promedic

by COMEN

Model: **STAR5000**

FETAL & MATERNAL MONITOR

EN Instruction Manual

www.promedic-health.com

Statement

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Responsibility on the manufacturer party

Our company is responsible for safety, reliability and performance of this equipment only in the condition that:

- all installation, expansion, change, modification and repair of this equipment are conducted by our qualified personnel;
- applied electrical appliance is in compliance with relevant National Standards;
- the monitor is operated under strict observance of this manual.

⚠ **Note**
This equipment is not intended for family usage.

⚠ **Warning** ⚠
For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

- **Do not rely only on audible alarm system to monitor patient. When monitoring adjusting the volume to very low or completely muting the sound may result in the disaster to the patient. The most reliable way of monitoring the patient is at the same time of using monitoring equipment correctly, manual monitoring should be carried out.**
- **This maternal/fetal monitor is intended for use only by medical professionals in health care institutions.**
- **To avoid electrical shock, you shall not open any cover by yourself. Service must be carried out by qualified personnel.**
- **Use of this device may affect ultrasonic imaging system in the presence of the interfering signal on the screen of ultrasonic imaging system. Keep the distance between the monitor and the**

ultrasonic imaging system as far as possible.

- **It is dangerous to expose electrical contact or applicant coupler to normal saline, other liquid or conductive adhesive. Electrical contact and coupler such as cable connector, power supply and parameter module socket-inlet and frame must be kept clean and dry. Once being polluted by liquid, they must be thoroughly dried. If to further remove the pollution, please contact your biomedical department or our company.**

⚠ **Warning** ⚠

This monitor is not intended for treatment purpose.

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

Upon request, our company may provide, with compensation, necessary circuit diagrams, calibration illustration list and other information to help qualified technician to maintain and repair some parts, which our company may define as user serviceable.

Preface

Thank you for purchasing our STAR5000 patient monitor! This manual gives detailed description to the Monitor concerning its performance, operation, safety guide, and precautions. Reading through this manual is the first step to get familiar with the equipment and make the best use of it.

Following symbols indicates some important notes that you have to pay special attention to:

⚠ **Warning** ⚠ **Points to be noted to avoid injury to the patient and the operator.**

'Note' Important points to be noted.

Intended Use

This product is intended to be used in surgeries, ICU wards, CCU wards and other places requiring monitoring for patients. It can display in real time the fetal heart rate (FHR), blood volume map, TOCO, fetal movement mark.

Working Environment

1. Working temperature: 5℃~40℃
2. Relative humidity: <80%
3. Atmospheric pressure: 860hPa~1060hPa
4. Supply voltage: a.c.100V～250V d.c.14.8V
5. Power frequency: 50Hz /60Hz ± 1Hz

Storage Temperature

Transport: Must avoid severe shock ,vibration, rain and snow during transport

Storage : Packed monitors must be stored in well ventilated rooms with -10℃～+40℃ temperature, relative humidity no more than 80%, and without corrosive gases

Please read through this Manual carefully before use.

Contents

Chapter I Safety Guide

The design of this maternal/fetal monitor is complied with the internal and international safety requirements in medical electrical equipments which include IEC60601-1, EN60601-2-27, and EN60601-2-30. The Monitor has protection against interference from defibrillation and high-frequency electrotome. If correct electrodes are applied following the guidance of the manufacturer, screen display will be recovered within 10 seconds.

 This is to remark that the equipment is of Type CF, which is designed with special shockproof protection (especially with the Type F ground-free insulating equipment for the allowable electric leakage) and defibrillator resistance.

⚠ Warning

No touch with patients, hospital beds or the Monitor during defibrillation.

Environment
Temperature
Working Temperature: 5~40℃

Humidity
Working Humidity: <80%

Altitude Height:
Working Altitude: -500~4,600 meters (-1,600~15,000 feet)
Transportation and Storage Altitude: -500~13100 meters (-1,600~43,000 feet)

Power Supply:
100~250(V) AC, 50/60 (Hz) ± 1Hz

For absolute safety of the equipment, the following guidance must be followed: the locating environment of the Monitor shall reasonably avoid shock, dust, corrosive or explosive gases, extreme temperature, and moisture. In case of being installed inside a chamber, the Monitor shall have sufficient space in its front to make convenience for operations. If with chamber door open, the Monitor shall have sufficient space in its back to guarantee air communication inside the chamber.

Approximately 15 minutes after power on, the Monitor may meet all the technical parameters within the ambient temperature of 0~45℃; in case of ambient temperature out of 0~45℃, accuracy of the Monitor could be affected and some parts and circuits could also be damaged. At least 2 inches (5cm) shall be reserved around the Monitor so as to keep air communication.

Power supply
The standard power supply for the Monitor is: 100~250 V, 50/60 Hz.

Ground Connection
To protect patients and medical care personnel, the Monitor must have its cover connected with the ground. Thus the Monitor is furnished with a removable 3-line cable; when the cable is plugged into a corresponding 3-line

socket, the Monitor is connected with the ground through the ground line inside the 3 lines. In case of no 3-line sockets, please consult with the persons in charge of electrical affairs of the user hospital.

⚠Warning

The 3-line cable is disallowed to be connected with a 2-line plug.

Equal-potential Ground Connection

First-class protection of the equipment has been included in the ground protection system of houses in the way of ground connection of power plugs. For internal checks of heart or brain, the Monitor must be individually connected with the equal-potential ground-connected system; one end of the equal-potential ground-connected lead (potential-balanced lead) is connected with the equal-potential ground-connected terminal located in the back panel of the equipment, while the other end is connected with one joint of the equal-potential system. In case of any damages happening to the protective ground-connected system, the equal-potential ground-connected system may take all the duties of protecting the ground-connected leads. Heart or brain checks shall only be conducted inside those medical houses furnished with the protective ground-connected system; each time before using, the user shall check whether the equipment is under good work status. The user shall also keep the cable connecting patients and the equipment away from electrolyte pollution.

Connect the ground line with the ground-connected terminal with equal potential of the Monitor. In case of unable to judge whether a certain apparatus grouping is dangerous from the given apparatus specifications, for example, whether there will be risks from accumulation of electric leakage, please consult with the applicable manufacturers or experts so as the necessary safety of all the apparatuses inside the grouping will not be destroyed by the recommended grouping.

⚠ Warning

If the equal-potential ground-connected system is not stable, the monitor will use internal power supply.

Condensation

There shall be no condensation when the equipment works. The reason why condensation could be formed is that when the equipment is moved from one room to another room, the equipment is disclosed to humid atmosphere and different temperature.

⚠ Warning⚠

The Monitor shall not be used during MRI scan; otherwise the induced current will result in burns.

⚠ Warning⚠

The Monitor, if used where there is flammable anesthetic, may result in explosion.

Remarks or symbols:

Remarks	Instruction
PRINTER	Connection with printer (interface to printer)

COMM	Connection with central unit (interface to central unit)
CRT	Connection with CRT monitor (interface to CRT monitor)
	Connected (only used in some part of the equipment)
	Disconnected (only used in some part of the equipment)
	Equal potential
	Warning! Note! Please the documents attached with this Monitor (this User Manual)
	CF-type shockproofness
	CF-type
	BF-type

⚠ Warning ⚠

The Monitor is intended for clinical monitoring application with operation only granted to appropriate medical staff.

⚠ Warning ⚠

There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by Our Company.

⚠ Warning ⚠

Possible explosion hazard if used in the presence of flammable anesthetics.

⚠ Warning ⚠

The user must verify if the device and accessories can function safely and normally before use.

⚠ Warning ⚠

The user must customize the alarm setups according to individual patient situation and make sure that alarm sound can be activated when alarm occurs.

⚠ Warning ⚠

Do not use cellular phone in the vicinity of this device. High level electromagnetic radiation emitted from such devices may greatly affect the monitor performance.

⚠ Warning ⚠

Devices connected to the monitor shall form an equipotential system (protectively earthed).

⚠ Warning ⚠

When used with Electro-Operation equipment, the user (doctor or nurse) must give top priority to the patient safety.

⚠ **Warning** ⚠

Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

⚠ **Warning** ⚠

This equipment is accord with the standard CISPR11 (EN55011) class A.

⚠ **Note**

The software was developed per IEC601-1-4. The possibility of hazards arising from errors in the software program is minimized.

⚠ **Note**

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulation the disposal of such products. If the user has questions concerning disposal of the product, please contact us or its representatives.

⚠**Note**

For safe running of the Monitor, please use the spare parts, accessories and various types of consumptive materials (such as probe and electrode) provided or appointed by our company.

The safety and correctness is only guaranteed when the Monitor is connected with equipments provided us; in case the user connect the Monitor with other electric equipments or apparatuses, safety problems may be resulted from electric leakage.

Periodic tests to the Monitor and its accessories are conducted once per half year.

Chapter II Installation

I. Unpacking and Check

II. Electric Connection

III. Power on

IV. Connect the Accessories

V. Check the Recorder

⚠ **Note**

For normal performance of the monitor, please read this chapter and safety guide before use. Then install the monitor as required.

Section I Unpacking and Check

Carefully take out the monitor and accessories from the package. Reserve the packing materials for future transportation or storage. Please check the accessories listed on the packing list.
The Monitor shall include the following items:

Main machine	1
Packing list	1
Power line	1
Fetal monitoring probe	1
Coupling agent	1
Bandage	2
Ground cable	1
User Manual	1

Please refer to the packing list for specific contents. Please check carefully whether the spare parts are all included; any absence shall be reported to the sales department of our company or local sales agent. Use and maintenance to each spare part will be described in the following chapters, please read carefully.

Section 2 Electric Connection

1. Make sure the AC power supply is: 110V~240V AC, 50Hz/60 Hz

2. Use the power cable attached with the Monitor. Plug one end of the power cable into the power interface of the Monitor, and the other end into a grounded three-phase socket.

'Note'

Plug the power supply cable of the Monitor into those sockets specially used in hospitals.

3. Please connect isoelectric ground cable when necessary. Refer to the part of Isoelectric Grounding in Chapter I Safety Guide.

'Note'

The Monitor deploys batteries, which must be charged after monitor transportation or storage. To start the machine directly without connecting the AC power source may cause the Monitor unable to work normally for battery state low. Putting through the AC power source will charge the batteries, no matter the Monitor is started or not.

'Note'

If the battery indicator is always on when charging the batteries, it indicates that the battery power is used out and the battery cannot be charged again. Notify our After-sales Service Department to replace batteries for you.

Section 3 Power On

Switch on the power supply button, system will make a "Du" sound and a flash from the alarm light. After about 10 seconds, the Monitor will complete its self-check and enter into the main display interface, then normal monitoring may be started.

'Note'

In case of fatal error is found in self-check process, system will make alarm.

'Note'

Please check all the functions to ensure the normal performance of the Monitor.

'Warning'

In case of any damages to the Monitor or any error information, the Monitor shall not be used onto patients for any monitoring purposes and the user shall consult with the biochemical engineers of the user hospital or the maintenance engineers of our Company.

'Note'

Please wait for at least 1 minute to power on the monitor after power off it.

Section 4 Connect the Accessories

Connect the required accessories to the monitor and the position to be monitored of patients.

Note: Please refer to the relevant chapter for correct connection of accessories and relevant requirements.

Section 5 Check the Recorder

If there is a recorder attached with the Monitor, the user shall check whether the paper inlet has paper there; in case of no paper, please place heat-sensitive recording paper following the guidance in Chapter III.

Chapter III Work Interface

Section 1 Interface Introduction

Main interface is set as below:

1. Power switch To switch on/off the monitor.

2. Power indicator To indicate the working status of power supply.

3. Battery indicator To indicate the power storage situation of the batteries. If the indicator ligths up, it shows that the batteries need to be charged.

4. Freeze/Playback button Press the button to freeze waveform display, and rotate the knob for waveform playback.

5. Mute button To switch on/off the alarm sound of the Monitor.

6. Print button Press the button to activate the recorder to print

7. NIBP measure button Press the button to start blood pressure measurement. If the monitor is in the process of the blood pressure measurement, press the key to stop.

8. Multi-function button TOCO reset button. It can also be used for menu selection or fast backtracking.

9. Trim knob It is used to move the cursor or change parameter setting. Click the mouse to execute menu option.

10. FHR 1 socket US1

11.TOCO socket TOCO

12. FM socket FM

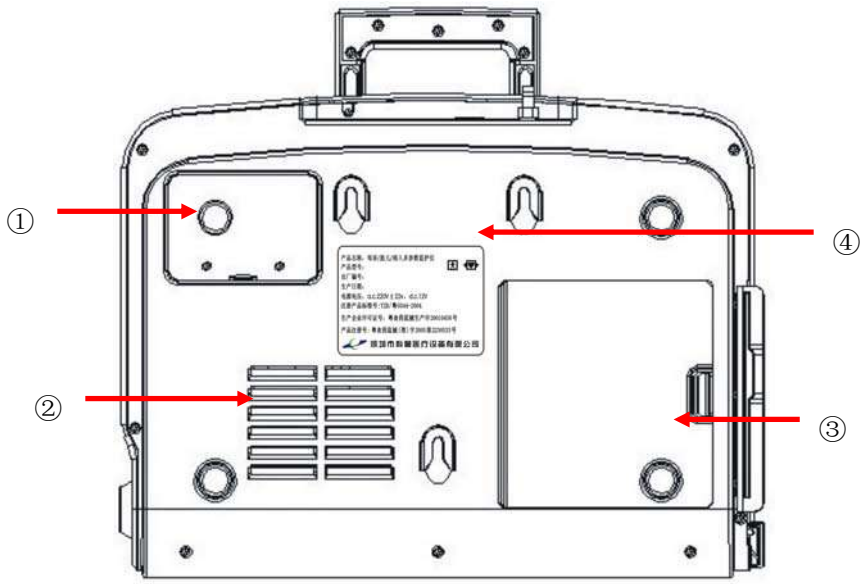
13. Handle

14. Product model

15. Alarm light Flash different colors of light according to alarm grades while alarming.

16. Display screen (touch screen) 12.1” LCD display is applied to display waveform, menu, alarm and various parameter values.

The rear view is as shown on the right:



①Battery box ②Air outlet. ③Paper feeder ④Name plate

Section 2 Function Operation Interface

2.1 System Setup

(1) Date: Year Month Day

(2) Time: Hour Minute

(3) Monitoring mode

(4) Language

(5) Standard signal

The system setup of this product is very flexible. The setting of date, time, monitoring mode, language, standard signal and display interface are all subject to the user. Press the hot key “MENU” on the right corner of the screen

to pop out the system menu as shown below and set the items as you wish.

Figure 1 System Setup

2.1 .1System Time Setting

Select “System Time Setting” option in “System Setting” menu to enter into the menu as shown below. The system time will be displayed in the form of year, month, day, hour, minute, second. Move the cursor on the item for amendment and fix upon it, rotate the knob to select time, and select “ “button to return to the previous menu.

2.1.2 Button Volume

Select “Button Volume” option in “System Setting” menu. There are five volume grades (0~4) for selection. Move the cursor on the item for amendment and fix upon it, rotate the knob to select desired volume grade, and select “ “button to return to the previous menu.

2.1.3 Monitoring Mode

Select “Demonstration” or “Real-time” in “Monitoring Mode” menu. Move the cursor on the item for amendment and fix upon it, rotate the knob to select desired monitoring mode, and select “ “button to return to the previous menu.

2.1.4 Language

Select “Chinese” or “English” in “Language” menu. Move the cursor on the item for amendment and fix upon it, rotate the knob to select desired language, and select “ “button to return to the previous menu.

2.1.5Standard Signal

Select “ON” or “OFF” in “Standard Signal” menu. Move the cursor on the item for amendment and fix upon it, rotate the knob to select desired mode, and select “ “button to return to the previous menu.

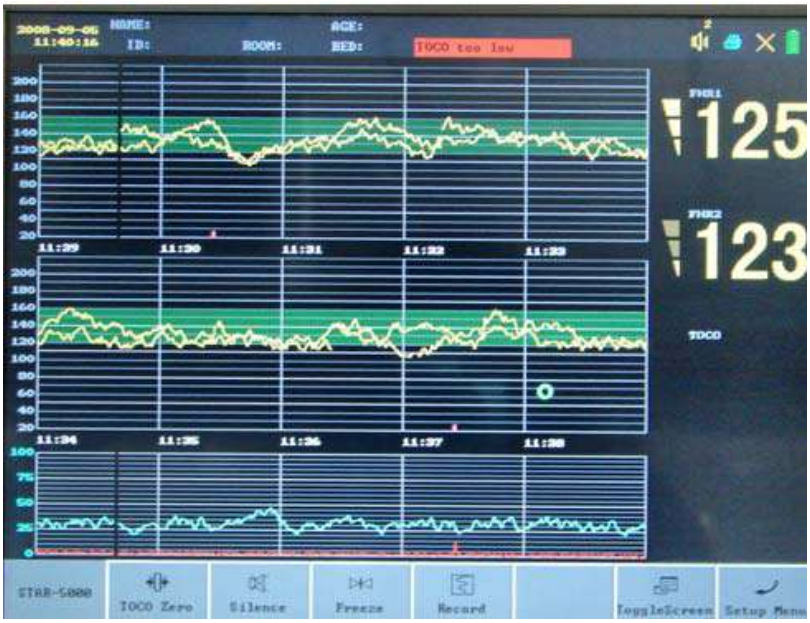
2.1.6 Display Interface

Press “Interface Switch” option (as shown below) in “Display Interface” to select between the six interfaces.

2.1.6.10 Main Interface (automatically enters after power-on)

The monitor operation interface is fully in English. The main interface of this Monitor has 4 waveform display windows: FHR, TOCO and FM.

2.1.6.2 Fetal Monitoring Cascading Interface



Note: It supports both real-time printing and freeze printing.

2.2Function Operation Interface

2.2.1 Alarm Limitation Setting:

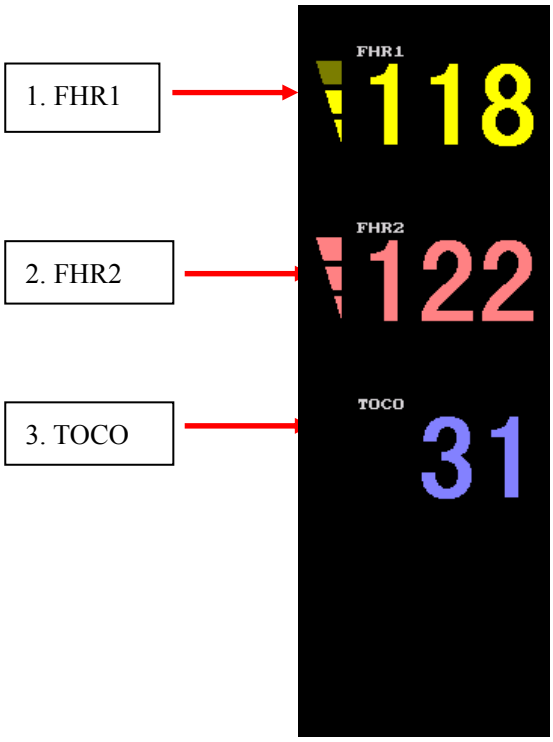
Rotate the knob to move the cursor to "🔔". Then press the knob to set the interface as shown below:

Move the green cursor "◀" to the option which needs to set up. Press the TRIM knob, "◀" will turn to red. Rotate the TRIM knob up and down to select and adjust each parameter. If alarm sound needed, please move the cursor to the limitation data for related parameters. Press MUTE button, the red alarm sign "🔔" comes out. Press the

MUTE button again, the sign disappear.

Section 3 Parameter Section Illustration

The right part of the screen is the parameter section. Each parameter is set as below:



The parameter values are shown below:

1. FHR1

2. FHR2

3. TOCO

Section 4 System Menu

The system menu options are as shown below:

Options:

1. User Info 2. Fetal Setup 3. Record Setting

4. Alarm Setup 5. System Setup 6. Main Interface

4.1 User Profile

Display the basic information of patient.

4.2 Fetal Parameter Setting Interface

The optional parameter items in fetal parameter setting interface include:

1. Fetal heart beat channel:

There are two options: “1”, “2”.

2. Fetal heart beat volume:

There are eight options: “0”, “1”, ‘2”, “3”, “4”, “5”, “6”, ‘7”.

3. TOCO zeroing:

There are five options: ‘0”, “5”, “10”, “15”, “20”.

4. FHR cascading:

There are two options: “ON”, “OFF”.

5. Color of FHR1

There are seven color options: “pink”, “light red”, “yellow”, “white”, “blue”, “cyan”, “light blue”

6. Color of FHR2

There are seven color options: “pink”, “light red”, “yellow”, “white”, “blue”, “cyan”, “light blue”

7. Color of TOCO

There are seven color options: “pink”, “light red”, “yellow”, “white”, “blue”, “cyan”, “light blue”

8. Touch screen options

There are four options: “previous item” “select”, “next item”, “print” and “close”.

4.3 Printing Setting Interface

The optional parameter items in printing setting interface include:

1. Printing speed:

There are three options: “1”, “2”, “3”. (unit: cm/min.)

2. Toner density:

There are eight options: “0”, “1”, “2”, “3”, “4”, “5”, “6”, “7”.

Section 5 Operating Instructions for Recorder

Steps of paper installation:

* Open the door of the recorder (on the bottom of the machine);

* Make the recording face of the new paper to be upward;

* Out-pull the paper for a short length until it extends over the open door of the recorder; adjust the paper for a right position.

* Close the recorder door and ensure there is a part of paper disclosed.

'Note'

Under fast printing mode, the recorder will only be stopped when all the recorded waveforms and data are outputted; during the period, please don't repress the [PRINT] button, otherwise the recording process will be re-initiated.

During normal service, recording paper is out-taken at uniform speeds; the user shall not pull it at that moment so as to prevent the recorder from being damaged.

The recorder shall not be used without recording paper put inside.

⚠ **Warning** ⚠

*** Must use qualified heat-sensitive recording paper, otherwise recording failure, recording quality loss or damages to the heat-sensitive probe may be resulted.**

*** It is prohibited to user other coarse materials or hands to touch the heat-sensitive probe, otherwise the recorder may be damaged.**

'Note'

Be careful when loading record paper. Avoid damaging the printhead. Unless when loading paper or shooting troubles, do not leave the recorder catch open.

*** Paper jam:**

When the users hear the recording is running while no paper is outputted, the user shall open the recorder door to check whether there is a paper jam.

Chapter IV Parameter Specifications and Precautions

Section 1 FHR Specifications and Precautions

The principle of fetal monitoring:

Nowadays, the fetal electronic monitoring products are divided into two basic types: the ANTEPARTUM monitoring and the INTRAPARTUM monitoring. The main difference between ANTEPARTUM monitoring and INTRAPARTUM monitoring is that the former has no internal monitoring ability, that is, it cannot supervise FHR (Fetal Heart Rate) through the electrode of the fetal scalp directly, also it cannot supervise the IUP (Internal Uterine Pressure) through the internal pressure drive pipe. However, the ANTEPARTUM monitoring put Ultrasound Transducer onto maternal abdomen to examine the FHR, while put uterus constriction probe (TOCO Transducer) in the base of the maternal womb to examine UA (Uterine Pressure).

The INTRAPARTUM monitoring seldom use in clinic for the following reasons:

The ANTEPARTUM monitoring adopted high sensitive ultrasound transducer, good capable signal processing electric circuit and advanced fetal heart rate computational method, which, to some extent, guaranteed the accuracy and reliability of the fetal heart rate examination effectively.

While the INTRAPARTUM monitoring bring certain wound to the pregnant women, and its operation is complex, moreover, it uses the disposable electrode or the pressure drive pipe. Therefore, it is difficult for the pregnant women to accept its high cost.

Brief introduction of the ANTEPARTUM monitoring:

Doppler fetal heart rate monitoring:

The Doppler fetal heart rate monitoring is realized on the basis of the Doppler Effect. A certain frequency ultrasonic must have reflection when it meets obstacle in its transmission. If the object is still, reflected wave frequency and emitted wave frequency are the same. Once the object moves, the reflected wave frequency will change. The reflection frequency is getting higher when the moving object is facing the sound. The reflection frequency is getting lower when the moving object is behind the sound. The object move faster, the change is bigger. It is called the Doppler Effect. Clinic use ultrasonic sensor to emit the ultrasonic into body. While the ultrasonic meet moving organ, for example heart, to get the changed return wave. It is by processing the return

signal to get the heart rate information to reflect heart movement.

The best position for using Doppler to monitor heart rate is the position that the fetus is back against the maternal abdomen. If the fetus faces towards the maternal abdomen, its hands and feet may affect echo, and its movement will make the heart deviate from the reflection zone of sensor, and the echo signal will become weaker.

FHR Probe Connection

1. First place the strap under the back of the pregnant woman. The pregnant woman is resupine. Then use stethoscope to confirm the fetal heart position.

2. Apply some coupling agent on the surface that the probe touches the human body to ensure the maximum fetal heart rate ultraphonic monitoring scope.

Please refer to the figures below:

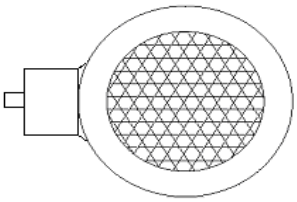


Figure 1

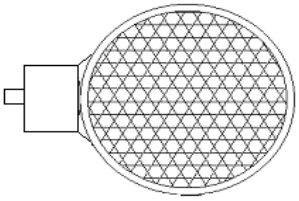


Figure 2

Figure 1 Before binding the probe, the user should apply some coupling agent in the middle of probe (2/3 of the probe).

Figure 2 After fixing the probe on the pregnant women's abdomen, the coupling agent will cover the whole surface due to pressure.

3. Put the ultrasonic probe onto maternal abdomen. Adjust the position of the probe to get the best fetal heart signal.

4. Use elastic strap to fix the probe.

'Note'

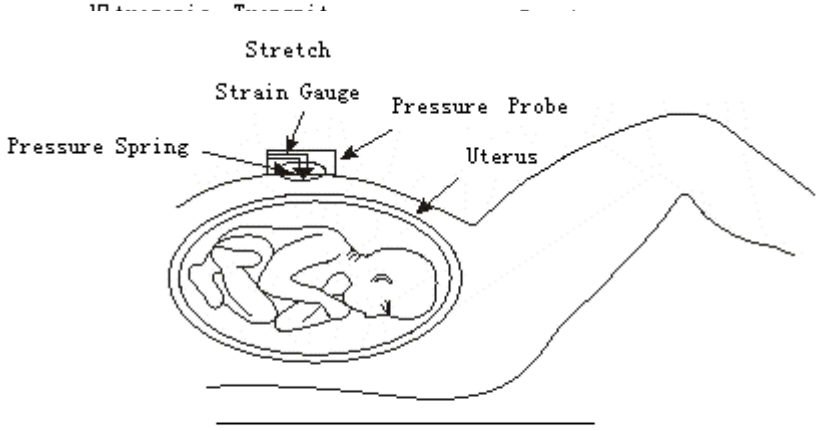
The strap should be in the right position, and the elasticity should be suitable.

5 In the monitoring process, the monitor should keep hearing obvious fetal heart sound. **Do not turn off the volume completely.** If the monitor can not get good fetal heart signal, the FHR curve is not reliable.

6. The fetal heart position might have big change while strong fetal move, uterine contraction and the body movement of pregnant woman, the fetal heart sound is not clear enough. The user needs to adjust the position of ultrasonic probe to regain better fetal heart signal.

Monitoring terms:

Continuous wave working mode: It means emission part and receipt part of ultrasonic probe working



UCP Measure Sketch Map

simultaneously. In this mode, the circuit is simple, however, the goal distance can not be recognized and may cause other noises and lead to large emission power and small probe effective area.

Impulse wave working method: Emission power is small, the effective receipt is large. The user can select the ultrasonic signal at some extent to eliminate the interference and voice. But the circuit is complicated.

The emitted frequency apply for fetal monitoring is normally 1MHZ~2.5MHZ. The frequency is high while the penetrability is low. But the resolution for structure is relatively high. On the other side, the frequency is low while the penetrability is high. But the resolution for structure is relatively low. Thus the emitted frequency of ultrasonic probe to diagnose shallow surface blood vessel is up to 810MHZ. ultrasonic probe emitted power: International safety standard 10MW/CM2. To excess the standard might cause bad effect on the fetal tissue.

Precautions during FHR Monitoring

⚠ **Note:**

3. In the monitoring process, the monitor should keep hear obvious fetal heart sound. Do not turn off the volume completely. If the monitor can not get good fetal heart signal, the FHR curve is not reliable.
4. The fetal heart position might have big change while strong fetal move, uterine contraction and the body

movement of pregnant woman, the fetal heart sound is not clear enough. The user needs to adjust the position of ultrasonic probe to regain better fetal heart signal.

Section 2 TOCO Specifications and Precautions

Pressure monitoring

Pressure monitoring is special monitoring for uterine contraction situation. TOCO is the index for childbirth strength. Clinic shows that the situation of uterine contraction can influence fetal movement and childbirth directly. The curves can offer much information by pressure monitoring records. For example uterine strength, frequency and lasting time, regularity and shape and speed up/slow down of FHR by uterine contraction effect. The medical staffs can diagnose the fetal heart variation from fetal monitoring and pressure monitoring.

Out-pressure monitoring means to get the TOCO from the maternal abdomen. Once uterine contraction happens, the celiac strain oppresses the under pressure sensor. Pressure will change the electronic signal to pressure. The pressure signal zooms out and then prints out.

TOCO Probe Connection

1. Use the strap through the back of pressure probe, and then put the probe at the end of uterus. Fix the strap and adjustable place, the strap should bind suitable.

'Note'

The strap should be in the right position, and the elasticity should be suitable.

2. Press the multi-function button on the right of the panel to reset the pressure to about 10 or 20 (Continues wave reset to 10, impulse reset to 20), and the TOCO value measured shall be its relative value.

3. Uterine contraction probe is tied on the pregnant woman. Pay attention to the TOCO data:

In case the pregnant women do not uterine contraction, the arrangement is 20-50. If bind too tight (data show is excess 90), the user need to loose the strap until get the range. Then press the ENTER button to reset the pressure to 10. (Continues wave reset to 10, impulse reset to 20).

In the monitoring status, whenever the user find the uterine contraction data is below 2, press ENTER button to reset the data to 10. (Continues wave reset to 10, impulse reset to 20).

Section 3 FM Specifications and Precautions

FM instruction and important notes

Remind pregnant woman to press the marker when the fetal start moving. Press marker once from the beginning to the end.

FM Mark-making Device Connection

⚠ Deliver the FM Mark-making device to the pregnant, and let the pregnant press it when the fetus moves.

'Note'

Press mark making device when the fetus begins to move. Keep in mind to press once only from start to stop.

Chapter V Maintenance & Cleaning

Maintenance check

Before monitoring patients, the user shall:

■ Check whether there is any physical damage;

■ Check all the disclosed leads, plugs, and accessories;

■ Check all the functions to be used to monitor the patients and ensure the equipment works well; if any phenomenon is observed with the possibility of damaged functions, the Monitor shall not be used onto the patients and please contact the biochemical engineers of the user hospital or the maintenance engineers of our company.

■ Comprehensive checks, including safety checks, must be conducted by qualified personnel once per 6-12 months and after each time of repair.

⚠ **Warning** ⚠

If any hospital or agency responsible for using the Monitor fails to implement a set of satisfying maintenance plan, unusual functional failure may be resulted to the Monitor and may threaten the people's health.

Normal care and clean

The Monitor shall be kept without dust.

It is recommended to clean the outer surface of the cover and the monitor screen. To clean the cover, soft clothes moistened with soap water or diluted non-corrosive cleaning liquid shall be used.

⚠ **Warning** ⚠

Before cleaning the Monitor or the sensor, please power-off the Monitor.

⚠**Note**

Pay attention not to damage the Monitor:

■ No strong solvent such as acetone shall be used;

■ Most of cleaning liquids shall be used only after diluted, and the user shall dilute them following the instructions given by manufacturers;

■ No abrasive material (such as fiber wire or silver polisher) shall be used;

■ No liquid shall enter the cover, and the user shall not immerse any part of the Monitor into any liquid;

■ No cleaning liquid shall be remained on the surface of the Monitor.

Use of cleanser

Except those listed as "For careful use", any other solutions that may be classified into the following types may be used as cleaning liquids for the Monitor:

■ Diluted ammonia

■ Diluted sodium hypochlorite (bleaching powder)

Attention: sodium hypochlorite of 500ppm (diluted in 1:100) to 5000ppm (diluted in 1:10) is very effective.

The specific ppm value is up to how many organics (blood, grume of animals or plants) remained on the surface to be cleaned and sterilized.

■ Diluted formaldehyde (35~37%)
■ Hydrogen peroxide (3%)
■ Alcohol
■ Isopropyl alcohol

⚠**Note**

The surface of the Monitor and the sensor may be swept with medical alcohol, dried within natural wind, or cleaned with clean and dry clothes.

⚠ **Note**

Our company is not responsibly for the effectiveness of taking these chemicals or methods as infection control methods. Please consult with the persons in charge of infection control of the user hospital or epidemic experts.

Sterilization and disinfection

Sterilization

To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Sterilization facilities must be cleaned first.

Recommended sterilization materials: Ethylate, and Acetaldehyde.

Appropriate sterilization materials for ECG lead, blood pressure cuff, SPO2 sensor, RESP probe are introduced in "care and cleaning" of relevant chapter.

⚠ **Caution**

- **Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible concentration.**
- **Do not let liquid enter the monitor.**
- **Do not immerse any part of the monitor into liquid.**
- **Do not pour liquid onto the monitor during sterilization.**
- **Use a moistened cloth to wipe off any agent remained on the monitor.**

Disinfection

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. Disinfection facilities should be cleaned first.

Appropriate disinfection materials for ECG lead, SpO_2 sensor, blood pressure cuff and TEMP probe are introduced in "maintenance and cleaning" of relevant chapters.

⚠ **Note**

Do not use EtO gas or formaldehyde to disinfect the monitor.

Appendix I Accessories

⚠ Warning

- **Only use the accessories designated in this user manual, or the monitor could be damaged.**
- **To avoid cross infection, do not reuse any disposable accessory.**
- **The disposal of the reusable or disposable accessories shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital.**

PN	Model	Description
40-000195-00	250ML	Ultrasonic coupling agent
040-000616-00	CM-FSUS1	Primary FHR probe, Waterproof
040-000617-00	CM-FSUS2	Secondary FHR probe, Waterproof
040-000618-00	CM-FST	TOCO Probe,Waterproof
040-000619-00	CM-FSM	FM Marker, Waterproof
040-000226-00	HX-1	Wake Probe
040-000867	FS-TC1	Adult Electrode
040-000868		Adult Electrode
040-000320-00	98ME01AC473	ECG Cable
040-000321-00	98ME01AC474	ECG Cable
040-000322-00	98ME01AC475	ECG Cable
040-000368-00	98ME01EC477	ECG Cable
040-000369-00	98ME01EC478	ECG Cable
040-000370-00	98ME01EC479	ECG Cable
040-000479-00	98ME01AC458	ECG Cable
040-000480-00	98ME01AC457	ECG Cable
040-000487-00	98ME01EB075	ECG Cable
040-000481-00	98ME01AB076	ECG Cable
040-000485-00	98ME01EC681	ECG Cable
040-000486-00	98ME01EC680	ECG Cable
040-000312-00	SAL104 REV:A.0	Adult SPO2 probe for finger
040-000726-00	SAS104 REF:AS104-068-01	Adult SPO2 probe for finger
040-000730-00	SES104 REF:ES104-068-01	Neonate SPO2 probe
040-000646-00	A1418-SA203MV	Adult SPO2 probe for finger

040-000334-00	A1418-SW203MU	Neonate SPO2 probe
Masimo SpO2		
040-000203-00	M-LNCS DCI/>30KG PN:2501	Adult SPO2 probe for finger
040-000361-00	M-LNCS YI >1KG PN:2505	Reusable neonate Y-model SPO2 probe
Nellcor SpO2		
040-000010-00	DS-100A ＞40KG	Nellcor SpO2 sensor
040-000075-00	DURA-Y® D-YS	Nellcor SpO2 sensor
040-000243-00	SLZ068	Cable extender
040-000769-00	SLZ122	Cable extender
040-000313-00	S-A1202026	Cable extender
NIBP Cuff		
040-000591-00	U1880S	NIBP Cuff
040-000592-00	U1880S	NIBP Cuff
040-000593-00	U1881S	NIBP Cuff
040-000594-00	U1882S	NIBP Cuff
040-000595-00	U1883S	NIBP Cuff
040-000596-00	U1884S	NIBP Cuff
040-000597-00	U1885S	NIBP Cuff
040-000598-00	U1869S	NIBP Cuff
040-000599-00	U1889S	NIBP Cuff
Temp Probe		
040-000246-00	TAS03-04	Surface Probe
040-000387-00	TPS03-03	Surface Probe
040-000385-00	TAE03-03	Cavity Probe
040-000386-00	TPE03-04	Cavity Probe
040-000534-00	TPS03-07	Surface Probe
040-000650-00	TPS03-06	Surface Probe
040-000652-00	TAE03-08	Cavity Probe
040-000651-00	TAE03-07	Cavity Probe

Appendix II Remarks to the error codes during NIBP measurement

Error codes	Failure reasons
E20	No tough tie of the cuff; No connection with the cuff; An adult cuff is used under children/neonates mode.
E21	Gas leakage in air valves, air pipes or cuffs
E22	Pressure error. No stable cuff pressure is maintained, for example, twisting of air pipes.
E23	Loose cuff Weak pulse of the patient
E24	Exceeding the measurement range
E25	Frequent patient movement during measurement Heavy vibration during measurement Irregular HR, such as arrhythmia
E26	Cuff pressure exceeding safety limits (305mmHg for adults and 160mmHg for children); quick sneezing of patients or hit with cuffs during measurement may also result such an error
E27	Signal saturation
E28	Gas leakage in air valves
E29	System failure
E33	Measurement overtime. The maximum measurement time for adults is 120s, and for children is 90s.

Appendix III　Performance Indexes

1）Classification

Anti-electroshock degree: equipment belonging to application part of BF, CF Type (among which, ECG testing part belongs to CF-based application, remaining all other testing parts belong to BF type application parts);

Classification of medical equipment management： the fetus multi-parameter monitor is a medical ultrasonic instruments and related equipment (6823) in ultrasound maternal and child care equipment, management category of II

2）Operation Environment

Power: AC100-250V, 50/60Hz.
Temperature: 5-40℃
Humidity: ＜80%
Rated Power：80VA

Transportation and Storage

Transport: Must avoid severe shock ,vibration, rain and snow during transport

Storage : Packed monitors must be stored in well ventilated rooms with -10℃～+40℃ temperature, relative humidity no more than 80%, and without corrosive gases

3）product specification

Size and weight

Size: 352mm×269.5mm×101mm

Weight : about 5kg

Display: 12.1　inch TFT touch folding up LCD
Resolution: 800 x 600

Parameter setting options:

Pulse beep: ON, OFF

Alarm sound: ON, OFF

Waveform and parameter color: true color

Printing mode: real-time printing

DEMO mode: ON, OFF, true color

Record

Sensitivity conversion error: ≤5%

Recording speed: 25mm/s

Recording speed error: ≤5%

Hysteresis characteristics: ≤0.5mm

Amplitude-frequency characteristics:

Diagnosis mode: 0.05~130Hz monitor mode: 0.5~40Hz Operation mode: 1~20Hz

Time constant:

monitor mode: ≥0.3s Diagnosis mode: ≥3.2s

Fetal Monitoring:

Working mode: pulse wave

Probe working frequency: 1.0MHz±10％

P_ (peak negative acoustic pressure): ＜1Mpa

I_{ob} (output beam intensity): ＜20mW/c ㎡

I_{spta} (intensity peak temporal average): ＜100mW/c ㎡

FHR measuring range: 50bpm~210bpm

FHR measurement precision: ±2bpm

TOCO measuring range: 0~100%

TOCO measuring nonlinearity error: ±8%

Probe model: KM311

Probe serial No.: Refer to the serial number label on the probe.

Appendix IV Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions The STAR5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the STAR5000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The STAR5000 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.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicke r emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The STAR5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the STAR5000 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	±6 kV contact ±8 kV air	±4kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV 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	<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 for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the STAR5000 requires continued operation during power mains interruptions, it is recommended that the STAR5000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance And Manufacturer'S Declaration – Electromagnetic Immunity – for equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity The STAR5000 is intended for use in the electromagnetic environment specified below. The customer or the user of the STAR5000 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the STAR5000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 p d = 1.2 p 80 MHz to 800 MHz d = 2.3 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:

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the STAR5000			
The STAR5000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the STAR5000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the STAR5000 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 = 1.2 p	80 MHz to 800 MHz d = 1.2 p	800 MHz to 2.5 GHz d = 2.3 p
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

promedic
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Read the instructions carefully before using this device.

CE 0120

Promedic_IB_STAR5000_verA_01
Revision Date: 09/01/2018

www.promedic-health.com