting point for the intended heart rate measurement.

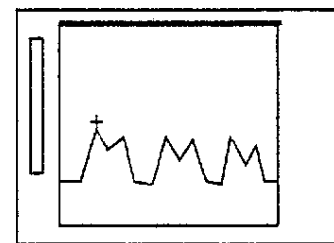


Fig. 2-6-2

- c. Press the **MARK REF** switch, and operate the **TRACKBALL** to move the mark over an M-mode image portion covering two heartbeats (in mutually corresponding phases).

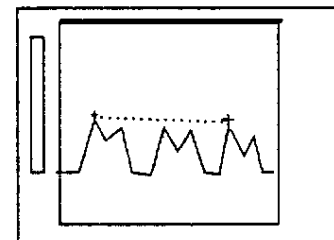


Fig. 2-6-3

The small mark remains on the spot and the large mark may be moved by the **TRACKBALL**. The measured timed interval and the calculated time interval are displayed.

BASIC MEASUREMENTS

Each time the MARK REF switch is pressed, the movable mark under TRACKBALL control is switched from one of the marks to the other.

- d. Another heart rate may be measured with the "x", " ·:· ", or " :: " mark. Press the " x ", " ·:· ", or " :: " switch and operate the mark in the same manner as the "+" mark.
- e. To terminate the measurement, select "1 CLEAR" in the MEASUREMENT FUNCTION Menu.
All the measurement marks and results are erased.

H-RATE Measurement Data Display Example:

HEART RATE

+ : 067 b/m

T : 1.78s

Heartbeats per minute.

Time interval between " + " and "+" marks.

BASIC MEASUREMENTS

2.7 Histogram Display

This function permits displaying the echo intensity of an area in an ultrasonic image by histogram. The histogram represents the echo distribution intensity of the image. There are two ways to define the area to be computed. The "HIST-B" function displays the distribution ratio in a fixed area, and the "HIST-T" function displays the distribution ratio in an optional area.

In the following figure, the horizontal axis represents 0 to 63 shades of gray and the vertical axis the distribution ratio of each shade with the number of picture elements (pixels) of the most common shade in the fixed or optional area assumed to be 100%.

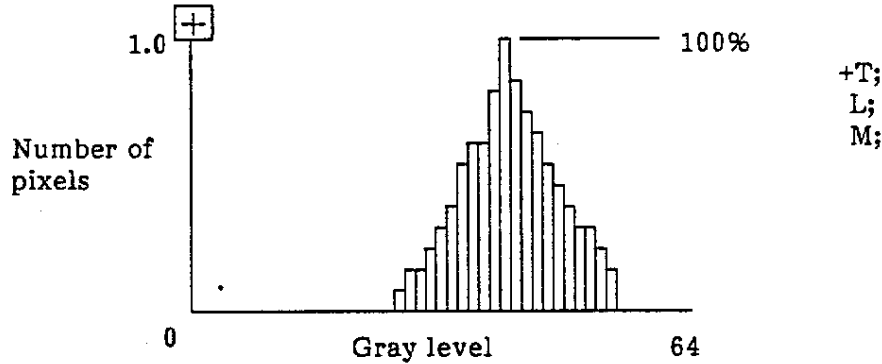


Fig. 2-7-1

"T": Total number of pixels in an optional or fixed area.

"L": Gray scale level of the shade component that is most common in the specified area.

"M" Number of pixels of the shade component that is most common in the specified area.

(1) Histogram of fixed area:

- a. Display a B-mode ultrasound image.
Freeze the image by pressing the **FREEZE** switch.
Press the **MEASUREMENT** switch to display the "MEASUREMENT" menu, then select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

Select "5 HIST".

NOTE: If a histogram measurement is made without pressing the **FREEZE** switch, "FRZ Req." is displayed in the lower part of the information display area.

- b. The menu changes as follows, select "3 HIST-B".

HISTOGRAM	1	2	3	4	5	6
	EXIT	CLEAR	HIST-B	HIST-T		

BASIC MEASUREMENTS

A box cursor for histogram measurement (1 cm x 1 cm) is displayed on the monitor, and the "+" TRACKBALL FUNCTION switch lights.

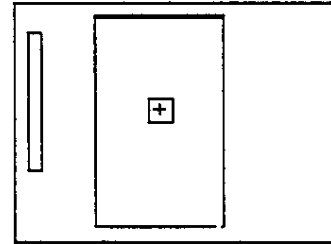


Fig. 2-7-2

- c. Operate the TRACKBALL to move the box cursor to the place where the histogram measurement is to be made.
- d. Press the "MARK REF" switch. The histogram in the box cursor and its numeric value are calculated and displayed.

NOTE: Though the box cursor can be moved by operating the TRACKBALL, the histogram is redisplayed after each movement. Therefore, movement speed is very low.

- e. When the "MARK REF" switch is repressed, the numeric value of the histogram disappears. The box cursor can then be moved rapidly by the TRACKBALL. After the box cursor is moved, the histogram can be displayed by pressing the MARK REF switch.
 - f. Another histogram measurement is possible by pressing the "x" TRACKBALL FUNCTION switch.
 - g. Selecting "2 CLEAR" erases all the measurement marks and measurement results.
 - h. To terminate the measurement, select "1 EXIT" in the menu.
- (2) Histogram of optional area:
- a. Display a B-mode ultrasound image.
Freeze the image by pressing the FREEZE switch.
Press the MEASUREMENT switch to display the "MEASUREMENT" menu, then select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

Select "5 HIST".

NOTE: If a histogram measurement is made without pressing the FREEZE switch, "FRZ Req." is displayed in the lower part of the information display area.

- b. The menu changes as follows:

HISTOGRAM	1	2	3	4	5	6
	EXIT	CLEAR	HIST-B	HIST-T		

Select "4 HIST-T" in the menu.

BASIC MEASUREMENTS

The "+" mark for histogram measurement is displayed on the screen and the "+" TRACKBALL FUNCTION switch lights.

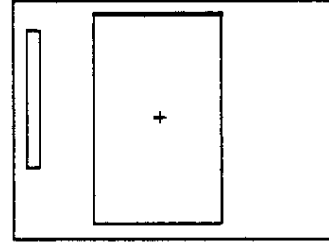


Fig. 2-7-3

- c. Using the TRACKBALL, enclose the area for histogram display with the trace. (The same procedure as for the area/circumference measurement by trace.) It is possible to return the trace to the position to be corrected by continuously pressing the "MARK REF" switch.

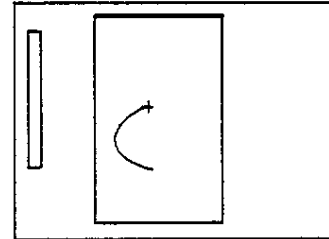


Fig. 2-7-4

- d. Press the "MARK REF" switch. The histogram of the part enclosed by the trace and its numeric values are calculated and displayed.

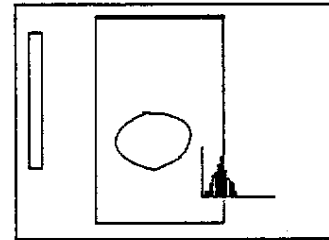


Fig. 2-7-5

- e. Another histogram is possible by pressing the "x" TRACKBALL FUNCTION switch.
- f. Selecting "2 CLEAR" erases all the measurement marks and measurement results.
- g. To terminate the measurement, select "1 EXIT" in the menu. All the measurement marks and measurement results are erased.

BASIC MEASUREMENTS

2.8 Percent Stenosis

Degree of stenosis is expressed as a value.

The ratio between a non-stenotic point and stenotic point is calculated using the measurement values of distance, circumference, and area. Any measurements among distance, circumference and area can to be compared. Further, the circumference and area measurement values do not depend on the method used, either ellipse or trace. The percent stenosis is calculated by the following expression:

$$\text{Percent stenosis} = (A - B) \div A \times 100 (\%)$$

Where A is the measurement of a non-stenotic point, B is stenotic point.

Against two entered data (A and B), Percent Stenosis is automatically calculated as a A of larger data.

In the following conditions, Percent Stenosis is displayed to "***%" on the screen.

- 1) A=B=0
- 2) B=0

NOTE; Though it is possible to calculate two measurements of different units (e.g. distance and area), it has no clinical utility to do this comparison.

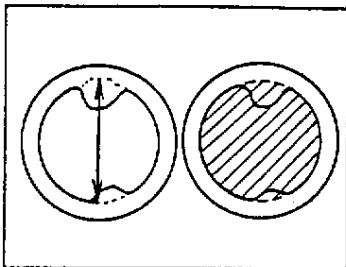


Fig. 2-8-1 Measurement for "A"

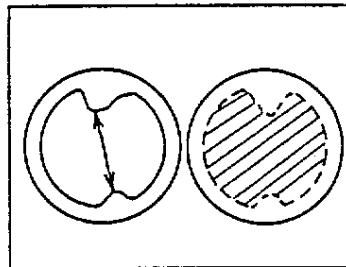


Fig. 2-8-2 Measurement for "B"

Example of measurements

Step:

- a. Press the **MEASUREMENT** switch to display the **MEASUREMENT** menu. First, make measurements of the part where ratio is to be calculated. (See the above example.) Without erasing the menu displayed at present, select "**5 NEXT**" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

- b. Select "**4 %STENO**" in the menu. The menu changes as follows;

PERCENT	1	2	3	4	5	6
STENOSIS	EXIT					SET

BASIC MEASUREMENTS

- c. The measurement value in the top area is highlighted. The highlighted value is entered into the "A" position. When the value is suitable to substitute for "A" in the above expression, select "5 SET" to set the value. If the value is not suitable, press the MARK REF switch to lower the highlighting downward till an suitable value is highlighted, then select "5 SET".

```
STENOSIS
(A-B)/A:  %
A: 05.9
B:
```

- d. The measurement value at the top of the measurement value display area is highlighted. The highlighted value is entered into the "B" position. When the value is suitable to substitute for "B" in the expression, select "5 SET" to set the value. If the value is not suitable, press the MARK REF switch to lower the highlighting downward till an suitable value is highlighted, then select "5 SET".

```
STENOSIS
(A-B)/A:  %
A: 05.9
B: 02.9
```

- e. After the above setting, the calculated value is displayed on the screen.

```
STENOSIS
(A-B)/A: 51 %
A: 05.9
B: 02.9
```

To terminate the calculation, select "1 EXIT". The calculated value is erased.



OBSTETRICAL CALCULATIONS

3. OBSTETRICAL CALCULATIONS

Introduction

This section provides the procedure for calculating gestational age and fetal weight.

(1) Gestational Age (Subsection 3.1 and 3.2)

There are two ways to perform this calculation. One method is by measuring a parameter such as the BPD (Biparietal Diameter). (Subsection 3.1) The other method is by entering the date of the first day of the last menstrual period. (Subsection 3.2)

"3.1 Gestational Age Calculation (Parameter Method)" (page 3-2)

This method is based on a fetal growth table for calculating the gestational week. See subsection "3.1.1 Fetal Growth Table Setting" for the programming procedure.

For the calculation procedure, see subsection "3.1.2 Procedure for Gestational Age Calculation." on page 3-13.

For the method of entering the date of first day of the last menstrual period, see subsection "3.2 Gestational Age Calculation (Date Calculation)."

(2) Fetal weight estimation (Subsection 3.3 page 3-14)

Estimated fetal weight may be calculated from the BPD and other parameters.

OBSTETRICAL CALCULATIONS

3.1 Gestational Age Calculation (Parameter method)

3.1.1 Fetal growth table setting

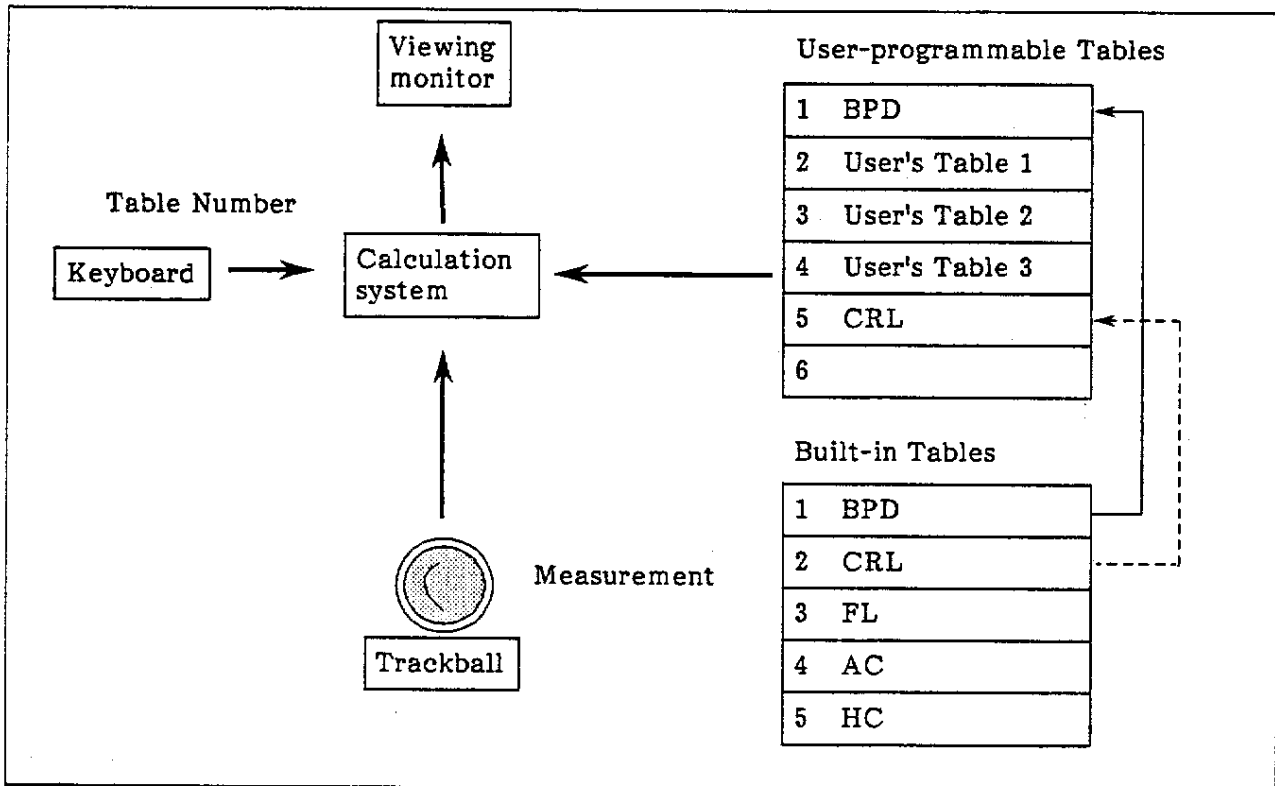
The system has six user-programmable tables which are used for gestational age calculations.

In the user-programmable table, the user can program any desired growth table (User's Table). (See paragraph (2) page 3-6 for table programming.)

In the built-in tables, commonly used tables are already programmed. (See tables from page 3-8 onward.) By transferring built-in tables to the user-programmable tables beforehand, it is possible to use the transferred built-in table for a calculation. (See subsection (1) page 3-3 for the transfer.)

After the above growth table programming, gestational age calculation is possible using a measurement. (See "3.1.2 Procedure for Gestational Age Calculation".)

The following information demonstrates the above state.



OBSTETRICAL CALCULATIONS

At the time of shipment of the equipment, no fetal growth table are registered. A growth table may be registered and its title will appear in a blank on the MEASUREMENT menu on pages "2" or "3". (See the step below.) By selecting a title, that growth table may be used for a gestational age calculation.

Step for display of MEASUREMENT menu pages "2" and "3":

Select B mode with the MODE switch.

Press the MEASUREMENT switch and press the "6" FUNCTION switch two or three times. The following menu appears.

MEASURE	1	2	3	4	5	6
B	CLEAR					NEXT

MEASURE	1	2	3	4	5	6
B	CLEAR			RATIO	FETL-W	NEXT

There are blanks as noted, indicating that the user can input a maximum of six kinds of growth tables.

For the user who has no data, the system contains five kinds of built-in tables.

(1) Step for Transferring built-in table:

The system has 5 kinds of tables based on the Hadlock and others. The contents of the tables are shown from page 3-8 onward.

a. Select B mode with the MODE switch.

Press the MEASUREMENT switch to display the MEASUREMENT menu and select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	OB-PRO				NEXT

b. Select "2 OB-PRO", and the menu changes as follows:

GESTATION	1	2	3	4	5	6
PROGRAM	EXIT	RETURN	USER	INT	CLEAR	SET

OBSTETRICAL CALCULATIONS

- c. The message as shown to the right appears on the screen.

```
LIST TABLE=[ USER ]
1 ( )
2 ( )
3 ( )
4 ( )
5 ( )
6 ( )
TABLE NO.= _
```

List of user programmable tables

- d. Determine the number to which the built-in table is to be transferred, and enter the number from the keyboard. (Do not press the FUNCTION numeral switch at this stage.) The entered number appears to the right of "TABLE NO.=". After the entry, select "6 SET" to set the number.

* In the calculation menu, tables of lower listing number are displayed in advance. If a table that is used frequently is set at a lower number, the number of key operations can be reduced.

- e. The table to be transferred is highlighted. A question appears on the screen, querying whether an internal table or a user table is to be used (PROGRAM TABLE = [USER/INT]).

```
LIST TABLE=[INTERNAL]
BASED ON
1 BPD ( KURTZ )
2 CRL ( ROBINSON )
3 FL ( O'BRIEN )
4 AC ( Hadlock )
5 HC ( Hadlock )
TABLE NO.=
```

In this case, an internal built-in table is to be transferred. Thus, select "4 INT" in the menu. The display becomes as shown to the right.

List of Built-in Tables

The menu changes as follows:

PROGRAM	1	2	3	4	5	6
INTERNAL	EXIT	RETURN				SET

- f. Select one of the 5 kinds of obstetrical calculation data tables and enter its number from the keyboard. The entered number appears to the right of "TABLE NO.=", After this entry, select "6 SET" in the menu, to complete the operation. The operation sequence is automatically returned to step "b". The transfer procedure can then be started anew.
- g. To terminate all transfer operations, select "1 EXIT" or press the "MEASUREMENT" switch.

OBSTETRICAL CALCULATIONS

(2) Step for Making User's Tables:

A maximum of six kinds of tables can be programmed by the user. The input procedure is described below.

- a. Define the table in which user's table is to be input. The procedure is the same as steps "a". to "d" in the preceding paragraph.
- b. The table to be set is highlighted. A question appears on the screen asking whether an internal data table or a user table will be input. (PROGRAM TABLE = (USER/INT)). In this case, data is input by the user. Thus, select "3 USER". Then, the display as shown to the right appears.

LIST TABLE=[USER]	
TABLE NAME=[]	
DIMENSION =]	
BASED ON =]	
W	+d	W	+d
1		22	
2		23	
3		24	

At the same time, the menu changes as follows;

PROGRAM	1	2	3	4	5	6
USER	EXIT	RETURN				SET

- c. The item "TABLE NAME=" is highlighted.

Here, enter the abbreviation characters to be displayed on the MEASUREMENT menu from the keyboard.

The maximum number of abbreviation characters to be input is 3. These characters comprise the title of this table.

After this input, select "6 SET" for setting.

LIST TABLE=[USER]	
TABLE NAME=[■■■]	
DIMENSION =]	
BASED ON =]	
W	+d	W	+d
1		22	
2		23	

- d. After setting, the highlighted part proceeds to "DIMENSION=". Here, select a measurement method to be used for this obstetrical calculation. Five measurement methods are available for obstetrical calculations. For these, abbreviation characters (D/T/E/A/V) are displayed.

LIST TABLE=[USER]	
TABLE NAME=[BPD]	
DIMENSION =	■■■■]	
BASED ON =]	
W	+d	W	+d
1		22	
2		23	

D: DIST	(Distance measurement)
T: TRACE	(Circumference measurement)
E: AREA-E	(Ellipse approximation area measurement)
A: AREA-T	(Trace area measurement)
V: VOLUME	

LIST OF ABBREVIATIONS

OBSTETRICAL CALCULATIONS

Then, enter one of these abbreviation characters (D,T,E,A or V) from the keyboard. After entering one alphabetic character, select "6 SET" for setting.

The unit automatically changes according to the measurement method.

- e. After setting, the highlighted part proceeds to "BASED ON=". Here, enter the obstetrical calculation data implementer, hospital name, etc. It is possible to enter a maximum of 15 characters from the keyboard.

LIST TABLE=[USER]			
TABLE NAME=[BPD]			
DIMENSION =[DIST]			
BASED ON =[■■■■■■]			
W <u>±</u> d cm		W <u>±</u> d cm	
1		22	
2		23	

Following this input, select "6 SET" for setting.

- f. The highlighted part proceeds to the top of the data table (first week). Enter the standard deviation at the "d" column and the numeric value of this week at the "cm" column from the keyboard. For a week that has no data, select "6 SET" to proceed to the next week.

LIST TABLE=[USER]			
TABLE NAME=[BPD]			
DIMENSION =[DIST]			
BASED ON =[ALOKA]			
W <u>±</u> d cm		W <u>±</u> d cm	
1	01 000.5	22	
2		23	

- g. The highlighted part proceeds to the next line (second week). Enter the data in the same manner as the first week. Then select "6 SET". For a week that has no data, select "6 SET" to proceed to the next week.

LIST TABLE=[USER]			
TABLE NAME=[BPD]			
DIMENSION =[DIST]			
BASED ON =[ALOKA]			
W <u>±</u> d cm		W <u>±</u> d cm	
1	01 000.5	22	
2		23	

- h. After completion of all data input, select "1 EXIT" in the menu. To proceed to make another obstetrical calculation data table, select "2 RETURN" and then perform the procedure starting from step "a".

OBSTETRICAL CALCULATIONS

Table NO. 1
Biparietal Diameter
KURTZ

BPD (cm)	Number of Weeks	Standard Deviation (\pm days)
2.0	12	4
2.3	13	4
2.7	14	4
3.1	15	6
3.4	16	6
3.8	17	8
4.1	18	10
4.5	19	15
4.8	20	13
5.1	21	11
5.4	22	13
5.7	23	12
6.0	24	11
6.3	25	11
6.6	26	11
6.8	27	9
7.1	28	8
7.4	29	7
7.6	30	7
7.8	31	9
8.1	32	10
8.3	33	11
8.5	34	12
8.7	35	11
8.9	36	11
9.1	37	9
9.2	38	8
9.4	39	8
9.6	40	8

OBSTETRICAL CALCULATIONS

Table NO. 2
Crown-Rump Length
ROBINSON

CRL (cm)	Number of Weeks	Standard Deviation (±days)
0.9	7	5
1.5	8	5
2.2	9	5
3.1	10	5
4.0	11	5
5.2	12	5
6.4	13	5
7.8	14	5

OBSTETRICAL CALCULATIONS

Table NO. 3
Femur Length
O'Brien

FL (cm)	Number of Weeks	Standard Deviation (±days)
1.3	13	7
1.7	14	7
2.0	15	7
2.2	16	7
2.6	17	7
3.0	18	7
3.3	19	7
3.5	20	7
3.8	21	7
4.1	22	7
4.4	23	7
4.6	24	7
4.8	25	7
5.1	26	7
5.3	27	7
5.5	28	7
5.7	29	7
5.9	30	7
6.1	31	7
6.3	32	7
6.5	33	7
6.6	34	7
6.8	35	7
7.0	36	7
7.1	37	7
7.2	38	7
7.4	39	7

OBSTETRICAL CALCULATIONS

Table NO. 4
Abdominal Circumference
Hadlock

(cm)	Number of Weeks	Standard Deviation (±days)
10.4	16	13
11.6	17	13
12.8	18	14
13.9	19	14
15.0	20	14
16.2	21	14
17.3	22	14
18.4	23	14
19.5	24	15
20.6	25	15
21.6	26	15
22.7	27	15
23.8	28	15
24.8	29	15
25.9	30	21
26.9	31	21
27.9	32	21
28.9	33	21
29.9	34	21
30.9	35	21
31.9	36	18
32.9	37	18
33.9	38	18
34.8	39	18
35.8	40	18

OBSTETRICAL CALCULATIONS

Table NO. 5
Head Circumference
Hadlock

HC (cm)	Number of Weeks	Standard Deviation (±days)
9.0	14	9
10.5	15	9
12.1	16	9
13.5	17	9
14.9	18	11
16.3	19	11
17.5	20	11
18.8	21	11
19.9	22	11
21.0	23	11
22.1	24	11
23.1	25	16
24.1	26	16
25.1	27	16
26.0	28	16
26.9	29	16
27.7	30	19
28.5	31	19
29.3	32	19
30.1	33	19
30.9	34	19
31.6	35	19
32.3	36	19
33.0	37	24
33.7	38	24
34.4	39	24
35.0	40	24

OBSTETRICAL CALCULATIONS

3.1.2 Procedure for Gestational Age Calculation

This function permits calculating the gestational age and estimated delivery date from the measured values such as biparietal diameter (BPD), crown rump length (CRL), femur length (FL), abdominal circumference (AC) and head circumference (HC). This function adopts the multiple fetal growth index adding method. As various indexes are registered continuously, the mean gestational age and mean estimated delivery date are obtained by averaging the gestational ages and estimated delivery dates calculated when individual indexes are calculated and displayed.

Steps:

Select B mode with the MODE switch. When the desired image is displayed, freeze the image with the FREEZE switch. Press the "MEASUREMENT" switch to display the menu. Select "6 NEXT" till the menu containing the title of the growth table to be used is on the screen.

The following is an example using a BPD table. (This BPD table is what was transferred to the menu by the obstetrical calculation data table built into the Aloka-650.)

(Example of menu)

MEASURE	1	2	3	4	5	6
B	CLEAR	BPD	CRL	FL	AC	NEXT

(1) Where measurement has been finished:

a. Select "2 BPD" in the menu, and the display shown at right appears in the lower right part of the screen. The measured value at the top is highlighted, and the value is used for the computation of a BPD.

```

                BPD      : 05.3CM
                    : W d± d
                    : / /
AVE: W d± d : / /
                ↑
            Average
    
```

b. If the measured value highlighted is not appropriate for the computation, press the "MARK REF" switch to lower the highlighted part to a lower line. When the display is lowered to the lower line, the measured value in the lower line is automatically used as the BPD value.

```

                BPD      : 05.3CM
                    : 22W 0d± 10d
                    : 87/ 05/ 27
AVE: 22W 0d±10d : 87/ 05/ 27
                ↑
            Average
    
```

OBSTETRICAL CALCULATIONS

- c. If one or more of the measured values in the measurement information display area are still not appropriate, lower the highlighted part to the bottom and then press the "MARK REF" switch. The distance measurement caliper mark "+" is displayed on the screen and measurement is ready.

BPD	1	2	3	4	5	6
	EXIT					SET

Measure the distance of the region suitable for the obstetrical measurement in use. After completion of the measurement, select "6 SET". The gestational age is calculated by referring to the fetal growth table. (The caliper mark in the above step disappears.)

The estimated delivery date is calculated by the following expression:

$$\text{EDC} = \text{DATE} + (\text{PW} - \text{GW}) \times 7$$

EDC: Estimated date of confinement

DATE: Date displayed in the upper right part of monitor

PW: Pregnancy week. This is set at 40 weeks.

GW : Gestational week calculated by referring to the fetal growth table

- d. When another obstetrical calculation is performed continuously with a different menu, the average between the previous calculation result and the new calculation result is displayed under "AVE". In calculations using this multiple fetal index adding method, the mean gestational week and mean estimated delivery date for a maximum of 4 measurements are displayed.

Note: When the probe or mode is changed for the second and subsequent measurements, the marks on the tomographic image and the calculation results displayed on the right side of the screen disappear. However, the results of gestational week and estimated delivery date displayed in the lower part of the screen are retained.

- e. To terminate the calculation select "1 CLEAR" in the menu. All the displayed measured values and measurement marks are erased.

OBSTETRICAL CALCULATIONS

3.2 Gestational Age Calculation (Date Calculation Method)

Enter the starting date of the last menstruation from the keyboard to calculate the gestational week and estimated delivery date. As this calculation uses no measurement results, no previous measurement is required.

- a. Check that the date of diagnosis (today's date) is correctly displayed in the line of "DATE;" in the upper right part of the screen.
- b. Select "B" (B/M or B/D is also selectable) by the MODE switch and press the "MEASUREMENT" switch to display the measurement menu on the screen. Then select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

Select "3 G-CALC" in the menu, and "LMP = / " (Month/day) will be displayed in the upper right part of the screen. The menu changes as follows:

GESTATIONAL	1	2	3	4	5	6
CALCULATION	EXIT					SET

- c. Enter the starting date of the last menstruation from the keyboard. If the month or day number is less than 10, enter 0 for the first digit.

Enter 4 numbers (MO/DAY) from the keyboard and select "6 SET" for setting.

The gestational age and estimated delivery date will be calculated and displayed.

CGW and EDC are calculated by the following expressions:

$$\text{CGW} = (\text{DATE} - \text{LMP}) \div 7$$

$$\text{EDC} = \text{LMP} + \text{PW} \times 7$$

CGW: Calculated Gestational Week
EDC: Estimated Date of Confinement
LMP: Date of first day of Last Menstrual Period
PW: Pregnancy Week

- d. After completion of the measurement, select "1 EXIT". The menu returns to the original one.

OBSTETRICAL CALCULATIONS

3.3 Fetal Weight Calculation

The fetal weight is estimated from the measured values of Biparietal Diameter (BPD), Abdominal Circumference (AC) and Femur Length (FL).

For fetal weight estimation, the following two formulas are available:

Formula A :SHEPARD

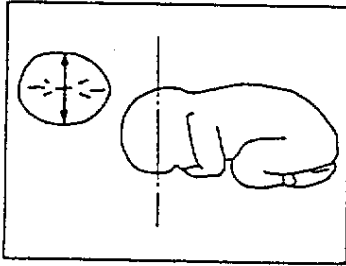
$$FW (g) = 10EXP [(AC \times 0.046) - (BPD \times AC \times 0.002646) + (BPD \times 0.166) + 1.2508]$$

Formula B :HADLOCK

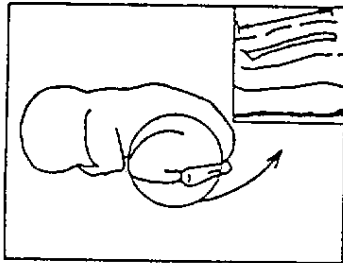
$$FW (g) = 10EXP [1.3598 + (AC \times 0.051) + (FL \times 0.1844) - (AC \times FL \times 0.0037)]$$

The figures below show the measurement necessary for the above formulas.

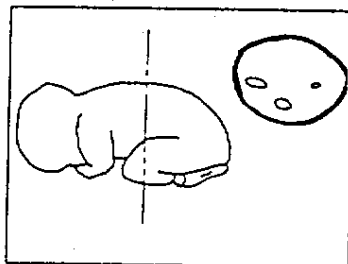
BPD: Biparietal Diameter



FL: Femur Length



AC: Abdominal Circumference



OBSTETRICAL CALCULATIONS

Steps:

Select "B" with the MODE switch and press the "MEASUREMENT" switch to display the MEASUREMENT menu. Then select "6 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR			RATIO	FETL-W	NEXT

- (1) Where measurements have been finished:

When two to four parameter measurements have been finished, follow the following procedure:

- a. Select "5 FETL-W" in the menu, and the menu changes as follows:

FETLWEIGHT	1	2	3	4	5	6
	EXIT	SHEPARD HADLOCK		C		SET

- b. Select a formula for fetal weight estimation between SHEPARD or HADLOCK in the menu.

As an example, a description will be made where the formula for SHEPARD has been selected.

- c. When SHEPARD is selected, the BPD and the numeric value in the top line of the measurement information display area among the measured values are first highlighted. If the highlighted value is to be used for the calculation, select "6 SET" to register it.

If the measured value differs from the value to be used as BPD, press the "MARK REF" switch to lower the highlighted part in the measurement information display area down line by line.

When an appropriate numeric value is highlighted for BPD, select "6 SET" in the menu to register it.

- d. If no values in the measurement information display area are appropriate, lower the highlighted part to the bottom by using the "MARK REF" switch and press the "MARK REF" switch once again. Then, the "+" caliper mark will appear on the screen. With the caliper mark, measure the region suitable for BPD.

After completion of the measurement, select "6 SET" in the menu for setting.

- e. Next AC is highlighted. Perform the above steps "c" and "d" to register all the parameters.

Calculated value is displayed to the right of "F-W:" in grams.

- f. To terminate the calculation, select "1 EXIT" in the menu.

OBSTETRICAL CALCULATIONS

(2) Where no measurements have been finished:

- a. Select "5 FETL-W" in the menu, and the menu changes as follows:

FETAL WEIGHT	1	2	3	4	5	6
	EXIT	SHEPARD	HADLOCK	C		SET

- b. Select a formula for fetal weight estimate between SHEPARD or HADLOCK.

As an example, following description is when SHEPARD has been selected.

- c. When SHEPARD is selected, the BPD is first highlighted. The distance measurement caliper mark "+" is displayed on the image.

Measure the region suitable for a BPD by using these caliper marks and select "6 SET" in the menu to enter it.

- d. Then the (AC) is automatically started. The AC and the measured value at the top are highlighted.

After that, perform the same operations as those for BPD. For each input, select "6 SET" for setting.

CARDIAC ANALYSIS

4. CARDIAC ANALYSIS

This calculating function is available on B-mode and M-mode images. Refer to the individual instructions per mode in the following sections.

The use of the optional physiological signal unit (PEU-650) enables accurate measurements.

4.1 Left Ventricular Function Calculations (for B-mode)

For cardiac function (left ventricular function) calculations using the B-mode image, the sectional area of the left ventricle is measured by using area measurements (ellipse method). The volume of the ellipse whose axis of revolution is the long axis is found. The contents of the calculations are as listed below:

Parameter (Abbreviation)	Parameter (in full spelling)	Expression or operation	Unit
ESA	End-Systolic Area	(Measurement)	cm ²
ESS	End-Systolic Short Axis	(Measurement)	cm
ESL	End-Systolic Long Axis	(Measurement)	cm
ESV	End-Systolic Volume	$ESV = \frac{8}{3\pi} \times ESA \times \frac{ESA}{ESL}$	ml
EDA	End-Diastolic Area	(Measurement)	cm ²
EDS	End-Diastolic Short Axis	(Measurement)	cm
EDL	End-Diastolic Long Axis	(Measurement)	cm
EDV	End-Diastolic Volume	$EDV = \frac{8}{3\pi} \times EDA \times \frac{EDA}{EDL}$	ml
SV	Stroke Volume	$SV = EDV - ESV$	ml
CO	Cardiac Output	$CO = SV \times HR \div 10^3$	l/min
EF	Ejection Fraction	$EF = SV \div EDV$	
HR	Heart Rate	Automatic or manual input	beat/min

Table 4-1 List of Left Ventricle Function Calculations for B-mode

CARDIAC ANALYSIS

Procedure for Calculations for B-mode:

- a. Display a left ventricular long-axis image at end systole. Press the **MEASUREMENT** switch, and display the following menu:

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

Select "4 LV-B" from the menu. The area measurement mark "⊕" will appear at the center of the screen, and the "☐" TRACKBALL FUNCTION switch will light.

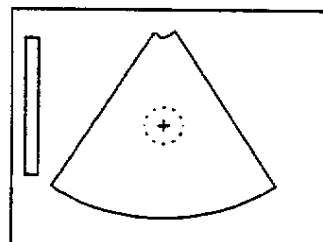


Fig. 4-1-1

At the same time, the "+ESA" is highlighted and the menu changes as follows:

LV FUNCTION	1	2	3	4	5	6
	EXIT	HR				SET

2 HR: When an ECG is not displayed, it is possible to enter it from the key board.

- b. Use the **TRACKBALL** to position the mark to the center of a target.

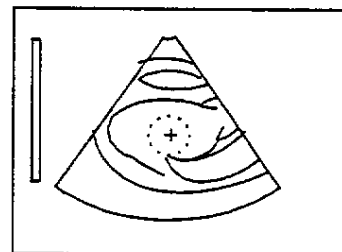


Fig. 4-1-2

- c. Press the **MARK REF** switch.

The trackball works to lengthen or shorten the vertical and horizontal axes of the mark. (See Fig. 4-1-3.)

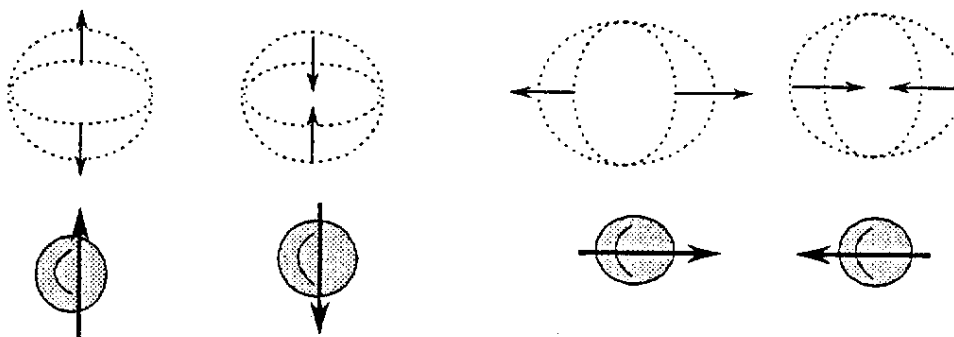


Fig. 4-1-3

CARDIAC ANALYSIS

- d. Press the **MARK REF** switch and turn the "+" mark by operating the **TRACKBALL** as shown below.

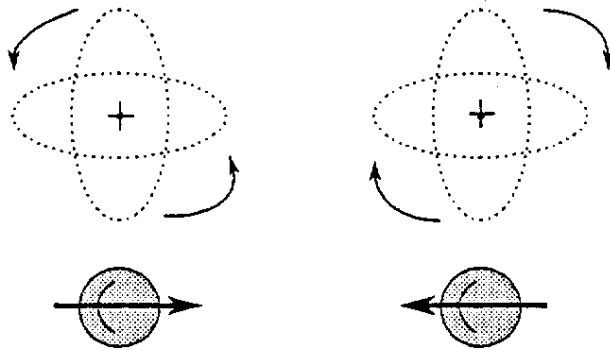
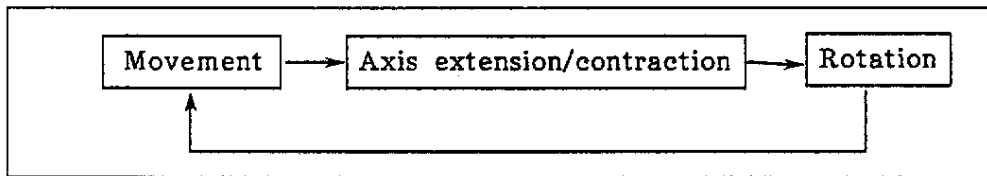


Fig. 4-1-4

NOTE: When the **MARK REF** switch is pressed, the **TRACKBALL** function is switched in this sequence: movement, axis extension/contraction, rotation and movement.



- e. After the **ESA** (end-systolic area) is measured, **ESS** (End-Systolic Short Axis), **ESL** (End-Systolic Long Axis) and **ESV** (End-Systolic Volume) are automatically calculated.

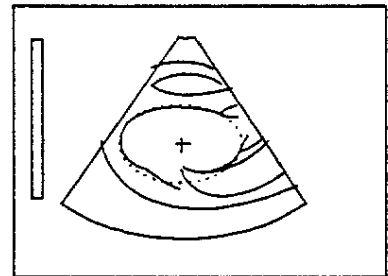


Fig. 4-1-5

- f. By using the **ECG SYNC** (Electrocardiogram Synchronization) function (with optional unit), re-scan to display an end-systolic image.

However, when an end-systolic long axis image and an end-diastolic image are displayed beforehand by the dual-image display function, transfer the active mark "▼" to the end-diastolic image by the **SELECTOR** switch after step "e".

- g. Press the "x" **TRACKBALL FUNCTION** switch. The "x" mark is displayed. Then, perform an **EDA** (end-diastolic area) measurement in the same way as the systolic measurement. Immediately, **EDS** (end-diastolic short axis), **EDL** (end-diastolic long axis), **EDV** (end-diastolic volume) **SV** (stroke volume) and **EF** (ejection fraction) are calculated and displayed.

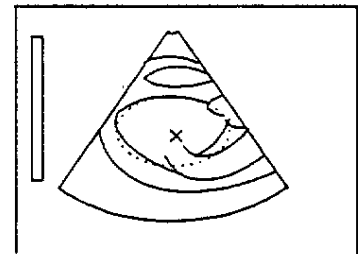


Fig. 4-1-6

CARDIAC ANALYSIS

- h. When the ECG is displayed, the heart rate is automatically read and the CO value is calculated.

If there is no ECG displayed, select "2 HR" in the menu and enter the value from the keyboard. Then select "6 SET". The CO value is calculated.

To redo left ventricular function measurements, the value can be changed freely by pressing the TRACKBALL FUNCTION caliper mark switches (+ and x) alternately.

- i. To terminate the measurements, select "1 EXIT".

Example of LV-B measurement information display:

LV FUNC.				
AREA-LENGTH				
+ESA:10.1 cm ²	LV end-systolic <u>area</u>	:	10.1 cm ²	} Measured by " + " mark
ESS:03.2 cm	LV end-systolic <u>short axis</u>	:	3.2 cm	
ESL:04.5 cm	LV end-systolic <u>long axis</u>	:	4.5cm	
ESV:025 ml	LV end-systolic <u>volume</u>	:	25 ml	} Measured by " x " mark
xEDA:23.8 cm ²	LV end-diastolic <u>area</u>	:	23.8 cm ²	
EDS:04.4 cm	LV end-diastolic <u>short axis</u>	:	4.4 cm	
EDL:05.0 cm	LV end-diastolic <u>long axis</u>	:	5.0cm ²	
EDV:070 ml	LV end-diastolic <u>volume</u>	:	70 ml	
SV: 0.45 ml	Stroke volume		45 ml	
HR: 065b/m	Heart rate		65 beat/min	
CO: 2.9l/m	Cardiac output		2.9 liter/min	
EF: 0.64	Ejection fraction		0.64	

CARDIAC ANALYSIS

4.2 Left Ventricular Function Calculations (for M mode)

Contents of the calculations are listed below:

Parameter (Abbreviation)	Parameter (in full name)	Expression or operation	Unit
ESD	End-Systolic Dimension	(Measurement)	cm
ESV	End-Systolic Volume	See NOTE below	ml
EDD	End-Diastolic Dimension	(Measurement)	cm
EDV	End-Diastolic Volume	See NOTE below	ml
SV	Stroke Volume	SV=EDV - ESV	ml
CO	Cardiac Output	CO=SV x HR ÷ 10 ³	l/min
EF	Ejection Fraction	EF= SV ÷ EDV	-
FS	Fractional Shortening	FS=(EDD - ESD) ÷ EDD x 100	%
ET	Ejection Time	(Measurement)	sec
MSER	Mean Systolic Ejection Rate	MSER= SV ÷ ET	ml/sec
MVCF	Mean Velocity of Circumferential Fiber Shortening	MVCF= EDD- ESD) ÷ (EDD x ET)	circ/sec
HR	Heart Rate	Automatically or manual input	beat/min

Table 4-2 List of Left Ventricle Function Calculations for M-mode

NOTE: Two methods are selectable depending on the size of the left ventricle: one uses Pombo's expression, and the other Teichholz's expression

Pombo's expression

$$V = L^3$$

V (ml) = ESV, EDV
L (cm) = ESD, EDD

Teichholz's expression

$$V = 7L^3 / (2.4 + L)$$

As the left ventricular volume becomes larger and the ventricular shape approaches a sphere, the real long axis dimension becomes less than twice the short axis dimension. Accordingly, the use of the POMBO expression causes a large error. Therefore when the left ventricular volume is 200 ml or more, the TEICHHOLZ expression should be used.

NOTE: For the sake of numeric processing in this equipment, if an ESD/EDD value below 0.7 cm is input, the ESV/EDV display becomes 0 (zero) ml. Calculations are unable to be processed with values below 0.7 cm.

CARDIAC ANALYSIS

Procedure

There are no differences in the measurement procedure and measurement result display between the POMBO and TEICH methods. However, different approximate expressions are used for the end systolic volume (ESV) and end diastolic volume (EDV).

- a. Display a left ventricular M-mode image.
Press the "MEASUREMENT" switch, and display the following menu:

MEASURE	1	2	3	4	5	6
M	CLEAR	VEL	H-RATE	POMBO	TEICH	NEXT

Select "4 POMBO" (or "5 TEICH") from the menu. The caliper mark " + " will appear at the center of the screen and the " + " TRACKBALL FUNCTION switch will light.

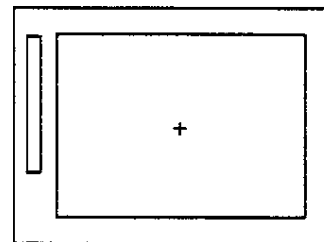


Fig. 4-2-1

At the same time, the "+ESD" (end-systolic dimension) is highlighted and the menu changes as follows:

POMBO (or TEICH)	1	2	3	4	5	6
	EXIT	HR				SET

- b. Move the + mark to the measurement starting position with the TRACKBALL.

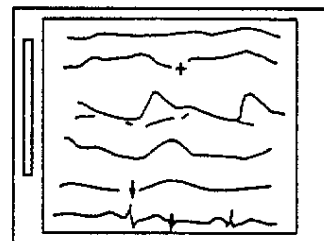


Fig. 4-2-2

- c. Press the MARK REF switch and measure the ESD (end-systolic dimension) with the TRACKBALL.

ESD and the ESV (end-systolic volume) are calculated and displayed.

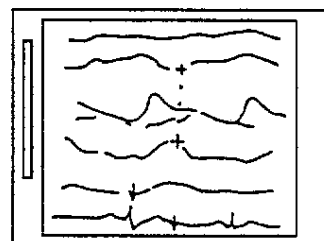


Fig. 4-2-3

CARDIAC ANALYSIS

- d. Press the " x " TRACKBALL FUNCTION switch. The "x" mark is displayed in the center of the screen and the EDD (end-diastolic dimension) is highlighted.

Position the mark at the starting point for the EDD measurement. The target of end-diastolic dimension measurement will correspond with the top of the R wave of the ECG trace.

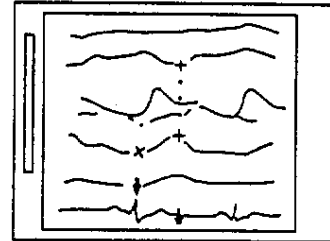


Fig. 4-2-4

- e. Measure EDD by the same procedure as used for ESD.

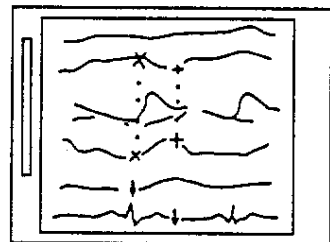


Fig. 4-2-5

EDD, EDV (end-diastolic volume), SV (stroke volume), EF (ejection fraction) and FS (fractional shortening) are calculated. When ECG is displayed, the HR (heart rate) value is automatically read out and the value of CO (cardiac output) is calculated.

- f. When an ECG is not displayed, select the "2 HR" in the menu, input the heart rate from the keyboard, then select "6 SET".
- g. Press the ".:" TRACKBALL FUNCTION switch.

The ".:" mark is displayed at the center of the screen and the "ET" is highlighted. Using the TRACKBALL, move the "+" mark to the starting point for a ET measurement.

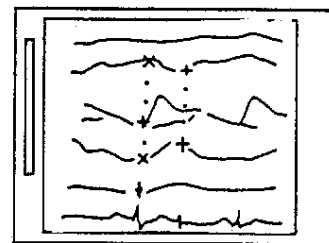


Fig. 4-2-6

- h. Press the "MARK REF" switch and measure the ET (shown in the circle in the figure to the right).

Note: The LV ejection time means the time from a waveform rise to the dirotic notch "DN:Dirotic Notch" after the display of carotid arterial pulse wave.

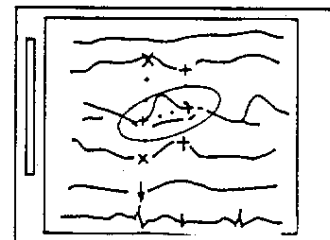


Fig. 4-2-7

CARDIAC ANALYSIS

After the ET is set, MSER (Mean Systolic Ejection Rate) and MVCF (Mean Velocity of Circumferential Fiber Shortening) are automatically calculated and displayed.

- i. If a correction is necessary, press the caliper mark switch (+ or x) for the measurement to be corrected and redo the measurement.
- j. To terminate the measurement, select "1 EXIT".

Example of measurement information display:

LV FUNC

POMBO

ESD: 2.2 cm	End systolic dimension between + and + marks 2.2 cm
ESV: 011 ml	End systolic volume 11 ml
EDD: 4.0 cm	End diastolic dimension between X and x marks 4.0 cm
EDV: 064 ml	End diastolic volume 64 ml
SV: 053 ml	Stroke volume 53 ml
HR: 060 b/m	Heart rate (input from the keyboard for playback measurement) 60 beats/min
CO: 3.21/m	Cardiac output 3.21/min
EF: 0.82	Ejection fraction 0.82
FS: 45%	Fractional shortening 45%
ET: 0.27 s	Ejection time between + and + mark 0.27 sec
MSER: 196 ml/s	Mean systolic ejection rate 196 ml/sec
MVCF: 1.6 cir/s	Mean velocity of circumferential fiber shortening 1.6 cir/sec
+; 2.2 cm	Indicates the current measurement item (highlighted).

DOPPLER ANALYSIS

5. DOPPLER ANALYSIS (option)

NOTE: Doppler measurement and analysis are possible when the optional Doppler module is installed.

5.1 Velocity Measurement (on D mode)

- a. Display a Doppler pattern on the screen in either D or B/D mode. Freeze the pattern with the **FREEZE** switch. Press the **MEASUREMENT** switch to display the following menu, then select "2 VEL".

MEASURE	1	2	3	4	5	6
D	CLEAR	VEL	ACCEL	AVE		NEXT

The mark " —+—" for velocity measurement is displayed in the center of the screen. In the message area, "POINT" is displayed. The " + " switch lights.

- b. Move the mark to the measurement position with the **TRACKBALL**. The measured value is displayed.

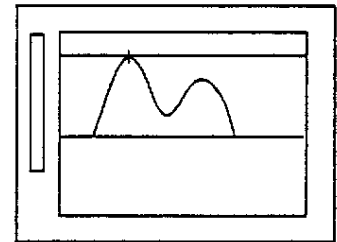


Fig. 5-1-1

- c. To measure another velocity and obtain the ratio of velocity between the two points, press the **MARK REF** switch.

The second mark is superimposed on the first mark. By operating the trackball, the second mark moves and the first mark remains stationary. (The first mark becomes a dotted line.)

- d. Move the line to the measurement position with the **TRACKBALL**.

The measured value of the second mark and the ratio (first/second) are displayed.

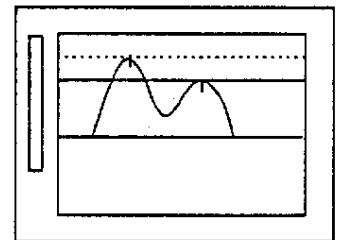


Fig. 5-1-2

NOTE: Each time the **MARK REF** switch is pressed, the movable mark is switched between the first and the second mark. The solid line is always movable.

- e. By pressing the "x", " ∴ ", or " :: " switch, another pair of velocity measurements is possible in the same manner.
- f. To terminate the measurement, select "1 CLEAR"

DOPPLER ANALYSIS

Example of VEL measurement information display:

VEL(D)

+: 52.48cm/s

Velocity measured by the first "—+—" mark

27.13cm/s

Velocity measured by the second "—+—" mark

R: 192.00%

Ratio of the measured values between the first and the second marks.

DOPPLER ANALYSIS

5.2 Acceleration Measurement

- a. Display a Doppler pattern on the screen in either D or B/D mode. Freeze the pattern with the **FREEZE** switch. Press the **MEASUREMENT** switch to display the following menu, then select "3 ACCEL".

MEASURE	1	2	3	4	5	6
D	CLEAR	VEL	ACCEL	AVE		NEXT

The mark " \dagger " for an acceleration measurement is displayed in the center of the screen. In the message area, "POINT" is displayed. The " + " switch lights.

- b. Move the mark to the starting point with the **TRACKBALL**. (Position the mark so that the crossed point of the mark moves to the measurement point.)
- c. Press the **MARK REF** switch.

The end point setting mark is displayed and the first mark becomes a dotted line.

- d. Move the " \dagger " mark to the end point with the **TRACKBALL**.

The acceleration is displayed.

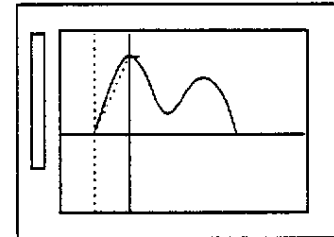


Fig. 5-2-1

NOTE: Each time the **MARK REF** switch is pressed, the movable mark is switched between the first and the second mark. The solid line mark is always movable.

- e. By pressing the "x", " .:.", or " :: " switch, another pair of velocity measurements is possible in the same manner.
- f. To terminate the measurement, select "1 CLEAR".

Example of ACCEL measurement information display:

ACCELERATION

+:

034.60 cm/s² Acceleration between the " \dagger " mark and " \dagger " mark
 62.21 cm/s Velocity component of the first mark
 36.95 cm/s Velocity component of the second mark
 00.73 s Time difference between the " \dagger " and " \dagger " mark

DOPPLER ANALYSIS

5.3 Average Flow Velocity Measurement

- a. Display a Doppler pattern on the screen in either D or B/D mode. Freeze the pattern with the FREEZE switch. Press the MEASUREMENT switch to display the following menu, then select "4 AVE".

MEASURE	1	2	3	4	5	6
D	CLEAR	VEL	ACCEL	AVE		NEXT

The caliper mark "+" is displayed on the screen. In the message area, "TRACE" is displayed.

- b. Move the "+" mark to the trace starting point with the TRACKBALL.

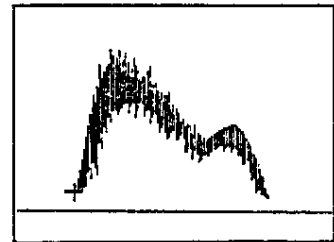


Fig. 5-3-1

- c. Press the MARK REF switch.

- d. Trace the average flow velocity portion of the spectrum pattern with the TRACKBALL.

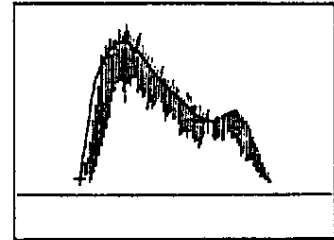


Fig. 5-3-2

NOTE: Pressing and holding the MARK REF switch erases the trace little by little from the end of the trace for correction.

- e. Press the MARK REF switch. Average flow velocity is displayed.
- f. By pressing the "x", " :. ", or " :: " switch, another trace for average flow velocity measurement is possible in the same manner..
- g. To terminate the measurement, select "1 CLEAR".

Example of "AVERAGE VELOCITY" measurement information display:

```
AVE-VEL
+: 00.34cm/s   Average flow velocity
FL-T: 1.37ss   Blood flow time (time between the start and end point of the
                trace)
FL-D:000.5 cm  Blood flow time
```


DOPPLER ANALYSIS

5.4 Valve Orifice Area Measurement

- a. Display a Doppler pattern on the screen in either D or B/D mode. Freeze the pattern with the **FREEZE** switch. Press the **MEASUREMENT** switch and select "6 NEXT" to display the following menu, then select "2 **CARDIO**".

MEASURE	1	2	3	4	5	6
D	CLEAR	CARDIO	SV/CO	PV	V.UNIT	NEXT

The line mark "—+—" for measurement is displayed in the center of the screen. The menu changes as follows. In the message area, "POINT" is displayed.

CARDIO	1	2	3	4	5	6
	EXIT	CLEAR	ENTER	ERASE	AVE	

- b. Move the mark to the maximum velocity position with the **TRACKBALL**. **PK** (Peak Velocity) and **PPG** (Peak Pressure Gradient) are calculated and displayed.

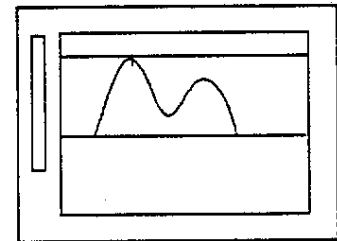


Fig. 5-4-1

- c. Press the "x" **TRACKBALL FUNCTION** switch. The "x" mark for mean velocity measurement is displayed.

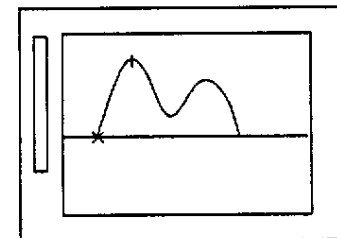


Fig. 5-4-2

- d. Move the "x" mark to the measurement starting position with the **TRACKBALL**.

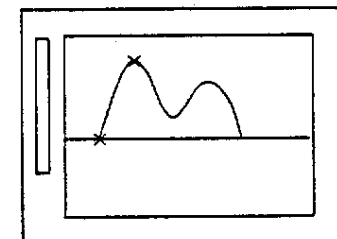


Fig. 5-4-3

- e. Press the **MARK REF** switch.
 f. Trace the average part of the Doppler pattern with the **TRACKBALL**.

NOTE: Pressing and holding the **MARK REF** switch erases the trace little by little from the end of the trace for correction. Pressing the "x" switch restarts the trace all over again.

DOPPLER ANALYSIS

g. Press the MARK REF switch. MN (mean value of maximum velocity, MPG (mean pressure gradient), T-PK (time to peak), ACCEL (acceleration) and FL-T (flow time) are calculated and displayed.

h. Press the "⊕" switch.

The "⊕" mark is displayed at the center of the screen. In the message display area "SLOPE" is displayed.

Position the mark to the peak of the pattern with the TRACKBALL. Then press the MARK REF switch.

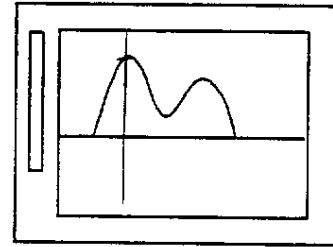


Fig. 5-4-4

i. Move the "⊕" mark to the end point of the pressure half-time with the TRACKBALL. P1/2T (Pressure Half-Time) and M/TVA (Mitral/Tricuspid Valve Area) are calculated and displayed.

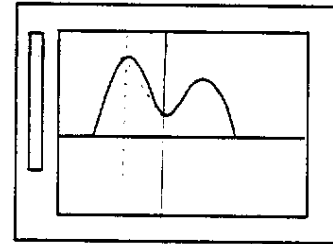


Fig. 5-4-5

j. ① To register the measurement result, select "3 ENTER".

② To erase the measurement result, select "4 ERASE".

③ To average the registered data, select "5 AVE".

k. To terminate the measurement, select "2 CLEAR".

l. To make another measurement, select "1 EXIT".
The menu returns to the original one.

DOPPLER ANALYSIS

Example of "CARDIO" measurement information display:

DDP No. 00	Number of measurements executed
+PK:00.79 m/s	Maximum flow velocity (velocity between base line and mark)
PPG:	Peak Pressure Gradient
001.3 mmHg	
XMN:00.00 m/s	Average value of instantaneous maximum velocity (average value traced by bright line)
MPG:	
000.0 mmHg	
T-PK:0.00 s	Time to peak
ACCEL:	Acceleration
00.00 m/s ²	
FL-T:0.00 s	Flow time
P1/2T:0.00 s	Pressure half time (calculated from mark-to-mark gradient)
M/TVA:	Mitral/tricuspid valve area
00.00 cm ²	
Result OK?	Usability of CARDIO measurement data as averaging (EN/ER) data

DOPPLER ANALYSIS

5.5 Cardiac Output Measurement

(Expression)

$$ET = t_e - t_s$$

$$SV = \left[\int V(t) dt \right] \times CSA \times 10^2$$

$$CSA = \pi / 4 \times (CSD)^2$$

$$CO = SV \times HR \div 10^3$$

(Abbreviations and units)

ET	:	Ejection Time (sec)
SV	:	Stroke Volume (ml)
V (t)	:	Mean Velocity (m/sec)
CSA	:	Cross Sectional Area (cm ²)
CSD	:	Cross Sectional Diameter (cm)
CO	:	Cardiac Output (l/min)
HR	:	Heart Rate (beat/min)

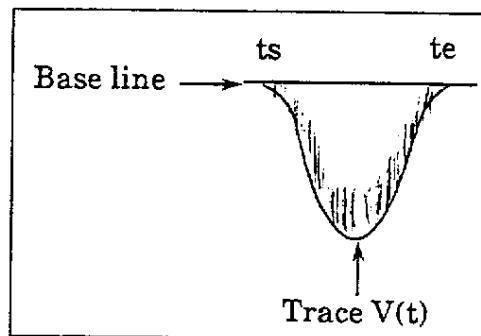


Fig. 5-5-1

- a. Display a left ventricular image as shown in the figure at the right (the plane that permits detecting Doppler information of the left ventricular outflow tract). Also display a spectrum for the end-systolic left ventricular outflow tract in Doppler mode.

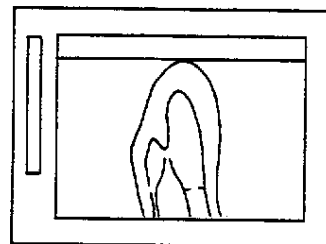


Fig. 5-5-2

Press the "MEASUREMENT" switch and select "NEXT" till the following menu is displayed:

MEASURE	1	2	3	4	5	6
D	CLEAR	CARDIO	SV/CO	PV	V.UNIT	NEXT

Select "3 SV/CO". The caliper mark "+" is displayed on the screen and the menu changes to the following:

SV/CO	1	2	3	4	5	6
	EXIT	HR	CSD			SET

- "2 HR" : When no ECG waveform is displayed, it is possible to input heart rate from the keyboard.
- "3 CSD" : It is possible to input the value of CSD from the keyboard.

DOPPLER ANALYSIS

- b. Move the mark to the trace starting point ("ts" in the figure) with the TRACKBALL.
- c. Press the MARK REF switch.

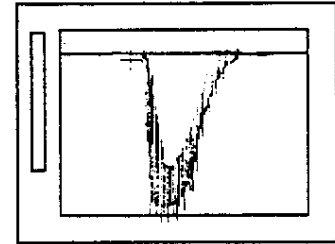


Fig. 5-5-3

- d. Trace the spectrum pattern of the LV systolic mean velocity (highest-brightness part).

NOTE: It is possible to erase the trace little by little from the end point by pressing and holding the MARK REF switch.

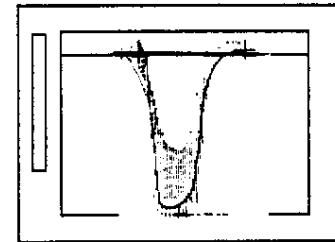


Fig. 5-5-4

- e. Press the MARK REF switch, and the ejection time is displayed.

Next, measure the left ventricular cross-sectional diameter either in B-mode or M-mode.

- f. Press the MODE switch "B" or "M".

(1) When B mode is selected:

- g. Display an LV long axis image.
- h. Press the " x " TRACKBALL FUNCTION switch.

NOTE: In the case of simultaneous display (e.g., B/D), move the "+" mark on the B-mode image.

- i. The "x" measurement mark is displayed. Position the mark at the starting point for the CSD measurement (at the level of the anterior aortic root).

Note: Care should be taken to make this measurement in the area of the maximum diameter. Press the MARK REF switch.

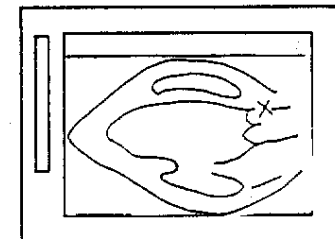


Fig. 5-5-5

- j. Position the mark at the end point for the CSD measurement.

CSD (Cross-Sectional Diameter), CSA (Cross Sectional Area) and SV (Stroke Volume) are displayed.

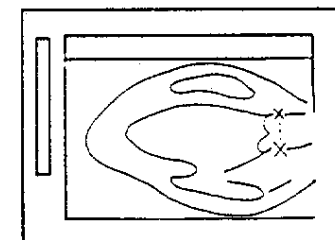


Fig. 5-5-6

DOPPLER ANALYSIS

NOTE: To correct the CSD value, select "3 CSD" and enter a numeric value from the keyboard. Then, select "6 SET".

Example 2.1 cm → Press 0 2 . 1
 10.0cm → Press 1 0 . 0

k. When an ECG is displayed, HR (Heart Rate) and CO (Cardiac Output) are automatically calculated and displayed.

When no ECG is displayed (or for correction), select "2 HR" and enter the heart rate from the keyboard. Then, select "6 SET".

l. To terminate the measurement, select "1 EXIT".

(2) To find an LV systolic cross sectional diameter via M-mode image:

m. Display an M-mode image.

n. Press the "x" TRACKBALL FUNCTION switch.

o. Move the "†" mark to the starting position to measure the systolic aortic diameter with the TRACKBALL.

p. Press the MARK REF switch.

q. Move the "†" mark to the end position of the systolic aortic diameter with the TRACKBALL.

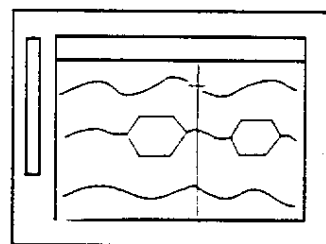


Fig. 5-5-7

CSD (Cross-Sectional Diameter), CSA (Cross-Sectional Area) and SV (Stroke Volume) are displayed.

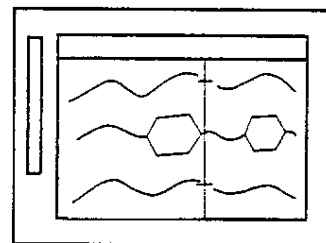


Fig. 5-5-8

NOTE: To correct the CSD value, select "3 CSD" and enter a numeric value from the keyboard. Then, select "6 SET".

r. When an ECG is displayed, HR (Heart Rate) and CO (Cardiac Output) are automatically calculated and displayed.

When no ECG is displayed (or for correction), select "2 HR" and enter the heart rate from the keyboard. Then, select "6 SET".

s. To terminate the measurement, select "1 EXIT".

Example of 'SV/CO' calculation information display:

SV/CO	
+ET:1.00s	Ejection time (seconds)
XCSD:00.2cm	Cross-sectional diameter of left ventricle outflow tract (aorta) (cm)
CSA:00.03cm ²	Cross sectional area of left ventricle outflow tract (aorta) (cm ²)
SV: 99ml	Stroke volume (milliliter)
HR: 60b/m	Heart rate (beat/minute)
CO: 5.93l/m	Cardiac output (liter/minute)

DOPPLER ANALYSIS

5.6 Peripheral Vascular Measurement (peripheral vascular blood flow measurement)

This measurement is suitable for obtaining the flow velocity of a peripheral vascular system such as an artery.

Two methods are available: Pulsatility Index method and Pourcelot Index method. The Pulsatility Index method measures the blood flow velocity by trace using a Doppler waveform. (See Fig. 5-6-1.) The Pourcelot Index method measures two blood flow velocities in blood flow. (See Fig. 5-6-2.)

* Pulsatility Index = $| (A - B) / \text{Average peak velocity} |$

* Pourcelot Index = $(|A| - |B|) / |A|$

A: Peak flow velocity 1 B: Peak flow velocity 2

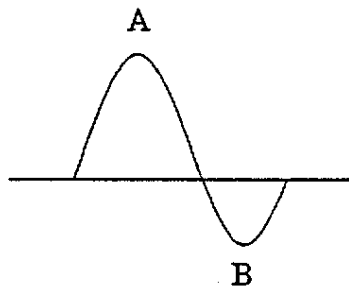


Fig. 5-6-1

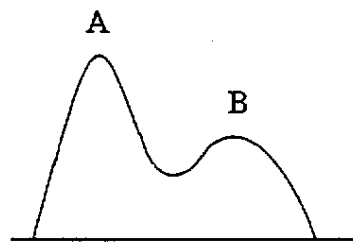


Fig. 5-6-2

1. Select D mode (B/D mode is also selectable) with the MODE switch (M for D mode and B/M for B/D mode), and display a Doppler pattern.

After displaying a Doppler pattern, press the MEASUREMENT switch, and select "6 NEXT" till the following menu appears. Then select "4 PV".

MEASURE	1	2	3	4	5	6
D	CLEAR	CARDIO	SV/CO	PV	V.UNIT	NEXT

2. The menu changes as follows:

PERIPHERAL	1	2	3	4	5	6
VASCULAR	EXIT	CLEAR	PULSA	POUR		

The two methods will be described separately.

DOPPLER ANALYSIS

5.6.1 PV measurement by Pulsatility Index method

- a. Select "3 PULSA". The caliper mark "+" for a Pulsatility Index measurement appears on the image. Move the mark to the trace starting point with the TRACKBALL, then press MARK REF switch.
- b. Trace the Doppler pattern clearly with the TRACKBALL.

After the trace comes to the ending point, press the MARK REF switch to complete the operation. Measurement result is displayed.

+

- c. To terminate the measurement, first select "1 EXIT". Then select "1 CLEAR". All the measurement marks and measurement results disappear.

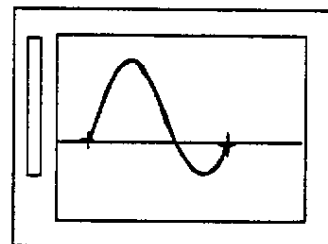


Fig. 5-6-3

5.6.2 PV measurement by Pourcelot Index method

- a. Select "4 POUR". The line mark for the Pourcelot Index measurement appears on the image.

Move the line mark to the maximum velocity point of the first peak of the Doppler pattern with the TRACKBALL then press the MARK REF switch.

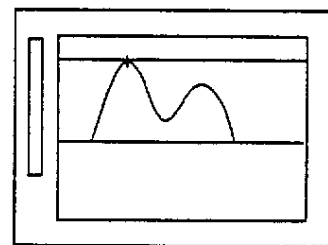


Fig. 5-6-4

- b. Press the MARK REF switch, and another line mark appears. Move the line mark to the second peak (or inverted peak) of the Doppler pattern with the TRACKBALL. The calculated value and measured value are automatically displayed.

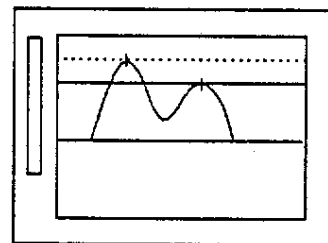


Fig. 5-6-5

- c. To terminate the measurement, first select "1 EXIT". Then select "2 CLEAR". All the measurement marks and measurement results are erased.

DOPPLER ANALYSIS

Description of measured values:

(Pulsatility Index)	(Pourcelot Index)	
PULS ID	POUR ID	
000.00	000.00	Stenotic rate
PK1:	PK1:	
00.00cm/s	00.00cm/s	Velocity at the first peak
PK2:	PK2:	
00.00cm/s	00.00cm/s	Velocity at the second peak
AV:		
00.00cm/s		Average velocity

DOPPLER ANALYSIS

5.7 Selection of Unit for Doppler Measurement

Unit of measurement result display and interval of the velocity mark may be changed by the following procedure:

- a. Select a display mode that includes a Doppler mode (e.g. B/PW). Press the **MEASUREMENT** switch to display the following menu:

MEASURE	1	2	3	4	5	6
D	CLEAR	VEL	ACCEL	AVE	V-UNIT	NEXT

- b. Select "5 V.UNIT" in the menu. The menu changes as follows;

VELOCITY	1	2	3	4	5	6
UNIT	EXIT	m/s	cm/s	kHz		

- c. Select the desired unit in the menu.
- d. To complete the selection, select "1 EXIT".

MEASUREMENTS ON PLAYBACK IMAGE

6. VTR PLAYBACK MEASUREMENT

To facilitate a diagnosis, it is convenient that each patient's ultrasound images be recorded beforehand via an optional video tape recorder (VTR). After completion of an examination, the various measurement functions provided in the SSD-650 can be performed on the played-back images.

NOTES:

(1) To perform measurements on played-back images, you must first record images on which no measurements are performed. Otherwise, the original marks and measurement results will be superimposed on the playback measurement results, causing both sets of data to be unreadable.

(2) Scale Calibration:

Before starting a measurement, be sure to perform the calibration.

There are two types of calibration: one for Aloka-650 images (See subsection 6.1.); and the other for images from other models (See subsection 6.2).

(3) When the following conditions are changed, the calibration is canceled. Redo the calibration.

PROBE
MODE
MAGNIFICATION
SWEEP SPEED

(4) Histogram measurement on played-back image is impossible.

MEASUREMENTS ON PLAYBACK IMAGE

6.1 Calibration for SSD-650 Played-back Images:

- a. Set the IMAGE switch to EXT.
- b. Play back the VTR.
- c. Press the B or M/D of FREEZE switch.

Press the stop switch (PAUSE or STILL) on the VTR. However, when "FRAME" of the VTR memory function is selected, perform the calibration in the playback mode.

- d. Press the MEASUREMENT switch.

The "CALIBRATION" menu is displayed.

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- e. Select "2 S-650". The menu changes as follows:

SYSTEM 650	1	2	3	4	5	6
	EXIT					SET

At the same time, calibration information is displayed on the upper left part of the screen. The status of equipment parameters just before setting the IMAGE switch to EXT will be displayed.

(Example of display and description)	
DATE	: 87/04/02 Date
TYPE	: A Probe code
MODE	: B Display mode of image
B-MAG	: MAG 1 B-mode display magnification factor or diagnostic range
M-MAG	: MAG 1 M-mode display magnification factor or diagnostic range
SWEEP	: 3 Sweep speed of M or D mode image
TOWARD FLOW	: 04.50 Velocity of the blood flow coming toward the probe (D mode)
AWAY FLOW	: 04.50 Velocity of the blood flow going away from the probe (D mode)

- f. Enter the date of the played-back image from the keyboard.

DATE : 87/04/20

Note: The date is necessary only for gestational age calculations. In cases other than gestational calculations, proceed to the next step.

- g. Select "6 SET" in the menu.

MEASUREMENTS ON PLAYBACK IMAGE

- h. Enter from the keyboard the probe code of the probe used at recording . For the probe code, refer to Table 6-1 in subsection 6.3.
- i. Select "6 SET" in the menu.

TYPE : A

NOTE: If you entered an alphabetic character that is not listed in the probe code table, the highlighted part will not shift to the next item when "6 SET" is selected. Enter a correct character.

The following explanation is made independently for mode B, M and D. See the individual instructions.

- * For simultaneous display mode (B/M, B/D), press the MODE switch suitable for the image mode to be calibrated.

(1) B-mode image calibration:

- a. Press the "B" of the MODE switch.

MODE : B

- b. Select "6 SET" in the menu.

- c. Press the **MAGNIFICATION** switch till the correct magnification factor is displayed. To find the magnification factor, see Table 6- 2 in subsection 6.3

B-MAG:MAG 2
(For electronic scan probe)
or
B-MAG:RNG 12
(For mechanical sector probe)

- d. Select "6 SET", and then select "1 EXIT" in the menu. The menu goes back to "CALIBRATION" menu.

MEASUR	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

B-mode calibration is now completed.

- e. Select "6 NEXT". The menu changes as follows;

MEASUR	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Now measurements are possible in the same manner as when performing real-time measurements.

(2) M-mode image calibration:

- a. Press the "M" of the MODE switch.

MODE : M

- b. Select "6 SET".

MEASUREMENTS ON PLAYBACK IMAGE

- c. Enter the display magnification factor with the **MAGNIFICATION** switch. For information about how to find the magnification factor, refer to Table 6-2.

M-MAG:MAG 2
 (For electronic scan probe)
 or
 M-MAG:RNG 12
 (For mechanical sector probe)

- d. Select "6 SET" in the menu.
- e. Set the SWEEP SPEED switch to enter the value.
- f. Select "6 SET" and then select "1 EXIT".
 The menu goes back to "CALIBRATION" menu.

SWEEP : X 2

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

M-mode CALIBRATION is now completed.

- g. Select "6 NEXT" in the menu.

After this, follow the same procedure as for each measurement.

(3) D-mode calibration:

NOTE: If "SV/CO" is selected in the Doppler measurements, reference paragraph (4) for detailed instructions.

- a. Press the MODE switch "PW" or "CW", according to the displayed pattern.

MODE: PW or CW

- b. Select "6 SET" in the menu.
- c. Set the SWEEP SPEED switch to enter the value.
- d. Select "6 SET" in the menu.
- e. Using the keyboard enter the velocity range of the toward flow.
- f. Select "6 SET" in the menu.
- g. Using the keyboard enter the velocity range of the away flow.

SWEEP : X 2

TOWARD FLOW : 04.50

AWAY FLOW : 04.50

- h. Select "6 SET" and then select "1 EXIT".
 The menu goes back to the "CALIBRATION" menu.

MEASUREMENTS ON PLAYBACK IMAGE

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- i. Select "6 NEXT". The menu changes as follows:

MEASURE	1	2	3	4	5	6
D	CLEAR	VEL	ACCEL	AVE		NEXT

Once again, select "6 NEXT".

- j. Select the number corresponding to the desired Doppler measurement. The base line mark (——) is displayed at the center of the screen.

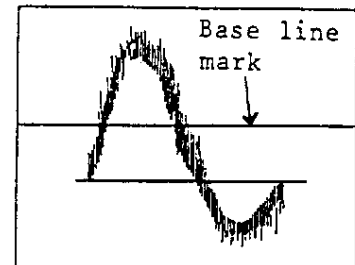


Fig. 6-1-1

- k. Adjust the base line mark to the displayed base line position using the TRACKBALL.

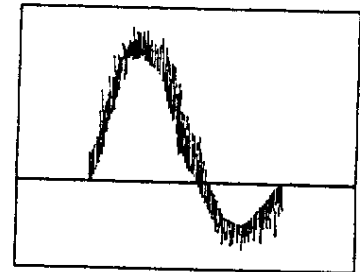


Fig. 6-1-2

- l. Select "6 SET" in the menu.
- 1.-1 When "SV/CO" has been selected, proceed to the next paragraph (4).
- 1.-2 In other cases, the D-mode calibration is completed. Follow the same procedure for each measurement.

Note 1: To correct any of the characters entered during calibration setting, you can move the highlighted part by selecting "6 SET". Then, enter the correct data again.

Note 2: If any great error in measurement is found, perform calibration for all the display modes, that is, B, M and D.

Note 3: Original characters on the VTR played-back image in the calibration data display area are not displayed.

MEASUREMENTS ON PLAYBACK IMAGE

- (4) When SV/CO is selected as a Doppler measurement:

Perform the following steps after D-mode calibration has already been completed (Reference Paragraph (3)).

- a. When "6 SET" is selected, the trace mark (+) is displayed in the center of the screen. Adjust the mark to the starting point for a Doppler spectrum measurement. Then, press the "MARK REF" switch.
- b. Trace the spectrum pattern using the TRACKBALL.
- c. If it is necessary to measure the aortic root diameter in systole, display a B or M mode image from the VTR and stop it.
- d. Press the " x " of TRACKBALL FUNCTION. Calibration information is displayed in the upper left part of the screen.
- e. Enter the mode by pressing MODE switch B or M.
- f. Enter B-MAG (or M-MAG) with the MAGNIFICATION switch.
- g. Select "6 SET" and then "1 EXIT". Then, measure the systolic aortic diameter.

Enter the value of CSD using the keyboard. It is the same with HR (heart rate).
- h. To complete the measurement, select "1 EXIT".

MEASUREMENTS ON PLAYBACK IMAGE

6.2 Calibration for played-back images from equipment other than the SSD-650.

6.2.1 B mode

- a. Set the IMAGE switch to EXT.
- b. Play back the VTR.
- c. Press the B or M/D FREEZE switch. Stop the VTR with the PAUSE or stop switch of the VTR. (However, when "FRAME" of VTR MEMORY function is selected, set the VTR to play mode).
- d. Press the "MEASUREMENT" switch to display the following menu:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- e. Select "3 CAL-B".

Calibration information will be displayed in the measurement information display area. The status just before setting the IMAGE switch to EXT will be displayed.

DATE: 87/09/20	Date
CALIBRAT-B	CALIBRATION name
CAL.H:	Horizontal calibration
CAL.V:	Vertical calibration

The menu changes as follows:

CALIBRATION	1	2	3	4	5	6
B	EXIT					SET

- f. Enter date of the played-back image from the keyboard.

DATE : 87/04/20

The date is used for obstetrical calculations. If no date is necessary, proceed to the next step.

- g. Select "6 SET" in the menu. The "+" mark is displayed in the center of the screen.

- h. Move the "+" mark to the end of the horizontal scale using the TRACKBALL.



Fig. 6-2-1

- i. Press the "MARK REF" switch.

- j. Adjust the "+" mark to the scale interval using the TRACKBALL.

- k. Enter the set value of the scale interval from the keyboard. For example, using the interval shown in Fig. 6-2-2 a "3" (3cm) would be inputted via the keyboard.

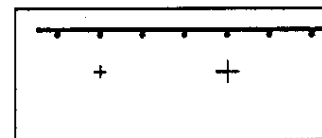


Fig. 6-2-2

MEASUREMENTS ON PLAYBACK IMAGE

- l. Select "6 SET".

"X" is displayed in the center of the screen.

Note: If "INV. MODE" is displayed in the message display area, enter the value again. Make sure that it is a correct value.

- m. Perform CAL.V (vertical calibration in the same way as CAL.H (horizontal calibration).

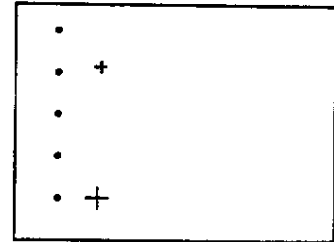


Fig. 6-2-3

- n. Enter the scale interval of CAL.V, and then select "6 SET".
- o. Select "1 EXIT". B-mode CALIBRATION is now completed.

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- p. Select "6 NEXT".

After this, follow the same procedure for each measurement.

MEASUREMENTS ON PLAYBACK IMAGE

6.2.2 M mode:

- a. Set the IMAGE switch to EXT.
- b. Play back the VTR.
- c. Press the B or M/D FREEZE switch. Then , press the PAUSE or stop switch on the VTR. (However, when "FRAME" of VTR MEMORY function is selected, set the VTR to play mode).
- d. Press the "MEASUREMENT" switch to display the following menu:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- e. Select "4 CAL-M".

CALIBRATION information will be displayed in the measurement information display area. The status before setting the VIDEO switch to EXT will also be displayed.

CALIBRAT-M Calibration name
 CAL.D: Vertical (distance) calibration
 CAL.T: Horizontal (time) calibration
 +:00.0 cm

At the same time, the "+" mark is displayed in the center of the screen. The menu changes as follows:

CALIBRATION	1	2	3	4	5	6
M	EXIT					SET

- f. Move the "+" mark to the end of the vertical scale using the TRACKBALL.

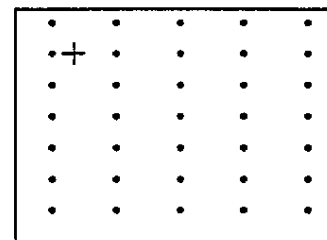


Fig. 6-2-4

- g. Press the TRACKBALL FUNCTION "MARK REF" switch.

- h. Adjust the "+" mark to the a scale interval by using TRACKBALL. For example, using the interval shown in Fig. 6-2-5, a "5" (for 5cm) would be inputted via the keyboard.

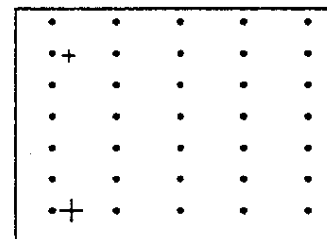


Fig. 6-2-5

- i. Enter the set value of the scale interval from the keyboard.

MEASUREMENTS ON PLAYBACK IMAGE

6.2.2 M mode:

- a. Set the IMAGE switch to EXT.
- b. Play back the VTR.
- c. Press the B or M/D FREEZE switch. Then , press the PAUSE or stop switch on the VTR. (However, when "FRAME" of VTR MEMORY function is selected, set the VTR to play mode).
- d. Press the "MEASUREMENT" switch to display the following menu:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- e. Select "4 CAL-M".

CALIBRATION information will be displayed in the measurement information display area. The status before setting the VIDEO switch to EXT will also be displayed.

CALIBRAT-M Calibration name
 CAL.D: Vertical (distance) calibration
 CAL.T: Horizontal (time) calibration
 +:00.0 cm

At the same time, the "+" mark is displayed in the center of the screen. The menu changes as follows:

CALIBRATION	1	2	3	4	5	6
M	EXIT					SET

- f. Move the "+" mark to the end of the vertical scale using the TRACKBALL.

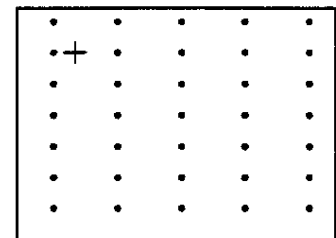


Fig. 6-2-4

- g. Press the TRACKBALL FUNCTION "MARK REF" switch.

- h. Adjust the "+" mark to the a scale interval by using TRACKBALL. For example, using the interval shown in Fig. 6-2-5, a "5" (for 5cm) would be inputted via the keyboard.

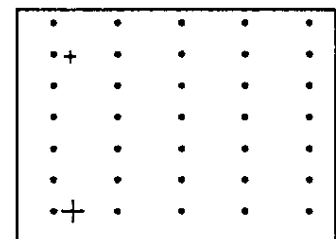


Fig. 6-2-5

- i. Enter the set value of the scale interval from the keyboard.

MEASUREMENTS ON PLAYBACK IMAGE

- j. Press "6 SET". "X" is displayed in the center of the screen.

CALIBRAT-M
 CAL.D: 0.1.0 cm
 CAL.T:

x:0.0 s

Note: If "Over Rng" is displayed in the message display area enter the value again. Make sure that the value is correct.

- k. Perform CAL.T (horizontal calibration) in the same way as CAL.D (vertical calibration).

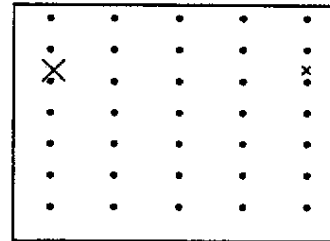


Fig. 6-2-6

- l. Enter the scale interval of CAL.T, and then select "6 SET".
- m. Select "1 EXIT". M-mode calibration is now completed. The menu changes as follows:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

NOTE: When CALIBRATION is completed after only CAL.T or CAL.D is executed, CALIBRATION is not set.

Be sure to perform both horizontal and vertical calibration.

- n. Select "6 NEXT".

After this, follow the same procedure for each measurement.

MEASUREMENTS ON PLAYBACK IMAGE

6.2.3 D mode:

- a. Set the IMAGE switch to EXT.
- b. Play back the VTR.
- c. Press the B or M/D FREEZE switch. Then , press the PAUSE or stop switch on the VTR. (However, when "FRAME" of VTR MEMORY function is selected, set the VTR to play mode.
- d. Press the "MEASUREMENT" switch to display the following menu:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

- e. Select "5 CAL-D".

CALIBRATION information will be displayed in the measurement information display area. The status before setting the IMAGE switch to EXT will also be displayed.

```

CALIBRATION-M  Calibration name
CAL.V:  Vertical (velocity) calibration
CAL.T:  Horizontal (time) calibration
+:00.0 cm
    
```

At the same time, the "+" mark is displayed in the center of the screen. The menu changes as follows:

CALIBRATION	1	2	3	4	5	6
D	EXIT					SET

- f. Move the "+" mark to the end of the vertical scale using the TRACKBALL.

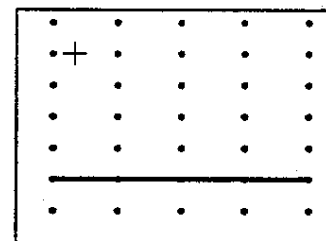


Fig. 6-2-7

- g. Press the TRACKBALL FUNCTION "MARK REF" switch.

- h. Adjust the "+" mark to the a scale interval by using TRACKBALL. For example, using the interval shown in Fig. 6-2-8, a "2" would be inputted via the keyboard.

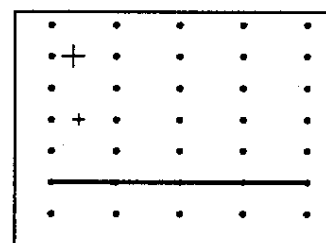


Fig. 6-2-8

- i. Enter the set value of the scale interval from the keyboard.

MEASUREMENTS ON PLAYBACK IMAGE

- j. Press "6 SET". "X" is displayed in the center of the screen.

CALIBRATION-D
 CAL.V: 01.00 m/sec
 CAL.T:
 x:0.0 s

Note: If "Over Rng" is displayed in the message display area, enter the value again. Make sure that the value is correct.

- k. Perform CAL.T (horizontal calibration) in the same way as CAL.D (vertical calibration).

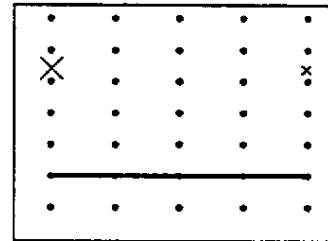


Fig. 6-2-9

- l. Enter the scale interval of CAL.T, and then select "6 SET".
- m. Select "1 EXIT" in the menu. The menu changes as follows:

MEASURE	1	2	3	4	5	6
	CLEAR	S-650	CAL-B	CAL-M	CAL-D	NEXT

NOTE: When CALIBRATION is completed after only CAL.T or CAL.D is executed, CALIBRATION is not set.
 Be sure to perform both horizontal and vertical calibration.

- n. Select "6 NEXT".
- o. Select the number corresponding to the desired Doppler measurement.
- The BASE LINE mark (——) is displayed in the center of the screen.
- o.-1 When "SV/CO" is selected, proceed to step "r."
- o.-2 When measurements other than "SV/CO" are selected, proceed to step "p" next.
- p. Adjust the BASE LINE mark to the displayed base line position using the TRACKBALL.
- q. Select "6 SET".
 Follow the same procedure as for general measurements.

Note: To correct any of the characters entered during CALIBRATION setting, you can move the highlighted part by selecting "6 SET".
 Then, enter the data again.

MEASUREMENTS ON PLAYBACK IMAGE

* Where SV/CO is selected as the Doppler measurement:

r. Adjust the BASE LINE mark (—) to the base line position of the played back image by using TRACKBALL.

s. Select "6 SET".

The trace mark (+) is displayed in the center of the screen. Adjust the mark to the starting point for a Doppler spectrum measurement. Then, press the "MARK REF" switch.

t. Trace the spectrum pattern using the TRACKBALL.

After completing the trace, press the "MARK REF" switch.

u. Press the TRACKBALL FUNCTION "x" switch.

CALIBRATION information will be displayed in the upper left part of the screen. The menu will change to:

SV/CO	1	2	3	4	5	6
MODE	B	M				SET

v. Select the mode to measure the systolic aortic diameter. Then select "6 SET".

If calibration has already been completed, the "x" mark will appear on the screen. If calibration has not been completed yet, calibration for the measurement mode will start.

For the contents of calibration, refer to the preceding description.

w. Measure the systolic aortic diameter.

The measured value is displayed automatically.

x. To complete the calibration, select "1 EXIT".

MEASUREMENTS ON PLAYBACK IMAGE

6.3 List of Parameters

(1) Probe Codes:

In case of linear and convex probe
Table 6-1

Probe code	Model No.
A	UST-5035-3.5 UST-5037P-3.5
B	UST-5036-3.5 UST-5018P-3.5 UST-5024-3.5 UST-939-3.5 UST-940-3.5 UST-941-3.5
C	UST-5038-5 UST-5814-5 UST-587T-5 UST-587I-5 UST-657-5 UST-545-5
D	UST-5512U-5 UST-5512U-7.5 UST-556TU-7.5 UST-556I-7.5 UST-5514U-7.5
E	UST-943-3.5
F	UST-944-3.5 UST-942-7.5 UST-932-3.5 UST-937U-5 UST-936-3.5
G	UST-932-7.5 UST-938PU-5 UST-936-5 UST-936-7.5 UST-932-5 UST-945P-5

In case of Sector probe
Table 6-2

Probe code	Model No.
S	ASU-32-3 ASU-32-3.5 ASU-32-5 ASU-32WL-7.5 ASU-32WN-7.5 ASU-32WSJ-7.5 ASU-32H-2.3 ASU-32H-3.5 ASU-32CWD-2 ASU-32CWD-3 ASU-32CWD-5 Independent probe (UST-2263-2/3) Static probe (UST-2234B-2.25-7.5R)

MEASUREMENTS ON PLAYBACK IMAGE

- (2) How to find the magnification factor from the vertical scale mark of image by linear or convex probe

Table 6-3 When in single or dual image display:

Magnification factor	MAG 0.7	MAG 1	MAG 1.5	MAG 2
UST-5035-3.5	22.1	16.6	11.1	7.4
UST-5036-3.5	25.3	17.0	11.3	8.5
UST-5038-5	19.5	13	8.6	6.5
UST-5814-5	19.5	13	8.7	6.5
UST-5037P-3.5	22.2	16.6	11.1	7.4
UST-5018P-3.5	25.0	17.0	11.4	8.5
UST-5512U-5	12.3	8.9	6.6	4.4
UST-5512U-7.5	11.9	7.9	5.3	4
UST-556TU-7.5	11.9	7.9	5.3	4
UST-5561-7.5	11.9	7.9	5.3	4
UST-587T-5	19.5	13	8.7	6.5
UST-587I-5	19.5	13	8.7	6.5
UST-657-5	19.5	13	8.7	6.5
UST-545-5	19.5	13	8.7	6.5
UST-556T-7.5	12.3	8.9	6.6	4.4
UST-939-3.5	24.6	16.1	10.5	7.6
UST-940-3.5	24.6	16.1	10.6	7.8
UST-941-5	25.0	16.5	10.9	8.0
UST-943-3.5	18.0	14.8	11.8	8.7
UST-944-3.5	17.8	11.7	7.6	5.5
UST-932-3.5	18.2	12.1	7.9	5.9
UST-932-7.5	11.6	7.6	5.0	3.7
UST-937U-5	17.8	11.7	7.6	5.6
UST-938PU-5	11.6	7.6	5.0	3.7
UST-936-3.5	18.2	12.1	7.9	5.9
UST-936-5	11.6	7.7	5.0	3.7
UST-936-7.5	11.6	7.6	5.0	3.7

(Unit in cm)

MEASUREMENTS ON PLAYBACK IMAGE

Table 6-4

Magnification factor	MAG 0.7	MAG 1	MAG 1.5	MAG 2
UST-5035-3.5	10.8	8.1	5.3	3.6
UST-5036-3.5	12.4	8.3	5.5	4.1
UST-5038-5	9.5	6.3	4.2	3.2
UST-5814-5	9.5	6.3	4.2	3.2
UST-5037P-3.5	10.8	8.1	5.4	3.6
UST-5018P-3.5	12.4	8.2	5.5	4.1
UST-5512U-5	6.5	4.3	3.2	2.1
UST-5512U-7.5	5.8	3.9	2.6	1.9
UST-556TU-7.5	5.8	3.9	2.6	1.9
UST-5561-7.5	5.8	3.9	2.6	1.9
UST-587T-5	8.5	6.3	4.2	3.2
UST-5871-5	9.5	6.4	4.2	3.2
UST-657-5	9.5	6.4	4.2	3.2
UST-545-5	9.5	6.4	4.2	3.2
UST-556T-7.5	6.5	4.3	3.2	2.1
UST-939-3.5	11.5	7.3	4.6	3.3
UST-940-3.5	11.7	7.6	4.8	3.5
UST-941-5	11.8	7.7	5.0	3.7
UST-943-3.5	8.5	6.9	5.4	4.0
SUT-944-3.5	8.3	5.3	3.3	2.3
UST-932-3.5	8.7	5.7	3.7	2.7
UST-932-7.5	5.5	3.6	2.3	1.7
UST-937U-5	8.3	5.3	3.4	2.4
UST-938PU-5	5.5	3.6	2.3	1.7
UST-936-3.5	8.7	5.7	3.7	2.7
UST-936-5	5.5	3.6	2.3	1.7
UST-936-7.5	5.5	3.6	2.3	1.7

(Unit in cm)

MEASUREMENTS ON PLAYBACK IMAGE

- (3) How to find magnification factor of image with a mechanical sector image:

B-mode image:

Enter the numeric value displayed on the screen (e.g. RNG: 15) from the keyboard.

M or D mode image:

Read the length of range mark displayed on the screen and enter the numeric value from the keyboard.



APPENDIX A

ULTRASOUND ACOUSTIC OUTPUT DATA

As recommended by the AIUM and NEMA, "Use of Minimum Acoustical Exposure is Prudent". The acoustic measurements contained in this appendix were made with the ultrasound system set to the maximum output per mode used. Measurements were obtained in water following the procedure outlined by the AIUM/NEMA Safety Standard for Diagnostic Ultrasound Equipment (UL1-1981). The in-situ intensities provided are estimated from the intensity measured in water, the focal distance and the acoustic frequency of the transducer as described in the U.S. Food and Drug Administration 510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices.

Notes:

- 1) Use the Power Control Knob to reduce acoustic power to that level that provides satisfactory imaging performance.
- 2) Do not place the transducer on the patient any longer than necessary.
- 3) The acoustic characteristics presented for the individual transducers in this appendix are absolute maximum values. Operation at settings other than those listed will produce lower acoustic outputs.

Caution: THESE TRANSDUCERS ARE NOT TO BE USED FOR FETAL APPLICATIONS.

A. DEFINITIONS:

INTENSITY: The instantaneous acoustic power transmitted in the direction of acoustic wave propagation, per unit area normal to this direction at the point measured.

SPTA: (SPATIAL PEAK - TEMPORAL AVERAGE INTENSITY)

The value of the temporal average intensity at the point in the acoustic field where the temporal average intensity is a maximum.

SPPA: (SPATIAL PEAK - PULSE AVERAGE INTENSITY)

The value of the pulse average intensity at the point in the acoustic field where the pulse average intensity is a maximum.

IM: (MAXIMUM INTENSITY)

The ultrasound intensity at the spatial maximum averaged temporally over the pulse half-cycle having the greatest temporal average intensity.

In-situ intensities are estimated from the intensity measured in water, the measurement depth, and the acoustic frequency using the formula below:

$$I(\text{in-situ}) = I(\text{water}) \exp(-0.069 fz)$$

f = acoustic frequency in megahertz

z = Focal distance in centimeters

SAFETY OF ULTRASOUND STATEMENT

AIUM STATEMENT ON CLINICAL SAFETY

OCTOBER 1982, REVISED MARCH 1983 and OCTOBER 1983

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

DIAGNOSTIC ULTRASOUND IMAGING IN PREGNANCY

National Institutes of Health
Consensus Development Conference
Consensus Statement

Volume 5 Number 1



Introduction

From crude initial studies in the 1950s, ultrasonography in pregnancy has become a highly developed technology capable of detecting many fetal structural and functional abnormalities. It has found application in detecting ectopic pregnancy and multiple pregnancy, assessing fetal life and function, diagnosing physical anomalies, and guiding physicians as they make efforts to treat the fetal patient. The advent of ultrasound has overcome many of the diagnostic limitations of X-ray and has virtually eliminated the need for fetal exposure to ionizing radiation.

With these advantages and marked improvements in the technology and equipment, the use of ultrasound in obstetric practice has grown rapidly. The procedure is available in nearly all hospitals, and many physicians have acquired equipment for use in their offices. Further, because of the absence of clinically perceived risk of ultrasound and its usefulness in assessing structural anomalies, multiple pregnancy, and fetal size and gestational age, many practitioners have begun to advocate its routine use as a screening device in all pregnancies.

Lack of risk has been assumed because no adverse effects have been demonstrated clearly in humans. However, other evidence dictates that a hypothetical risk must be presumed with ultrasound. Likewise, the efficacy of many uses of ultrasound in improving the management and outcome of pregnancy also has been assumed rather than demonstrated, especially its value as a routine screening procedure.

The marked increase in the use of ultrasound, coupled with concerns regarding its safety and efficacy, prompted three NIH components - the National Institute of Child Health and Human Development (NICHD), the Office of Medical Applications of Research (OMAR), and the Division of Research Resources (DRR) - and the FDA National Center for Devices and Radiological Health to join in sponsoring a Consensus Development Conference to assess the use of diagnostic ultrasound imaging in pregnancy. The conference was held on February 6-8, 1984, after a year of preparation by the panel. After presenting a preliminary report at the conference, hearing the testimony of experts, and receiving comments and criticisms from the medical/scientific community, as well as from the public at large, the panel, consisting of physicians, basic scientists, epidemiologists, nurses,

educators, sonographers, and public representatives, considered all of the information received and provided answers to the following questions that were posed to the panel:

1. What types of ultrasound scanning are currently used in obstetric practice? How extensive is this use? What is known about the dose/exposure to the fetus and the mother from each type?
2. For what purposes is ultrasound now used in pregnancy? For each use, what is the evidence that ultrasound improves patient management and/or outcome of pregnancy?
3. What are the theoretical risks of ultrasound to the fetus and the mother? What evidence exists from animal, tissue culture, and human studies on the actual extent of the risk?
4. Based on the available evidence, what are the appropriate indications for, and limitations on, the use of ultrasound in obstetrics today?
5. What further studies are needed of efficacy and safety of use of ultrasound in pregnancy?

The National Institutes of Health urges that this consensus statement be posted, duplicated, and distributed to interested staff.

1.

What types of ultrasound scanning are currently used in obstetric practice? How extensive is this use? What is known about the dose/exposure to the fetus and the mother from each type?

On the basis of the collective experience of members of the panel, the material presented, and the literature review that was conducted, we conclude that in obstetric practice in the United States, use of diagnostic ultrasound imaging has an expanding role, and its use is becoming widespread. Information on the extent of use of diagnostic ultrasound in pregnancy was available from single institutions and states, marketing studies, the office survey conducted by the American College of Obstetricians and Gynecologists, and the 1980 National Natality Survey. These data lead to estimates of the percentage of pregnant women exposed to at least one ultrasound examination ranging from a low of 15 percent to a high of 40 percent. There is reason to believe that all of these data sources seriously underestimate the true extent of exposure to ultrasound since they do not necessarily include exposure via Doppler devices, including those used to listen to fetal heart tones and in antepartum and intrapartum fetal heart rate monitoring.

Exposure to imaging devices in the recent past has been to static scanners, real-time equipment of the linear array type, and mechanical sector scanners. The quantity used most often to report instrumentation output is

intensity. Typical time average value ranges of intensity are 0.1-60 mW/cm² (spatial average, temporal average intensity) and 1-200 mW/cm² (spatial peak, temporal average intensity). The spatial peak, pulse average intensity typically ranges from 1-200 W/cm² for such pulsed ultrasound equipment.

The time average intensities of the typical obstetrical Doppler devices used to listen to the fetal heart and for fetal heart rate monitoring in the antepartum and intrapartum period are within the same range as for pulsed equipment. These systems operate in the continuous wave mode, viz, 0.2-20 mW/cm² (spatial average, temporal average intensity) and 0.6-80 mW/cm² (spatial peak, temporal average intensity). As new technologies and applications evolve, for example, measurement of blood flow using pulsed Doppler, exposure levels may be substantially higher.

Manufacturers of ultrasound equipment introduced into U.S. commerce are required to report outputs to the FDA. We recommend that these quantities be measured and reported to the user in a form consistent with the requirements of the AIUM/NEMA Safety Standard for Diagnostic Ultrasound Equipment.

Dose is a quantitative measure of an agent that is given or imparted and combines quantities such as intensity and exposure time. No dose quantity has been identified for ultrasound. Variation in tissue properties between individuals as well as scanning conditions influence dose in

an unpredictable way. For all practical purposes, fetal dose cannot be quantitated precisely. For this reason, there are no data on the dose to either the mother or the fetus in the clinical setting. Documentation of dwell time and type of machine and transducer used would begin to address this problem. It is recommended that at least this specific exposure information be recorded for each examination. Thus, it is important that each exposure to ultrasound by all Doppler and imaging devices be recorded.

2.

For what purposes is ultrasound now used in pregnancy? For each use, what is the evidence that ultrasound improves patient management and/or outcome of pregnancy?

Ultrasound has been used in a wide variety of clinical situations to aid in managing pregnancy. For each of these applications, there is literature recording the clinical experience from various centers, with evidence of benefits ultrasound has had in each respective application, although these applications have not been subjected to the rigorous evaluation provided by a randomized, controlled clinical trial. The following should not be considered circumstances in which use of diagnostic ultrasound imaging is mandatory. Rather, where significant clinical questions exist, the resolution of which would alter the remainder of prenatal care, ultrasound can be of benefit for:

- Estimation of gestational age for patients with uncertain clinical dates, or verification of dates for patients who are to undergo scheduled elective repeat cesarean

delivery, indicated induction of labor, or other elective termination of pregnancy.

Ultrasonographic confirmation of dating permits proper timing of cesarean delivery or labor induction to avoid premature delivery.

- Evaluation of fetal growth (e.g., when the patient has an identified etiology for uteroplacental insufficiency, such as severe pre-eclampsia, chronic hypertension, chronic renal disease, severe diabetes mellitus, or for other medical complications of pregnancy where fetal malnutrition, i.e., IUGR or macrosomia, is suspected). Following fetal growth permits assessment of the impact of a complicating condition on the fetus and guides pregnancy management.
- Vaginal bleeding of undetermined etiology in pregnancy. Ultrasound often allows determination of the source of bleeding and status of the fetus.
- Determination of fetal presentation when the presenting part cannot be adequately determined in labor or the fetal presentation is variable in late pregnancy. Accurate knowledge of presentation guides management of delivery.
- Suspected multiple gestation based upon detection of more than one fetal heartbeat pattern, or fundal height larger than expected for dates, and/or prior use of fertility drugs. Pregnancy

management may be altered in multiple gestation.

- Adjunct to amniocentesis. Ultrasound permits guidance of the needle to avoid the placenta and fetus, to increase the chance of obtaining amniotic fluid, and to decrease the chance of fetal loss.
- Significant uterine size/clinical dates discrepancy. Ultrasound permits accurate dating and detection of such conditions as oligohydramnios and polyhydramnios, as well as multiple gestation, IUGR, and anomalies.
- Pelvic mass detected clinically. Ultrasound can detect the location and nature of the mass and aid in diagnosis.
- Suspected hydatidiform mole on the basis of clinical signs of hypertension, proteinuria, and/or the presence of ovarian cysts felt on pelvic examination or failure to detect fetal heart tones with a Doppler ultrasound device after 12 weeks. Ultrasound permits accurate diagnosis and differentiation of this neoplasm from fetal death.
- Adjunct to cervical cerclage placement. Ultrasound aids in timing and proper placement of the cerclage for patients with incompetent cervix.
- Suspected ectopic pregnancy or when pregnancy occurs after tuboplasty or prior ectopic gestation. Ultrasound is a valuable

diagnostic aid for this complication.

- Adjunct to special procedures, such as fetoscopy, intrauterine transfusion, shunt placement, in vitro fertilization, embryo transfer, or chorionic villi sampling. ultrasound aids instrument guidance that increases safety of these procedures.
- Suspected fetal death. Rapid diagnosis enhances optimal management.
- Suspected uterine abnormality (e.g., clinically significant leiomyomata, or congenital structural abnormalities, such as bicornuate uterus or uterus didelphys, etc.). Serial surveillance of fetal growth and state enhances fetal outcome.
- Intrauterine contraceptive device localization. Ultrasound guidance facilitates removal, reducing chances of IUD-related complications.
- Ovarian follicle development surveillance. This facilitates treatment of infertility.
- Biophysical evaluation for fetal well-being after 28 weeks of gestation. Assessment of amniotic fluid, fetal tone, body movements, breathing movements, and heart rate patterns assists in the management of high-risk pregnancies.
- Observation of intrapartum events (e.g., version/extraction of second twin, manual removal of placenta, etc.). These procedures may be done more safely with the visualization provided by ultrasound.

- Suspected polyhydramnios or oligohydramnios. Confirmation of the diagnosis is permitted, as well as identification of the cause of the condition in certain pregnancies.
- Suspected abruptio placentae. Confirmation of diagnosis and extent assists in clinical management.
- Adjunct to external version from breech to vertex presentation. The visualization provided by ultrasound facilitates performance of this procedure.
- Estimation of fetal weight and/or presentation in premature rupture of membranes and/or premature labor. Information provided by ultrasound guides management decisions on timing and method of delivery.
- Abnormal serum alpha-fetoprotein value for clinical gestational age when drawn. Ultrasound provides an accurate assessment of gestational age for the AFP comparison standard and indicates several conditions (e.g., twins, anencephaly) that may cause elevated AFP values.
- Followup observation of identified fetal anomaly. Ultrasound assessment of progression or lack of change assists in clinical decision-making.
- Followup evaluation of placenta location for identified placenta previa.
- History of previous congenital anomaly. Detection of recurrence may be permitted, or psychological benefit to patients may result from reassurance of no recurrence.
- Serial evaluation of fetal growth in multiple gestation. Ultrasound permits recognition of discordant growth, guiding patient management and timing of delivery.
- Evaluation of fetal condition in late registrants for prenatal care. Accurate knowledge of gestational age assists in pregnancy management decisions for this group.

The information presented in the material reviewed by the panel, including the studies of Bennett, Eik-Nes, Bakkeiteig, Grennert, and others, allowed no consensus that routine ultrasound examinations for all pregnancies improved perinatal outcome or decreased morbidity or mortality. There was, however, evidence that there was a higher rate of detection of twins and congenital malformations, as well as more accurate dating of pregnancy, but without significant evidence of improved outcome. The evidence with respect to the number of antepartum days of hospitalization and induction rates was contradictory among trials. The data on perinatal outcome were inconclusive. The panel recognized the inadequacy of the clinical trials on which these conclusions are drawn. Furthermore, it is acutely aware of the difficulty associated with conducting ideally controlled clinical trials and the large numbers of patients that must be included

to uncover differences between control and experimental groups, where a morbid event occurs infrequently and spontaneously in the control population.

The panel concludes that diagnostic ultrasound for pregnant women improves patient management and pregnancy outcome when there is an accepted medical indication. Randomized, controlled clinical trials would be the best way in the United States to determine the efficacy of routine screening of all pregnancies.

3.

What are the theoretical risks of ultrasound to the fetus and the mother? What evidence exists from animal, tissue culture, and human studies on the actual extent of the risk?

The panel conducted an extensive review of the primary literature on this subject and of reports by the Bureau of Radiological Health (1976), Food and Drug Administration (1982), World Health Organization (1982), and the National Council on Radiation Protection and Measurements (1984).

A number of epidemiological studies tend to support the safety of diagnostic ultrasound exposure in humans. In particular, in the three randomized clinical trials in which half of the women were exposed routinely to ultrasound, there was no association of routine ultrasound exposure with birth weight. In the two studies that addressed the subject, no association of ultrasound exposure with hearing loss was observed. On the other hand, many of the studies reporting on the safety of diagnostic ultrasound in humans were considered inadequate to

address many other important issues because of technical problems in conducting such research.

Some of the more than 35 published animal studies suggest that in utero ultrasound exposure can affect prenatal growth. When teratological effects have been found, energies capable of causing significant hyperthermia have usually existed.

A number of biological effects have been observed following ultrasound exposure in various experimental systems. These include reduction in immune response, change in sister chromatid exchange frequencies, cell death, change in cell membrane functions, degradation of macromolecules, free radical formation, and reduced cell reproductive potential. It should be noted that (a) some of the studies employed energy levels greater than would be expected to exist in clinical use; (b) in vitro exposure conditions to ultrasound used in many of the experiments are hard to place in perspective for risk assessment; (c) some of the observations, for example, sister chromatid exchange frequency changes and induction of chromosomal abnormalities, have not been reproducible, tending to refute the original findings. Nevertheless, some of the reported effects cannot be ignored or overlooked and deserve further study as outlined in our answer to Question 5. The existence of these studies is one of the factors that contributed to our decision that routine ultrasound screening cannot be recommended at this time.

4.

Based on the available evidence, what are the appropriate indications for, and the limitations on, use of ultrasound in obstetrics today?

From the body of information reviewed, taking into account the available bioeffects literature, data on clinical efficacy, and with concern for psychosocial, economic, and legal/ethical issues, it is the consensus of the panel that ultrasound examination in pregnancy should be performed for a specific medical indication. The data on clinical efficacy and safety do not allow a recommendation for routine screening at this time.

Ultrasound examinations performed solely to satisfy the family's desire to know the fetal sex, to view the fetus, or to obtain a picture of the fetus should be discouraged. In addition, visualization of the fetus solely for educational or commercial demonstrations without medical benefit to the patient should not be performed.

Prior to an ultrasound examination, patients should be informed of the clinical indication for ultrasound, specific benefit, potential risk, and alternatives, if any. In addition, the patient should be supplied with information about the exposure time and intensity, if requested. A written form may expedite this process in some cases. Patient access to educational materials regarding ultrasound is strongly encouraged. All settings in which these examinations are conducted should assure patients' dignity and privacy.

Given that the full potential of diagnostic ultrasound imaging is critically dependent on examiner training and experience, the panel recommends minimum training requirements and uniform credentialing for all physicians and sonographers performing ultrasound examinations. All health care providers who use this modality should demonstrate adequate knowledge of the basic physical principles of ultrasound, equipment, recordkeeping requirements, indications and safety.

5.

What further studies are needed of efficacy and safety of use of ultrasound in pregnancy?

It is critical, in view of the existing data and the special considerations affecting fetal and embryonic development, to encourage and support a sustained research effort aimed specifically at test systems that can help provide a better data base for developing reasonable estimates of bioeffects and of risk. In particular, we recommend:

1. The study of fundamental mechanisms leading to bioeffects.
2. Laboratory experiments that focus especially on those cellular processes that are most likely to be affected during embryonic and fetal development.
3. Postnatal studies in animals after in utero exposure to ultrasound.
4. Exploration of interactions between administered ultrasound and such developmentally significant agents as drugs, nutrition, ionizing radiation, hyperthermia, and hypoxia.
5. Development of improved dosimetry.

A long-term followup of infants involved in a randomized clinical trial would help clarify questions about the effect of ultrasound on development in humans, and other epidemiologic studies using a wide variety of methods should be considered. Studies of the psychosocial, ethical, and legal aspects of ultrasound use are also needed.

Further nonexperimental studies that seek to establish the clinical efficacy of ultrasound should address the question of its contribution to reducing morbidity and mortality. Randomized, controlled clinical trials of routine ultrasound screening in pregnancy should be conducted in the United States.

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INTENDED DIAGNOSTIC USES

Based on the final rules of the Food and Drug Administration published in the Federal Register (42 F.R. 42.528) January 1978.

A = Abdominal
C = Cardiac
F = Fetal
P = Pediatric
S = Small Parts
PV = Peripheral Vessel
O = Other

Other: Veterinarian
 Transvaginal
 Transesophageal
 Transrectal
 Transurethral
 Neonatal Cephalic
 Adult Cephalic
 Prostate

SSD-650 ACOUSTIC OUTPUT DATA

CAUTION: SOME TRANSDUCERS ARE NOT FOR FETAL APPLICATIONS
(SEE INTENDED USE SECTION BELOW)

<u>TRANSDUCER</u>	<u>INTENDED USE</u>	<u>MODE</u>	<u>WATER</u>	<u>ESTIMATED IN-SITU</u>		
			SPTA (mW/cm ²)	SPTA (mW/cm ²)	SPPA (W/cm ²)	IM (W/cm ²)
UST-657-5 Frequency: 5.0MHz Focal Length: 4.0cm	Transrectal	B-Mode	10	3.5	190	310
		B/M-Mode	110	36	190	310
		M-Mode	71	24	190	310
UST-5036-3.5 Frequency: 3.5MHz Focal Length: 5.7cm	Fetal Abdominal	B-Mode	14	3.6	190	230
		B/M-Mode	140	35	190	230
		M-Mode	100	26	190	230
UST-941-5 Frequency: 5.0MHz Focal Length: 3.8cm	Fetal Abdominal	B-Mode	14	46	150	220
		B/M-Mode	110	37	150	220
		M-Mode	76	25	150	220
UST-945P-5 Frequency: 5.0MHz Focal Length: 3.2cm	Transvaginal	B-Mode	18	6.2	69	72
		B/M-Mode	49	17	69	72
		M-Mode	30	10	69	72
UST-943-3.5 Frequency: 3.5MHz Focal Length: 5.0cm	Other	B-Mode	5.5	1.7	67	57
		B/M-Mode	39	12	67	57
		M-Mode	31	9.6	67	57
ASU-32CWD-2 Frequency: 2.0MHz Focal Length: 3.6cm	Cardiac	B-Mode	1.7	1.1	18	25
		M-Mode	16	10	18	25
ASU-32CWD-3 Frequency: 3.0MHz Focal Length: 4.3cm	Fetal	B-Mode	9.7	4.1	100	230
	Other	M-Mode	99	42	100	230
ASU-32WSJ-7.5 Frequency: 7.5MHz Focal Length: 1.4cm	Peripheral Vessel	B-Mode	0.64	0.31	39	58
		M-Mode	12	5.5	39	58
UST-5035-3.5 Frequency: 3.5MHz Focal Length: 6.2cm	Fetal	B-Mode	5.0	1.2	120	120
	Other	B/M-Mode	88	20	120	120
		M-Mode	68	16	120	120

SSD-650 ACOUSTIC OUTPUT DATA

CAUTION: SOME TRANSDUCERS ARE NOT FOR FETAL APPLICATIONS
(SEE INTENDED USE SECTION BELOW)

<u>TRANSDUCER</u>	<u>INTENDED USE</u>	<u>MODE</u>	<u>WATER</u>	<u>ESTIMATED IN-SITU</u>		
			<u>SPTA</u> (mW/cm ²)	<u>SPTA</u> (mW/cm ²)	<u>SPPA</u> (W/cm ²)	<u>IM</u> (W/cm ²)
ASU-32H-3.5 Frequency: 3.5MHz Focal Length: 8.9cm	Fetal	B-Mode	1.6	0.22	9.8	22
		M-Mode	22	2.9	7.3	17
UST-939-3.5 Frequency: 3.5MHz Focal Length: 6.8cm	Fetal	B-Mode	3.0	0.95	60	53
		B/M-Mode	24	7.1	39	39
		M-Mode	17	5.1	39	39
UST-556TU-7.5 UST-556T-7.5 UST-556I-7.5 Frequency: 7.5MHz Focal Length: 2.0cm	Peripheral	B-Mode	1.9	0.71	61	67
	Vessel	B/M-Mode	22	8.2	61	67
		M-Mode	11	4.3	61	67
UST-660-7.5 Frequency: 7.5MHz Focal Length: 2.0cm	Other	B-Mode	1.9	0.71	61	67
		B/M-Mode	22	8.2	61	67
		M-Mode	11	4.3	61	67
UST-5038-5 Frequency: 5.0MHz Focal Length: 3.8cm	Fetal	B-Mode	1.8	0.54	51	54
	Abdominal	B/M-Mode	29	8.7	51	54
	Other	M-Mode	15	4.6	51	54
ASU-32-3 Frequency: 3.0MHz Focal Length: 4.4cm	Cardiac	B-Mode	3.9	1.4	45	100
	Fetal Other	M-Mode	58	21	45	100
ASU-32-3.5 Frequency: 3.5MHz Focal Length: 5.5cm	Cardiac	B-Mode	2.5	0.56	23	50
	Fetal Other	M-Mode	40	8.7	23	50

ALL VALUES STATED ARE THE ABSOLUTE MAXIMUM OUTPUT

DOPPLER OPTION ACOUSTIC OUTPUT DATA

Caution: These transducers are not for fetal applications when using the SSD-650 option.

<u>TRANSDUCER</u>	<u>MODE</u>	<u>SETTINGS</u>	<u>WATER</u>	<u>ESTIMATED IN-SITU</u>		
			SPTA (mW/cm ²)	SPTA (mW/cm ²)	SPPA (W/cm ²)	IM (W/cm ²)
ASU-32CWD-3 Frequency: 3.0MHz Focal Length: 3.2cm	Pulsed Wave	Sample Volume: 3mm PRF: 19.2KHz	620	280	4.0	4.5
	Continuous Wave Doppler		180	91	/	0.097
ASU-32CWD-2 Frequency: 2.0MHz Focal Length: 2.9cm	Pulsed Wave	Sample Volume: 10mm PRF: 19.2KHz	630	390	4.3	4.3
	Continuous Wave Doppler		330	240	/	0.24
ASU-32WSJ-7.5 Imaging frequency: 7.5MHz Doppler frequency: 5.0MHz Focal Length: 1.4cm	Pulsed Wave	Sample Volume: 10mm PRF: 19.2KHz	850	490	4.5	13
ASU-32-3 Frequency: 3.0MHz Focal Length: 4.0cm	Pulsed Wave	Sample Volume: 10mm PRF: 19.2KHz	440	140	1.5	1.7

ALL VALUES STATED ARE THE ABSOLUTE MAXIMUM ACOUSTIC OUTPUT

DOPPLER OPTION ACOUSTIC OUTPUT DATA

Caution: These transducers are not for fetal applications when using the SSD-650 option.

<u>TRANSDUCER</u>	<u>MODE</u>	<u>SETTINGS</u>	<u>WATER</u>	<u>ESTIMATED IN-SITU</u>		
			SPTA (mW/cm ²)	SPTA (mW/cm ²)	SPPA (W/cm ²)	IM (W/cm ²)
ASU-32-3.5 Frequency: 3.5MH Focal Length: 3.6cm	Pulsed Wave Doppler Continuous Wave Doppler	Sample Volume: 10mm PRF: 19.2KHz	170	69	0.73	0.81
ASU-32H-3.5 Frequency: 3.5MHz Focal Length: 8.3cm	Pulsed Wave Continuous Wave Doppler	Sample Volume: 10mm PRF: 19.2KHz	150	37	0.40	0.46
ASU-32H-5 Frequency: 5.0MHz Focal Length: 5.7cm	Pulsed Wave Continuous Wave Doppler	Sample Volume: 10mm PRF: 4.2KHz	150	21	1.0	1.3
Imaging frequency: Doppler frequency: Focal Length:	Pulsed wave	Sample Volume: PRF:				
Frequency: Focal Length:	Pulsed Wave	Sample Volume: PRF:				
Frequency: Focal Length:	Pulsed Wave	Sample Volume: PRF:				

ALL VALUES STATED ARE THE ABSOLUTE MAXIMUM ACOUSTIC OUTPUT



APPENDIX B

SSD-650

This appendix applies to serial number 71M17232 and above (version 3.0 onward).



BASIC MEASUREMENTS

APPENDIX B

Manual Change Information

(Effective S/N:71M17232 and above, System version 3.0)

The operation procedures written in this Appendix B are applied to systems which have been up-graded to Software version 3.0 (S/N:71M17232 and above). Only those functions which reflect an operational change are covered in this Appendix. Functions not affected by this software upgrade will remain the same. Refer to the appropriate instructions in the system operation manual if necessary.

Volume I

(6) Frame Correlation

This function adds "afterimage" to make the movement of image smooth.

Press the MENU switch to display "MENU PAGE-1" menu, then select "5 FRM-CO" in the menu.

FRAME	1	2	3	4	5	6
CORRELATION	EXIT	OFF	ON	AUTO		

2 OFF: Turns off the frame correlation function irrespective of the probe. Suitable for fast moving imaging, such as the heart.

3 ON: Turns on the frame correlation function irrespective of the probe. Suitable for slowly moving images such as the liver

4 AUTO: Turns the frame correlation on or off automatically depending on the probe in use and line density setting.

NOTE: Normally set "4 AUTO".

BASIC MEASUREMENTS

2.2 Area and Circumference

Area and circumference measurements may be performed by either of two methods. One is "AREA-E" method which encloses the target with an elliptical measurement mark, and the other "AREA-T" method which traces the outline of the target.

2.2.1 AREA-E (Elliptical Enclosure Method)

- a. Select B mode (B/M or B/D mode is also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.

Press the MEASUREMENT switch to display the following menu:

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

Select "3 AREA-E" from the menu. The area measurement mark "+" will appear at the center of the screen. And the "⊕" TRACKBALL FUNCTION switch lights.

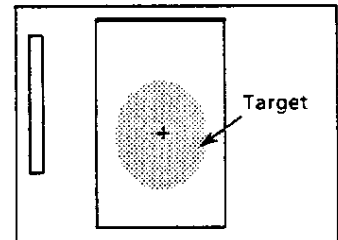


Fig. 2-2-1

- b. Use the TRACKBALL to position the mark to one end of the long axis of the target.

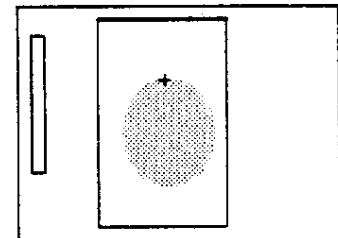


Fig. 2-2-2

- c. Press the MARK REF switch. Use the TRACKBALL to position the + mark to the another end of the long axis.

NOTE: Original + mark remains on the spot and another + mark may be moved by the TRACKBALL.

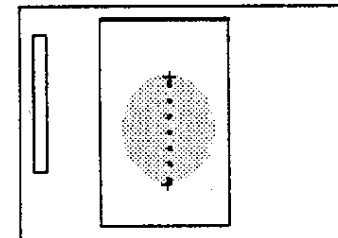


Fig. 2-2-3

- d. Press the MARK REF switch, and ellipse mark appears.

It is possible to adjust the short axis length of the ellipse mark by the TRACKBALL.

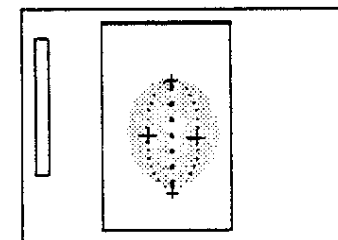


Fig. 2-2-4

BASIC MEASUREMENTS

Use the TRACKBALL to adjust the short axis length of the mark.

- : Rightward rolling lengthens the short axis length
- ← : Leftward rolling shortens the short axis length

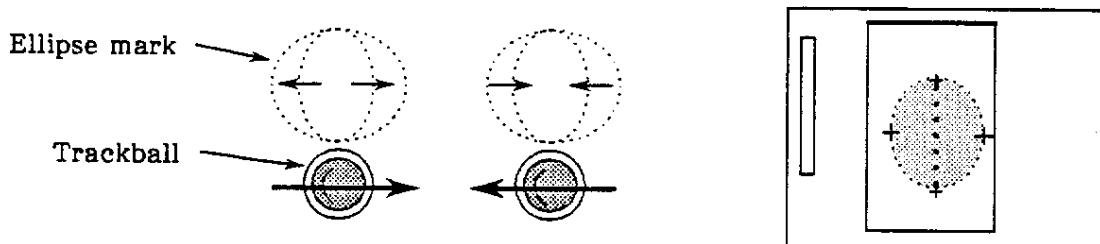


Fig. 2-2-5

If the position and/or shape of the mark are still not the same as that of the target, follow the procedure below.

- e. Press the **MARK REF** switch. At this stage, the following two things are possible by the TRACKBALL:
- Lengthening or shortening of long axis
 - Rotating the ellipse mark around the base point

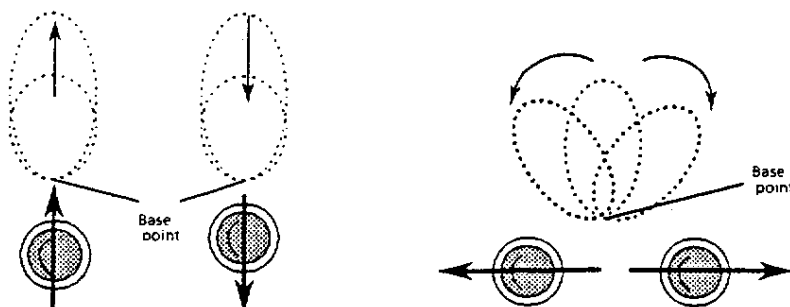


Fig. 2-2-6

- ↑ : Upward rolling lengthens the long axis length
- ↓ : Downward rolling shortens the long axis length
- : Rightward rolling rotates the mark clockwise
- ← : Leftward rolling rotates the mark counterclockwise

Roll the TRACKBALL upward or downward to readjust the vertical length.
Roll the TRACKBALL rightward or leftward to readjust the position.

- f. Press the **MARK REF** switch. The base point of rotation shifts to another side.
Readjust the position or vertical length.

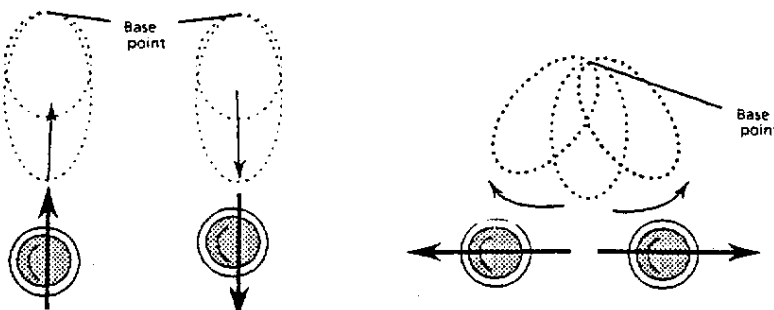


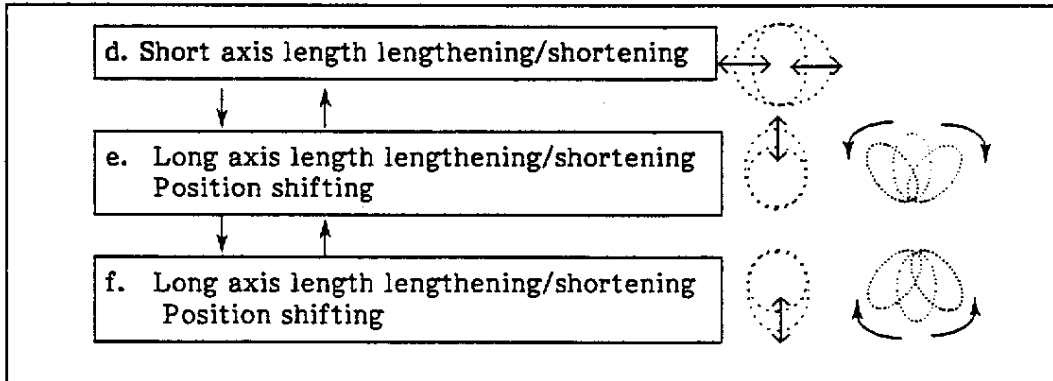
Fig. 2-2-7

BASIC MEASUREMENTS

The area, circumference (C), short axis (S), and long axis (L), of the ellipse are computed and displayed.

- g. By repressing the MARK REF switch, the short axis length may be readjusted with the TRACKBALL rolling. (Same as step "d.")

Steps "d." through "f." may be repeatedly carried out by pressing the MARK REF switch.



- h. By pressing the "x" TRACKBALL FUNCTION switch, another area measurement is possible by the "x" mark.
- i. To terminate the measurement, select "1 CLEAR" in the menu. All the measurement marks and results will be erased.

NOTE: If it is desired to erase only one set of calipers and measurement results, turn on the appropriate "+" or "x" switch corresponding the mark then repress it to erase.

Area Measurement Data Display Examples:

ELLIPSE

+:041.2 cm² The area enclosed in a "+" mark ellipse in square centimeter.

C:25.7 cm The circumference of a "+" mark ellipse in centimeter.

S:05.0 cm The short axis length of a "+" mark ellipse in centimeter.

L:10.4 cm The long axis length of a "+" mark ellipse in centimeter.

(The measurement data of "x" mark is displayed under the measurement data of "+" mark.)

BASIC MEASUREMENTS

2.4 Volume

Measurement and calculating method:

There are two ways to measure a volume, one is the two-axis method and the other the three-axis method. The two-axis method requires only a vertical sectional image. The three-axis method requires a vertical sectional image and a transverse sectional image.

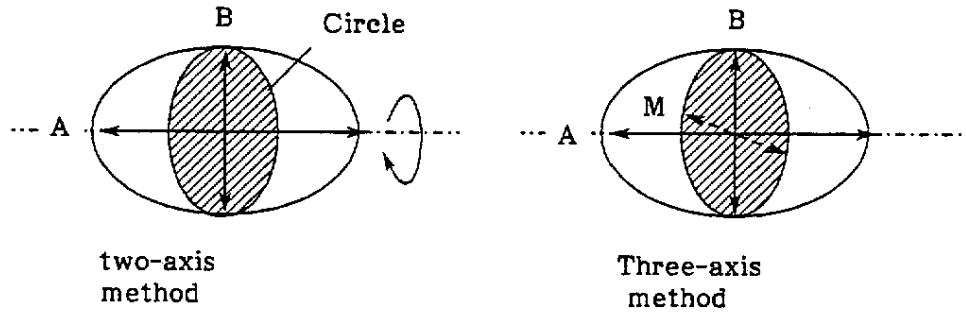


Fig. 2-4-1

The equation of two-axis method is;

$$\text{Volume} = (\pi/6) \times A \times B^2 \quad (\text{A is long axis, B is short axis length.})$$

The equation of three-axis method is;

$$\text{Volume} = (\pi/6) \times A \times B \times M \quad (\text{M is the third axis length.})$$

The following description is made first for the two-axis method with which three-axis method overlaps from step "a" to "j".

Step:

- a. Select B mode (B/M or B/D mode is also possible) with the MODE switch. When a desired image is displayed, freeze the image with the FREEZE switch.

In three-axis method, it is convenient that the user displays two images using Dual-B mode.

- b. Press the MEASUREMENT switch to display the MEASUREMENT menu, then select "5 NEXT" till the following menu is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	VOLUME	NEXT

- c. Select "5 VOLUME" from the menu. The area measurement mark "+" will appear at the center of the screen. And the "+" TRACKBALL FUNCTION switch lights.

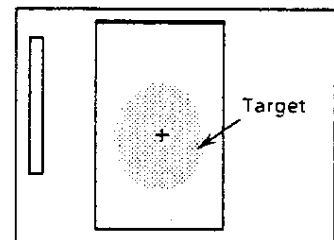


Fig. 2-4-2

BASIC MEASUREMENTS

- d. Use the TRACKBALL to position the mark to one end of the long axis of the target.

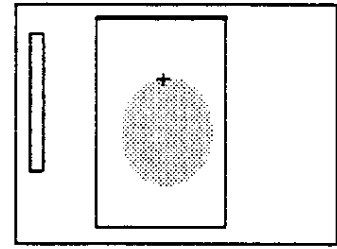


Fig. 2-4-3

- e. Press the MARK REF switch.
Use the TRACKBALL to position the + mark to the another end of the long axis.

NOTE: Original + mark remains on the spot and another + mark may be moved by the TRACKBALL.

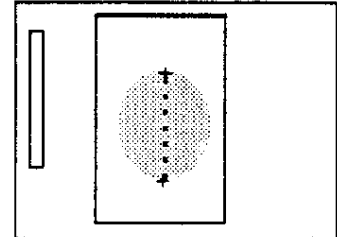


Fig. 2-4-4

- f. Press the MARK REF switch, and ellipse mark appears.

It is possible to adjust the short axis length of the ellipse mark by the TRACKBALL as follows:

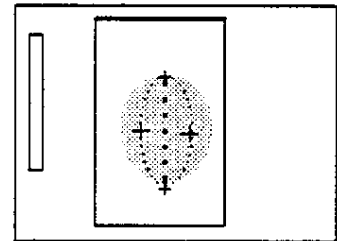
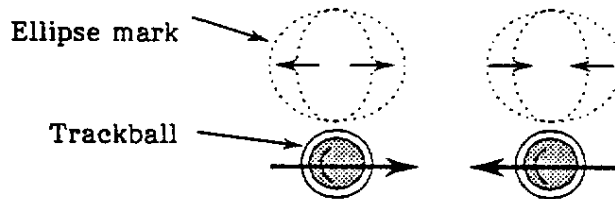
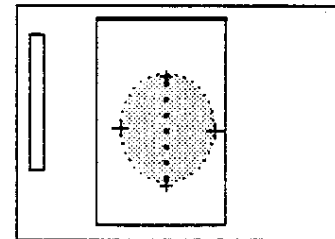


Fig. 2-4-5

- : Rightward rolling lengthens the short axis length
- ← : Leftward rolling shortens the short axis length



2-4-6



Use the TRACKBALL to adjust the short axis length of the mark.

If the position and/or shape of the mark are still not the same as that of the target, follow the procedure below.

- g. Press the MARK REF switch. At this stage, the following two things are possible by the TRACKBALL:

- Lengthening or shortening of long axis
- Rotating the ellipse mark around the base point

- ↑ : Upward rolling lengthens the long axial length
- ↓ : Downward rolling shortens the long axial length

- : Rightward rolling rotates the mark clockwise
- ← : Leftward rolling rotates the mark counterclockwise

Roll the TRACKBALL upward or downward to readjust the long axis length.

BASIC MEASUREMENTS

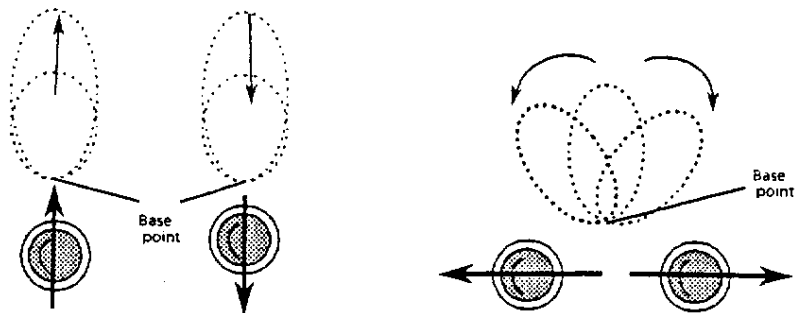


Fig. 2-4-7

Roll the TRACKBALL rightward or leftward to readjust the position.

- h. Press the MARK REF switch. The base point of rotation shifts to the another side.
Readjust the position or vertical length.

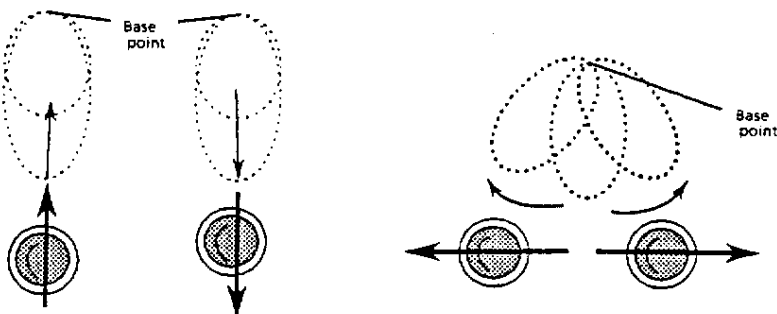
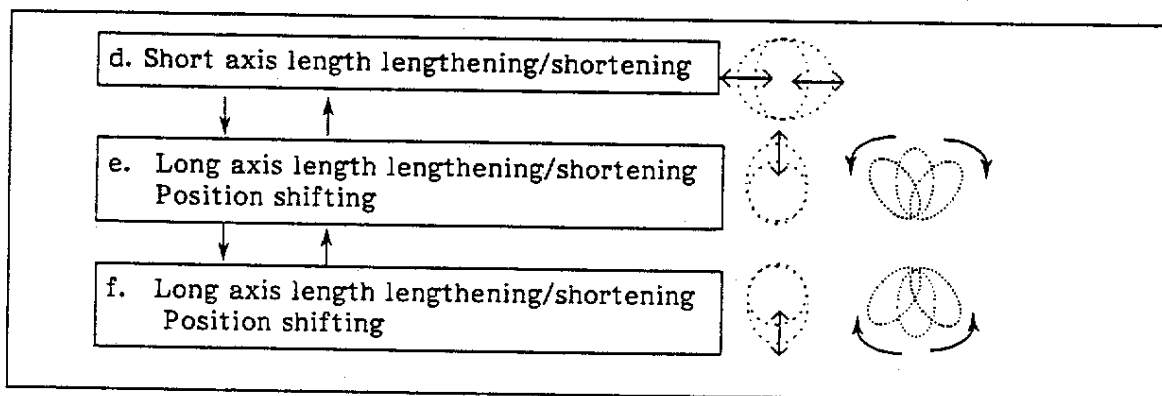


Fig. 2-4-8

The volume, short axis (S), and long axis (L), are computed and displayed.

- i. By repressing the MARK REF switch, the short axis length may be readjusted with the TRACKBALL rolling.

Steps "d." through "f." may be repeatedly carried out by pressing the MARK REF switch.



- * At this stage, the two-axis measurement method is complete, and the three-axis measurement method follows from the next step.
- j. Rescan the area of interest to display an orthogonal cross section of the initially set spheroid, passing through the latter's short axis.

BASIC MEASUREMENTS

- k. Press the " + " TRACKBALL FUNCTION switch. The "+" mark appears at the center of the screen.

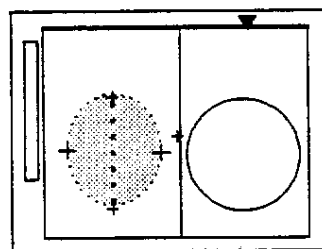


Fig. 2-4-9

- l. Measure the third axis by a distance measuring process. When the third axis is measured, the volume is newly computed, and displayed.

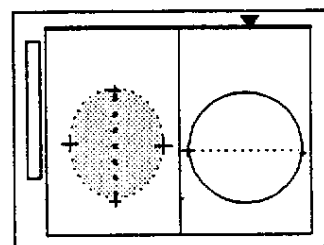


Fig. 2-4-10

- m. To restart the measurement repress the "+" TRACKBALL FUNCTION switch twice. The volume measurement data generated thus far may be reset, and the parameters again made resettable. Then follow steps "d." onward.
- n. To measure another volume, press the "x" switch of the TRACKBALL FUNCTION group. The "x" mark is operated in the same manner as the "+" mark.
- o. To terminate the volume measurement, select "1 CLEAR" in the menu.

All the measurement marks and results will be erased.

Volume Measurement Data Display Examples:

VOLUME	
+:111.8 cm ³	The volume enclosed in a "+" mark spheroid.
S:04.0 cm	The short axis length of a "+" mark ellipse.
M:05.8 cm	The length of the third axis. (In two-axis measurement, it is displayed as "M:--.- cm".)
L:09.2 cm	The long axis length of a "+" mark ellipse.

CARDIAC CALCULATIONS

Procedure for Calculations for B-mode

- a. Display a frozen left ventricle long-axis image at end stole.
 (An end-systolic image is easily available by ECD SYNC function by optional Physiological Signal Display Unit.)
 Press the **MEASUREMENT** switch, and display the following menu.

MEASURE	1	2	3	4	5	6
B	CLEAR	%STENO	G-CALC	LV-B	HIST	NEXT

Select "4 LV-B" from the menu. The area measurement mark "+" will appear at the center of the screen. And the " TRACKBALL FUNCTION switch lights.

- b. Use the **TRACKBALL** to position the mark to one end of the long axis of the target.

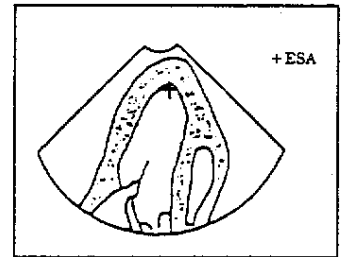


Fig. 4-1-1

- c. Press the **MARK REF** switch.
 Use the **TRACKBALL** to position the + mark to the another end of the long axis.

NOTE: Original + mark remains on the spot and another + mark may be moved by the **TRACKBALL**.

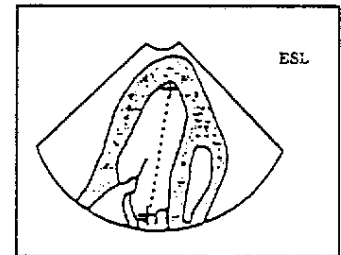


Fig. 4-1-2

- d. Press the **MARK REF** switch, and ellipse mark appears.

It is possible to adjust the short axis length of the ellipse mark by the **TRACKBALL** as follows:

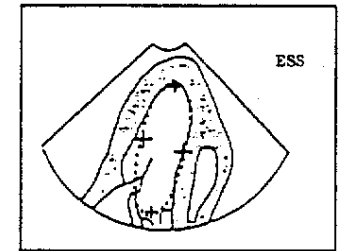


Fig. 4-1-3

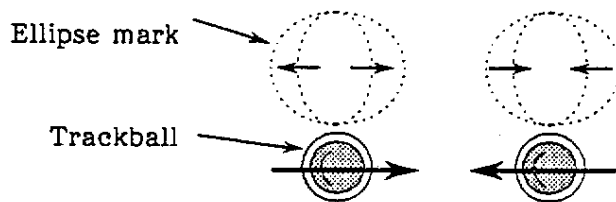


Fig. 4-1-4

- : Rightward rolling lengthens the short axial length
 ← : Leftward rolling shortens the short axis length

CARDIAC CALCULATIONS

If the position and/or shape of the mark are still not the same as that of the target, follow the procedure below.

- e. Press the **MARK REF** switch. At this stage, the following two things are possible by the **TRACKBALL**:

- Lengthening or shortening of long axis
- Rotating the ellipse mark around the base point

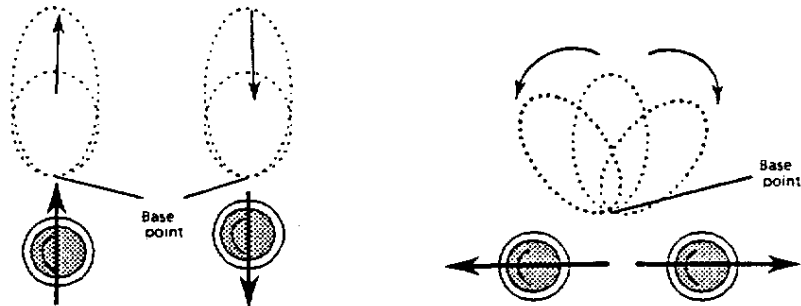


Fig. 4-1-5

- ↑ : Upward rolling lengthens the long axis length
- ↓ : Downward rolling shortens the long axis length
- : Rightward rolling rotates the mark clockwise
- ← : Leftward rolling rotates the mark counterclockwise

Roll the **TRACKBALL** upward or downward to readjust the long axis length.
Roll the **TRACKBALL** rightward or leftward to readjust the position.

- f. Press the **MARK REF** switch. The base point of rotation shifts to another side.
Readjust the position or long axis length.

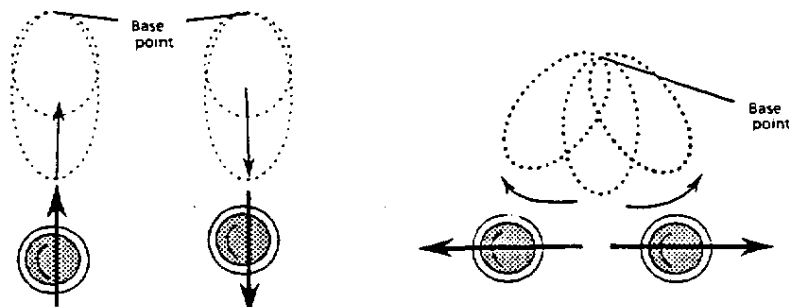


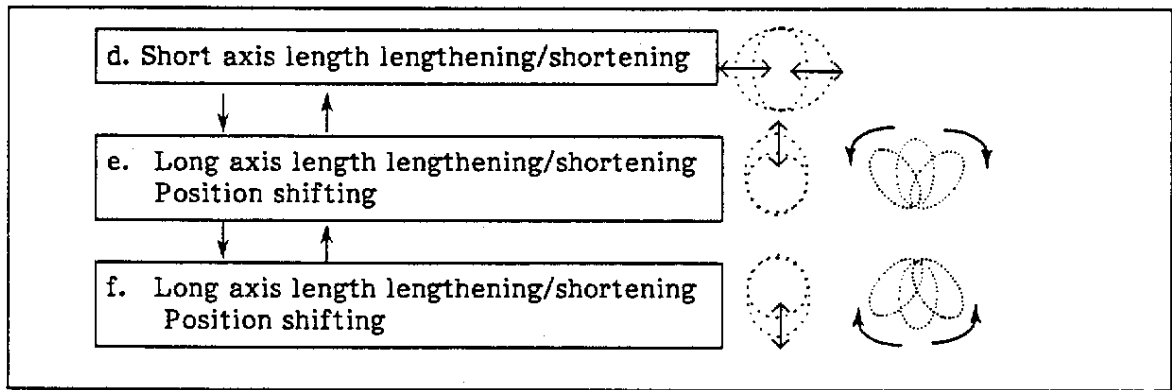
Fig. 4-1-6

At this stage, **ESA**, **ESS**, **ESL** and **ESV** are automatically computed and displayed.

- g. By repressing the **MARK REF** switch, the short axis length may be adjusted with the **TRACKBALL** rolling.

Steps "d." through "f." may be repeatedly carried out by pressing the **MARK REF** switch.

CARDIAC CALCULATIONS



- h. By using the ECG SYNC (Electrocardiogram Synchronization) function (with optional unit), rewrite the image into an end-diastolic image. Then freeze it.

However, when an end-systolic long axis image and an end-diastolic image are displayed beforehand by the dual-image display function, transfer the active mark "▼" to the end-diastolic image by the SELECTOR switch.

- i. Press the " x" TRACKBALL FUNCTION switch. The " x " mark is displayed. Then, perform an EDA (end-diastolic area) measurement in the same way as the end-systolic measurement. Immediately, EDL (end-diastolic long axis), EDS (end-diastolic short axis), EDV (end-diastolic volume) SV (stroke volume) and EF (ejection fraction) are calculated and displayed.

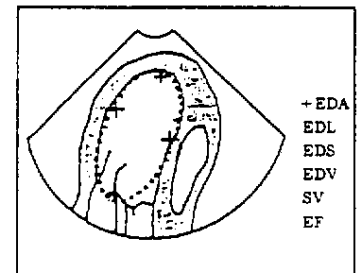


Fig. 4-1-7

- j. During the ECG display, the heart rate is automatically read out and the CO value is calculated.

	1	2	3	4	5
LV FUNCTION	EXIT	HR			SET

If there is no ECG display, select "2 HR" in the menu and enter the heart rate value from the keyboard. Then select "5 SET".

If correction is necessary, press an appropriate caliper mark switch (+ or x) for the measurement to be corrected and retry measurement.

- k. To terminate the measurements, select "1 EXIT".

CARDIAC CALCULATIONS

Example of LV-B measurement information display:

LV FUNC.

AREA-LENGTH

+ ESA	: 10.1 cm ²	LV end-systolic <u>area</u>	:	10.1 cm ²	} Measured by " + " mark
ESL	: 04.5 cm	LV end-systolic <u>long axis</u>	:	3.2 cm	
ESS	: 03.2 cm	LV end-systolic <u>short axis</u>	:	4.5cm	
ESV	: 025 ml	LV end-systolic <u>volume</u>	:	25 ml	} Measured by " x " mark
xEDA	: 23.8 cm ²	LV end-diastolic <u>area</u>	:	23.8 cm ²	
EDL	: 05.0 cm	LV end-diastolic <u>long</u>	:	4.4 cm	
EDS	: 04.4 cm	LV end-diastolic <u>short axis</u>	:	5.0cm ²	
EDV	: 070 ml	LV end-diastolic <u>volume</u>	:	70 ml	
SV	: 0.45 ml	Stroke volume			
HR	: 065b/m	Heart rate			
CO	: 2.9l/m	Cardiac output			
EF	: 0.64	Ejection fraction			

APPENDIX C

SSD-650

This appendix applies to serial number 81M8522 and above (version 4.1 onward).



Difference

New version software differs from the original in the following way:

1. OB report function is available. See the attached operating instructions.
2. As a result of the above change, the contents of the MEASUREMENT menu change as follows:

There are 3 pages for the MEASUREMENT menu.

Page One:

MEASURE	1	2	3	4	5	6
B	CLEAR	DIST	AREA-E	AREA-T	<u>OB</u>	NEXT

"OB" is added.

Selecting "OB" enters into OB measurement area.

Page Two:

MEASURE	1	2	3	4	5	6
B	CLEAR	VOLUME	LV-B	RATIO	%STENO	NEXT

Page Three:

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	<u>OB-PRO</u>			NEXT

Selecting "OB-PRO" enters into gestational table programming.



OB REPORT FUNCTION

Operating Instructions



CONTENTS

1. INTRODUCTION
2. GESTATIONAL TABLE PROGRAM AREA
 - 2.1 Transfer/Program of Growth Table Page 2-2
 - (1) Transfer of built-in table Page 2-2
 - (2) Programming of User's Table Page 2-4
 - (3) Erasure of Registered Table Page 2-6
 - 2.2 Setting of User's Ratio Expression Page 2-7
 - 2.3 Setting of Measurement Method Page 2-9
3. MEASUREMENT AREA
4. MEASUREMENT RESULT DISPLAY AREA
5. REPORT AREA
 - 5.1 Procedure for Entering Report Area Page 5-1
 - 5.2 Explanation of Report Display Page 5-3
6. GENERAL ROUTINE FOR REPORT
7. CONTENTS OF BUILT-IN TABLES



INTRODUCTION

1. INTRODUCTION

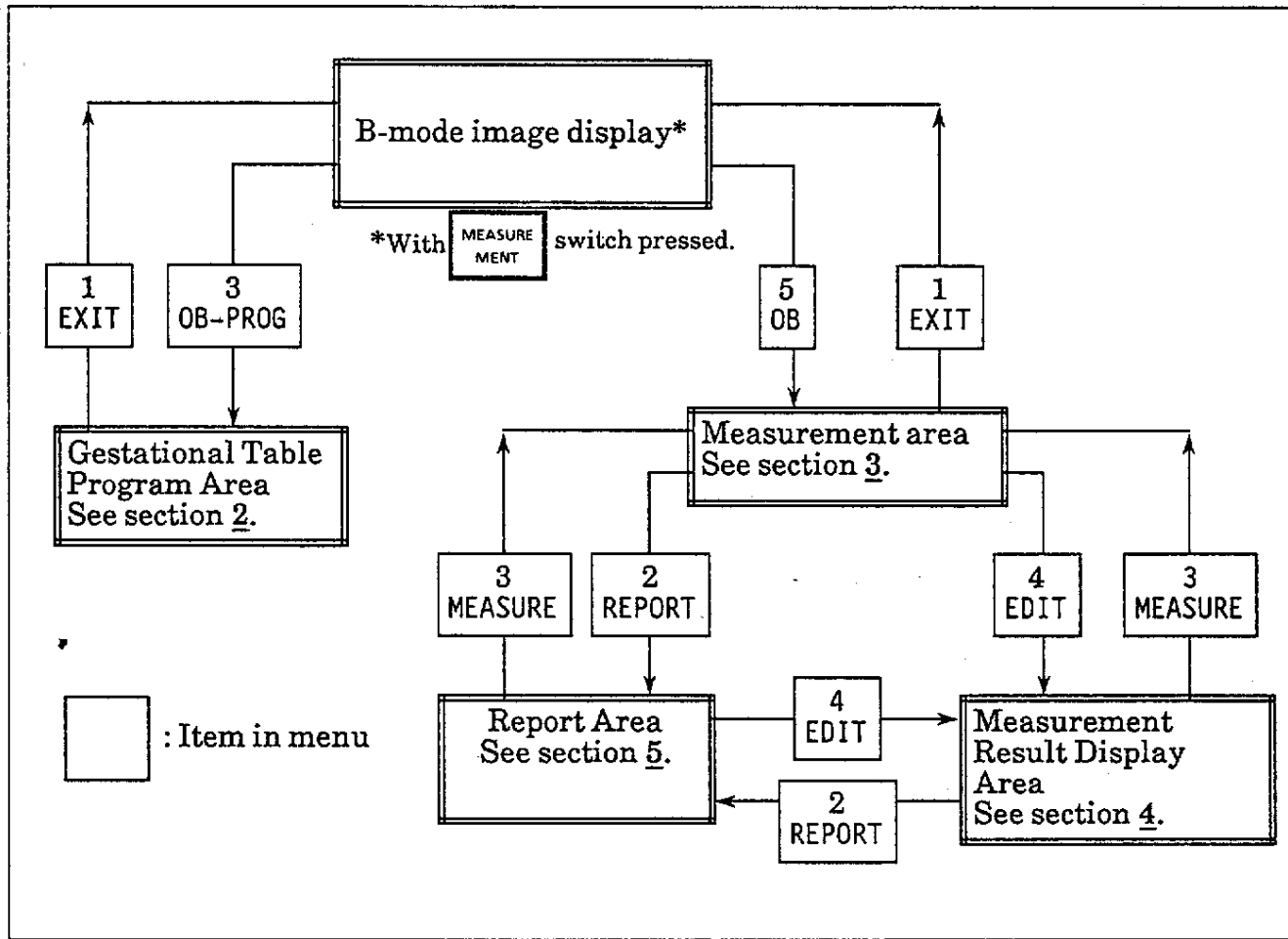
This system can calculate the following 4 items and display all the calculated results on the screen as a report. (Report function)

1. Gestational age and date of confinement by a measurement such as the BPD.
2. Gestational age and date of confinement by manual input of last menstrual period.
3. Ratio of two measurements, such as cephalic index.
4. Fetal weight (Shepard and Hadlock methods)

This subsection explains the operation of the revised software. See next page for its outline.

INTRODUCTION

Operational Flow Chart



<Gestational Table Program Area> Section 2

The gestational tables are blank at first. The user must register a fetal growth table (either built-in or user-programmed) for a gestational age calculation.

<Measurement area> Section 3.

User performs measurement according to the selected parameter.
Up to 5 measurements per each parameter can be stored.

<Measurement Result Display Area> Section 4.

Measurement results and average of multiple measurements of the same parameter are displayed. It is possible to check parameter(s) that is(are) not measured yet.

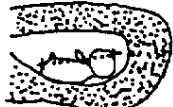
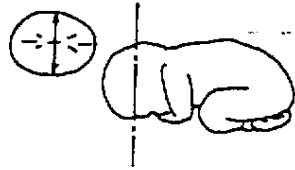
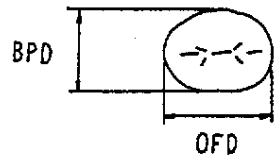

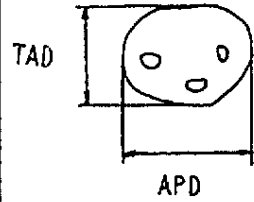
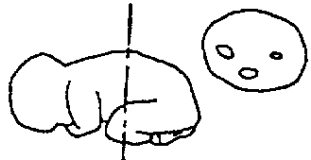

<Report Area> Section 5.

Data obtained by measurement is arranged for report. In this report, the name of the doctor, date, patient's number and name, and comment can be entered. Gestational age and date of confinement are graphed.

INTRODUCTION

List of Parameters and US Cross Section

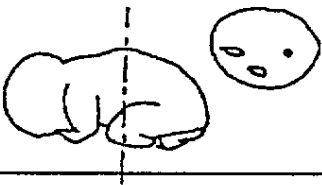
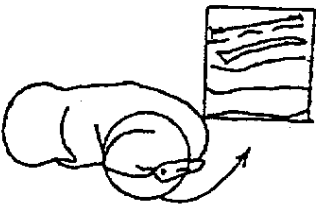
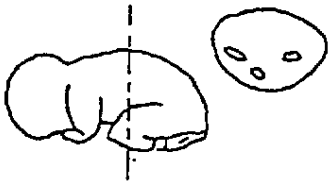
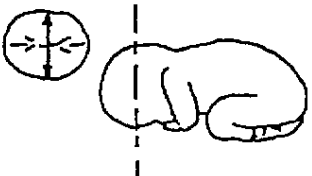
The following parameters can be entered the report. (* indicates built-in table)

Abbreviation	Parameter	Measurement method	Reference	Measurement Area
*CRL	Crown-Rump Length	DIST	ROBINSON (British Journal of OB/GYN 1975)	
*BPD	Biparietal Diameter	DIST	Kurtz (J of Clinic Ultras 1980) Hadlock (J of Ultras in Medicine 1982) Sabbagha (Am. J. of Obstet. GYN.1976)	
OFD	Occipital Frontal Diameter	DIST	When BPD and OFD are measured, Cephalic Index (CI) and Head Circumference (HC) are automatically calculated. (CI = BPD/OFD)	
*HC	Head Circumference	AREA-E or AREA-T	HADLOCK (Am. J. of Roent. 1982) NOTE: Measured value precedes calculated value by BPD and OFD.	
TAD	Transverse Abdominal Diameter	DIST	Using TAD and APD, AC (Abdominal Circumference) and FTA (Fetal Trunk Area) are calculated.	
APD	Anteroposterior Diameter	DIST	$AC = \pi \times \sqrt{\frac{(TAD)^2 + (APD)^2}{2}} \times \delta$ $FTA = \frac{\pi}{4} \times (TAD) \times (APD)$	
*AC	Abdominal Circumference	AREA-E or AREA-T	HADLOCK (Am. J. of Roent. 1982)	
*FL	Femur Length	DIST	Hadlock (Am. J. of Roent. 1982) O'Brien (Am. J. of Obstet. GYN. 1981) Jeanty (J of Ultras in Medicine 1984)	
USR 1 USR 2	Arbitrary	Select from DIST, AREA-E, AREA-T and VOLUME		Arbitrary

INTRODUCTION

Fetal Weight Method

(When measurements of the parameters listed on the previous page are completed, there is no need to remeasure the parameters below.)

Method	Parameter	Measurement Method	Measurement Area
Hadlock	$FW = 10 \exp(AC \times 0.051 - AC \times FL \times 0.0037 + FL \times 0.1844 + 1.3598) \text{ g}$		
	AC (Abdominal Circumference)	AREA-E or AREA-T	
	FL (Femur Length)	DIST	
Shepard	$FW = 10 \exp(AC \times 0.046 - BPD \times AC \times 0.002646 + BPD \times 0.166 + 1.2508) \text{ g}$		
	AC Abdominal Circumference	AREA-E or AREA-T	
	BPD Biparietal Diameter	DIST	

Ratio Calculation

Name of Ratio	Parameters for comparison
Cephalic Index (Hadlock)	BPD/OFD
HC/AC (Campbell)	HC/AC

Two other expressions for ratio calculation can be set arbitrarily.

Gestational Age Calculation from LMP (Last Menstrual Period)

LMP + 40 weeks

GESTATIONAL TABLE PROGRAM AREA

2. GESTATIONAL TABLE PROGRAM AREA

In this area, it is possible to program a fetal growth table for calculation of gestational age and date of confinement.

Initially, the gestational tables are blank. Registration is necessary.

There are two registration methods, that is, built-in table transfer and table programming by user.

Up to 6 tables can be registered in the blank areas. (See the figure below) Using either the built-in tables or the user's tables.

The registered tables are also used in the report function.

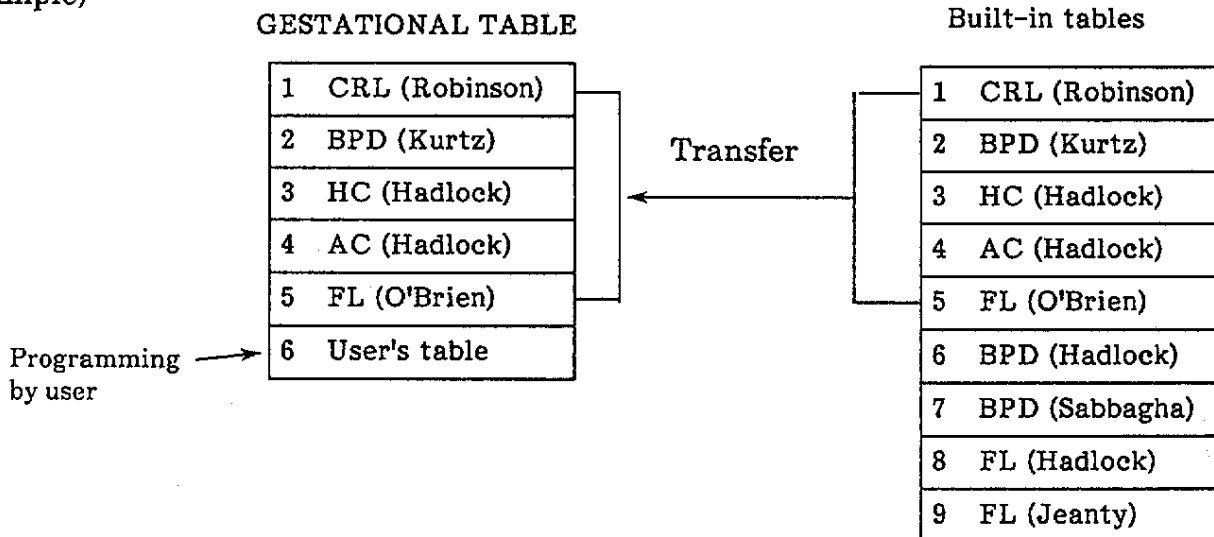
The built-in tables are as follows:

<Built-in Tables>

Parameter	Table Reference
CRL	Robinson
BPD	Kurtz
HC	Hadlock
AC	Hadlock
FL	O'Brien
BPD	Hadlock
BPD	Sabbagha
FL	Hadlock
FL	Jeanty

NOTE: Once a table is registered, it is retained even after the power is turned off.

(Example)



GESTATIONAL TABLE PROGRAM AREA

2.1 Transfer/Program of Growth Table

(1) Transfer of built-in table:

Transfer is necessary to make the table usable for calculations and the report function.

- a. In B-mode, press the **MEASUREMENT** switch. A menu is displayed. Select "**5 NEXT**" until the following page is displayed:

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	OB-PRO			NEXT

- b. Select "**3 OB-PRO**" in the menu. The following display appears on the screen:

```

      OB REPORT PROGRAM

      GESTATIONAL TABLE      DIMENSION
      1 ( ) ( ) ( )          HC : (CIR-T)
      2 ( ) ( ) ( )          AC : (CIR-T)
      3 ( ) ( ) ( )          USR1: (DIST )
      4 ( ) ( ) ( )          USR2: (DIST )
      5 ( ) ( ) ( )
      6 ( ) ( ) ( )

      RATIOS
      1 N/D
        N: (IFL )
        D: (BPD )
      2 N/D
        N: (IFL )
        D: (IAC )

      OB REPORT PROGRAM      1 EXIT      2      3      4      5      6 SET
  
```

- c. The highlighting is now at the top of the **GESTATIONAL TABLE** list. Use the trackball to shift the highlighting to the desired table number to which a table is to be transferred. Then select "**6 SET**" in the menu.

GESTATIONAL TABLE		
1	()	()
2	()	()
3	()	()
4	()	()
5	()	()
6	()	()

- d. At the upper right of the screen, the display shown on the right appears. Ensure that the highlighting is on "**INTERNAL**". If not, use the trackball to adjust. Then select "**6 SET**" in the menu.

INTERNAL
USER/EDIT
CLEAR

GESTATIONAL TABLE PROGRAM AREA

- e. Titles of built-in tables are displayed as shown to the right. The highlighting is now at the top of the list.

Use the trackball to shift the highlighting to the title of the table to be transferred.

Then select "6 SET" in the menu.

```

CRL (ROBINSON)
BPD (KURTZ )
HC (HADLOCK )
AC (HADLOCK )
FL (O'BRIEN )

ALL
NEXT
    
```

- f. When it is desired to shift all 5 tables shown here, use the trackball to shift the highlighting to "ALL". Then select "6 SET" in the menu.

(This step is done regardless of the table number selected at step "c".)

```

CRL (ROBINSON)
BPD (KURTZ )
HC (HADLOCK )
AC (HADLOCK )
FL (O'BRIEN )

ALL
NEXT
    
```

NOTE: When all tables are transferred by the above method, they are automatically transferred in order starting with #1.

(At the same time tables #1 - #5 are replaced by the transferred tables even if tables are already registered.)

NOTE: The remaining 4 built-in tables can be displayed as follows:

Use the trackball to shift the highlighting to "NEXT".

Then select "6 SET" in the menu.

```

CRL (ROBINSON)
BPD (KURTZ )
HC (HADLOCK )
AC (HADLOCK )
FL (O'BRIEN )

ALL
NEXT
    
```

- g. After the transfer, the display returns to step "c" automatically.

Confirm that the title of a transferred table is displayed in the GESTATIONAL TABLE list.

```

GESTATIONAL TABLE
1 CRL (ROBINSON)
2 ( )
3 ( )
4 ( )
5 ( )
6 ( )
    
```

NOTE: Selecting "1 RETURN" in the menu returns the display to step "c" at any point in the procedure.

- h. To terminate the transfer operation, select "1 EXIT". B-mode image display is resumed.

GESTATIONAL TABLE PROGRAM AREA

(2) Programming of User's Table

When a user has data that can be used for gestational age calculation, the user can program up to 6 growth tables (when there is room in GESTATIONAL TABLE) as follows:

- a. In B-mode, press the MEASUREMENT switch. A menu is displayed. Select "6 NEXT" until the following page is displayed:

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	OB-PRO			NEXT

- b. Select "3 OB-PRO" in the menu. The following display appears on the screen:

GESTATIONAL TABLE		DIMENSION
1	()	MC : (CIR-T)
2	()	AC : (CIR-T)
3	()	USR1 : (DIST)
4	()	USR2 : (DIST)
5	()	
6	()	

RATIOS	
1 N/D	
N: (FL)	
D: (BPD)	
2 N/D	
N: (FL)	
D: (AC)	

OB REPORT PROGRAM	1 EXIT	2	3	4	5	6 SET
-------------------	--------	---	---	---	---	-------

- c. The highlighting is now at the top of the GESTATIONAL TABLE list. Use the trackball to shift the highlighting to the desired table number in which the table is to be programmed. Then select "6 SET" in the menu.

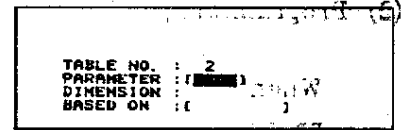
GESTATIONAL TABLE	
1	()
2	()
3	()
4	()
5	()
6	()

- d. At the upper right of the screen, the display shown on the right appears. Use the trackball to shift the highlighting to "USER/EDIT". Then select "6 SET" in the menu.

INTERNAL
USER/EDIT
CLEAR

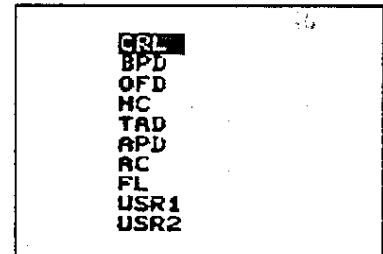
GESTATIONAL TABLE PROGRAM AREA

- e. The highlighting shifts to "PARAMETER".
 Select "6 SET" in the menu. List of parameters appears at the right of the screen. (Lower figure)
 Use the trackball to place the highlighting on the desired parameter. Then select "6 SET".



The "DIMENSION" is automatically set according to the parameter selected in step "e".

The highlighting proceeds to "BASED ON".
 Enter the table reference. Up to 8 characters can be inputted.
 Then select "6 SET" for registration.



- f. The highlighting shifts to the top of the table (1st week).
 Enter value for each week as follows:

Enter deviation days in $\pm d$ column with two digits, average value in cm column (effective to first place of decimal).

After each data entry, select "6 SET". The value is set and the highlighting shifts to the next week.

	$\pm d$	cm		$\pm d$
1				22
2				23
3				24
4				25
5				26
6				27
7				28
8				29
9				30
10				31
11				32
12				33
13				34
14				35
15				36
16				37
17				38
18				39
19				40
20				41
21				42

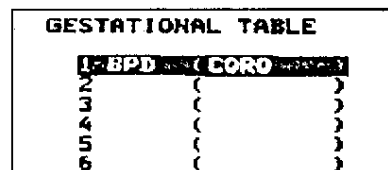
NOTE: For a week no data is available, select "6 SET" to proceed to the next week. It is also possible to shift the highlighting by the trackball.

- g. When an input error is found, shift the highlighting to the error part and reenter the correct value, then select "6 SET".

NOTE: Shifting the highlighting by trackball cannot set data. When a correction is made, be sure to select "6 SET" before shifting the highlighting.

NOTE: In this system, the total number of pregnancy weeks is determined as 40 (fixed). Data input at 41 or 42 weeks is impossible.

- g. To terminate the table programming, select "1 RETURN". Display returns to step "b".
 Confirm that the title of the programmed table is displayed in the GESTATIONAL TABLE list.



GESTATIONAL TABLE PROGRAM AREA

(3) Erasure of Registered Table

- a. In B-mode, press the **MEASUREMENT** switch. A menu is displayed.
Select "**6 NEXT**" until the following page is displayed.

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	OB-PRO			NEXT

- b. Select "**3 OB-PRO**" in the menu.
- c. Using the trackball, highlight the table to be erased.
Then select "**6 SET**".

GESTATIONAL TABLE	
1 BPD	(CORO)
NUM	()
NUM	()
NUM	()

- d. At the upper right of the screen, the display shown on the right appears.
Using the trackball, shift the highlighting to "**CLEAR**".
Then select "**6 SET**" in the menu.

INTERNAL
USER/EDIT
CLEAR

- e. Confirm that the desired title is erased in the **GESTATIONAL TABLE** list.

2.2 Setting of User's Ratio Expression

2-7 (2)

In this system two ratio expressions (CI: Cephalic Index and HC/AC) are built in. The user can program up to two additional ratio methods.

Procedure for Setting User's Ratio Expression:

- a. In B-mode, press the MEASUREMENT switch. A menu is displayed. Select "6 NEXT" until the following page is displayed:

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	OB-PRO			NEXT

- b. Select "3 OB-PRO" in the menu. The following display appears on the screen:

GESTATIONAL TABLE		DIMENSION	
1	()	HC	:(CIR-Y)
2	()	AC	:(CIR-Y)
4	()	USR1	:(DIST)
5	()	USR2	:(DIST)
6	()		

RATIOS	
1 N/D	
N: [FL]	
D: [BPD]	
2 N/D	
N: [FL]	
D: [AC]	

OB REPORT PROGRAM	1 EXIT	2	3	4	5	6 SET
-------------------	--------	---	---	---	---	-------

- c. Using the trackball, shift the highlighting to the "N : []" item in the "1 N/D" part. Then select "6 SET". At the upper right of the screen, parameters for comparison are displayed. (Lower figure)

RATIOS	
1 N/D	
N: [FL]	
D: [BPD]	
2 N/D	
N: [FL]	
D: [AC]	

- d. Using the trackball, highlight the parameter suitable for the numerator (N). Then select "6 SET".

CRL
BPD
OFD
HC
TAD
APD
AC
FL
USR1
USR2

GESTATIONAL TABLE PROGRAM AREA

e. Using the trackball, shift the highlighting to the "D" part in the "1 N/D" part.
Then select "6 SET".

At the upper right of the screen, parameters for comparison are displayed. (Lower figure)

```
RATIOS
  1 N/D
    N: [CRL ]
    D: [B20 ]
  2 N/D
    N: [FL ]
    D: [AC ]
```

f. Using the trackball, highlight the parameter suitable for the denominator (D).
Then select "6 SET".

```
CRL
B20
OFD
HC
TAB
APD
RC
FL
USR1
USR2
-----
```

g. Follow steps "c" through "f" to program a second ratio expression.

h. To terminate the operation select "1 EXIT" in the menu. B-mode image display is resumed.

NOTE: It is possible to erase parameters once registered by the following methods:

- Using the trackball, highlight the item to be erased, then select "6 SET".
- Using the trackball, highlight the blank mark (- - -) in the list of parameters.
Then select "6 SET".

When both N and D items are blank, no user's expression is displayed in the report.

NOTE: The table titles of "USER1" (user #1) and "USR2" (user #2) are fixed and cannot be changed.

GESTATIONAL TABLE PROGRAM AREA

2.3 Programming of Measurement Method:

This procedure is necessary for parameters HC, AC, USR1 and USR2 since two or more measurement methods are possible.

Two measurement methods (elliptical approximation and trace) are available for area and circumference measurements.

For HC and AC, CIR-E (elliptical approximation) or CIR-T (trace) can be selected.

For USR1 and USR2, all the measurement methods (shown below) can be selected.

- a. In B-mode, press the **MEASUREMENT** switch. A menu is displayed.
Select "6 NEXT" until the following page is displayed:

MEASURE	1	2	3	4	5	6
B	CLEAR	HIST	OB-PRO			NEXT

- b. Select "3 OB-PRO". The following display (left figure) appears on the screen:

```

                                OB REPORT PROGRAM

    GESTATIONAL TABLE          DIMENSION
    -----
    SWAIN                       HC : [CIR-T]
                                AC : [CIR-T]
                                USR1 : [DIST ]
                                USR2 : [DIST ]

    RATIOS
    1 N/D
      N:FL [ ]
      D: [ ]
    2 N/D
      N:FL [ ]
      D: [ ]

    OB REPORT PROGRAM          1 EXIT  2  3  4  5  6 SET
  
```

Explanation of abbreviation

DIST: Distance
 CIR-E: Circumference by ellipse approximation
 CIR-T: Circumference by trace
 AREA-E: Area by ellipse approximation
 AREA-T: Area by trace
 VOL: Volume

- c. Using the trackball shift the highlighting to the desired parameter. (Rotate the trackball downward until the highlighting shifts under the "DIMENSION" section.)
Then select "6 SET". The list of measurement methods appears at the right of the screen. (Bottom figure)

```

    DIMENSION
    HC : [CIR-T]
    AC : [CIR-T]
    USR1 : [DIST ]
    USR2 : [VOL ]
  
```

- d. Using the trackball, shift the highlighting to the desired measurement.
Then select "6 SET".

```

    DIST
    CIR-E
    CIR-T
    ARE-E
    ARE-T
    VOL
  
```

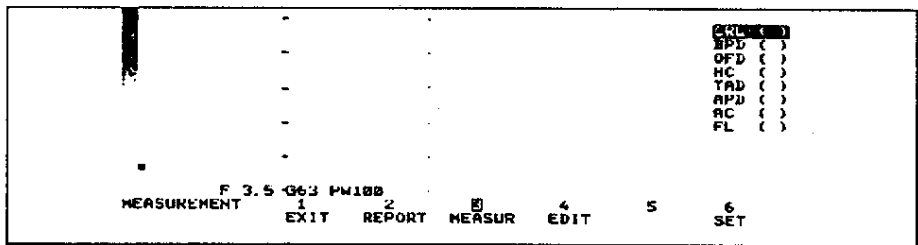

MEASUREMENT AREA

3. MEASUREMENT AREA

This area is for measuring parameters for obstetrical calculations. Up to 5 measurements per parameter can be stored and averaged. There is no need to remeasure the same parameter for fetal weight and ratio (such as CI) calculation. Once a parameter has been measured, the measurement is automatically used for the said calculation.

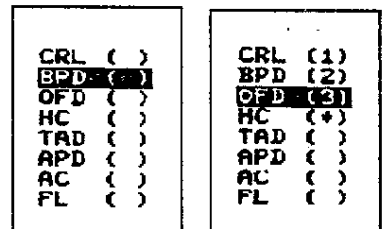
3.1 Measurement Procedure

- a. In B-mode display, press the **MEASUREMENT** switch. A menu is displayed. Select "5 OB" in the menu. The display as shown below appears:

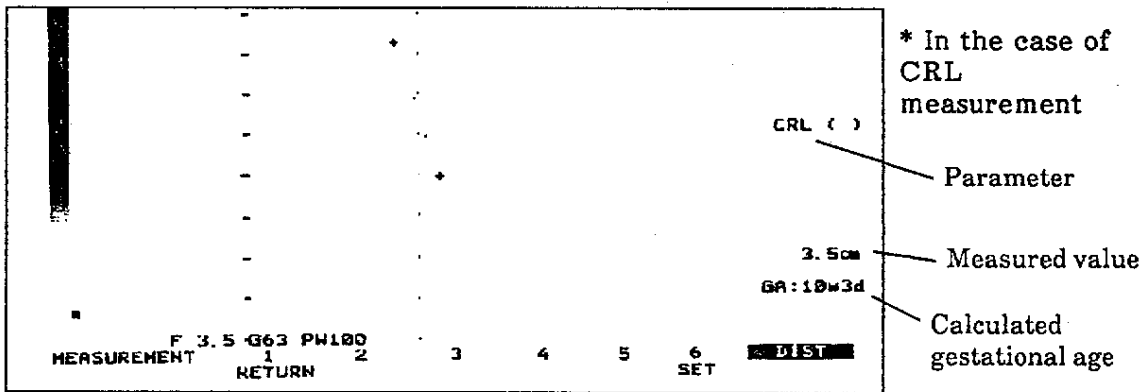


- b. Using the trackball, shift the highlighting to the parameter to be measured. Then select "6 SET".

The number of measurements performed is displayed in the parenthesis. (Example in right figure)



- c. A caliper mark corresponding to the selected parameter is displayed on the screen. Using the displayed mark, measure the parameter. Then select "6 SET" to register the measurement.



MEASUREMENT AREA

d. To measure another parameter without registering the present measurement, select "1 RETURN", then repeat from step "b".

NOTE: In the case of AC (Abdominal Circumference), measuring TAD and APD automatically calculates the AC, however, the actual measurement value takes priority in registration for the calculated value.

* When LMP (Last Menstrual Period) is set in the report (see Section. 5), the gestational age calculated from the LMP is displayed as follows:

```

LMP-GA
31w0d

CRL ( )
BPD ( )
OFD ( )
HC ( )
TAD ( )
APD ( )
AC ( )
FL ( )

F 3.5 G63 PW100
MEASUREMENT 1 2 3 4 5
              EXIT REPORT MEASUR EDIT SET
```

Gestational age from LMP

MEASUREMENT RESULT DISPLAY AREA

4. MEASUREMENT RESULT DISPLAY AREA

For each parameter, up to 5 measurements can be stored, and their average is automatically calculated.

4.1 How to use the measurement result display area.

In this area it is possible to confirm the registered measurement results. Also it is possible to enter known measurement values manually from the keyboard.

- a. In B-mode display, press the **MEASUREMENT** switch. Select **"5 OB"** in the menu. Then select **"4 EDIT"** in the menu. The following display results:

	1	2	3	4	5	AVE
CRL	██████					-----CB
BPD						-----CB
OFD						-----CB
HC						-----CB
TAD						-----CB
APD						-----CB
AC						-----CB
FL						-----CB

- b. It is possible to shift the highlighting from #1 - #5 of each parameter using the trackball.
If there is a measurement to be corrected, use the trackball to shift the highlighting to the measurement. Then select **"6 SET"**. Next, enter correct value from the keyboard. Then reselect **"6 SET"**.

	1	2	3	4	5	AVE
CRL	5.6	3.2				4.4cb
BPD	3.5 (3.0 (3.5)			3.3cb
OFD	4.0	4.1	██████			4.0cb
HC						+ 11.5cb
TAD						-----CB
APD						-----CB
AC	13.1	11.8				12.5cb
FL						-----CB

Or if there are measurements to be manually added, use the trackball to shift the highlighting to a blank in the line of the parameter. Then select **"6 SET"**. Enter the value from the keyboard. Then reselect **"6 SET"**.

When a value is manually entered, the value is enclosed by parentheses.

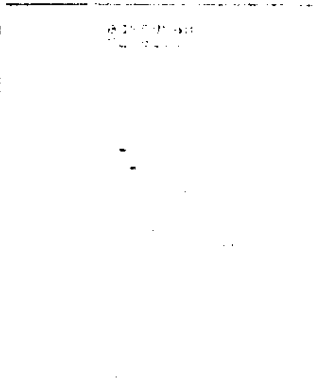
MEASUREMENT RESULT DISPLAY AREA

NOTE: The average value with asterisk (*) is an automatically calculated value using other measurements. For example, the HC value in the above data derives from BPD and OFD average values.

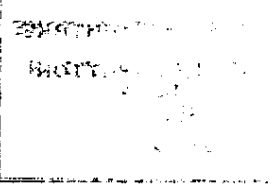
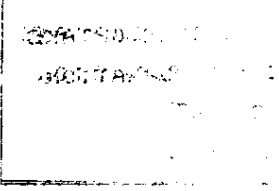
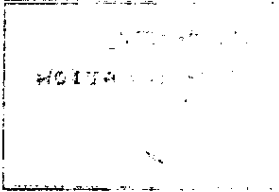
- e. To return to measurement area, select "3 MEASUR" in the menu.
- d. To return to B-mode display, select "1 EXIT" in the menu.

awollof as any cable ps...

neltsnnsqxs sader d/1
ed mas m of dno o
nel ed n d n d
sawlof as any cable ps...



"GI" nns nns...



REPORT AREA

5. REPORT AREA

This area is for the report which contains the gestational age, date of confinement, and fetal weight in graphs and values.

5.1 Procedure for Entering Report Area

- a. In B-mode display, press the **MEASUREMENT** switch. Select "5 OB" in the menu. Then select "2 REPORT" in the menu. The display changes as follows:

```

DOCTOR'S NAME: .                               88/09/06
                                                13:19:33
PATIENT INFORMATION
ID : -
NAME : -
LMP: / /

-----
CRL (ROBINSON)   CR  W d 1 d  .....
BPD (KURTZ )    CR  W d 1 d  .....
HC (HADLOCK )   CR  W d 1 d  .....
AC (HADLOCK )   CR  W d 1 d  .....
FL (O'BRIEN )   CR  W d 1 d  .....

OFD : - CR
TAB : - CR
APD : - CR

-----
LMP-GA : W d      US-GA : W d
LMP-EDB: / /      US-EDB: / /

C1 :
HC/AC :
EFW(SHEPARD ) :
EFW(HADLOCK ) :

COMMENTS:

REPORT      1 2 3 4 5 6
            EXIT REPORT MEASUR EDIT SET
    
```

Detailed explanation of each part can be found on the last page (5-3) of this section.

* Every time the report area is selected, the cursor will default to the "ID" area.

- b. To enter the doctor's name, use the trackball to shift the highlighting to "DOCTOR'S NAME:". Enter doctor's name from the keyboard. The doctor's name is retained until power is turned off.

```

DOCTOR'S NAME: _
PATIENT INFORMATION
ID :
NAME :
LMP: / /
    
```

- c. To enter patient's ID number, use the trackball to shift the highlighting to "ID:". Enter patient's number from the keyboard.

```

DOCTOR'S NAME: OHTAKE
PATIENT INFORMATION
ID : 1234
NAME :
LMP: / /
    
```

- d. Use the trackball to shift the cursor to "NAME:". Enter patient's name from the keyboard.

```

DOCTOR'S NAME: OHTAKE
PATIENT INFORMATION
ID : 1234
NAME :
LMP: / /
    
```

REPORT AREA

- e. When a graphical plot of the gestational age and date of confinement calculated by LMP (last menstrual period) is desired, use the trackball to shift the cursor to "LMP:". Then enter the date of the first day of the last menstrual period from the keyboard.

DOCTOR'S NAME: OHTAKE	
PATIENT INFORMATION	
ID	: 1234
NAME	: ALOKA
LMP:	_ / _ / _

NOTE: There are three date formats as follows:

Enter two digits each for year (Y), month (M) and day (D)
YY/MM/DD
DD-MM-YY
MM.DD.YY (U.S. version)

The date must be formatted in the U.S. version to insure accurate calculations. For changing the format, see pages 9-4 and 9-5.

- f. Select "6 SET". The gestational age calculated by LMP is displayed as a dotted line on the graph and numerically in the "LMP-GA:" section.

LMP	1	1	1	EDB	1
.....					
.....					
.....					
.....					

LMP-GA: Gestational age by LMP
LMP-EDB: Estimated date of birth by LMP

LMP-GA: 35W4D		
LMP-EDB: 08/10/07		
CI	:	:
HC/RC	:	:
COMMENTS:	_	

- g. When it is desired to enter comments, press the COMMENT switch on the keyboard. Then enter the comment from the keyboard.

To return the cursor to the original position (at "ID:"), press the ID switch on the keyboard.

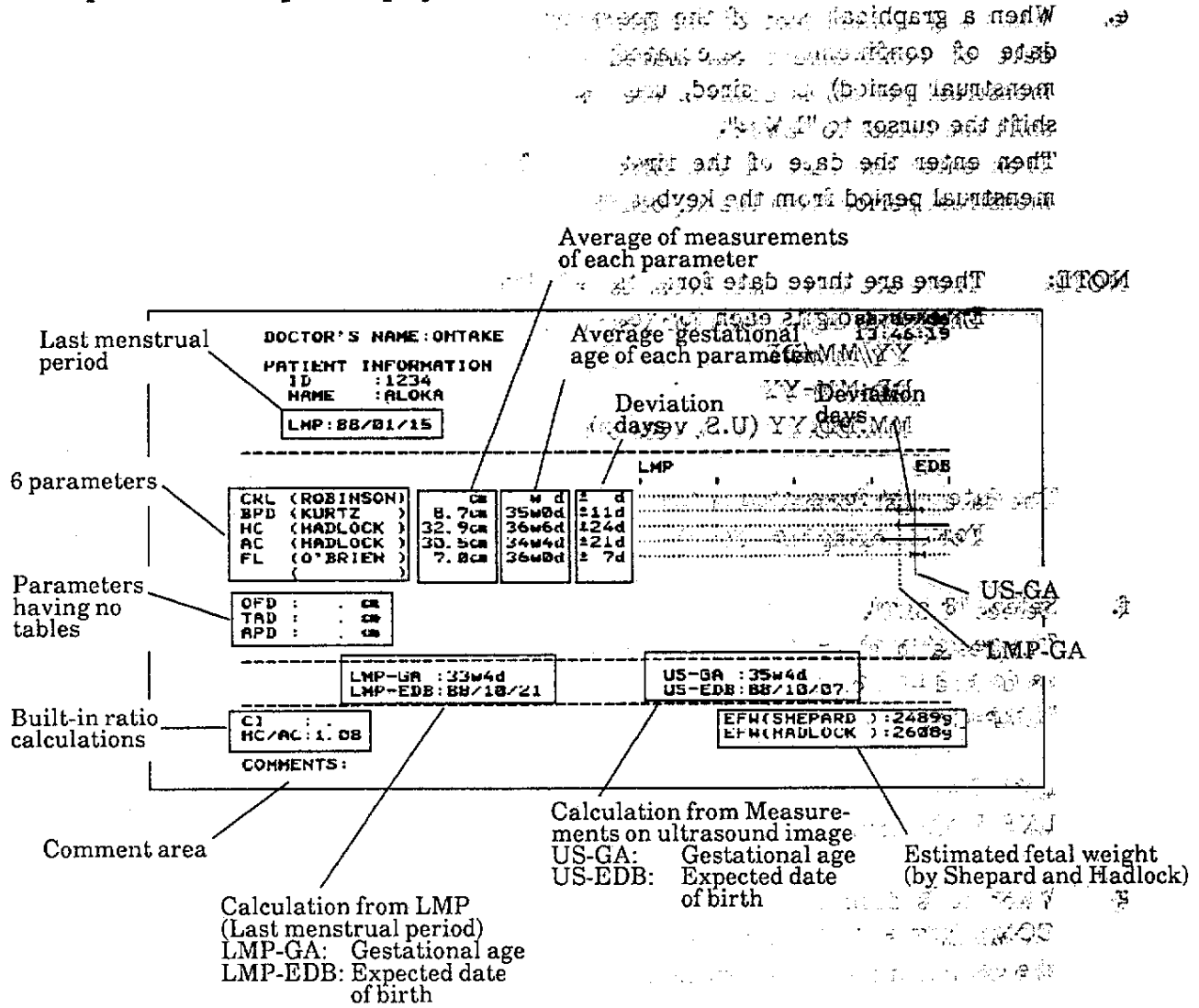
See the next page for explanation of each item in the report.

- h. To record the report, use the optional photography unit, thermal printer, etc. When a Polaroid photography unit is connected, press the CAMERA switch to take a photo.
- i. To return to measurement area, select "3 MEASUR".
- j. To return to B-mode imaging, select "1 EXIT" or press the MEASUREMENT switch.

NOTE: Pressing the NEW PATIE switch erases all the measured and calculated data.

REPORT AREA

5.2 Explanation of Report Display

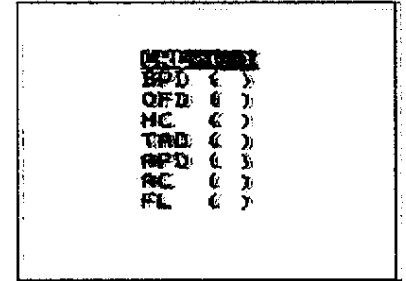


GENERAL ROUTINE FOR REPORT

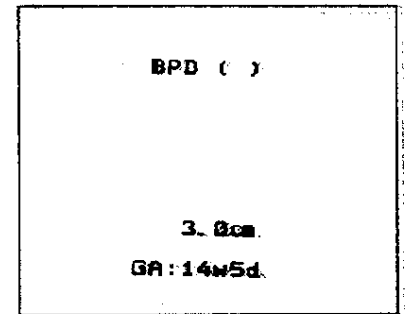
6. GENERAL ROUTINE FOR MAKING REPORT

Following is a general flow of operation. (Omitted is selection of parameter to be listed on the report.)

- a. In B-mode display, press the **MEASUREMENT** switch. Select "5 OB" in the menu. Parameters as shown to the right appear at the lower right of the screen.
The displayed parameters are the all that can be used for gestational age calculation.



- b. Using the trackball, shift the highlighting to the parameter to be measured. Select "6 SET". measure the parameter. Then select "6 SET" for registration.



NOTE: When it is desired to see measurement results, select "4 EDIT". Measurement result display area is displayed. Also, it is possible to correct or add new data.

- c. Select "2 REPORT" in the menu. Enter doctor's name, patient's name, date of last menstrual period, etc.

DOCTOR'S NAME: OHTAKE		88/09/06 13:46:19
PATIENT INFORMATION		
ID	: 1234	
NAME	: ALOKA	
LMP	: 88/01/15	

	LMP	EDB
CRL (ROBINSON)	cm	w d 2 d
BPD (KURTZ)	8.7cm	35w0d 211d
HC (HADLOCK)	32.9cm	36w6d 124d
AC (HADLOCK)	30.5cm	34w4d 121d
FL (O'BRIEN)	7.8cm	36w0d 17d
OFD	: cm	
TAD	: cm	
APD	: cm	

LMP-GA	: 33w4d	US-GA : 35w4d
LMP-EDB	: 88/10/21	US-EDB: 88/10/07
C1	: 1.08	EFW(SHEPARD) : 2489g
HC/AC	: 1.08	EFW(HADLOCK) : 2608g
COMMENTS:		

REPORT	1	2
	EXIT	REPORT
	3	4
	MEASUR	EDIT
	5	6
		SET

CONTENTS OF BUILT-IN TABLES

7. CONTENTS OF BUILT-IN TABLES

BPD (Kurtz) (cm) Week	Standard Deviation (days)	BPD (Robinson) (cm) Week	Standard Deviation (days)	PL (O'BRIEN) (cm) Week	Standard Deviation (days)
2.0	12	± 4	0.9	7	± 5
2.3	13	± 4	1.5	8	± 5
2.7	14	± 4	2.2	9	± 5
3.1	15	± 6	3.0	10	± 5
3.4	16	± 6	4.0	11	± 5
3.8	17	± 8	5.2	12	± 5
4.1	18	± 10	6.4	13	± 5
4.5	19	± 15	7.8	14	± 5
4.8	20	± 13			
5.1	21	± 11			
5.4	22	± 13			
5.7	23	± 12			
6.0	24	± 11			
6.3	25	± 11			
6.6	26	± 11			
6.9	27	± 9			
7.1	28	± 8			
7.4	29	± 7			
7.6	30	± 7			
7.9	31	± 9			
8.1	32	± 10			
8.3	33	± 11			
8.5	34	± 12			
8.7	35	± 11			
8.9	36	± 11			
9.1	37	± 9			
9.2	38	± 8			
9.4	39	± 8			
9.6	40	± 8			

CONTENTS OF BUILT-IN TABLES

AC (Hadlock)		Standard	HC (Hadlock)		Standard
(cm)	Week	Deviation	(cm)	Week	Deviation
(2/5D)	(mo)	(days)			(days)
10.4	16	+13	9.0	14	+9
11.6	17	+13	10.5	15	+9
12.8	18	+14	12.1	16	+9
13.9	19	+14	13.5	17	+9
15.0	20	+14	14.9	18	+11
16.2	21	+14	16.3	19	+11
17.3	22	+14	17.5	20	+11
18.4	23	+14	18.8	21	+11
19.5	24	+15	19.9	22	+11
20.6	25	+15	21.0	23	+11
21.6	26	+15	22.1	24	+11
22.7	27	+15	23.1	25	+16
23.8	28	+15	24.1	26	+16
24.8	29	+15	25.1	27	+16
25.9	30	+21	26.0	28	+16
26.9	31	+21	26.9	29	+16
27.9	32	+21	27.7	30	+19
28.9	33	+21	28.5	31	+19
29.9	34	+21	29.3	32	+19
30.9	35	+21	30.1	33	+19
31.9	36	+18	30.9	34	+19
32.9	37	+18	31.6	35	+19
33.9	38	+18	32.3	36	+19
34.8	39	+18	33.0	37	+24
35.8	40	+18	33.7	38	+24
			34.4	39	+24
			35.0	40	+24

CONTENTS OF BUILT-IN TABLES

BPD (Hadlock) (cm)	Week	Standard Deviation (days)	BPD (Sabbagh) (cm)	Week	Standard Deviation (days)	FL (Hadlock) (cm)	Week	Standard Deviation (days)
2.3	13	+ 8				1.1	13	+10
2.6	14	+ 8				1.4	14	+10
3.0	15	+ 8				1.8	15	+10
3.3	16	+ 8	3.7	16	+ 7	2.1	16	+10
3.7	17	+ 8	4.0	17	+11	2.4	17	+10
4.0	18	+12	4.3	18	+12	2.7	18	+13
4.3	19	+12	4.5	19	+12	3.0	19	+13
4.6	20	+12	4.7	20	+12	3.3	20	+13
4.9	21	+12	5.0	21	+11	3.6	21	+13
5.2	22	+12	5.3	22	+12	3.9	22	+13
5.5	23	+12	5.6	23	+11	4.1	23	+13
5.8	24	+15	5.9	24	+9	4.4	24	+15
6.1	25	+15	6.2	25	+11	4.6	25	+15
6.4	26	+15	6.6	26	+14	4.9	26	+15
6.6	27	+15	6.9	27	+20	5.1	27	+15
6.9	28	+15	7.2	28	+19	5.3	28	+15
7.2	29	+15	7.5	29	+21	5.6	29	+15
7.4	30	+22	7.8	30	+20	5.8	30	+21
7.6	31	+22	8.0	31	+25	6.0	31	+21
7.9	32	+22	8.3	32	+23	6.2	32	+21
8.1	33	+22	8.5	33	+25	6.4	33	+21
8.3	34	+22	8.7	34	+25	6.6	34	+21
8.6	35	+22	8.8	35	+22	6.9	35	+21
8.8	36	+22	9.0	36	+22	7.1	36	+22
9.0	37	+22	9.2	37	+22	7.3	37	+22
9.2	38	+22	9.3	38	+28	7.4	38	+22
9.4	39	+22	9.4	39	+32	7.6	39	+ 22
9.6	40	+22	9.5	40	+37	7.8	40	+ 22

CONTENTS OF BUILT-IN TABLES

FL (Jeanty) (cm) - Week	Standard Deviation (days)
1.2	13
1.5	14
1.8	15
2.0	16
2.3	17
2.6	18
2.9	19
3.1	20
3.2	21
3.7	22
4.0	23
4.2	24
4.5	25
4.7	26
5.0	27
5.2	28
5.5	29
5.7	30
6.0	31
6.2	32
6.4	33
6.7	34
6.9	35
7.1	36
7.3	37
7.6	38
7.8	39
8.0	40