Caddo 17B
Fetal Monitor

Learning Material

Ver 1.1

An ISO 9001:2008 company

Innovative Technology Ecosystem

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Certificate

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TÜV Rheinland India Pvt. Ltd.:

Certificate Holder: **Scientech Technologies Pvt. Ltd.**

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Scope: **Design, Manufacture of Electronic Test & Measuring Instruments, Training Products for Electrical & Electronics Education and Providing Technology Training**

An audit was performed, Report No. 10182. Proof has been furnished that the requirements according to ISO 9001:2008 are fulfilled.

The due date for all future audits is 04-10 (dd.mm).

Validity: The certificate is valid from **2010-12-13 until 2013-12-12.**

Bangalore, 2010-12-20

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Caddo 17B
Fetal Monitor

Table of Contents

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Attention

Responsibility of the Manufacturer

Contec only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Contec, and the electrical installation of the relevant room complies with national standards, and the instrument is used in accordance with the instructions for use.

Note: This device is not intended for home use.

⚠ **Warning** ⚠ This device is not intended for treatment.

If there is doubt as to fetal well-being after using the unit, further investigations should be undertaken immediately using alternative techniques.

The accuracy of FHR is controlled by the equipment and can not be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify or contact the local distributor or manufacture to get help.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

⚠ **Warning** ⚠'

A Warning label advises against certain actions or situations that could result in personal injury or death.

⚠ **Caution** ⚠

A Caution label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Note: A Note provides useful information regarding a function or procedure.

Safety Guidance

1.1 Introduction for the Safe Operation

- The Caddo 17B Ultrasonic Fetal Doppler Monitor (Monitor) is Class I equipment and designed to comply with IEC 6060 I-I.
- Switching within I minute, at ambient temperatures between 5.C and 40.C. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) clearance around the instrument for- proper air circulation.
- The user must check the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per week or less. If damage is evidence, replacement is recommended before use.
- The user must be serviced only by authorized and qualified personnel, The manufacturer can not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- Perform period safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- The protection categories against electric shock of the patient connections are:

  (1) FHR1 (2) FHR2 (3) TOCO (4) MARK

This symbol indicates that the instrument is IEC 6060 I-I Type B equipment. Type B protection means that these patient connections will comply with permitted leakage currents, dielectric strengths and protective earthing limits of IEC 6060 I-I.

- The monitor described in this user manual is not protected against:
  a. The effect of defibrillator shocks
  b. The effects of defibrillator discharge
  c. The interference of high frequency currents
  d. The interference of electro surgery equipment
  e. The interference of mobile phone

1.2 Ultrasound Safety Guide

Ø Fetal Use

The Monitor is designed for continuous fetal heart rate monitoring during pregnancy and labour. Clinical interpretation of fetal heart rate patterns can diagnose fetal and/or maternal problems and complications.

Ø Instructions for Use in Minimizing Patient Exposure

The acoustic output of the Monitor is internally controlled and can not be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure.

1.3 Safety Precautions

Warning and Caution messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

⚠ Warning ⚠ Explosion Hazard-Do not use the in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

⚠ Warning ⚠: Shock Hazard-the power receptacle must be a three-wire grounded outlet.

A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

⚠ Warning ⚠: Shock Hazard-Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

⚠ Warning⚠: The monitor should be installed by an authorized and qualified service engineer.

⚠ Warning ⚠: Shock Hazard-Do not remove the top panel covers during operation or while power is connected.

⚠ Warning ⚠: Only connect the device to Contec supplied or recommended accessories, to avoid the injury of the doctors and patient.

⚠ Warning ⚠: Do not switch on device power until all cables have been properly connected and verified.

⚠ Warning ⚠: Don't touch signal input or output connector and the patient simultaneously.

⚠ Warning ⚠ Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 6060 I-I-I. Everybody who connects additional equipment to the signal input connector or signal output connector 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. If in doubt, consult our technical service department or your local distributor.

- Caution : The device is designed for continuous and is "ordinary" (i.e. not drip or splash-proof).
- Caution : Keep the environment clean. Avoid vibration. Keep it far ITom corrosive medicine, dust area, high-temperature and humid environment.
- Caution : Do not operate the unit if it is damp or wet because of condensation or spills.

  Avoid using the equipment immediately after moving it ITom a cold environment to a warm, humid location.
- Caution : Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducers.
- Caution : Do not use high temperature heating or gas to disinfect the monitor and its accessories.
- Caution : Turn off the power supply before clean the machine.
- Caution : The temperature should not exceed 60.C when clean the belt.
- Caution : Electromagnetic Interference-Ensure that the environment in which the fetal monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.
- Caution : The monitor must serviced by proper training and knowledge, practical personnel. The recommended testing interval is once twice year or under the leakage current measurement and insulation testing.
- Caution : The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

Introduction

The Fetal Monitor can provide different configurations according to different user requirements: FHRI (Ultrasonic Channel I), FHR2 (Ultrasonic Channel II), TOCO, FMOV (Fetal Movement Marker). Monitoring results can be recorded by built-in recorder for continuous or intermittent records.

The monitor can be used individually or connected with PC through RJ45 Interface for the purpose of central monitoring.

2.1 Intended Use and Application

Fetal Monitor can acquire fetal heart rate, maternal uterine contraction when pregnancies over 28 weeks to provide reference data for clinical use.

Dual Heart Rate Monitoring allows simultaneous monitoring of two heart rates for twins. This is achieved by using the facilities of two ultrasound transducers and an external contractions (TOCO) transducer with a recorder.

The monitor can display FHR, TOCO, MARK (remote) sinuously, by analyzing their mutual' relations, to judge fetal physiology, pathology and maternity status, and so on, for medical professionals reference.

It is only suitable for the equipment in hospitals, clinics, doctors offices and patients at home by trained medical personnel.

2.2 Features

- Light dexterous appearance, tops horizontally and walls can be hoisted
- 8.4screen color LCD display, rotatable screen to 60°
- Display of the patient data and curve clearly
- Print paper fetal heart rate 120-160bpm normal range label
- Manual records fetal movement
- Sound and color alarm for high and low fetal heart rate
- Continuous 24-hour real-time monitoring function
- Continuous 12-hour patient curve and data storage and playback
- With picture freeze function
- Optional English interface
- Single, Twins Monitoring optional
- 9 chip pulse width beam probe
- Extra-long life, high-resolution built-in thermal printer matrix, the output waveform, text, and other information
- Built-in communication port, can be connected with central monitoring system.

Monitor and Setup

3.1 The Monitor

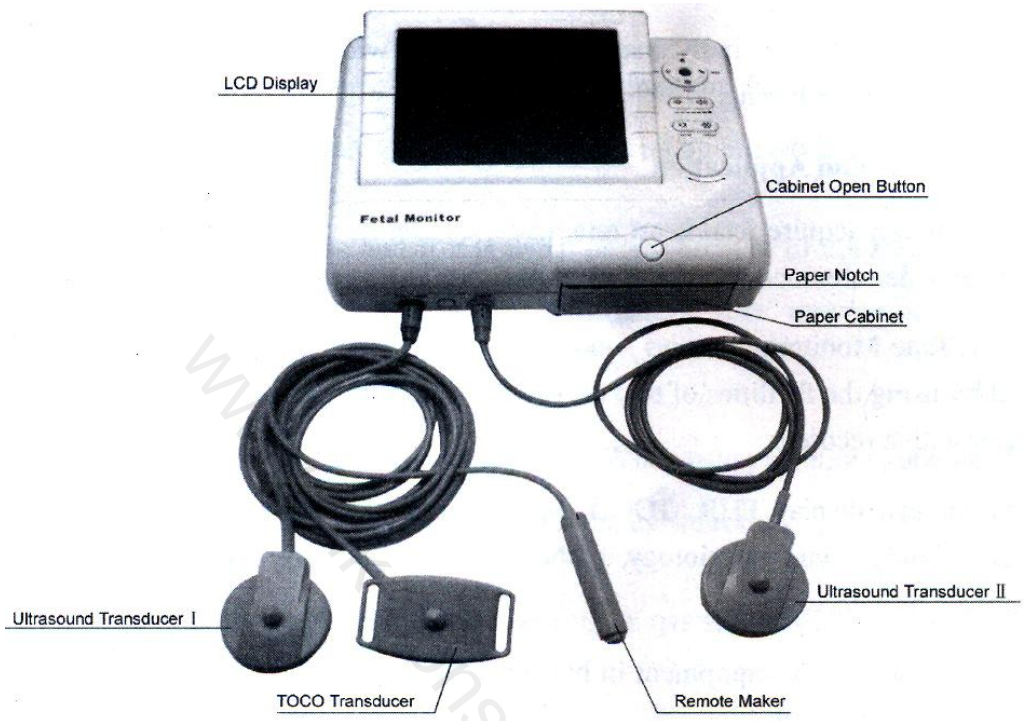


Figure 3.1 Appearance (Twins configuration, only for reference)

3.1.1 Transducer Introduction

Ultrasound Transducer I , TOCO Transducer, Remote Marker, Ultrasound Transducer II

(1) Ultrasound Transducer I

The multi-crystal, broad beam ultrasound transducer is used for monitoring fetal heart rate (FHR1).The ultrasound transducer operates at a frequency of 1.0MHz. Put the ultrasound transducer on maternal abdomen to transmit lower energy ultrasound wave to fetal heart, then receive the echo signal from it.

(2) TOCO Transducer

This transducer is a too tonometer whose central section is depressed by the forward displacement of the abdominal muscles during a contraction. It is used for assessment of frequency and duration of uterine contractions. It gives a subjective indication of contractions pressure.

(3) Remote Marker

The remote marker is a hand-held switch operated by patient. The mother is normally instructed to push down the switch when feeling fetal movement.

Ultrasound Transducer I TOCO Transducer, Remote Marker are three in one transducers, their sockets are marked FHRl/TOCO/MARK on the monitor panel.

4) Ultrasound Transducer II is the transducer for FHR 2(Twins Configuration), it's socket is marked FHR2 on the monitor panel.

3.1.2 Left Side Sockets

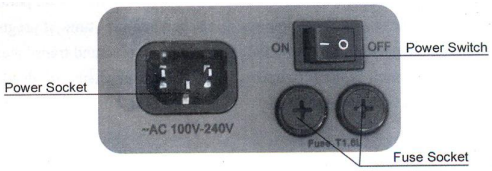


Figure 3.2 Left Side Sockets

3.1.3 Interfaces and Symbols

FHRl/TOCO/MARK ; socket: Socket for FHRl/TOCO transducer and remote Marker
FHR2 socket: Socket for FHR2 Transducer

: Socket for Grounding Cable

NET: Socket for network

⚠ : Warning Symbol

Push: LCD Screen rotation lock

3.1.4 Main Interface

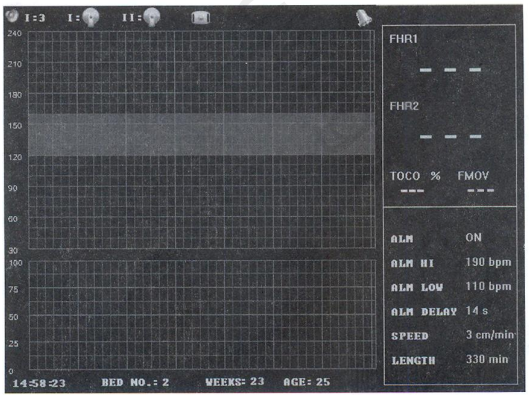


Figure 3.3 Twins monitoring interface

The main monitoring interface(Twins Monitoring) is divided into 5 parts according to display content, they are status bar, data section, parameter section, indicate bar and wave display section. It displays in status bar that sound channel and volume, connection status of ultrasound Transducer I, ultrasound Transducer II(twins monitoring) and TOCO transducer, Freeze status, print status, alarm on /off*;* It displays FHR 1 from Ultrasound Transducer I, FHR 2 from Ultrasound Transducer II (Twins monitoring) and TOCO, Fetal Movement data; parameter section displays the important parameter of current settings; time, bed number, time of pregnancy and age of pregnant woman are displayed

in indicate bar; waves from ultrasound transducer I channel, ultrasound transducer II channel(Twins Monitoring) and TOCO transducer are displayed in wave display section. Detail instruction as followed.

(1) Status Bar

(A) Sound channel and volume

Icon:  I:3  I:0

 : Sound Icon

 : Sound Icon

I: The No. of FHR sound channel, it is I under single fetal monitoring mode which is default; I, II selectable under twins monitoring mode, it can be changed through the main menu

3: Volume level, ranging from 0-7, 0 stands for sound off. It can be changed through the buttons on the panel or set in the main menu.

(B) Connection status of ultrasound transducer

Icon: I:  II: 

I: Channel No. of ultrasound transducer, there is only I under single monitoring mode, there are I and II under twins monitoring mode

 : Normal connection of ultrasound transducer

 : Error connection of ultrasound transducer

(C) Connection Status of TOCO transducer

 : Normal connection of TOCO transducer

 : Error connection of TOCO transducer

(D) Freeze status

 Shows current screen is frozen; icon will disappear when unfrozen.

(E) Recorder status

 **:** Printing

 : Out of paper

 : Failed to print

(F) Alarm on/off status

 : Alarm on

 : Alarm off

(2) Data Section

FHR I Data of Ultrasound Transducer I: 3-digit data, it is in green color under normal status, it will be in red when alarm occurs; it displays "---" when there is no data.

FHR 2 Data of Ultrasound Transducer II: this data will show in twins monitoring mode, the display format is the same with the FHR 1.

TOCO data: Display the relative contraction data, ranging from 0-100, it will be 10 after Auto Zero.

Fetal Movement data : Display Fetal movement numbers, it will be "--" after Auto Zero.

(3) Parameter Bar

This section displays important setting parameters: it contains alarm on/off status, alarm upper limit, lower limit, alarm postpone time, print speed and print time.

(4) Indicate Bar

In this item, it includes system time, bed No., gestational age and patient age.

(4) Waveform Display Section

This section also be divided into 2 sections, FHR trend graph is displayed in the upper section, TOCO waveform is displayed in lower section. FHRI Trend is in green, FHR2 trend is in Yellow (only displayed in twins monitoring), the normal range of the fetal heart rate is 120-160bpm. Which be showed in green on the screen.

Fetal movement mark " "> alarm mark event mark"↓' will also be showed in this section.

3.1.5 Buttons

There are several buttons of different functions on the front panel of fetal monitor. The diagram is showed as Figure 3.4.

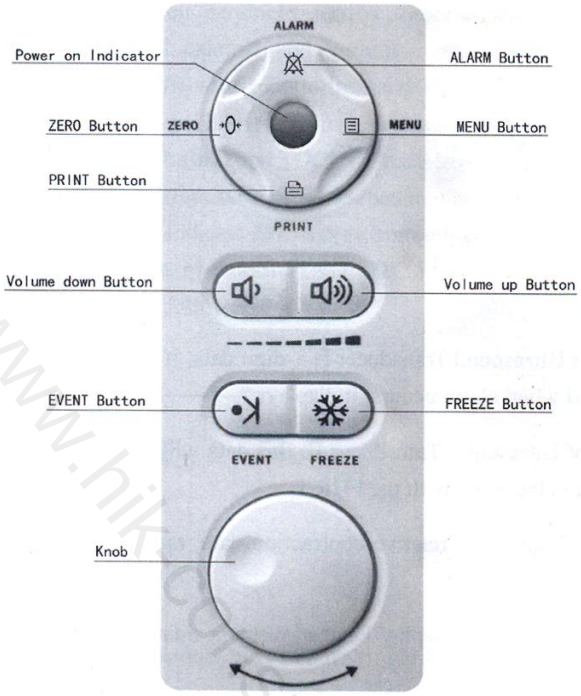


Figure 3.4 Buttons

1. Menu Button

Push Menu Button to enter setup menu, push it again to return monitor screen. When operating in other menu, push this button to return this menu. Only turning knob button can exit wave review mode.

Detailed operation please refer Figure 3.2

2. Alarm Button

Function: Enable/Stop audio alarm when FHR is in alarm range. When  symbol appears, the alarm indicator status is shut off.

Press the button to enable audio alarm, the alarm indicator becomes [3. when FHR is in alarm situation, the alarm sound will be given out.

3. Auto Zero Button

Function: Clear the screen, TOCO value back to 10 unit,

Press this button to clear the screen and adjust the present TOCO contractions trace/value to reference point 10 when in the status of monitoring, after pressing the Auto Zero button, the symbol  will be recorded at the trace.

4. Print Button

Function: Enable / Disable printing.

Press Print button in normal situation, if it not works, it begins real-time printing Press Print button in frozen situation, it prints the waveform on the screen.

5. Volume Control Button

 : Volume down  Volume up

Function: adjust the audio volume of the Fetal heart Sound.

6. Event Button

Function: Press this button to print an event symbol on the screen trend figure at the corresponding time. If user want to mark an event on the trend figure, he/she could achieve this by pushing this button.

7. Freeze Button

Function: Freezing the screen. Press the button to stop drawing and the screen becomes in frozen status, press the button again to continue drawing. This operation will clear the screen.

8. Knob Key

CD Press the button to activate the selected button, press it again to accept the configuration. @To choose and adjust the parameters by revolving the knob key.

9. Paper Cabinet Open Button

Push this button for opening the paper cabinet.

10. "Push" - LCD Screen Rotation Lock

Function: Push this button to unlock the screen for rotation purpose.

Note: Please lock the LCD Screen during transportation to avoid any damage of the monitor.

3.2 Setup

Under Main monitoring interface, Press the Menu button or knob key to enter setup mode, the diagram is showed as Figure 3.5

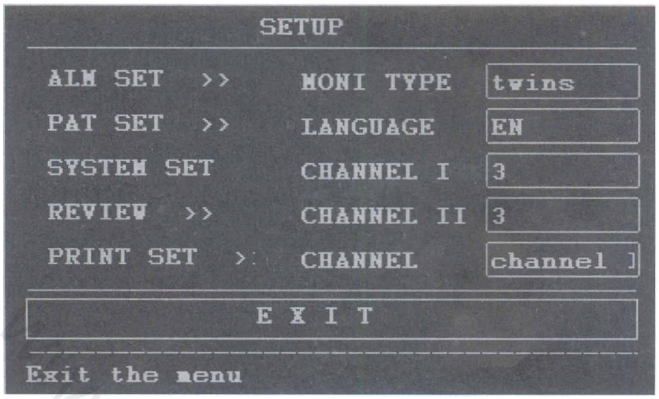


Figure 3.5 Setup

Revolving knob key to select different function. The Corresponding function and the adjustable ranges are showed in table3.1.

Table 3.1 the setup function and adjustable ranges

No	Function	Adjustable Ranges
1	ALM SET (Alarm Setup)	Enter Alarm Setup
2	PAT SET (Patient Setup)	Enter Patient Setup
3	System Set (System Setup)	Enter System Setup
4	Review (Waveform Review)	Enter Waveform Review
5	Print Set (Print Setup)	Enter Print Setup
6	MONI TYPE (Monitor Mode)	Optional: single, twins the default is single fetus
7	Language(Language Selection)	Optional: Chinese (CH), English (EN), the default is EN.
8	Channel Setup) I (Audio Channel I setup	Adjustable: 1 7 and mute, the default is 3
9	Channel II (Audio Channel II Setup)	Adjustable: I 7 and mute, the default is 3
10	Channel (Audio Channel)	Optional: I, II, fetal heart audio come from the selected channel.
11	Exit	Exit main menu, back to main interface

1. Alarm Setup

Revolving the knob key to enter alarm setup, the diagram is showed as Figure 3.6:

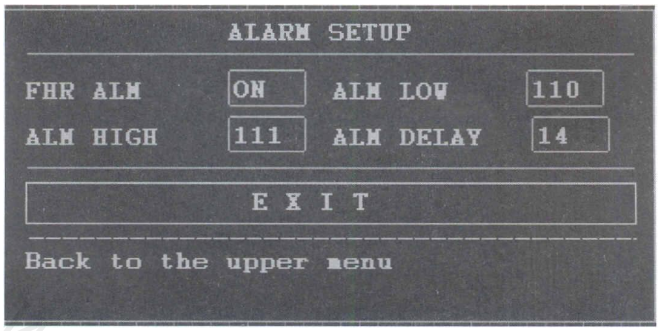


Figure 3.6 Alarm Setup

Revolving the knob key to setup alarm function. The Corresponding function and the adjustable ranges are showed in the table3.2:

Table 3.2 the alarm setup function and adjustable ranges

No	Function	Adjustable Range
1	FHR ALM(FHR Alarm)	Optional: Turn on, shut off The default situation is alarm on.
2	ALM High(FHR Upper Limit of Alarm)	Optional: lower limit of alarm-31O, the unit is BPM, and the default is 190
3	ALM Low(FHR Lower Limit of Alarm)	Optional: high limit of alarm O FHR, the unit is BPM, and the default is 110
4	ALM Delay(FHR Alarm Delay)	Optional:060,the unit is second, and the default is 30 seconds

Note:

1. When FHR is in alarm situation, alarm indicator becomes red
2. When FHR exceeds the alarm limit and time exceed the set alarm delay time continuously, alarm will occur and an alarm symbol will appear on the screen.

2. Patient Setup

Revolving the knob key to enter patient setup, the diagram is showed as Figure 3.7:

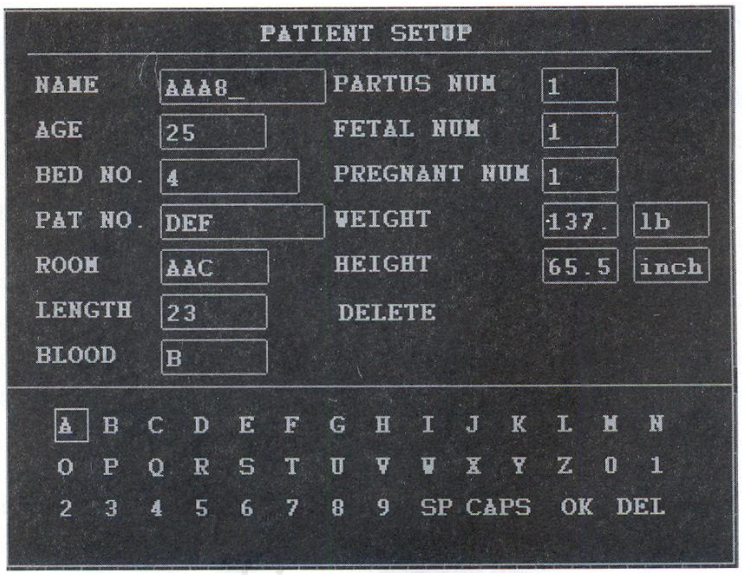


Figure 3.7 Patient Setup

Revolving the knob key to setup patient function. The Corresponding function and the adjustable ranges are showed in the table 3.3:

Table 3.3 the patient setup function and adjustable ranges

No	Function	Adjustable Ranges
1	Name(Name)	Optional: 12 letter or numeral. The default is blank
2	Age(Age)	Optional: numeral from 1-100. The default is 25
3	Bed No. (Bed No.)	Optional: numeral from 1-100. The default is I
4	Pat No (Case History No.)	Optional: 12 letter or numeral. The default is blank
5	Room (Ward No.)	Optional: 5 letter or numeral. The default is blank
6	Length(Time of Pregnancy)	Optional: 1-IOO.The unit is week. The default is 0
7	BLOOD(Blood Type)	Optional: A, B, AB, 0, and N(unknown). The default is N.
8	Partus NUM(Times of Giving Birth	Optional: 0-20, the default is 0
9	FETAL NUM.(Quantity of Fetus)	Optional: 0-20, the default is I
10	Pregnant Pregnancy) NUM(Times 0	Optional: 0-20, the default is I
11	Weight(Patient's Weight)	2-250, interval: 0.5Kg,unit: Kg or Pound; the default value is 65Kg
12	Height(Patient's Height)	20-300, interval: 0.5cm(inch), unit: cm or inch; the default value is 165cm
13	Delete(Delete Information)	Delete related patient information
14	SAVE(Save Information)	Save related patient information, return to previous menu
15	Exit	Return to previous menu

Note: 1 When adjustable range is letter or number, numeral and letter key will turn on automatically after entering the setup, in which:

SP : Space bar

CAPS : Capital letters lock

OK : Setup finished, exit keyboard output mode

DEL : Delete, delete one selected letter or number after each push.

2 The main interface prompt box will show the patient's data renewal after save the patient's data.

3. System Setup

Revolving the knob key to enter system setup, the diagram is showed as Figure 3.8:

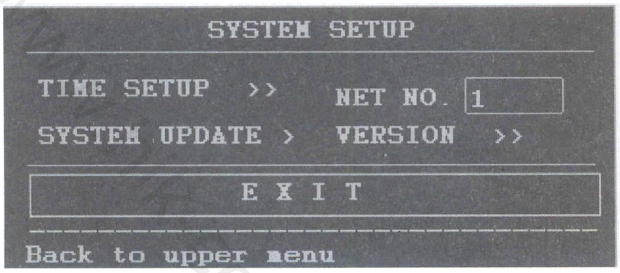


Figure 3.8 System Setup

(1) Time Setup

Revolving the knob key to enter time setup, the diagram is showed as Figure 3.9:

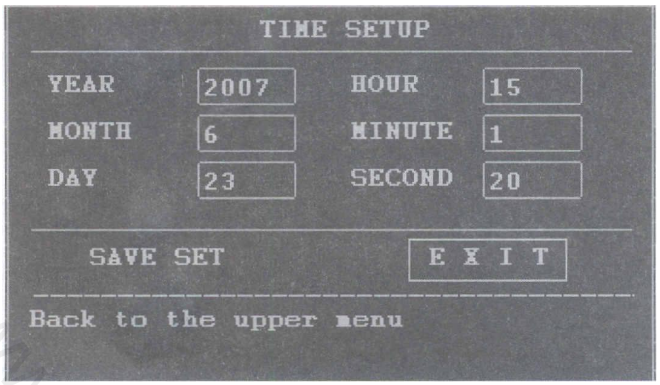


Figure 3.9 Time Setup

Revolving the knob key to enter time setup function. The Corresponding function and the adjustable ranges are showed in the table3.4:

Table 3.4 the time setup function

No	Function	Adjustable Ranges
1	Year	Optional:2005~2036
2	Month	Optional: ~ 12
3	Day	Optional: ~ 31
4	Hour	Optional: ~ 023
5	Minute	Optional:0 ~59
6	Second	Optional : 0 ~59
7	Save Set(Save)	Save setup and return to previous menu
8	Exit(Exit)	Exit to previous menu

Note: The main interface prompt box will show the time renewal after save the time setting.

(2) Net No.

Be used for connecting with central monitoring system.

(3) System Update

This device supports system update service. In system setup menu, revolving the knob key to enter System update.

Note: Please enter password under the item "USR KEY" before click "CONFIRM". This password is provided by manufacturer or distributor when Contec add new function to upgrade the system.

(4) Version

Revolving the knob key to enter System setup, choose version item and push the knob key to see the equipment version

4. Wave review

Choose the Wave Review in the setup menu to enter wave review, and press Wave Review in this item to review the history wave, which is showed as Figure 3.10

Figure 3.10 Review

Select (left or right), or revolve the knob key to view monitoring wave in different time, the end time for the current monitoring wave is showed at the down right comer in the show area. The wave form could be reviewed for twelve hours as the longest.

5. Print Setup

Revolving the knob key to enter print setup, the diagram is showed as Figure 3.11:

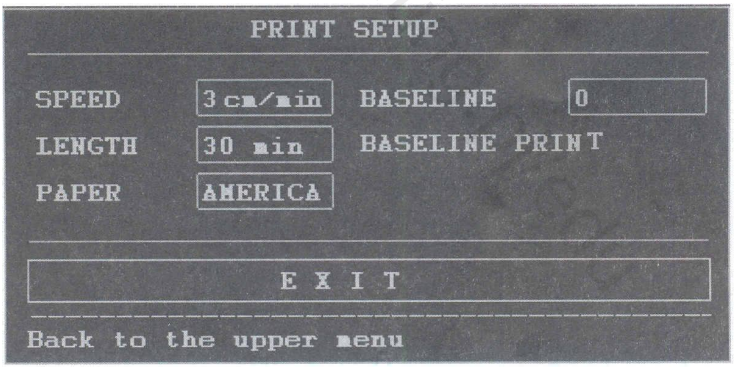


Figure 3.11 Print Setup

Revolving the knob key to setup print function. The Corresponding function and the adjustable ranges are showed in the table3.5:

Table 3.5 The print setup function and adjustable ranges

No	Function	Adjustable Range
1	Speed(Print Speed)	1 cm/min, 2cm/min, and 3cm/min. The default value is 3cm/min.
2	Length(Print Length)	024(hours) ,the interval is 10 minutes. The default value is 30 minutes.
73	Basellne (Baseline offset)	Adjustable:-l0-+ I 0, the interval is 1, the default value is 0.
4	baseline print	Print the ladder-from testing wave.
5	PAPER(Selection of printing paper type)	Please select it between American standard printing paper and Europe standard printing paper.
6	Exit	Return to the upper menu.

Installation

Note: To ensure that the monitor works properly, please read this chapter and Chapter 1 Safety Guidance. And follow the steps before using the monitor.

4.1 Open the Package and Check

Open the package and take out the monitor and accessories carefully. Put the monitor at safe and reliable place. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cable, and accessories.

If there is any problem, contact us for your local distributor immediately.

4.2 Connect the Power Cable

- Make sure the AC power supply of the monitor complies with the following specification:

  100V-240AV, 50/60Hz.
- Consider the local power supply range, if the power supply of the monitor exceeds the range, please add regulator equipment.
- Apply the power socket of the monitor. Plug one end of the power cable to the power socket of the monitor. Connect the other end of the power cable to a grounded 3-phase power output special for hospital usage.
- Connect the ground wire if necessary.

4.3 Connect with Network

If the network has been ready, insert the network cable into the RJ45 interface of the monitor.

4.4 Feeding Paper and Removing Paper Jam

If the paper is used up or paper jam happens, you have to feed paper into the recorder, the operation procedure is as follows:

1 Open the paper cabinet

2 Take out the "Z" type thermal sensitive paper from the wrapper. .Put the green safety band to the left and the face of the paper downward. Please refer to "paper installation note" on the bottom of the cabinet.

3 Feed the record paper into the slot of the recorder and push out form the middle of the notch.

4 Close the paper cabinet properly.

Removing Paper Jam

When the recorder sounds or the output of the paper improper, open the paper cabinet to check for a paper jam, then feed the paper again.

Note: Only use the manufacturer approved paper to avoid poor printing quality, deflection, or paper jam.

4.5 Power on the Monitor

Warning: If any sign of damage is detected, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.

Turn on the power, and the power indicator lights, the monitoring screen lights.

Note: There will be initialization time for some seconds after turn on the monitor to the monitoring screen shows data, and the system will enter normal monitoring after self-test.

4.6 Connect Transducers

Connect all the necessary transducers, and cables between the monitor and the patient.

Note: please pay attention to the direction when connecting transducer(s), the arrow mark in the connector should head upward.

Monitoring

5.1 Operation Procedure

Ultrasound Transducer and TOCO Transducer Positioning showed as Figure 5.1

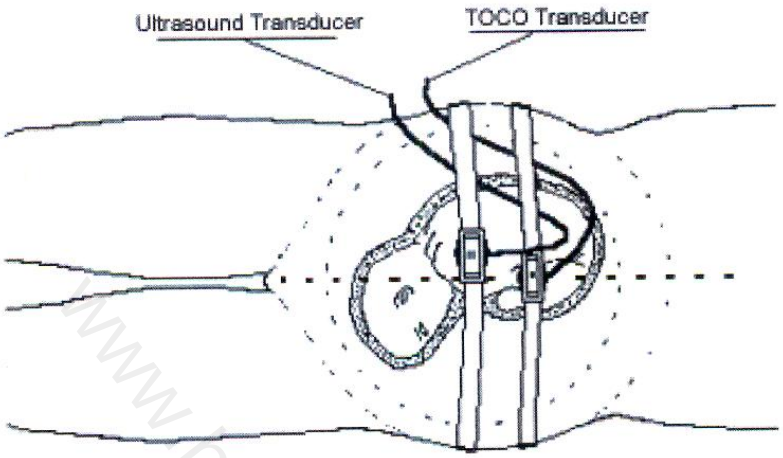


Figure 5.1 Ultrasound Transducer & TOCO Transducer Positioning

5.1.1 Ultrasound Monitoring of FHR

Ultrasound monitoring can be used for antepartum monitoring; it is a method to obtain FHR through maternal abdominal wall. Put the FHR transducer on maternal abdomen to transmit lower energy ultrasound wave to fetal heart, then receive the echo signal from it.

Operation Procedure:

1. **Preparing the Monitor**

   Turn the monitor on and verify that the normal monitoring screen appears on the display.

   Check the ultrasound transducer to verify proper attachment to the monitor. For twins monitoring, make sure the second ultrasound transducer if properly connected.

   Set the current heart rate channel to channel USI, and adjust FHRI volume well.

   Attach the buckle of the ultrasound transducer to the belt. Apply aquasonic coupling gel to the face of the transducer.

2. **Acquiring the Fetal Heart Signal**

   Determine the location of the fetal heart using palpation or a fetoscope.

   Place the ultrasound transducer on the abdomen over fetal site and move it slowly until the characteristic hoof-beat sound of the fetal heart is heard. And then fix up the ultrasound transducer. The elasticity of belt can be adjusted, which make the patient monitored in the comfortable situation, and the fetal heart rate value will be shown on the screen. At the same time, the ultrasound wave will be drawn in green color on the screen.

3. Acquiring Twins' Heart Rates Signal

CMS800G is able to monitoring twins' heart rates through two ultrasound transducers during the whole pregnant time.

Follow the step (2) mentioned above to acquire the heart rate for the first fetus.

Set the current heart rate channel to US2, and adjust FHR2 volume well so that the second heart sounds can be heard

Determine the location of the second fetal signal using palpation or a fetoscope.

Attach the buckle of the ultrasound transducer to the belt. Apply aquasonic coupling gel to the face of the transducer. Place the second ultrasound transducer on the abdomen over fetal site and move it slowly until the characteristic hoof-beat sound of the fetal heart "is heard.

The fetal heart rate value FHR2 will be shown on the screen. At the same time, the ultrasound wave will be drawn in yellow color on the screen.

Caution: Do not mistake the higher maternal heart rate for fetal heart rate.

(4) Monitor Adjustments:

Adjust the position of ultrasound scanner according to the need.

There is only one fetal heart sound can be heard from the speaker, change it by selecting different channel of fetal heart sound (the first sound channel for FHRI, and the second sound channel for FHR2) Readjust the volume setting for the desired loudness.

Note:

The ultrasound transducer measures the FUR; the misuse of it will be result in wrong measurement or misunderstanding of it. So it requires the doctor pay attention to it:

1. The best quality records will only be obtained if the transducer is placed in the optimum position.
2. Positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) should be avoided.
3. If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable to the mother.
4. It is not possible to FUR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.
5. During the monitoring, the doctor should observe the monitor screen, if the screen break off frequently, the position of the ultrasound transducer may had out of proper position due to the moving of the fetus.
6. During the monitoring, if the FUR can be heard without steadily sound of the fetal

heart, it may not proper positions. So move it slowly until the proper position is found. But if it is not found, the doctor should do other examination, to observe if the fetus is normal.

5.1.2 Monitoring Contractions

Operation Procedure:

1. Preparing the Monitor

Turn the monitor on and verify that the normal monitoring screen appears on the display. Insert the TOCO Transducer into the socket.

2. Acquiring Uterine Contraction Data

Fix the transducer. The transducer is retained on the midline half-way between the mother's funds and the umbilicus. The position is shown as figure5.l

The display of external pressure is shown as a percentage % of full scale. The uterine activity reading at this point should be greater than 30 units and less than 90 units. If the reading falls outside this range, the belt may be too tight or too loose.

3. Zero can be set more quickly by pressing the AUTO ZERO button on the front panel, provided the mother is not experiencing a contraction. The default contraction data will be 10% after press the AUTO ZERO button.

Caution: Under no circumstances are transducers to be used to monitor patients under water. Note: CD Do not use coupling gel on the TOCO transducer or transducer contact area.

Check the function by TOCO transducer, and observe the change of relevant value.

5.1.3 Event Marker Recording of Fetal Movement

The event marker is a hand-held switch the mother takes. When FHR is monitored, she operates the hand-held event marker press-switch when sensing fetal movement. At the moment, the mark " " will show in the correspond position of trend wave. The count of fetal movement will add 1 after each push of the button. Push the button and hold for one second then release for counting one fetal movement, the fetal movement will be only counted once if the button is pushed more than one time during 5 seconds. And the mark will show in the bottom area of FHR wave display section.

5.2 Print Operation

1. Baseline Adjustment

   When start the monitor, recorder will print the baseline automatically, please check if the base line snap to grid of the paper. If the baseline wave has some warp with the paper grid, operator can adjust the baseline by the baseline adjustment in main menu. Recorder will standby after printing baseline.

   Operator could choose baseline test function in the print setup menu to test baseline at any time.

2. **Real Time Print**

   Push print button under monitoring and recorder standby status to print real time wave, the print icon is  push the print button to stop the printing process when recorder is printing.

3. **Recall Print**

   Use know key to select wave to print in wave review status, and then push print button to print the selected wave.

4. **Freeze Print**

   Push print button in freeze status to print the wave displayed in screen.

5. **Print Content**

   The print output content contains: BED NO., NAME, WEEKS, PATIENT NO., FHRI trend, FHR2 trend (Twins Monitoring), TOCO wave, print speed, date, time.

   It also contains other icons like: auto zero mark  alarm mark  FMOV mark " ", event mark"↓" etc.

Note:

a. When paper is used out, printing will stop, and the data will be saved in memory, when paper reloaded, operator can use wave review function to print the saved data.

b. The monitor has the function of 12-hour wave storage, review and print. Record will not saved when monitor is turned off.

c. To ensure print precisely, recommend to print and adjust the baseline when paper is loaded.

d. If the paper coming out from the notch in deflection way when printing, the data may be not precise or paper jam will occur, operator should stop printing and reload paper.

e. Please set all print parameters well before printing, and do not try to change the setup in the process of printing.

5.3 Operation After Monitoring

(1) Remove transducers from patient. Wipe transducer with a soft cloth to remove remaining ultrasound coupling gel.

(2) Tear the paper at the folding place.

(3) Switch off the power of monitor.

6. Maintenance, Care and Cleaning

To ensure that the monitor works properly, please read the manual and operation procedure as well as the maintenance before using the monitor, and operate it as requested.

6.1 Preventive Maintenance

1. Visual Inspection

The user must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per week or less. If damage is evident, replacement is recommended before use.

2. Routine Inspection

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol

3. Mechanical Inspection

- Make sure all exposed screws are tight.
- Make sure all models and connector are in proper positions.
- Check the external cables for splits; cracks or signs of twisting replace any cable that shows serious damage.

  Warning: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

6.2 Care and Cleaning of Monitor

Keep the exterior surface of the monitor clean and free of dirt.

Regular cleaning of the monitor casing and the screen is strongly recommended. Use only non-caustic detergents such as soap and water to clean the monitor casing.

Take extra care when cleaning the display surface. These are more sensitive to rough handling, scratches and breakage than the other external surface of the monitor. Use dry, and soft cloth to wipe.

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

Caution:

1. Many cleaners must be diluted before use. Follow the manufacturer's direction carefully to avoid damaging the monitor.
2. Do not use strong solvent, for example, acetone.
3. Do not remain any cleaning solution on the surface of the monitor.
4. The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
5. The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

6.3 Care and Cleaning of Transducer

1. Maintenance

Usually, the transducer should keep clean and maintain in dry environment, where the temperature should be lower than 45 degrees. Gel must be wiped from the ultrasound transducer after use. These precautions will prolong the life of the transducer.

Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical movement. The cover is made of a soft plastic, and contact with hard or sharp objects should be avoided. Do not excessively flex the cables.

Warning: Under no circumstance are transducers to be used to monitor patients under water.

Caution: Be sure that the cleaning solution and transducers do not exceed a temperature of 45 degrees.

2. Cleaning of Ultrasound Transducer, TOCO Transducer and Remote Marker.

(1) Wipe the transducer with a cloth.

(2) Clean the transducer with a cloth soaked in a solution of soap and water, or a cleaning solution.

Do not immerse the transducer in the solution. Or a cloth soaked in a solution of 70% ethanol to clean the transducer. When using a cleaning solution, follow the manufacturer's directions carefully to avoid damaging the transducer..

(4) Wipe the transducer with a cloth soaked in water.

(5) Wipe the remained humidity with clean and dried cloth.

6.4 Care of Recorder and Paper

Note: Please do not use paper not recommended by CONTEC or we will not warrant to repair if any damage occurs.

When storing recorder paper (including used paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light. Do not exceed a storage temperature of 40℃.

Do not exceed a humidity of 80%.

Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trace unreadable.

6.5 Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed 60°C.

6.6 Sterilization

To avoid extended damage to the equipment, sterilization is only recommended when stipulated as necessary in the hospital maintenance schedule. Sterilization facilities should be cleaned first.

The sterilization the manufacturer recommended to cleaning the monitor and accessories are ethanol and Acetaldehyde.

Caution: To avoid damaging the monitor:

(1) Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.

(2) Do not let liquid enter the monitor.

(3) No part of this monitor can be subjected to immersion in liquid.

(4) Do not pour liquid onto the monitor during sterilization.

(5) Wipe the device with a clean moistened cloth to remove any remaining sterilant.

6.7 Disinfection

To avoid extended damage to the equipment, disinfect ion is only recommended when stipulated as necessary in the hospital maintenance schedule. Disinfections facilities should be cleaned first.

CAUTION:

(1) Follow the manufacturer's instruction to dilute the solution.

(2) Do not use bleaching powder containing chloros on any parts of the monitor.

(3) Do not disinfect the monitor and it's accessories with autoclave, gassing, formaldehyde process or radiation.

(4) Check carefully after cleaning, sterilization, or disinfect ion of monitor and accessories. If aging and damage are found, please do not use them to monitor.

Note: The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

7 Warranties

The manufacturer warrants that the Fetal Monitor we sell is free from defects in material and workmanship. In the status of normal operation and maintenance, if the manufacturer receives notice of such defects during the warranty period that begins on the date of shipment, the manufacturer shall, at its options, either repair or replace hardware products that prove to be defective. The unit is guaranteed for periods of 12 months, valid from the date of purchase. The manufacturer also provides long-term repair service for our clients.

The manufacturer's obligations or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the following conditions.

The following conditions are not included in the warranty:

(1) Assembly operation, extensions, re-adjustments are carried out by the importer.

(2) Application of the products or repaired by anyone other than the manufacturer authorized representative.

(3) This warranty shall not extend to any instrument that has been damaged subjected to misuse, negligence or accident.

(4) This warranty shall not extend to any instrument from which the manufacturer's original serial number tag or product identification marking have been altered or removed.

(5) The product were operated and used not properly.

Attachment I Product Specification

A1.1 Monitor

Physical Characteristics

Size: 320 (length) x 260 (width) x 80 (height) mm

Weight: about 3.35 Kg

Security: The Monitor obey the following norms and standards: IEC 60601-1-4, IEC 60601-1-2

Anti-shock types: Facilities I, no internal power supply

Anti-electric Shock Degree: B

Degree of protection against Harmful Ingress of Water: Moderate equipment and do not have the ability to waterproof immersion

Degree of Safety in Presence of Flammable Gases: not suitable for use in presence of flammable gases

Electromagnetic Compatibility: Group I Class A

Mode: continuous work

Power Supply

Working Voltage: AC 100V - 240V

Frequency: 50Hz/60Hz

P<60VA

Fuse: TI.6AL

Environment

Transport and storage

Temperature: -10°C -55°c

Relative Humidity: ≤ 93%

Atmospheric pressure: 70kPa - 106kPa

Working environment

Temperature: 5 °C~ 40°C

Relative Humidity: ≤ 80%

Atmospheric pressure: 70kPa - 106kPa

Display

Dimensions: 8.4 "color LCD display, folding 60 degree

Display Content: bed No. , pregnancy age, age, single/twins type, paper speed, date, time, volume, alarm status, transducer connection status, recorder status, FHR data and wave, Contraction data and wave, Fetal move times and mark etc.

Print: Record Paper two-double type Z

Print Width: 112mm

Valid Print Width: 104mm

Paper output speed: Icm/min, 2crn/min, 3cm/min (optional)

Data Precision: 5 % (X Roll), ±1:1% (Y Roll)

Record Content: bed No. ,name, pregnancy age, single/twins type, case No., paper speed, date, time, FHR data and wave, Contraction data and wave, Fetal move times and mark etc.

Signal Interface: RJ 45

Ultrasound probe: Nominal Frequency: 1.0MHz

Work Frequency: 1.0 MHz ±10%

Negative peak sound pressure: P _ <1MPa

Output beam intensity: $Iob<20mW/cm^2$

The peak time space peak intensity: Ispta< 100mW/cm^2

The average time space peak intensity: Ispta< 10mW/cm^2

FHR Rang: 65BPM~210BPM

Resolution: IBPM

Accuracy: ±:2BPM

TOCO

TOCO range: 0~ 100 %

Resolution: 1%

Nonlinear error: <±1:10%

RZ way: Manually

Fetal Marking

For the manual button (the operation of pregnant women), there will be a mark display in the bottom area ofFHR wave display section.

FHR Alarm:

Alarm for high and low FHR, which exceeds appointed limit.

A 1.2 Transducers

1) Ultrasonic Transducer

   System: Pulsed Doppler

   Dimension: 90mm x 65mm

2) TOCO Transducer

   System: Passive Strain gauge

   Dimension: 102mm x 50mm

(3) Remote Marker

   Length: 3.2m

Attachment 2 Troubleshooting

Note: If trouble occurs during operation, examine the product by the following ways. If it not works, please contact the local distributor or manufacturer; do not open the machine by the user.

(1) The screen not display

Shut off the power; pun out the power cord, to check the electrical current goes through the socket, and the power cord connects with the equipment properly. To check the fuse, if it is melt down, change the fuse.

(2) Noises

Symptom	Possible Cause	Solution
Noise	Too high volume sets other	Adjust the volume down
	Interfered by handset or interfering source	Keep the handset. or other interfering source far away

(3) Recorder Errors

Symptom	Possible Cause	Solution
Paper jam	Wrong feeding paper or paper is affected with damp	Feed paper correctly and keep paper from moist
Recorder does not work	PRINT button is disabled	Press the PRINT button again
	Out of paper	Feed paper
	Just push print button, the printing of last line not finished.	Waiting until it is finished.

4 Ultrasound Monitoring of FHR

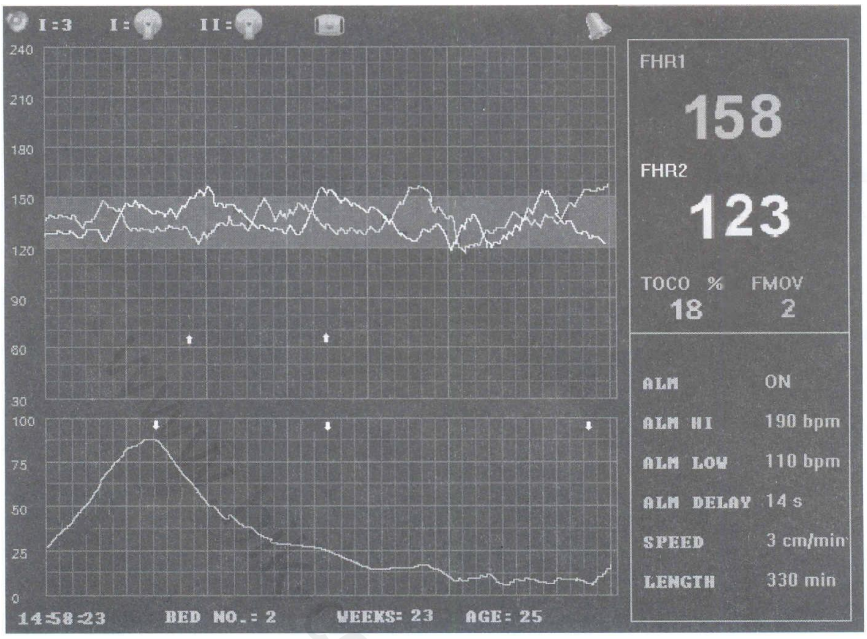
Symptom	Possible Cause	Solution
Inconstant trace Inconstant display	Wrong FHR	No
	The pregnant woman is too fat	No
	Improper ultrasound transducer position	Change the position of ultrasound transducer
	Loose abdomen belt	Tighten abdomen belt
	Superfluous coupling gel	Wipe off superfluous coupling gel
	Fetal movement	Wait for a moment then monitor
	Maternal movement	Relax patient's spirit
	Inadequate coupling gel	Use recommended coupling gel quantity
Doubtful FHR	Record Fetal heart rate wrongly	Change the position of

	The ultrasound transducer is not placed well on the abdomen, and the mixed noise has been recorded	Ultrasound transducer Change the position of ultrasound transducer
Feint trace or no trace	Improper paper	Use the paper recommended by manufacturer

5 Monitoring Contractions (External)

Symptom	Possible Cause	Solution
Worse trace quality or fluctuant TOCO baseline	Too tight or too loose Abdomen belt or no elasticity	Ensure the abdomen belt has been Used accurately and neither too tight, nor too loose
	Maternal Movement	Relax patient's spirit
	Fetal Movement	Wait for a moment then monitor
Too high TOCO sensitivity (higher than 100 unit)	The body pressure from Uterus to TOCO transducer is far higher than the average value.	Insure favourable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

Attachment 3 Monitoring Figure



Warranty

1) We guarantee this product against all manufacturing defects for 12 months from the date of sale by us or through our dealers. Consumables like dry cell etc. are not covered under warranty.

2) The guarantee will become void, if

- **a)** The product is not operated as per the instruction given in the Learning Material
- **b)** The agreed payment terms and other conditions of sale are not followed.
- **c)** The customer resells the instrument to another party.
- **d)** Any attempt is made to service and modify the instrument.

3) The non-working of the product is to be communicated to us immediately giving full details of the complaints and defects noticed specifically mentioning the type, serial number of the product and date of purchase etc.

4) The repair work will be carried out, provided the product is dispatched securely packed and insured. The transportation charges shall be borne by the customer.

List of Accessories