Model SRF618B5

Fetal Monitor

User's Manual

People's Republic of China

Sunray Medical Apparatus Co., Ltd.

Ver. E.3.0 2012-03

Manufacturer's Statement

This manual should be used as a reference for operating this instrument only. This company will not undertake any consequence and responsibility produced by using this manual for other purposes.

The information contained in this manual is subject to change without notice.

As a result of technical update or user's special requirement, some parts or components may be somewhat different from the standard configuration specified in this manual as long as the performance indexes of the instrument are not affected. Please keep this in mind.

Caution: Federal law restricts this device sale by or on the order of a physician

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Commitment

Our company guarantees that this instrument will not have any quality problem in material and technology within the guarantee period promised by our company. If the product purchased by the user has such a kind of quality problem, please notice our company. Our company will provide warranty for the user free of charge, and will repair or replace the product that is proved to be defective according to actual circumstances. Please see the "Stipulations for Warranty" specified on the "Warranty Card" for details.

The designed service life of this product is 5 years. This company will provide repair service for the user within the term of the service life.

Note: Consumables such as paper, ultrasonic jelly and recorder cartridge are out of the scope of warranty.

Contents

Indications for Use

SRF618B5 Fetal Monitor detects and displays single or twin (optional) Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) in a real time on the color LCD viewer, and also provides the fetal heart beat sound with internal speaker. Ten hours of tracing may be stored and later retrieved for printing. It is intended for antepartum use by trained healthcare personnel. It is not intended for home use.

Contraindications

None known.

Patient Populations

Pregnant women

Warning

- We recommend that ultrasound procedures be performed in accordance with the "ALARA" principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable. With the SRF618B5.

  The transmitted acoustic power is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.
- To avoid the risk of electric shock, this equipment must only be connected with the supply mains with protective earth. For this purpose, this instrument is equipped with a three-wire power cord. When this cord is plugged into a suitable three-wire socket, the casing of this instrument is connected to the earth wire. The operator shall check whether this instrument is properly earthed before using this instrument every time. Whenever there is a possibility that the protective earth is damaged, the use of this instrument shall be stopped, and measures shall be taken to avoid this instrument being operated by someone accidentally.
- All the transducers, buttons and their connecting cables shall never have any mechanical damage. When any of these components is damaged, the use of the damaged component shall be immediately stopped.
- According to the requirements for application environmental safety, this instrument cannot be used at a place where an inflammable anesthetic or gas mixture exists.

- This monitor can be used by trained doctors and nurses only.
- To avoid an expected electric shock, do not open the equipment cover or disassemble the equipment.
- This monitor is not a therapeutic instrument nor is it a device that can be used at home.
- In case the monitor is found to be working abnormally or indication of errors appears, please do not use this monitor for monitoring and should contact the service center of the manufacturer as soon as possible.
- When several parts of equipment are interconnected, the total leakage current is limited to the safety range according to standards IEC 60601-2-27:2005.
- Do not subject the transducer to autoclaving.
- Do not use any transducer or cable that may be damaged or deteriorated.
- The lower limit and the upper limit of parameter must be set based on clinical practices and general clinical experiences.
- Before cleaning the monitor or the transducers, make sure that the equipment is switched off and disconnected with the power line.
- Do not use EtO gas or formaldehyde to disinfect the monitor.
- Do not use the equipment in the vicinity of flammable anesthetics and solvents.
- Warning: Accessory equipment connected to the analog and digital interface must be certified according to the respective IEC standards (e.g. IEC 60950-1:2005 for data processing equipment and IEC 60601-1:2005 for medical equipment). Furthermore all configurations should be complied with the valid version of the system standard IEC 60601-1-1:2000. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1:2000. If in doubt, consult the technical service department or your local representative.
- Please pay attention to the ultrasonic energy radiation and reduce the time of ultrasonic radiation during the diagnoses.

Safety Notes

- This monitor is the CLASS I ME EQUIPMENT.
- APPLIED PARTS are the TYPE B APPLIED PARTS.
- The equipment conforms to Class I according to IEC/EN 60601-1 (Safety of Electric Medical Equipment)
- This equipment conforms to Level B according to IEC/EN 60601-1-2(Electromagnetic Compatibility Requirements)
- This instrument is a conventionally sealed device, which cannot prevent water from intruding.
- The degree of protection against harmful ingress of water and particulate matter of the FHR transducer is IP68.

- All the transducers, buttons and their connecting cables shall not be soaked in water or other liquid materials, and shall be cleaned, sterilized and operated according to the methods specified in this manual.
- This instrument is a continuously working device.
- The AC input at the back panel of the instrument can be connected with the 110V~230V AC Power by electrical wires supplied with this instrument.
- It shall be ensured that there is no condensed water with the instrument when it is being operated.
- The cable connecting the patient to the instrument shall not contact with other electrical equipment, and it shall be ensured that there is no electrolyte on it.
- Please place the monitor on level and stable supporting plane, not on the places that can easily shock or wake. Enough space should be left around the monitor so as to guarantee normal ventilation.
- A dedicated medical ultrasound jelly shall be used for the FHR transducer under normal operation, and cannot be replaced by water or other liquids.
- The uterine contraction pressure transducer shall not be coated with any ultrasound jelly or other liquid materials under normal operation, and shall be prevented from moisture at any other time.
- The monitor does not contain any parts for self-repair by users. The repair of the instrument must be conducted by the technical personnel authorized by the manufacturer.
- The voltage for normal running of this instrument is a.c.110V~230V. An a.c.110V~230V power voltage stabilizer must be used for this instrument in a voltage unstable area.
- The recorder paper should be stored in a cool, shady and dry environment.
- When an alarm occurs, you should always check the patient's condition firstly.
- The equipment should not be placed in the vicinity of electric generator X-ray, broadcasting apparatus to eliminate the electric noise during operation Otherwise, it may cause incorrect result. Self-power line is important for SRF618B5. To use same power source with other electric instruments may cause incorrect result.
- The equipment does not include elastic cotton band in end product package. The user must buy the suitable FDA listed or cleared band by themselves.

Description of Symbols

This symbol is located on the nameplate of the instrument's mainframe, indicating that this instrument is a type B electric shock prevention device. Type B device: A device that has particular prevention of electric shock.

This symbol is located on the nameplate of the instrument's mainframe, indicating that Attention, consult ACCOMPANYING DOCUMENTS.

IP68	This symbol is located on the FHR (Doppler ultrasound) transducer and the uterine contraction pressure transducer, indicating that this transducer is waterproof device. Waterproof device: Impervious to or unaffected by water. The Transducer can work normally in the one-meter deep water for an hour. This symbol is located on the instrument's protective earth terminal, indicating an Equipotentiality symbol.
US	This symbol is located on the FHR transducer, indicating that this transducer is a FHR transducer.
TOCO	This symbol is located on the uterine contraction pressure transducer, indicating that this transducer is a uterine contraction pressure transducer.
	This symbol, as a symbol of danger, is located on the inverter that provides backlight source for the LCD. The AC voltage outputted by the inverter is as high as 900 volts.
TOCO	This symbol id located on the mainframe panel, indicating that this receptacle is for uterine contraction pressure transducer.
FM	This symbol id located on the mainframe panel, indicating that this receptacle is for fetal movement transducer.
FHR1	This symbol id located on the mainframe panel, indicating that this receptacle is for fetal heart rate transducer receptacle 1.
FHR2	This symbol id located on the mainframe panel, indicating that this receptacle is for fetal heart rate transducer receptacle 2.
	Printing start/stop
	Uterine contraction pressure zeroing
	Sound volume decrease
	Sound volume increase
	Alarm switch
	Menu
	Event record
NET	Communication port

I. Overview of the Instrument

I) Expected Functions and Purposes

This fetal monitor is used to externally monitor fetal heart rate (FHR) and uterine activity (TOCO) during the prenatal period from the early stage of pregnancy (approximately 20 – 25 weeks) to mature pregnancy.

When fetal heart rate is monitored externally, an ultrasound transducer is clipped on a belt strapped on the pregnant woman's abdomen. The transducer sends a low energy ultrasound signal to the fetus's heart and detects the reflected signal.

When uterine activity is monitored externally, a "TOCO" transducer is clipped on the second belt. This transducer detects pressure variation, thus giving a relative measurement of uterine activity.

Information about fetal heart rate, uterine activity and fetal moment are all displayed on the monitor and recorded on recording paper in the form of trajectory graphic.

II) Structural Composition

The structure of the entire monitor is as shown on Fig.1-1:

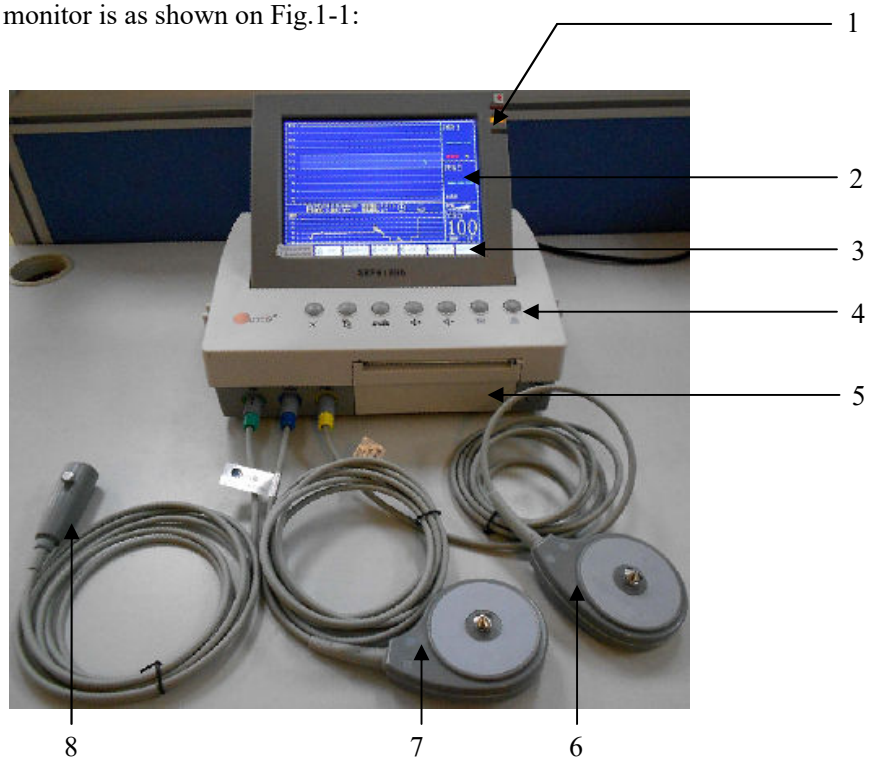


Fig.1-1

1. Mainframe: It includes a circuit detecting signals of fetal heart rate, uterine contraction pressure and fetal movement, a signal processing circuit, a printing drive circuit and a keyboard processing circuit. The mainframe is the core of signal acquisition, signal processing, data display and printing control.
2. Display: An 8.4-inch TFT LCD, on which the twin curves can be displayed on separate axes.
3. Touch screen buttons: Instrument operation control buttons that have the same functions as those on the control panel. Touch screen buttons are optional.
4. Control panel buttons: Instrument operation control buttons that are used for performing functions such as event recording, uterine pressure zeroing, system setting, saved data playback, network setting, volume adjusting, time setting, printing control, display mode switching, turning on and off of printing timing function, timing time setting, turning on sound alarm, etc.
5. Recorder: Built-in fast thermal dot matrix recorder.
6. First FHR transducer: With a US symbol this transducer transmits pulse ultrasound and receives the echo wave signal reflected by the fetus's heart, thus detecting fetal heart rate.
7. Uterine contraction pressure transducer: With a TOCO symbol this transducer measures the relative pressure of the pregnant woman's abdomen, which indicates uterine contraction intensity, hence is also called uterine contraction pressure.
8. Fetal movement marking button: A manual fetal movement marking button. When using the fetal movement marking button, the pregnant woman herself can hold it in her hand and press it once when feeling any fetal movement, and then the mainframe will place a fetal movement mark on corresponding time coordinate.

III) Mainframe Panel of the Instrument

The mainframe panel is as shown on Fig.1-2:

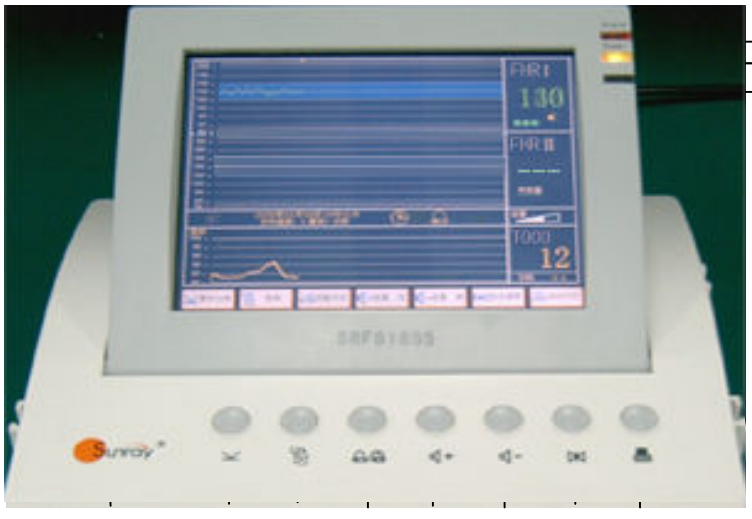


Fig. 1-2

A. **Alarm light:** For fetal heart rate limit exceeding alarm.

B. **Power light:** Mainframe working indicator light. This light illuminates when the mainframe is turned on and powered up.

C. : Printing start/stop**.** Pressing and holding this button (for more than 3 seconds) will feed the paper.

D. **Printing:** A touch screen button whose function is the same as .

E. : Pressing this button will zero uterine pressure, or the instrument will zero uterine pressure automatically in half a minute after the instrument is turned on.

F. **Uterine contraction pressure zeroing:** A touch screen button whose function is the same as .

G. : Pressing this button will reduce sound volume.

H. **Sound volume decrease:** A touch screen button whose function is the same as .

I. : Pressing this button will increase sound volume.

J. **Sound volume increase:** A touch screen button whose function is the same as .

K. : Pressing this button will start the sound alarm function temporarily, but will not change internal menu parameters and the icon, and the status will not be saved when the instrument is turned off.

L. **Alarm switch:** A touch screen button whose function is the same as .

M. : Pressing this button will open the menu to perform functions such as system setting, alarm setting, stored data playback, network setting, printing setting, and time setting.

N. **Menu:** A touch screen button whose function is the same as .

O. : Pressing this button will enter the event record menu.

P. **Event record:** A touch screen button whose function is the same as .

Q. "Company" logo.

NOTE: Since panel buttons correspond with touch screen buttons one by one and their functions are

completely consistent, in the descriptions below only the usage of panel buttons will be mentioned, and the usage will be fully applicable to touch screen buttons.

IV) Front Panel of the Instrument

The front panel of the instrument is as shown on Fig.1-3:

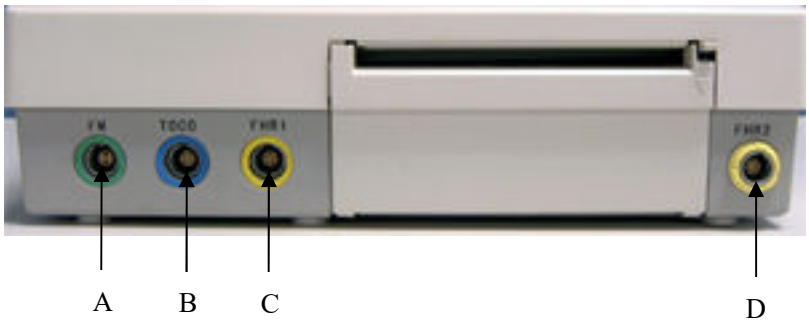


Fig.1-3

A. "Fetal Movement" socket: This green socket is connected to the plug of the fetal movement button.

B. "Uterine Contraction Pressure" socket: This blue socket is connected to the uterine contraction pressure transducer.

C. "Fetal Heart Rate" socket I: This yellow socket is connected to the ultrasound fetal heart rate monitoring transducer.

D. "Fetal Heart Rate" socket II: This yellow socket is connected to the ultrasound fetal heart rate monitoring transducer. (optional)

V) The Back of the Instrument

The back of the instrument is as shown on Fig.1-4:

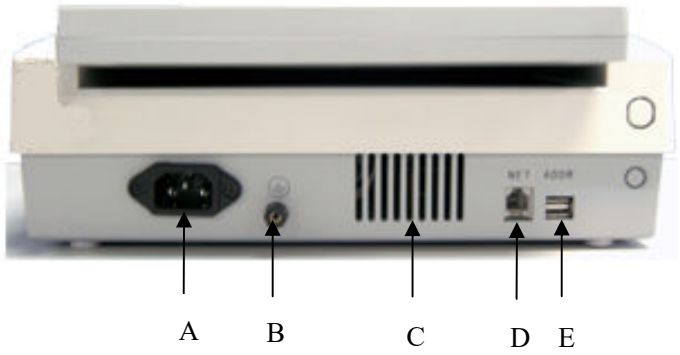


Fig.1-4

A. External power socket: External AC power socket.

B. Isopotential earthing wire terminal: Instrument earthing port.

C. Mainframe heat radiation vent.

D. "Communication" port: Network connecting cable port used when the instrument is connected to the central computer.

E. Reserved

F. Reserve

II. Technical Indexes

Power:	Voltage: 110~230Vac
	Frequency: 50/60Hz
	Rated power: 65VA
	Fuse: T2AL, 250Vac
Working environment:	Temperature: +5 ~ +40℃
	Relative humidity: ≤ 80%
	Atmospheric pressure: 86-106kPa
Storage environment:	Temperature: -10 ~ +40℃
	Relative humidity: ≤ 80%
	Atmospheric pressure: 50-106kPa
	Without corrosive gases and well ventilated.
Dimensions and weight:	This instrument is an integrated structure, whose dimensions and weight for storage and transportation are as follows:
	Dimensions: Length: 290mm, width: 230mm, height: 86mm
	Net weight: 3kg
Display:	TFT LCD
	3 Channels (FHR, UC, FM)
Recorder and printing paper:	Built-in fast thermal dot matrix recorder
	Folded thermal printing paper with 112mm in width and 20m in length for each load of paper
Fetal heart rate measurement:	Measurement method: Ultrasound Doppler
	Input signal: Ultrasound Pulse Doppler
	Measurement Range: 30~240 beats per minutes (BPM)
	Measurement Accuracy: ±1BPM over normal FHR range
	Ultrasound working frequency: 2MHz

	Ultrasound Power: See Part XVII "Ultrasonic Related Information"
	Display: Instantaneous fetal heart rate display
	Heart rate curve display: 30~240BPM
	FHR Detection Method: Auto Correlation
Uterine contraction pressure	Measurement method: External Transducer with strain gauge
measurement:	Frequency Response: Dc ~ 0.5 Hz
	Measurement scope: 0-1000g
	Measurement Range: 0~100 units
	Reference (Zero) Control: One touch switch
Fetal movement recording:	Manual button marking function
	FHR Detection Record Method:
	1) Spike-like waveform on UC channel denotes relative intensity and duration of Fetal Movement.
	2) Dot marks between FHR and UC channels when FM intensity exceeds threshold. Monitoring data storage: 16 data storage files can be established at most; the longest continuous storage time is 10 hours; the data can be played back and selected for printing at real time.
Data communication interface:	Data transmission rate: 9600BPS

Networking mode and number of subunits: Bus data transmission mode; 32 subunits can be connected at most

Paper feeding speed for printing: Three levels (1, 2 and 3cm/min) adjustable, the error: ≤±5%

Recorder:	Real time fetal heart rate curve recording
	Real time uterine contraction curve and fetal movement mark recording
	Recorder Method: Thermal Array Type
	Resolution: 8(vertical)/8(horizontal) dot/mm
	Paper Feeding Function
	Print Contrast: Five levels (1, 2, 3, 4 and 5) adjustable
	Auto Print Period: 10,15,20,25,30,35,40,45,50,55,60
Alarm:	a. Sound and light alarm of fetal heart rate limit exceeding
	Lower limit: 50BPM-200BPM adjustable

	Upper limit: 60BPM-210BPM adjustable
	b. Sound alarm triggered time: 0-30sec. Adjustable.
Indicators:	Heart rate signal quality (Green: Stable Red: Unstable)
	Alarm On
	Print On/Off State
	AC Power (Yellow LED)
Sound:	Doppler Sound with Volume Control (16 steps)
	Alarm Sound
Set-up	Alarm Upper/Lower Limit Value
	Alarm check delay time
	Print Speed
	Print Contrast
	Auto Print Period (NST time)
	Time/Date
	Auto Movement On/Off
Function	Event Mark Function
External Link	RS485: Central (Option)
Length of transducer wire:	2-2.5m

III. Installation of the Instrument

I) Unpacking

1. Unpack all external packing for the monitor and its accessories.
2. Count all items according to the Packing List.
3. Check the monitor and its accessories for any damage.
4. If any item is missing or damaged, please contact the consignment unit and our company.

II) Installation

1. This monitor is a desktop/ hanging instrument, which shall be placed on the desk or mounted on the wall when used. Installation position and manner shall be decided based on specific situation.

NOTE: When you use this instrument you shall keep a certain distance (more than 300mm) with other equipment around, so as to ensure the convenience and safety of the use of this instrument.

2. Connect the power cord to the mainframe.

NOTE: To ensure the instrument performance and operating safety, the operator shall check whether this instrument is properly earthed before using this instrument every time (refer to the Safety Notes).

- The power socket in the power grid shall be a three-receptacle socket;
- Inside the protective earth receptacle in the power socket in the power grid there shall be a reliably earthed earth wire;
- The plug from power wire connecting board must be reliably connected to the power socket on the mainframe.

Insert the plug (with a yellow marking) of the FHR transducer (with a US symbol) into the "Fetal Rate" receptacle on the instrument panel; Insert the plug (with a blue marking) of the uterine contraction pressure transducer (with a TOCO symbol) into the "Uterine Contraction Pressure" receptacle on the instrument panel; Insert the plug (with a green marking) of the fetal movement marking button into the "Fetal Movement" receptacle on the instrument panel.

3. Having checked out everything to be OK, turn on the power switch, the instrument will enter monitoring status.

4. And now use the following method to test whether the instrument has been installed correctly and able to work normally:

   - Wet your hand or dip a little bit of water with your hand and gently slide on the detecting surface of the FHR transducer, then you will hear the Doppler sound issued by the instrument. If the sound is not loud enough, you can improve it by means of increasing the sound volume, adding a little more water, speeding up the speed of relative movement between your hand and the transducer, or fully getting in touch with the detecting surface of the transducer.

   NOTE: Please never apply too much force on the FHR transducer so as to prevent the instrument from damaging.

   - A few minutes later the monitor will start to display the detected data. Now gently and periodically (approximately 120BPM) touch the surface of the FHR transducer. If a Doppler sound can be heard, this instrument should be able to detect the data of this simulated fetal heart rate.

   - Gently press the measured area of the TOCO transducer, the instrument should be able to detect the data of this simulated uterine contraction pressure. The range of weight measured is 0~1000g, the corresponding range of digital display is 0~100%, and the range of curve display is 0~100%. If the pressure exceeds 1000g, saturation will occur: Corresponding digital display will be always 100%, and curve display will be always100% too.

NOTE: Please never apply too much force on the uterine contraction pressure transducer so as to prevent the instrument from damaging. And never let the uterine contraction pressure transducer contact with water or ultrasound jelly or the circuit inside the transducer might be damaged.

   - Press the fetal movement marking button once, the instrument should be able to detect this simulated fetal movement signal.

   - If necessary, test whether the printing is normal: Press the button, the recorder will start plotting the curve.

5. Since this instrument is a monitoring type instrument, which uses an advanced and unique algorithm, the detected fetal heart rate signal, uterine contraction pressure signal and fetal movement signal will be delayed for approximately 3 seconds before they are displayed. This has no adverse effect on the clinical value of this instrument, on the contrary, this will be helpful for this instrument to capture each fetal heart beat more accurately, analyze the data, correct errors, and calculate fetal heart rate data precisely.

NOTE: When the Doppler Transducer is put not on the back but on the breast part of fetus, accurate ultrasonic waves cannot be caught from the fetal heart and fetal heat beat can be frequently missed.

IV. Parts

Repair parts, along with part numbers, are listed in the tables that follow.

Monitor

Description	Part No.	Qty
Power Supply Assembly	P4902-00012	1
Loudspeaker Assembly	P4501-08010	1
Stepper Motor Assembly	P4909-03005	1
Bottom Housing Assembly	P2223-04012	1
Top Cover Housing	P2224-04030	1
Top Cover Assembly	P2224-04032	1
Display Assembly	P1224-02031	1
Paper Drawer Assembly	P2262-01012	1
Main CPU Board	P1224-02011	1
Recorder Adapter Board	P1262-02033	1

Transducers

Description	Part No.	Qty
Ultrasound Transducer	P1221-05031	1
TOCO Transducer	P1224-05040	1
FM Transducer	P1221-12003	1

Accessories

Description	Model	Manufacturer
Paper for Recorder	30-240 FHR Scale 50-240 FHR Scale	Sunray Medical Apparatus. Inc

V. Clinical Operation

I) Preparation to Monitor

(1) Switching On

- Switch the monitor on
- The power-on LED comes on
- The monitor display comes on

(2) Adjusting the Display Angle

- You can tilt the display to different positions, or you can fold it completely down.

(3) Fastening Belts and Transducers

- Prepare the transducers, ultrasound jelly and straps.
- Insert the needed transducer(s) and fetal movement marking button into the monitor. The connection of the transducer(s) is one-to-one correspondence. If a transducer is inserted to a wrong receptacle, it cannot be connected correctly.

NOTE: The fetal heart rate transducer is different from the uterine contraction pressure transducer.

- If you prepare for fetal heart rate monitoring only, place a strap on the bed, and then let the pregnant women lie on it; if you prepare for fetal heart rate and uterine contraction pressure monitoring simultaneously, place two straps on the bed, and then let the pregnant women lie on them. The strap(s) is/are used for fixing the transducer(s).

II) Clinical Operation

(1) Locating the Monitoring Position

Locate the best position to monitor fetal heart rate by touching or hearing the pregnant woman's abdomen or by other means. This procedure will be somewhat different depending on how skilful the operator is and specific pregnant women, and needs to be practiced and experienced repeatedly.

(2) Coating Ultrasound Jelly

Coat a proper amount of ultrasound jelly on the FHR transducer. ***The amount of jelly used should be appropriate: Too little of which will cause serious attenuation of ultrasound, which is adverse to detecting fetal heart sound accurately; too much of which will cause the transducer deviating from its original position during monitoring and dirty the clothes and strap.***

(3) Fixing the Transducer

Place the transducer in the best position on the pregnant woman's abdomen for monitoring fetal heart rate, hold it in position with the strap, and slightly move the position and direction of the FHR transducer back and forth. In a certain position and direction the volume of the fetal heart sound is maximum, meaning that this position is the best. And now fix the transducer with the strap. It is the key to correct use of the fetal monitor whether this procedure is skillfully done. ***Maximum fetal heart sound is the only criterion to determine the best transducer position.*** If the sound is found to be too loud, the sound volume should be reduced by adjusting the sound volume rather than by moving the transducer.

(4) Adjusting Sound Volume

To adjust the sound volume to an appropriate level: Press the button to increase the sound volume or press the button to reduce the sound volume. The magnitude of sound volume can be seen on the sound volume status bar, as shown on Fig.4-1. During monitoring the sound volume can be turned down to the minimum, but it would be better not to turn off the sound volume, because that with the sound the operator or the pregnant woman can determine whether or not the transducer deviates from the best position.

Fig.4-1 Sound Volume Status Bar

(5) Monitoring Fetal Heart Rate

When fetal heart rate is monitored, the range of fetal heart rate measurement is 30-240BPM, the corresponding digital display is as shown on Fig.4-2, and the curve display is as shown on Fig.4-3.

Fig.4-2

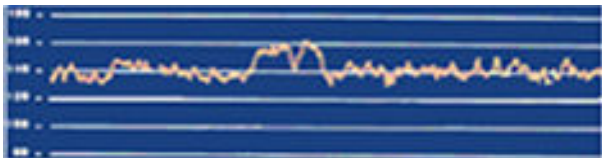


Fig.4-3

One thing to be noticed is that the best position of the FHR transducer may change during monitoring, the reasons for that are the fetus squirming, the pregnant woman turning her body to one side, and the strap sliding. Too serious deviation of the transducer position may result in no sound, no heart rate curve, or detection precision being affected. In order to reduce or avoid the occurrence of such a circumstance, the following procedures shall be done properly:

- The first thing to do is to locate the best position for FHR. This is the basic skill;
- Ask the pregnant woman to lie down naturally and comfortably;

- The strap shall be fixed reliably with a suitable tightness;
- Ultrasound jelly shall be applied in a proper amount;
- During monitoring the operator shall be earnest and responsible and carry out patrolling inspection once every few minutes. If finding that the fetal heart volume is obviously lower, the operator shall readjust the position of the transducer.

Technical Description:

a) The fetal heart sound issued by the monitor is not the real fetal heart beating sound, and there is not much diagnostic value with its sound quality either. Actually, the fetal heart sound issued by the monitor is the sound signal derived from fetal heart pulse through multiple times of conversion of physical variables of ultrasound signal and electronic signal, indicating the movement information of fetal heart beat. This is different from the fetal heard sound heard from a stethoscope.

b) This instrument cannot be used to measure an adult's heart rate. It is a wrong operation for an operator to direct the fetal heart rate transducer to the pregnant woman's heart to verify the measurement accuracy of the monitor.

c) If the sound is found to be unclear or too low, the transducer position should be adjusted or the earth wire checked for properly earthing; otherwise the heart rate curve may appear to be scrambled or have multiple breakpoints.

(6) Monitoring Uterine Contraction Pressure

If the uterine contraction pressure needs to be monitored, strap another strap and install a uterine contraction pressure transducer on the pregnant woman's abdomen with uterine contraction reaction. Key points in measuring uterine contraction pressure: There are not too many requirements for the position, which should be slightly away from the FHR transducer to prevent it from being dirtied by ultrasound jelly; the tightness should be proper and reliable. The range of uterine contraction pressure measurement is 0~1000g, and the range of corresponding digital display is 0~100%, shown as Fig.4-6, the range of curve display is 0-100%, shown as Fig.4-7. If the transducer is strapped too tightly, pressure measurement is prone to saturation, leaving the pressure curve a saturated flat top at the top of the table when uterine contraction occurs. If the transducer is strapped too loosely, the amplitude of the uterine contraction pressure curve is too small or the uterine contraction wave cannot even be seen from the curve when the pregnant woman is having a uterine contraction. This can only be skillfully mastered by the operator through the accumulation of experience and practice over a long period of time.

Fig.4-6 Uterine Contraction Curve Digital Display Bar

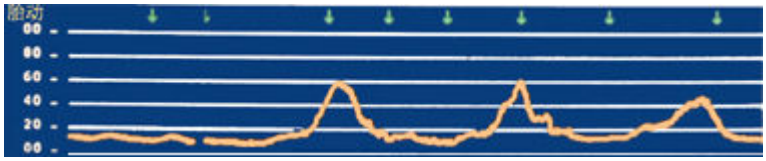


Fig.4-7 Uterine Contraction Pressure Curve Display Bar

(7) Zeroing Uterine Contraction Pressure

Having entered the monitoring status, the instrument displays the digital value and curve of fetal heart rate and uterine contraction pressure. And now uterine contraction pressure can be zeroed: When there is no uterine contraction, the tightness of the strap is suitable, and the displayed value of uterine contraction pressure is approximately 25%, press the ⋈ button to adjust current uterine contraction pressure value to 20%, as shown on Fig.4-9.

Fig.4-8 Zero Uterine Contraction Pressure

Fig.4-9 Uterine Contraction Pressure Digital Display Bar

Technical Description:

a) The data and curves from uterine contraction pressure measurement reflect the magnitude of relative value of the intensity of pressure inside the womb. Due to the influence of various factors such as the shape of the transducer, the placing position and direction of the transducer, and the magnitude of elasticity of the strap, the absolute value of uterine contraction pressure does not have any corresponding relationship with the intensity of pressure inside the womb.

b) During monitoring, it is necessary to adjust the zero of uterine contraction pressure, i.e. uterine contraction pressure zeroing shall be carried out whenever the zero is found having a relatively large change in a certain interval of time.

NOTE: The uterine contraction pressure transducer should never be coated with ultrasound jelly, otherwise the uterine contraction pressure transducer might be damaged, and more seriously safety risks may be produced. Measures should be taken routinely to prevent the transducer from moisture.

(8) Recording Fetal Movement Manually

If fetal movement needs to be recorded manually, then ask the examinee (pregnant woman) to hold the fetal movement button connected to the instrument, and tell her to press the button once when she feels fetal movement once. The detected fetal movement signal will be marked on corresponding time coordinate on the graphic. This monitor has one type of quickening recording methods: Manual as shown by the green arrows on Fig.4-10. This instrument has two ways to record fetal movement, namely, manual recording and automatic analysis recording, which can be carried out simultaneously as mutual complements.

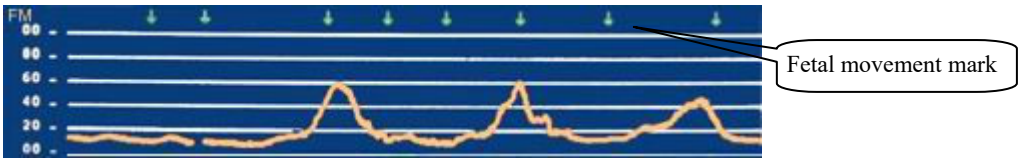


Fig.4-10 Fetal Movement Mark Display Bar

(8) Event Recording

Fig.4-11 Main Menu Bar

If it is necessary to mark the concerned position on the fetal heart rate curve, the operator can press the button on the main menu bar to enter the event recording status.

Fig.4-12 Event Recording Menu Bar

Now press the button on the event recording menu bar, the event recording mark "A" will appear on corresponding time coordinate on the monitor. Accordingly, press the + button, −button and button, the event recording marks "B", "C" and "D" will appear, as shown on Fig.4-13. Marking of 4 events-A,B,C,D is defined by user. If the recorder is in printing status, these event recording marks will also be shown on corresponding positions on the printing paper. The maximum event record is 26, with marking by "A"~"Z".

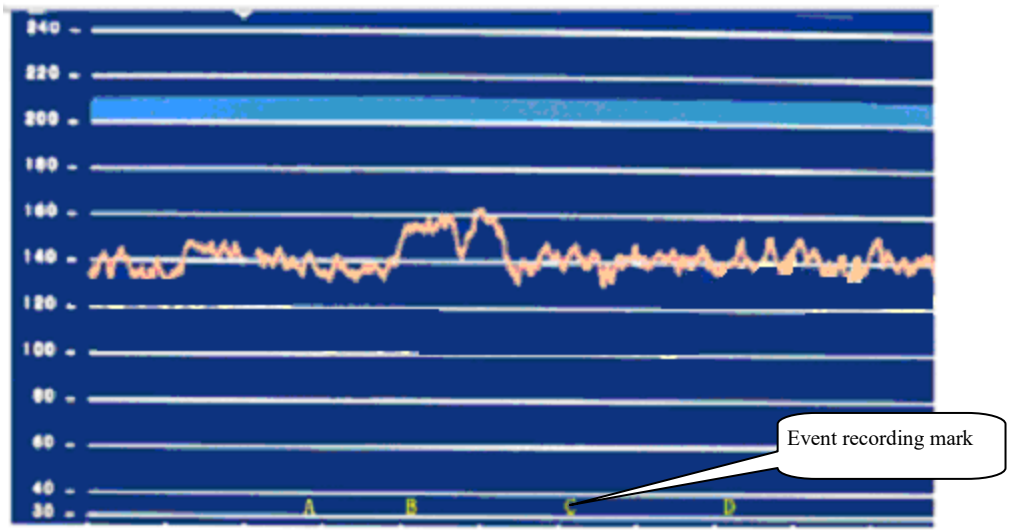


Fig.4-13 Event Recording Mark Display Bar

(9) Real-time Printing

Fig.4-14 Main Menu Bar

During monitoring, press the button on the main menu bar, the recorder will be in printing status, and press the button again, the recorder will stop printing. Printing status can be displayed on the status display bar (as shown on Fig.4-15 and Fig.4-16).

Fig.4-15 Printing Status

Fig.4-16 Non Printing Status

III) After Monitoring

(1) Switch off the recorder.

(2) Remove the transducer from the patient and, using a soft tissue, remove any gel from it. Then clean the transducer.

(3) Discharge the patient.

(4) Switch off the monitor.

VI. Alarm

Alarm Classification

There are two kinds' alarms in our device according to alarm condition: Physiological Alarm and Technical Alarm. All physiological alarms are latched alarm, while all technical alarms are non-latched alarm. Both physiological alarm and technical alarm include visual alarm indication and auditory alarm indication.

Physiological Alarm

When the patient's monitoring physiological value is out of the limitation, the Physiological Alarm will work. The physiological alarm default setting and limitation are as the below:

Alarm Setting	Options	Default
FHRI/FHRII Alarm	On, Off	On
FHRI/FHRII Lower Limit	50~205 bpm, in increments of 5	120 bpm
FHRI/FHRII Upper Limit	55~210 bpm, in increments of 5	160 bpm
Alarm Sound	Low, Middle or High	Middle
Alarm Delay	0~300 second(s), in increments of 5	0 second

Note: You can not close physiological alarm and change the limitation without password. This senior function is only for service or maintenance.

Technical Alarm

The device includes the alarms for some technical failures, e.g. interruption of power supply, disconnection of applied parts (transducers, FM marking button). You can see the Error Code in the EVENT column.

Alarm Message	Cause	Countermeasure
US1 UNPLUGGED or US2 UNPLUGGED	US transducer 1 or US transducer 2 is not well connected.	Check the connection of the transducer.
US1 SIGNAL LOSS or US2 SIGNAL LOSS	FHR1 or FHR2 signal is too weak for the system to analyze.	Check if the US transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the woman's condition.
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.
Battery Low	The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are aimed at the same fetal heart; the signals	Adjust one of the US transducers until another fetal heart signal is detected.

	overlap.	

Visual Alarm Indication

If the alarm is triggered by an alarm limitation violation, the digital display and the curve display of the fetal heart rate on the monitor screen will be shown in red. And the red alarm lights will be flashed. The visual alarm cannot be turned off.

Auditory Alarm Indication

Auditory alarm indicator patterns are repeated until the alarm condition ceases. You can change the Alarm Tone Volume according to the following operation:

1. Select the volume symbol  at the bottom right of the monitor screen, the volume scale pops up.
2. Press the ⋈ button on the alarm setting menu bar to switch alarm sound volume levels: Low, Middle or High.

Change Alarm Limitation

You can only change the alarm limitation with the password. This senior function is only for service or maintenance. Please contact your sale agent for this use.

1. In the alarm setting menu, select the alarm limit you want.
2. Select a value to adjust the alarm limitation.

VII. Setting Operation

This setting operation mainly explains how to set various functions of the instrument, including such contents as overview of the operation screen, setting of the year, month, hour and minute, setting of paper feeding speed, switching of display mode, timing function, turning on of sound alarm function, and setting of timing time.

The main operation screen of the monitor is as shown on Fig.5-1 below:

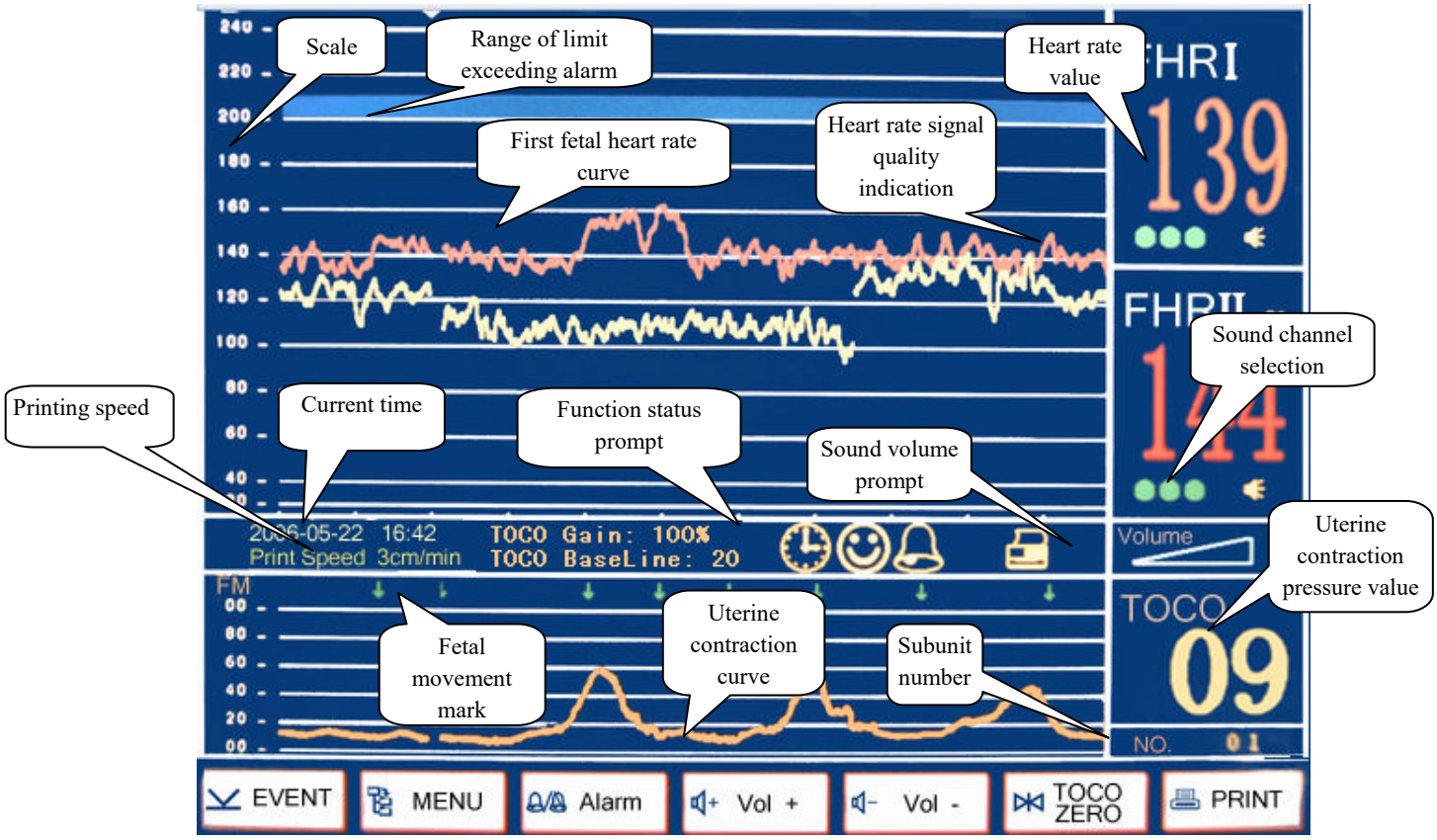


Fig.5-1 Main Operation Screen

I) System Setting Menu

Fig.5-2 Main Menu Bar

1. Press the button on the main menu bar to enter the setting menu, as shown on Fig.5-3.

Fig.5-3 Setting Menu Bar

2. Press the button on the setting menu bar to enter the system setting menu, as shown on Fig.5-4.

Fig.5-4 System Setting Menu Bar

3. Press the button on the system setting menu bar, the system will enter the demonstration status. Press the button again, the system will exit the demonstration status. The turning on or off status of demonstration can be displayed on the button on the system setting menu bar, as shown on Fig.5-5 and Fig.5-6.

Fig.5-5 Demonstration Turned on Status

Fig.5-6 Demonstration Turned off Status

4. Press the button on the system setting menu bar, the system will recover factory setting status.

Factory Default Settings:

- Sound volume: Medium
- Paper feeding speed: 3cm/min.
- Print contrast: 2
- Timing switch: Off
- Timing time: 20 minutes
- Alarm switch: On
- Alarm sound volume: Middle
- Alarm delay: 0 second
- Alarm upper limit: 160BPM
- Alarm lower limit: 120BPM
- Sound channel selection: Mixed sound
- TOCO Gain: 100%
- FHR Range: 50-240
- TOCO Baseline: 20

5. Press the button on the system setting menu bar, the system will enter the sound channel selection status. The sound channel selection status can be displayed on the button on the system setting menu bar, as shown on Fig.5-7、Fig.5-8、Fig.5-9.(The Fetal monitor for Twins support all options, but The single fetal monitor support only FHR Sound I's options)

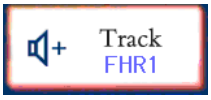


Fig.5-7 FHR Sound I

Fig.5-8 FHR Sound II

Fig.5-9 FHR Sound I+ FHR Sound II

6. Press the button on the system setting menu bar, the system will enter the display mode status, as shown on Fig.5-12、Fig.5-13、Fig.5-14. (The Fetal monitor for Twins support all options, but The single fetal monitor support only Single Coordinate Mode's options)

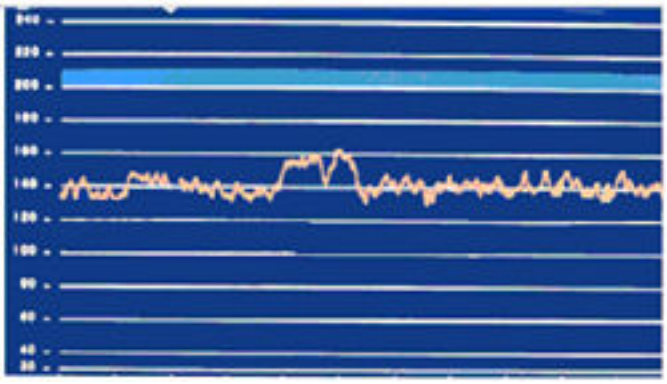


Fig.5-10 Single Coordinate Mode

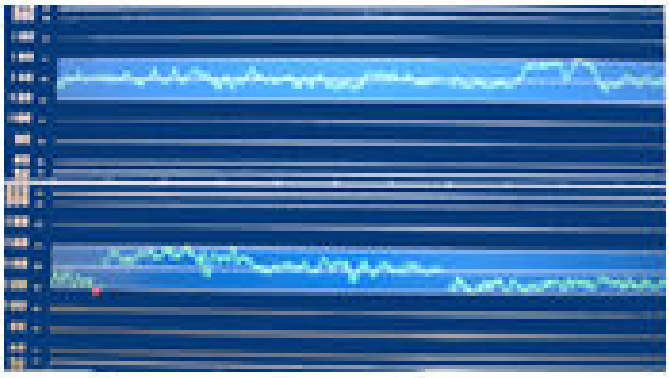


Fig.5-11 Double Coordinate Mode

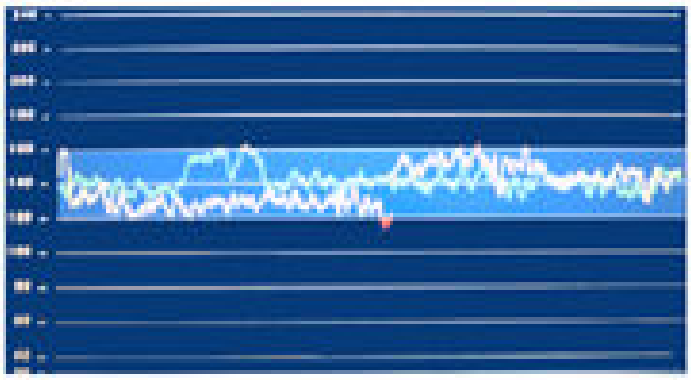


Fig.5-12 Coincidence Mode

7. Under system setting status, press the button, the system will exit the system setting status.

II) Alarm Setting Menu

Fig.5-11 Menu Bar

1. Press the button on the main menu bar to enter the setting menu, as shown on Fig.5-12.

Fig.5-12 Setting Menu Bar

2. Press the button on the setting menu bar, the system will enter the alarm setting menu, as shown on Fig.5-13.

Fig.5-13 Alarm Setting Menu Bar

3. Press the button on the alarm setting menu bar to realize the switching of settings of alarm upper limit, alarm lower limit and alarm delay.

4. Press the button on the alarm setting menu bar, the system will enter the alarm turned on status, as shown on Fig.5-14.

Fig.5-14 Alarm Turned on Status

5. Press the button on the alarm setting menu bar to increase the value to be set.

6. Press the button on the alarm setting menu bar to decrease the value to be set.

7. Press the button on the alarm setting menu bar to switch alarm sound volume levels: Middle or low sound volume. The alarm sound volume status can be displayed on the button on the alarm setting menu bar, as shown on Fig.5-15 and Fig.5-16.

Fig.5-15 Alarm Sound Low

Fig.5-16 Alarm Sound Middle

8. Press the button to exit the alarm setting menu

Fig.5-18 Main Menu Bar

III) Storage Playback Setting Menu

1. Press the button on the main menu bar to enter the setting menu, as shown on Fig.5-19.

Fig.5-19 Setting Menu Bar

2. Press the button on the setting menu to enter storage playback setting menu, as shown on Fig.5-20.

Fig.5-20 Storage Playback Setting Menu Bar

3. Press the button on the storage playback setting menu, storage playback file plus one.

4. Press the button on the storage playback setting menu, storage playback file minus one.

5. Press the on the storage playback setting menu to enter the storage playback printing submenu, as shown on Fig.5-21.

Fig.5-21 Storage Playback Printing Menu Bar

6. Press the button to exit the storage playback setting menu.

IV) Storage Playback Printing Submenu

1. Press the button on the storage playback setting menu to enter the storage playback printing page setting menu, as shown on Fig.5-22.

Fig.5-22 Storage Playback Printing Page Setting Menu Bar

2. Press the button on the storage playback printing submenu, current page plus one and that page is displayed.

3. Press the button on the storage playback printing submenu, current page minus one and that page is displayed.

4. Press the button on the storage playback printing submenu to select the printing start page.

5. Press the button on the storage playback printing submenu again to select the printing end page, and the Chinese characters on the button turns orange when set.

6. Press the button on the storage playback printing submenu to cancel the selection, and the Chinese characters on the button returns to black, and now the printing start page and printing end page can be reset.

7. Press the button on the storage playback printing submenu, the printing will be carried out according to the set start page and end page. If they are not set, the entire file will be printed.

V) Networking Setting Menu

Fig.5-23 Main Menu Bar

1. Press the button on the main menu bar to enter the setting menu, as shown on Fig.5-24.

Fig.5-24 Setting Menu Bar

2. Now press the button to enter the networking setting menu, as shown on Fig.5-25.

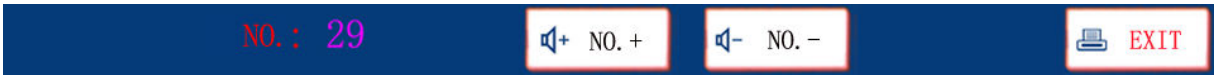


Fig.5-25 Networking Setting Menu Bar

3. Press the button on the networking setting menu, the unit number plus one.

4. Press the button on the networking setting menu, the unit number minus one.

5. Press the button to return to the setting submenu.

VI) Printing Setting Menu

Fig.5-26 Main Menu Bar

1. Press the button on the main menu to enter the setting menu, as shown on Fig.5-27.

Fig.5-27 Setting Menu Bar

2. Press the button on the setting menu to enter the printing setting menu, as shown on Fig.5-28.

Fig.5-28 Printing Setting Menu Bar

3. Press the button on the printing setting menu, the print contrast varies in the range of 1-5.

The magnitude of the print contrast can be displayed on the button on the printing setting menu bar, as shown on Fig.5-29, Fig.5-30 and Fig.5-31.

Fig.5-29 Print contrast 1

Fig.5-30 Print contrast 2

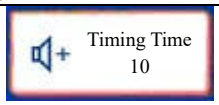
Fig.5-31 Print contrast 5

4. Press the button on the printing setting menu to realize the switching of the status of timing switch. The status of timing switch will be displayed on the status display bar on the main operation screen, as shown on Fig.5-32 and Fig.5-33.

Fig.5-32 Timing Turned on Status

Fig.5-33 Timing Turned off Status

5. Press the button on the printing setting menu, the timing time plus 5 minutes. The maximum setting is 60 minutes. The status of timing switch will be displayed on the status display bar of the main operation screen, as shown on Fig.5-34 and Fig.5-35.



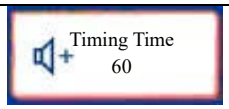


Fig.5-34 Timing Set to 10 Minutes Fig.5-35 Timing Set to 60 Minutes

6. Press the button on the printing setting menu to set the display width of the printing paper to one of two paper styles. The FHR pane range 30 bpm ~ 240 bpm indicates the paper style is American Standard. The FHR pane range 50 bpm ~ 210 bpm indicates the paper style is International Standard. Printing paper type can be displayed on the button on the printing setting menu bar, as shown on Fig.5-36 and Fig.5-37.

Fig.5-36 210 International Standard Fig.5-37 American Standard

7. Press the button on the printing setting menu, the printing speed varies in the range of 1 to 3. The printing speed can be displayed on the button on the printing setting menu bar, as shown on Fig.5-38, Fig.5-39 and Fig.5-40.

Fig.5-38 Printing Speed 1 Fig.5-39 Printing Speed 2 Fig.5-40 Printing Speed 3

8. Press the button on the printing setting menu to return to the setting submenu.

VII) Time Setting Menu

NOTE:

Timing time is the length of time that the recorder plotting automatically during monitoring.

You can press the button to set the status of Timing switch, turning on timing function or turning off timing function.

If the timing function is turned on, and the recorder is restarted to plot curves during monitoring, the recorder will stop plotting automatically after certain time (this time is determined by the timing time). If

the timing function is turned off, during monitoring the start/end of the job of the recorder is fully manual controlled.

Fig.5-41 Main Menu Bar

1. Press the button on the main menu bar to enter the setting menu, as shown on Fig.5-42.

Fig.5-42 Setting Menu Bar

2. Press the button on the setting menu to enter the time setting menu, as shown on Fig.5-43.

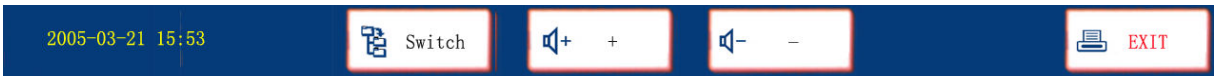


Fig.5-43 Time Setting Menu Bar

3. Press the button on the time setting menu to switch between the status of year setting, month setting, day setting, hour setting, minute setting and second setting.

4. Press the button on the time setting menu, the adjusted value plus one.

5. Press the button on the time setting menu, the adjusted value minus one.

6. Press the button to return to the setting submenu.

VIII. The Operation of the Recorder

I) Installing Recording Paper

1. Turn on the power switch.

2. Press the clip hook of the recorder cover, as shown on Fig.6-1.

Fig.6-1

3. Unfold the top page of a load of paper, place the "SUNRAY CO., LTD." marking to the right, and then slide the paper into the paper tray, as shown on Fig.6-2.

Fig.6-2

4. Gently insert the top page of the paper load into the bottom of the recorder paper inlet with the left and right sides balanced. The recorder will feed the paper automatically once it detects the paper, as shown on Fig.6-3 and

Fig.6-4.

Fig.6-3

Fig.6-4

5. Close the recorder cover, as shown on Fig.6-5.

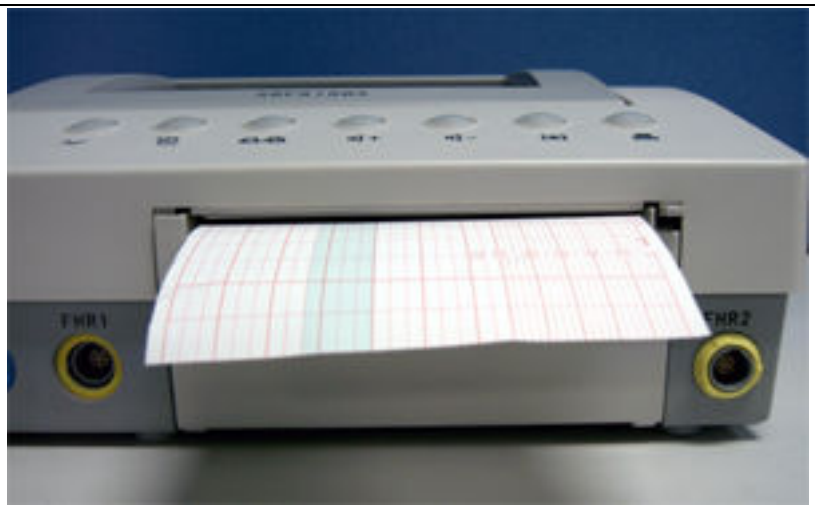


Fig.6-5

II) Recording Operation

Press the (real time printing) button, the recorder will start or stop printing.

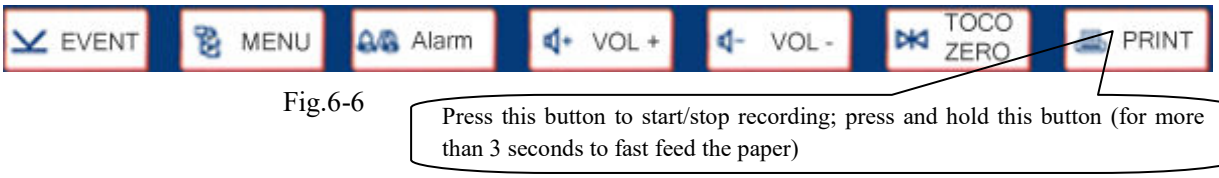


Fig.6-6

III) Paper Feeding Operation

Press and hold the button for 3 seconds or press the button and the button simultaneously to feed the paper manually.

IV) Paper Unloading Operation

Press the button and the button simultaneously to unload the paper manually. Please open the recorder cover when unloading the paper manually.

V) Recording Completion

When recording is done, tear off the recording paper along the folding line.

IX. Care and Cleaning

This chapter tells you how to care for your system.

I) Monitor

Keep the external surface clean and free of dust, dirt and residual liquids. Clean with a damp cloth using mild soap and water or hospital approved non-abrasive disinfectants.

Warning

Unplug the monitor and recorder from the AC power source and detach all accessories before cleaning. Do not immerse the monitor in water or allow liquids to enter casing.

Caution

Take extra care when cleaning the display surfaces, which are sensitive to rough handling. Rub the lens that covers them with a soft, dry cloth.

II) Transducers (Cleaning and Low Level Disinfection)

Before starting cleaning or disinfection, carefully review the technical information and follow all the precautions for use, safety, storage and disposal of the cleaning and disinfecting agents as listed by their manufacturers.

For devices intended for use on immune-compromised patients, use a sterile towel for cleaning the device during the cleaning and disinfection process.

Do not:

1) Immerse a transducer in water.

2) Handle transducers roughly. This could damage the cover, piezoelectric crystals and mechanical movement. Transducer covers are made of soft plastic; avoid contact with hard or sharp objects.

3) Flex the cables excessively.

4) Allow cleaning solutions or transducers to exceed a temperature of 45°C (113°F).

5) Autoclave the transducers and cables or heat them above 70°C (158 °F).

Caution

Do not immerse the transducers during any stage of the cleaning/disinfection process.

Caution

Do not autoclave. Do not gas sterilize.

The following cleaning and low level disinfection procedure is recommended.

CAUTION Solutions: Do not mix disinfecting solutions as hazardous gases may result.

The cleaning procedure will be more effective in reducing contamination if cleaning is done prior to drying of adherent visible soil (for example, organic matter or other debris) on the transducer.

Do not reuse alcohol for disinfection.

Cleaning and Disinfecting

Cleaning

1. Wipe the transducer using a damp towel and then a towel with a recommended detergent such as an enzymatic detergent. Prepare the detergent as recommended by its manufacturer.

2. Wipe the device with a damp towel for at least 3 times to remove detergent.

3. Visually inspect the transducer. If adherent soil is still present, repeat steps 1 and 2.

4. Dry the transducer thoroughly with a clean, soft towel.

Disinfecting

Using 70% Isopropanol

5. Wipe the transducer with clean towel soaking in 70% Isopropanol completely for a minimum of five (5) minutes, but not more than ten (10) minutes recommendations.

6. Wipe the transducer with a damp towel carefully for at least 3 times to remove residual Isopropanol.

7. Dry the transducer thoroughly with a clean soft towel.

8. Follow your facility's post-processing handling procedures to eliminate or minimize recontamination of the device before reuse. Contact your facility's Infection Control Office or Epidemiologist for information regarding such procedures.

III) Cleaning and Disinfection for Reusable Belts

Wash soiled belts with soap and water first. Water temperature must not exceed 60°C (140 °F).
Then follow the Cleaning and Disinfection method as transducers above.

IV) Recorder

Warning
Unplug the recorder from the AC power source and detach all accessories before cleaning. Do not immerse the recorder in water or allow liquids to enter the case.

Clean the print head at least once a year or more often if necessary. Wipe the printhead and roller with a cottonbud soaked in isopropyl alcohol.

X. Maintenance

1. Record the signs when a fault occurs during the running of the instrument for convenient query at repair.
2. Be careful not to damage the exterior, transducers, buttons and their connecting cables of the instrument. If any damage occurs, the damaged component should be immediately stopped using.
3. Do not turn off the instrument at will when it is working. Turn off the power supply after all the operations are done - a good habit that should be developed.
4. Each time when the monitoring is finished, use dry cloth or tissue dipped with a little bit of alcohol to rub the transducers. Be careful not to dip too much alcohol, otherwise it might get inside the transducers. Especially measures should be taken to prevent the uterine contraction pressure transducer from moisture. The transducers should be placed on the transducer rack.
5. Everyday when the job is done, turn off the power supply for the mainframe.
6. Keep the external surface of each part of the instrument clean, and use cloth dipped with cleaning solution to rub them periodically. Do prevent the cleaning solution from spattering the computer casing. Wipe it dry after cleaning, otherwise dew may occur.
7. Use soft dry cloth or lens tissue to rub the display.
8. The monitor cannot be unhooked, packed and transported within 10 minutes after it is turned off.
9. If the instrument will not be used for a long time, the power supply plug on the power grid should be pulled out, and components such as transducers and buttons should be kept properly.

XI. Disposing of the Equipment

Arrangements for the disposal of your monitor, recorder and transducers at the end of their working life should conform to your country's laws regarding the disposition of equipment containing electrical parts. Adhere to all applicable laws regarding disposal and recycling.

XII. Environmental Specifications

The monitor may not meet the given performance specifications if stored and used outside the specified temperature and humidity ranges.

Temperature Range

Operating: 5°C to 40°C (41°F to 104°F)
Transport and Storage: -10°C to 40°C (14°F to 104°F)

Humidity Range

Operating: <80% relative humidity @ 40°C/104°F
Transport and Storage: <80% relative humidity @ 40°C/104°F

Altitude Range

Operating: 86kPa～106kPa
Transport and Storage: 50kPa～106kPa
No corrosive gases and good ventilation

XIII. Electromagnetic Compatibility (EMC)

The device and its accessories, listed in the accessories section, comply with the following EMC standards:
• EN/IEC 60601-1-2: 2001+A1:2004
Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this book. Before using the device, assess the electromagnetic compatibility of the device with surrounding equipment.
CAUTION Although this is an electrical Class II device, it has a protective earth conductor which is needed for EMC purposes.
Always use the supplied power cord with the three-prong plug to connect the monitor to AC mains.
Never adapt the three-prong plug from the power supply to fit a two-slot outlet.
CAUTION The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.
WARNING Do NOT use cordless/mobile phones or any other portable RF communication system within the patient vicinity, or within a 1.0 m radius of any part of the fetal monitoring system.

EMC Testing

CAUTION Fetal parameters, especially ultrasound, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

Reducing Electromagnetic Interference

CAUTION The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.
The product and associated accessories can be susceptible to interference from continuous, repetitive, power line bursts, and other RF energy sources, even if the other equipment is compliant with EN 60601-1-2 emission requirements. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmissions.
When electromagnetic interference (EMI) is encountered, for example, if you can hear spurious noises on the fetal monitor's loudspeaker, attempt to locate the source. Assess the following:
• Is the interference due to misplaced or poorly applied transducers? If so, re-apply transducers correctly according to directions in this book or in the Instructions for Use accompanying the accessory.
• Is the interference intermittent or constant?
• Does the interference occur only in certain locations?
• Does the interference occur only when in close proximity to certain medical electrical equipment?
Once the source is located, there are a number of things that can be done to mitigate the problem:
1 Eliminating the source. Turn off or move possible sources of EMI to reduce their strength.
2 Attenuating the coupling. If the coupling path is through the patient leads, the interference may be reduced by

moving and/or rearranging the leads. If the coupling is through the power cord, connecting the system to a different circuit may help.

3 Adding external attenuators. If EMI becomes an unusually difficult problem, external devices such as an isolation transformer or a transient suppressor may be of help. Your Service Provider can be of help in determining the need for external devices.

Where it has been established that electromagnetic interference is affecting physiological parameter measurement values, a physician, or a suitably qualified person authorized by a physician, should determine if it will negatively impact patient diagnosis or treatment.

Electromagnetic Emissions and Immunity

The monitor is suitable for use in the electromagnetic environment specified in the table below. You must ensure that it is used in such an environment.

Table 1 - Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Emissions test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions CISPR 11	Group 1	The SRF618B5 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Voltage fluctuations and flicker IEC 61000-3-3	complies	
RF emissions CISPR 11	Class B	The SRF618B5 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

The monitor is suitable for use in the specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

Table 2-Guidance and manufacture's declaration – electromagnetic immunity			
The *SRF618B5* is intended for use in the electromagnetic environment specified below. The customer or the user of Low Frequency Therapeutic Device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2001	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4:2004	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output	Mains power quality should be that of a typical commercial or hospital environment.

		lines	
Surge IEC 61000-4-5:2005	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8:2001	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3-Guidance and manufacture's declaration – electromagnetic immunity

The *SRF618B5 i*s intended for use in the electromagnetic environment specified below. The customer or the user of Low Frequency Therapeutic Device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6:2006	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Low Frequency Therapeutic Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3:2006	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the

			transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Low Frequency Therapeutic Device is used exceeds the applicable RF compliance level above, the Low Frequency Therapeutic Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Low Frequency Therapeutic Device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4-Recommended separation distances between portable and mobile RF communications equipment and the Low Frequency Therapeutic Device

The *FD-M99P* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Low Frequency Therapeutic Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Low Frequency Therapeutic Device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

XIV Ultrasonic Related Information

Ultrasonic Principle

ALARA

Please observe ALARA (As Low As Reasonably Achievable) principle when using ultrasound. So far there is no confirmed evidence to prove that ultrasound has obvious harm to human, but the users shall be cautious when using ultrasound. Provided that sufficient diagnostic information is acquired, try to shorten the time to examine the patient with the probe on one body position. The ultrasound power and acoustic intensity are relevant to scanning time. The user shall observe ALARA principle to select an appropriate ultrasound power for the exam-based on his exam needs.

Ultrasound Effects

Ultrasound effect shall include heating and cavitation.

Heating effect: Ultrasound in nature is mechanical wave. During its propagation in human body, the human tissues are oscillated, heat is generated, and human tissue temperatures. Be vigilant to damage due to the heating effect, and always follow ALARA principle.

Cavitation: Cavitation can occur when sound passes through an area that contains small bubbles. With ultrasound impact on these small bubbles, temperature and pressure around the space of the bubbles will increase, or even oscillate and explode, which may result in physical or chemical effects on the surrounding tissues.

Relevant Parameters

The main parameters related to acoustic power are: transmit frequency, transmit focus number, transmit voltage, transmit angle, element pitch, etc. These parameters vary subject to exam modes. Follow ALARA principle to select the appropriate power for scanning.

A multiplicative factor applied to acoustic output parameters intended to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. In the calculation of all mechanical, the average ultrasonic attenuation is assumed to be 0.3dB/cm-MHz along the beam axis in the body.

References for Acoustic Power and Safety

(1) “Bio-effects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993

(2) “Medical Ultrasound Safety” issued by AIUM in 1994

(3) “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued by FDA in 2008

Statistics

Statistical Analysis of Measurement Data

A statistical analysis was performed on the data to examine the upper output limits, based on one-sided tolerance limit approach [17, 18]. The mean and standard deviation of the Spatial-Peak, Time-Average Intensity and Mechanical Index were found, and the upper output limits were calculated from the following formula:

X=x+K*Sx

Where X is the upper output parameter limit, x is the average of the measured output parameter, Sx is the standard deviation of the measured output parameter, and K is a factor from Reference [18], Table A-7. A value of K was chosen which corresponds to a 90% probability that 90% of all probes would fall below the calculated limits X. Since there were three samples, the K value used is 4.258.

Table 2 Results for SRF618B5 probes

Probes		2MHz Probe
Sample Size		3
Mode		PW
I_{SATA} (mW/cm²)	Mean (x)	0.650
	Std Dev (S_x)	0.010
	Limit (X)	0.693
I_{SAPA} (mW/cm²)	Mean (x)	9.400
	Std Dev (S_x)	0.140
	Limit (X)	10.00

Table 3 Track 1 Summary

System: Fetal Monitor, model: SRF618B5 Transducer: 2MHz PWD Probe

Clinical Application	**Global Maximum Output Level (est.)**		**Mode of Operation**
			PWD
Fetal heart rate monitor	I_{SATA} (mW/cm²)	Max.	0.693
		Min.	0.607
	I_{SAPA} (mW/cm²)	Max.	10.00
		Min.	8.800

Results

Track 1 Reporting Tables show the worst-case indices for each probe tested.

Acoustic Output Report

ACOUSTIC OUTPUT REPORTING TABLE TRACK 1
Non-Auto-scanning Mode

System Model: Fetal Monitor, Model: SRF618B5
Transducer: 2MHz Probe, S/N: S1
Operating Mode: PWD Mode
Application(s): Fetal

Acoustic Output			I_{SATA} (mW/cm²)	I_{SAPA} (mW/cm²)
Global Maximum Value			0.65	8.95
Associated Acoustic Parameter	$p_{r.3}$ (MPa)			
	W_o (mW)		18.48	18.48
	f_c (MHz)			
	z_{sp} (cm)			
	Beam dimensions	x_{-6} (cm)		
		y_{-6} (cm)		
	PD (μsec)			21.80
	PRF (Hz)			3330
	EBD	Az. (cm)	5.35	5.35
		Ele. (cm)	5.28	5.28
Operating Control Conditions	Control 1: AP=15, Frequency=2.0MHz, Depth=80mm		Control 1	Control 1

ACOUSTIC OUTPUT REPORTING TABLE TRACK 1

Non-Auto-scanning Mode

System Model: Fetal Monitor, Model: SRF618B5

Transducer: 2MHz Probe, S/N: S2

Operating Mode: PWD Mode

Application(s): Fetal

Acoustic Output			I_{SATA} (mW/cm²)	I_{SAPA} (mW/cm²)
Global Maximum Value			0.66	8.92
Associated Acoustic Parameter	$p_{r.3}$ (MPa)			
	W_o (mW)		18.53	18.53
	f_c (MHz)			
	z_{sp} (cm)			
	Beam dimensions	x_{-6} (cm)		
		y_{-6} (cm)		
	PD (μsec)			22.16
	PRF (Hz)			3340
	EBD	Az. (cm)	5.34	5.34
		Ele. (cm)	5.28	5.28
Operating Control Conditions	Control 1: AP=15, Frequency=2.0MHz, Depth=80mm		Control 1	Control 1

ACOUSTIC OUTPUT REPORTING TABLE TRACK 1

Non-Auto-scanning Mode

System Model: Fetal Monitor, Model: SRF618B5

Transducer: 2MHz Probe, S/N: S3

Operating Mode: PWD Mode

Application(s): Fetal

Acoustic Output			**I_{SATA} (mW/cm²)**	**I_{SAPA} (mW/cm²)**
Global Maximum Value			0.65	8.95
Associated Acoustic Parameter	$p_{r.3}$ (MPa)			
	W_o (mW)		18.46	18.46
	f_c (MHz)			
	z_{sp} (cm)			
	Beam dimensions	x_{-6} (cm)		
		y_{-6} (cm)		
	PD (μsec)			21.80
	PRF (Hz)			3330
	EBD	Az. (cm)	5.36	5.36
		Ele. (cm)	5.29	5.29
Operating Control Conditions	Control 1: AP=15, Frequency=2.0MHz, Depth=80mm		Control 1	Control 1

Uncertainties

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined as follows:

1). Hydrophone Sensitivity: ± 20% for intensity, ± 12% for pressure.
Based on the hydrophone calibration report, the uncertainty was determined within ±1dB in frequency range 1-15MHz.

2). Digitizer: ±5 % for intensity, ±2 % for pressure.
Based on the stated accuracy of the 8-bit resolution of the Digital Oscilloscope and the signal-to-noise ratio of the measurement.

3). Temperature: ± 1 %
Based on the temperature variation of the water bath of ± 1 ºC.

4). Spatial Averaging: ± 10 % for intensity, ± 5 % for pressure.

5). Non-linear Distortion: N/A. No effects of nonlinear propagation were observed
Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ± 23.8 % for all intensity values reported, ± 13.6 % for all the pressure values and ± 12.9 % for the Mechanical Index.

So, Uncertainties for I_{SAPA}, ultrasonic power and center frequency
Since the total power is based on the intensity, the uncertainty for I_{SAPA} and ultrasonic power is **± 26.0 %**.
The accuracy of the center frequency measurement is primarily dependent on the digitizer, and is therefore given as **± 1.8 %**.

Diagnostic Ultrasound Indications for Use Form

System: Fetal Monitor, model: SRF618B5 **Transducer: 2MHz PW Probe**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics			N				
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comment: The above probe is a 2 MHz PW transducer for the fetal heart rate (FHR) detection. There are two FHR transducers in this device. These two transducers are the same. Use one for single fetus, use two for twins.

XVII. The list of accessories with the Maintenance Guarantee

Accessory	Part Number
Ultrasound Transducer	12102.01.4
TOCO Transducer	12102.01.5
FM Button	12102.01.6

Except replaceable accessories mentioned above, the equipment must be only repaired by responsible service and maintenance personnel authorized by the manufacture.

XVII. The list of parts without the Maintenance Guarantee

Accessory	Part Number
Thermal Sensitive Printing Paper	22207.0.11.99
The core of Recorder	4419-0005

XIX. Faults and Troubleshooting

Note: Those items with a ※ prefix must be handled by professionals of our company.

Location	Sign	Possible Cause	Troubleshooting Method
Fetal heart sound	Weak or flat fetal heart sound	The sound volume is too low	Turn up the sound volume
		The fetal heart sound monitoring plug is not properly inserted	Reinsert the plug
		There is an air gap between the transducer and the skin	Add a little ultrasound jelly
		The transducer is defective	※ Replace it
		The signal processor is defective	※ Repair or repair it
	No fetal heart sound	The amplifier is defective	※ Repair it
		The transducer is defective	※ Replace it
		The ultrasound signal processor is defective	※ Repair or repair it
Uterine contraction pressure	Abnormal uterine contraction pressure display	The transducer is defective	※ Repair or repair it
		The signal processor is defective	※ Repair or repair it

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