GIMA

ARTICOLI & APPARECCHI PER MEDICINA

MONITOR FETALE
FETAL MONITOR
MONITEUR FŒTAL
DER FETALE MONITOR

GIMA 29585

CONTEC MEDICAL SYSTEMS CO., LTD
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Made in China

CE 0123

REF **CMS800G**

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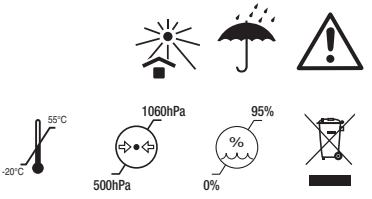

M29585-M-Rev.1-0725

Attention

The manufacturer assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material. The information contained in this document is subject to change without notice.

Responsibility of the Manufacturer

The manufacturer 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 the manufacturer, and the electrical assembly 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.

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

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.

IP: International Protection


: WEEE（2012/19/EU）


: Refer to instruction manual/booklet

CE 0123: Complies with the European Medical Device Regulation

The level of education:

-lower limit

21 years, and graduated from the regular medical treatment hygienic school that training under the supervisory condition.

-no upper limit

Contraindications

★Not found.

TABLE OF CONTENTS

1 Safety Guidance

1.1 Introduction For the Safe Operation

◆The Fetal Monitor (Monitor) is Class I equipment and designed to comply with IEC 60601-1.

◆Switching within 1 minute, at ambient temperatures between 5℃ and 40℃. 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 use of accessories, transducers and cables other than those specified may result in an increase in equipment or system emissions or a decrease in immunity.

◆The lead wire and other accessories provided by the manufacturer must be used, otherwise, other types of accessories may damage the instrument, thus taking a toll on the performance and safety of the instrument.

The protection categories against electric shock of the patient connections are:

 ①FHR1 ②FHR2 ③TOCO ④MARK

This symbol indicates that the instrument is IEC 60601-1 Type B applied part Type B protection means that these patient connections will comply with permitted leakage currents, dielectric strengths and protective earthing limits of IEC 60601-1.

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 electrosurgery equipment

E) The interference of mobile phone

1.2 Ultrasound Safety Guide

◆ **Fetal Use**

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

◆ **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 assembled 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 the manufacturer 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 62368-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1. 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 system standard IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

⚠**WARNING**⚠: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚠**WARNING**⚠: Modification of the system is prohibited.

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 from 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 from 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 accessories.

CAUTION: Turn off the power supply before clean the accessories.

CAUTION: Please use medical ultrasonic coupling gel, In case of allergic reaction, please see a doctor in time.

CAUTION: If the battery liquid touches the operator or patient´s body，it needs to be washed with water.

CAUTION: If the protective earthing system is unstable, the monitor should apply internal power supply.

CAUTION: The temperature should not exceed 60℃ when clean the belt.

CAUTION: The device can not be used with defibrillator or high frequency surgical unit.

CAUTION: Electromagnetic Interference-Ensure that the environment in which the fetal

monitor is assembled 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 valid period of this product is 5 years.

CAUTION: The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

CAUTION: The equipment and recyclable parts must be disposed by user according to local regulations after the effective life cycle.

CAUTION: Do not posit the equipment to make it difficult to operate the power plug.

CAUTION: The device can not be used with electrosurgery units (including high frequency surgical equipment) or during MRI examination. All probes and accessories must be removed during electrosurgery or MRI examination, to avoid any injury to the patient or user

CAUTION: Do not use the monitor in presence of electrosurgery units (including high frequency surgical equipment) or during MRI examination to avoid harm to doctors or pregnant women.

2 Introduction

The Fetal Monitor can provide different configurations according to different user requirements: FHR1 (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.

2.1 Intended purpose

The device has maternal TOCO and fetal FHR and FMOV monitoring functions, it can be used by professional medical staff in hospital, clinic and other medical institutions for continuous monitoring of fetuses during perinatal period, which provides reference data for clinical use.

2.2 Patient Population

Pregnant woman.

2.3 Intended users

Professional medical staff.

2.4 Medical indications

The device can monitor maternal TOCO and fetal FHR and fetal movements, which provides reference data for professional medical staff to judge the fetal and maternal physiological and delivery statuses.

2.5 Basic principles

The ultrasonic transmitting probe converts the high-frequency voltage signal generated by high-frequency oscillator into a mechanical vibration wave, and transmits ultrasonic to the abdominal wall of the pregnant woman. The beam passes through the abdominal wall to the fetus and is reflected by the fetal heart. The reflected wave occurred Doppler shift is received by the receiving probe and converted into a high-frequency voltage signal again. The obtained information is processed by the electronic circuit and the microprocessor, then displayed on the LCD in the form of figures or graphic, with audio output.

The contraction of the uterus causes a change in the pressure transducer of TOCO probe, so the change in the uterine contraction pressure can be monitored by the changes of pressure transducer.

2.6 Features

- ◆Light dexterous appearance, tops horizontally and walls can be hoisted.
- ◆8.0 "screen color LCD display, rotatable screen to 60°.
- ◆Display of the patient data and curve clearly.
- ◆FHR 120 BPM~160 BPM normal range label.
- ◆Manual records fetal movement.
- ◆Sound and color remind users of high and low fetal heart rate.

◆Continuous 24-hour real-time monitoring function.

◆Continuous 12-hour patient curve and data storage , playback and print.

◆With picture lock function.

◆Single, Twins Monitoring optional.

◆12 crystal board band pulsed wave transducer.

◆Built-in rechargeable batteries, insure that could still working normally for more than three hours after the power supply breaking off.

2.7 Clinical benefits

The device can monitor real-time FHR, TOCO and FMOV, which provides reference data for clinical use, so the dangerous situations can be detected in time and the fetal mortality during perinatal period can be reduced.

Device software Description

Version ： V1.0

3 Monitor and Setup

3.1 The Monitor

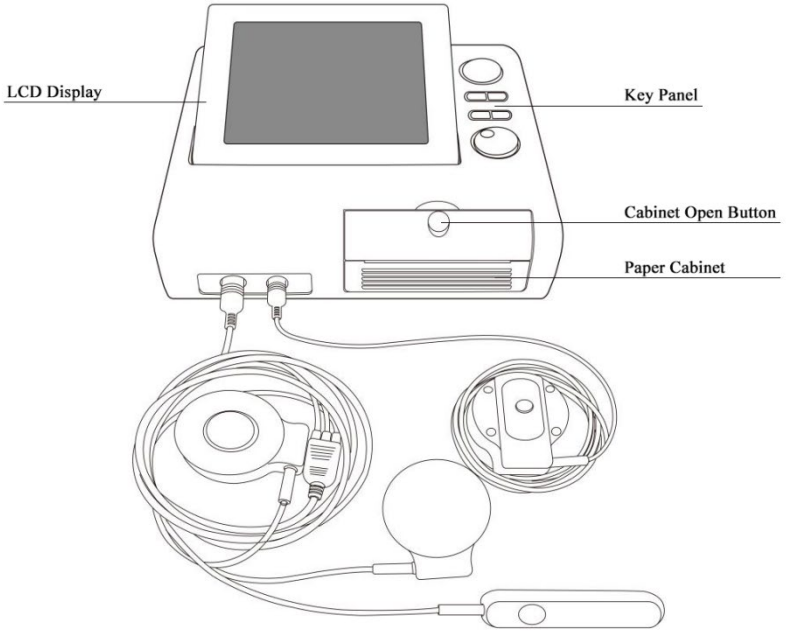

Figure 3.1 Appearance (Twins configuration, Only for Reference)

3.1.1 Transducer Introduction

UltrasoundTransducerI, TOCO Transducer, Remote Marker, UltrasoundTransducerII

(1) UltrasoundTransducerI

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 TOCO 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.

UltrasoundTransducerI、TOCO Transducer、Remote Marker are three in one transducers, their sockets

are marked FHR1/TOCO/MARK on the monitor panel.

(4) Ultrasound TransducerII is the transducer for FHR 2(Twins Configuration), The socket is marked FHR2 on the monitor panel.

3.1.2 Right Side Sockets

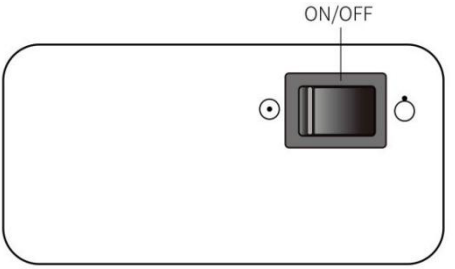

Figure 3.2 Right Side Switch

3.1.3 Interfaces and Symbols

FHR1/TOCO/MARK socket: Socket for FHR1/TOCO transducer and remote Marker

FHR2 socket: Socket for FHR2 Transducer

: Socket for Grounding Cable

: Socket for network

: USB Port（Reserved）

3.1.4 Main Interface

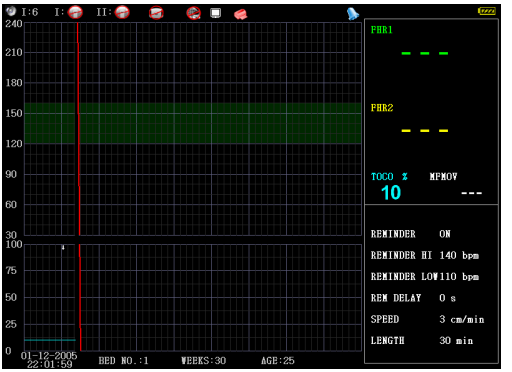

Figure 3.3 Twins Monitoring Interface

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, Lock status, Recorder status, reminder 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 reminder on/off，battery state，high/low limit，delay，print speed/length；current settings date, time, bed number, weeks 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 is as followed.

(1) Status Bar

(A) Sound channel and volume

Icon :  I: 3  I: 0

 : Sound Icon

 : Sound off Icon

I: The No. of FHR sound channel, it is I under single fetal monitoring mode which is default; Channel I, II is optional 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 volume 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) Lock status

 : Shows current screen is locked; icon will disappear when unlock.

(E) Recorder status

 : Printing

 : Out of paper

 : Failed to detect the recorder

(F) Reminder on/off status

 : Reminder on

 : Reminder off

(G) Network connection status

 : Network not connected

 : Network connected

(H) Battery status

 : It is four grids for fully charged; and the icon changes in sequence (1 ~ 4) while charging.

(2) Data Section

FHR 1 Data of Ultrasound Transducer I: 3-digit data, the system default is in green color under normal status, it will be in red when the reminder appears; it displays "———" when there is no data.

FHR 2 Data of Ultrasound Transducer II: this data will show in twins monitoring mode, the system

default is in yellow color under normal status. 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 Section

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

(4) Indicate Bar

In this item, it includes system date, time, bed No., weeks of pregnancy and patient age.

(5) 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. FHR1 Trend default is in green、FHR2 trend default 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  、reminder 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**.

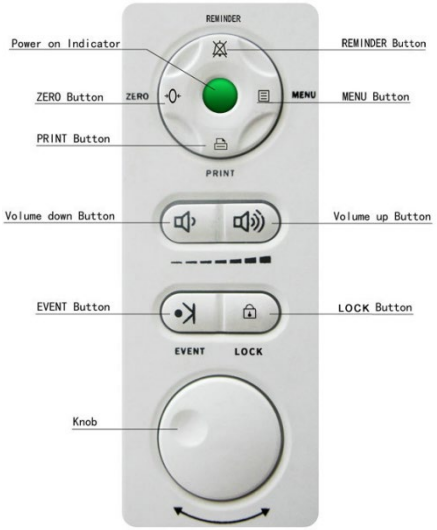

Figure 3.4 Buttons

1) Menu Button

Function: Enter setup menu.

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 Chapter **3.2.**

2) Reminder Button

Function: Enable/Stop audio reminder when FHR is in reminder range.

When  symbol appears, the reminder indicator status is shut off.

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

3) Auto Zero Button

Function: Clear the screen, TOCO value back to 10 unit, FMOV value back to 0 .

Press this button to clear the screen and adjust the present TOCO value back to 10 unit, FMOV value back to 0.

After pressing the **AUTO ZERO** button, the symbol "  " will be recorded at the trace.

4) Print Button

Function: Enable/Disable printing.

① In the condition of monitoring, if it is in the printing condition, it will stop when you press print button, otherwise Real-time start printing.

② In the lock or review condition, if it is in the printing condition, it will stop when you press print button, otherwise print the waveform of the selected time segment.

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) Lock Button

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

8) Knob Key

Function: Selection/ Confirmation button

① Press the button to activate the selected button, press it again to accept the configuration.

② To choose and adjust the parameters by revolving the knob key.

9) Paper Cabinet Open Button

Function: Push this button for opening the paper cabinet.

3.1.6 Indicator

Function ：

（1）Power-on state indicator

It is green when turning on the device.

（2）Charging indicator

Under “OFF” state, when the device works by AC, it is orange while charging, and green for fully charged.

（3）Low battery indicator

Under “ON” state, when the device works by battery, it flickers and displays yellow when low battery appears.

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**

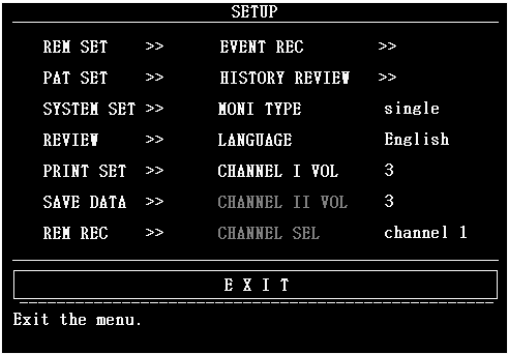

Figure 3.5 Setup

Revolving knob key to select different function. The Corresponding function and the adjustable ranges are showed in **Table 3.1**.

Table 3.1 The Setup Function and Adjustable Ranges

No	Function	Adjustable Ranges
1	REM SET(reminder Setup)	Enter reminder 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	SAVE DATA(Save Waveform Data)	Enter Save Data
7	REM REC	Enter to view each reminder review menu
8	EVENT REC	Enter to view event record menu
9	HISTORY REVIEW (History Waveform Review)	Enter History Waveform Review
10	MONI TYPE(Monitor Mode)	Optional: single, twins , the default is single fetus
11	LANGUAGE(Language Selection)	Optional: Chinese (CH), English (EN), the default is EN.
12	CHANNEL I VOL (Channel I volume Setup)	Adjustable:1~7 and mute,the default is 3
13	CHANNEL II VOL (Channel II volume Setup)	Adjustable:1~7 and mute,the default is 3
14	CHANNEL SEL(Channel Selection)	Optional: I, II, fetal heart audio come from the selected channel.
15	EXIT	Exit main menu, back to main interface

(1) Reminder Setup

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

Figure 3.6 reminder Setup

Revolving the knob key to setup reminder function. The Corresponding function and the adjustable ranges are showed in the **Table3.2:**

Table 3.2 The Reminder Setup Function and Adjustable Ranges

No	Function	Adjustable Range
1	FHR REMINDER(FHR Reminder)	Optional: Turn on, shut off The default situation is reminder on.
2	REMINDER HIGH (FHR Upper Limit of Reminder)	Optional: (lower limit of reminder +1)~240, the unit is BPM, and the default is 190
3	REMINDER LOW (FHR Lower Limit of Reminder)	Optional: 0~(high limit of reminder -1), the unit is BPM, and the default is 110
4	REMINDER VOLUME (FHR Reminder Volume)	The default is 5. Function setup is reserve .
5	REMINDER DELAY (FHR Reminder Delay)	Optional: 0~20,the unit is second, and the default is 0 seconds

Note:

① When FHR is in reminder situation, reminder indicator becomes red

② When FHR exceeds the reminder limit and time exceed the set reminder delay time continuously, reminder will occur and an reminder 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**:

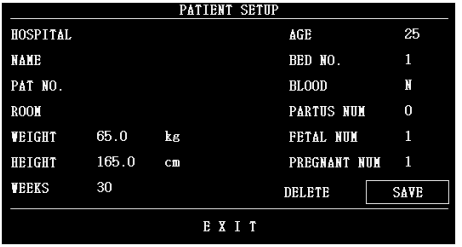

Figure 3.7 Patient Setup

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	HOSPITAL(Hospital name)	Optional: 20 letter,numeral,space,symbol. The default is blank
2	NAME(Name)	Optional: 20 letter,numeral,space,symbol. The default is blank
3	PAT NO.(Case History No.)	Optional: 20 letter,numeral,space,symbol. The default is blank
4	ROOM(Ward No.)	Optional: 20 letter,numeral,space,symbol. The default is blank
5	WEIGHT(Patient's Weight)	2~250, interval:0.5 kg,unit: kg or Pound; the default value is 65 kg
6	HEIGHT(Patient's Height)	20~300, interval:0.5 cm(inch)，unit: cm or inch; the default value is 165 cm
7	WEEKS(Time of Pregnancy)	Optional: 1~50.The unit is week. The default is30
8	AGE(Age)	Optional: numeral from 1~100. The default is 25
9	BED NO.(Bed No.)	Optional: numeral from 1~100. The default is 1
10	BLOOD(Blood Type)	Optional: A, B, AB, O, and N(unknown). The default is N.
11	PARTUS NUM (Times of Giving Birth)	Optional: 0~20, the default is 0
12	FETAL NUM. (Quantity of Fetus)	Optional: 0~20, the default is 1
13	PREGNANT NUM (Times of Pregnancy)	Optional: 0~20, the default is 1
14	DELETE(Delete Information)	Delete related patient information
15	SAVE(Save Information)	Save related patient information, return to previous

		menu
16	Exit	Return to previous menu

Note: ① When adjustable range is letter、numeral、space or symbol, 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 Fmov type

MFMOV：manual fetal movement

② 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 **Table 3.4:**

Table 3.4 The Time Setup Function

No	Function	Adjustable Ranges
1	YEAR	Optional: 2000~2036
2	MONTH	Optional: 1~12
3	DAY	Optional: 1~31
4	HOUR	Optional: 0~23
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.

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 "USER KEY" before click "CONFIRM". This password is provided by manufacturer or distributor when the manufacturer add new function to upgrade the system.

④ Maintain

Revolving the knob key to enter Maintain, the diagram is showed as **Figure 3.10**:

Figure3.10 Maintain

The user maintenance menu can be set as follows:

1.It is used for network IP setting.

2.For login verification of the open/close settings, factory agreement configuration is off.

3.It is used to set the session lock duration (10min、20min、40min、60min、120 min), and it is used to set the session lock duration when the key is not operated on the interface,factory agreement configuration is close.

4.For firewall setting,factory agreement configuration is off.

Note: Please enter password under the item “USER MAINTENANCE” before click “CONFIRM”. This password is 7718.After making changes to the above functions,the system must be restarted before it can take effect.

⑤ Color Setup

Revolving the knob key to enter Color Setup, the diagram is showed as **Figure 3.11:**

Figure 3.11 Color Setup

The device provides the users with 4 optional colors such as: light white, yellow, green and cyan. The display color for each parameter and waveform is up to the users' interest. The system would autosave the information after setting. After restarting the system, the color of each parameter is the users' final setting.

⑥ Fetal Score

This function is used to print out the fetal heart rate score monitored this time after the fetal heart rate waveform is printed. There are Fischer、NST and Krebs scoring options,and the factory agreed configuration is off.

⑦ Version

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

⑧ Enter Demo

Revolving the knob key to enter enter demo , the diagram is showed as **Figure 3.12:**

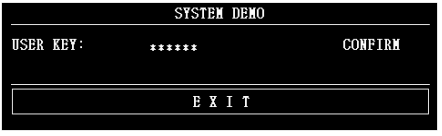

Figure 3.12 System Demo

The monitor provides the users with the function of data demo for the users's understanding of the system's working situation.

Notice: Please enter password under the item “USER KEY” before click “CONFIRM” so as to start data demo, the password is 8888.

(4) Review

Choose the REVIEW in the setup menu to enter wave review, and press REVIEW in this item to review the history wave, which is showed as **Figure 3.13**

Figure 3.13 Review

Select LRIGHT (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 corner in the show area. The wave form could be reviewed for twelve hours as the longest.

Note: Under the state of wave review, if you want to print a portion of the data, then press the Print button , the diagram for selecting time segment would appear on the screen which is showed as **Figure 3.14.** The users can select the time segment that is to be printed, then choose "PRINT",

otherwise choose "CANCEL". The default time segment for printing is the current screen.

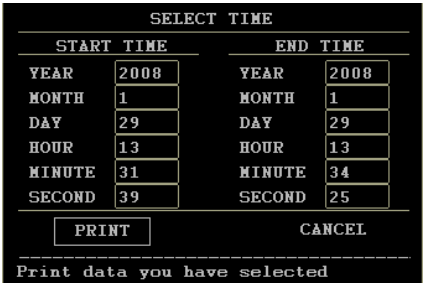

Figure 3.14 Selecting Time Segment

(5) Print Setup

Revolving the knob key to enter print setup, the diagram is showed as **Figure 3.15**:

Figure 3.15 Print Setup

Revolving the knob key to setup print function. The Corresponding function and the adjustable ranges are showed in the **Table 3.5:**

Table 3.5 The Print Setup Function and Adjustable Ranges

No	Function	Adjustable Range
1	SPEED(Print Speed)	1 cm/min, 2 cm/min, and 3 cm/min. The default value is 3 cm/min.
2	LENGTH (Print Length)	0~24(hours) ,the interval is 10 minutes. The default value is 30 minutes.
3	PAPER(Select the printing paper type)	Select between American standard printing paper and Europe standard printing paper.
4	OFFSET (Baseline offset)	Adjustable:-10~+10, the interval is 1, the default value is 0.
5	BASELINE PRINT	Print the ladder-from testing wave.

6	Print patient information	Choose the option which you want to print out: hospital, patient name, patient number , bed number, Pregnancy weeks. Selected by (√). If not selected by (√),it means not to print out,a line will appear on the corresponding position. The default option means selected.
7	EXIT	Return to the upper menu.

Note: If situations such as paper lack or paper jam happened in the process of real-time printing, the system would begin to autosave the data ever since the moment of unexpected interruption. After assembling paper to the printer, the diagram is showed as **Figure 3.16** , choose "YES" to continue printing, otherwise choose "NO".

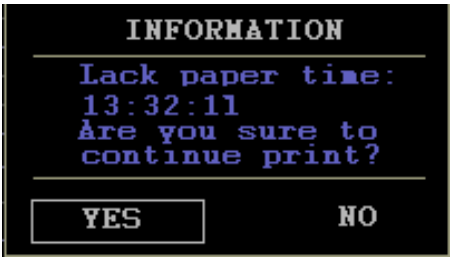

Figure 3.16 Information of Backup Print

(6) Save Data

Revolving the knob key to enter Save Data , the diagram is showed as **Figure 3.17:**

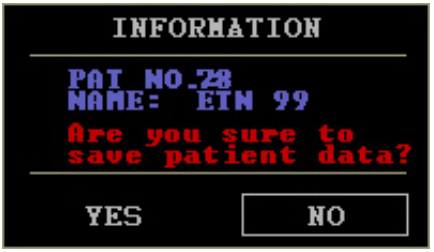

Figure 3.17 Save Data Information

Note: Only input the patient NO. and patient name in the patient setup menu, the data can be saved. The maximum data is 50 pieces, if it is over 50 pieces, the system will cover the earliest one.

(7) Rem Rec

1) Revolving the knob key to enter **Reminder Recall**，the diagram is showed as **Figure 3.18**

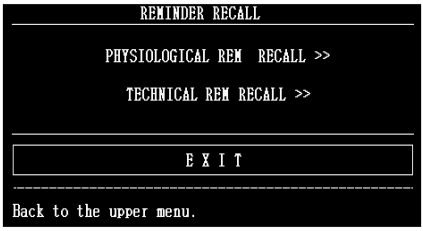

Figure 3.18 Reminder Recall

2) Revolving the knob key to enter Physiological **Reminder Recall,**The physiological **Reminder** of fetal heart rate exceeding limit can be reviewed.the diagram is showed as **Figure 3.19**

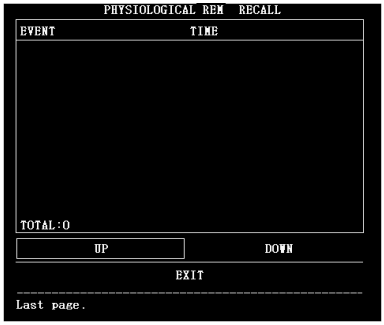

Figure 3.19 Physiological Reminder Recall

3) Revolving the knob key to enter Technical **Reminder Recall,**Technical **Reminders** such as module communication errors can be reviewed ,the diagram is showed as **Figure 3.20**

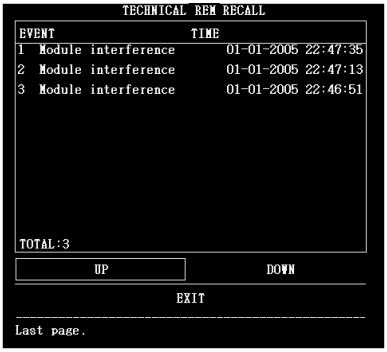

Figure 3.20　Technical Reminder Recall

(8) Event Rec

Revolving the knob key to enter Event Record ,the diagram is showed as **Figure 3.21**

Figure 3.21 Event Record

（9）History Review

Revolving the knob key to enter History Review, the diagram is showed as **Figure 3.22**:

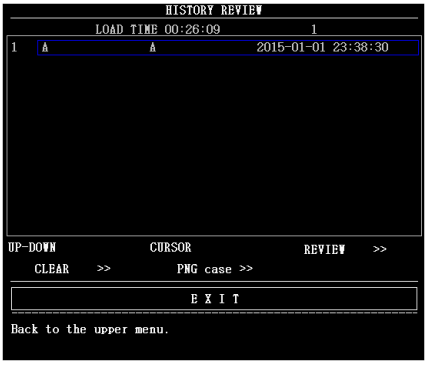

Figure 3.22 History Review

Note: In order to inquire easier, every data record has a number, the smaller the number is, the newer the data is, every page can show 10 data records.

Choose [UP-DOWN]: observe other data information on the other pages.

Choose [CURSOR]: move the Cursor, select the data in the data list.

Choose [REVIEW]: show the waveform of selected record.

Choose [CLEAR]: delete the saved records.

Attention: If you choose the option [CLEAR], and confirm it, all the saved records will be erased. Please users think over before using this function.

4 Assembly

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: 100 V~240 V AC, 50 Hz/60 Hz.

◆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 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 assembly 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.

4.4 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.

4.5 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 left.

4.6 Battery assembly

Attention

- If a battery is provided, charge the battery after the monitor is subject to transport or storage.
- If a battery is assembled, make sure it is fully charged after using the monitor, to provide sufficient power for the next time, regardless of whether the monitor is turned on. The battery can be charged by connecting the monitor to AC power.
- The monitor must be turned off and the AC power supply disconnected before assembling/removing the battery.

Assemble or remove the battery based on the following steps:

(1) Assemble battery

① Place the monitor with the bottom facing up on a flat surface covered with protective pads;

② Remove the screws on the battery case with a cross screwdriver and then remove the cover thereof;

③ Take the battery out of the package and put it into the battery case, with the labeled side facing up;

④ Put the battery and cable into the battery case, with the cable plug being inserted into the monitor battery outlet;

⑤ Close the case cover. assemble and tighten the screw.

(2) Remove the battery

Steps for removing battery from the monitor are exactly the opposite to assembly steps. Pay attention to lay the display flat before placing the monitor bottom-up.

4.7 Connecting potential equalization conductor

The monitor must be separately connected with the equipotential grounding system.One end of the equipotential grounding wire（potential equalization conductor）is connected to the equipotential grounding terminal on the rear panel of the instrument，and the other end is connected to an interface of the equipotential system.Before each use，check whether the instrument is in good working condition.

5 Monitoring

5.1 Operation Procedure

Ultrasound Transducer and TOCO Transducer Positioning showed as **Figure 5.1**

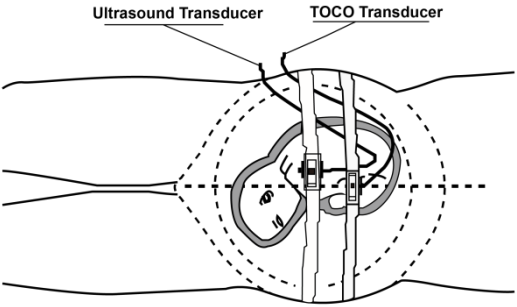

Figure 5.1 Ultrasound Transducer & TOCO Transducer Positioning

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 I**,** and adjust FHR1 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

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

Follow the step②mentioned above to acquire the heart rate for the first fetus.

Set the current heart rate channel to II, 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 FHR1, and the second sound channel for FHR2)

Readjust the volume setting for the desired loudness.

Note:

The ultrasound transducer measures the FHR; 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 FHR 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 FHR 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.

⑦ The maximum temperature of the probe surface does not exceed 41℃,which is measured by the temperature tester.

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 fundus and the umbilicus. The position is shown as Figure 5.1

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: ① Do not use coupling gel on the TOCO transducer or transducer contact area.

② Check the function by TOCO transducer, and observe the change of relevant value.

5.1.3 Remote Marker Recording of Fetal Movement

The remote marker is a hand-held switch the mother takes. When FHR is monitored, she operates the hand-held remote 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, . Push the button again and the count of fetal movement will add 1 after 10 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 knob key to select wave to print in wave review status, and then push print button to print the selected time segment wave.

(4) Lock Print

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

(5) Print Content

The print output content contains: Hospital, Name, PATIENT NO., BED NO., WEEKS., FHR1 trend, FHR2 trend (Twins Monitoring) , TOCO wave, print speed, date, time.

It also contains other icons like:auto zero mark  、reminder mark  、FMOV mark  、event mark  etc.

Note:

① When the paper use up, the system will save the data automatically (no more than 2 hours), after put the paper in again, the data will be printed out from the Breakpoint.

② Then monitor has the functions of 12-hour waveform saved,review and print, the data will be lost when the machine is turned off. Choose SAVE DATA to save the data,you can review the waveform through the history data review.

③ To ensure print precisely, recommend to print and adjust the baseline when paper is loaded..

④ 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.

⑤ 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.

Note: Disconnect supply wire can also cut off power supply.

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 and transducers for splits, cracks or signs of twisting, replace any cable and transducers 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 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.

Approved cleaner:

——Isopropanol (70 %)

Cleaning of ultrasonic transducer:

① Remove the ultrasonic transducer from the device.

② Wipe the couplant on the surface of the transducer with a medical gauze for one minute.

③ Clean the places (such as gaps) that are not easy to wipe on the surface of the transducer with a medical brush dipped in cleaner (no liquid drips from the brush) for two minutes.

④ Gently wipe surfaces of the transducer twice (one minute each time) with a medical gauze dipped in cleaner, then wipe it with a medical gauze dipped in clean water for one minute, finally wipe dry with a clean soft cloth.

⑤ After the cleaning steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

Cleaning of TOCO transducer:

① Remove the TOCO transducer from the device.

② Clean the places (such as gaps and grooves) that are not easy to wipe on the surface of the transducer with a medical brush dipped in cleaner (no liquid drips from the brush) for three minutes.

③ Gently wipe surfaces of the transducer twice (two minutes each time) with a medical gauze dipped in cleaner, then wipe it with a medical gauze dipped in clean water for two minutes, finally wipe dry with a clean soft cloth.

④ After the cleaning steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

Cleaning of Remote Marker:

① Remove the Remote Marker from the device.

② Clean the places (such as gaps) that are not easy to wipe on the surface of the Remote Marker with a medical brush dipped in cleaner (no liquid drips from the brush) for one minute.

③ Gently wipe surfaces of the Remote Marker twice (30 seconds each time) with a medical gauze dipped in cleaner, then wipe it with a medical gauze dipped in clean water for 45 seconds,finally wipe dry with a clean soft cloth.

④ After the cleaning steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

6.3 Care of Recorder and Paper

Note: Please do not use paper not recommended by the manufacturer 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 degree.

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.

6.4 Cleaning of Belt

Approved cleaner:

—— soapy water solution (5 %).

Wash an abdomen belt with soapy water for 12 minutes, the water temperature should not exceed 60 ℃, then wash it with clean water for two minutes. After the cleaning steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

6.5 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.

Approved disinfectant:

——Isopropanol (70 %)

Disinfection of ultrasonic transducer:

① The ultrasonic transducer should be cleaned before disinfection.

② Clean the places (such as gaps) that are not easy to wipe on the surface of the transducer with a medical brush dipped in disinfectant (no liquid drips from the brush) for two minutes.

③ Gently wipe surfaces of the the transducer twice (one minute each time) with a medical gauze dipped in disinfectant, then wipe it with a medical gauze dipped in clean water for one minute, finally wipe dry with a clean soft cloth.

④ After the disinfection steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

Disinfection of TOCO transducer:

① The TOCO transducer should be cleaned before disinfection.

② Clean the places(such as gaps and grooves) that are not easy to wipe on the surface of the

transducer with a medical brush dipped in disinfectant (no liquid drips from the brush) for three minutes.

③ Gently wipe surfaces of the the transducer twice (two minutes each time) with a medical gauze dipped in disinfectant, then wipe it with a medical gauze dipped in clean water for two minutes, finally wipe dry with a clean soft cloth.

④ After the disinfection steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

Disinfection of Remote Marker:

① The Remote Marker should be cleaned before disinfection.

② Clean the places(such as gaps) that are not easy to wipe on the surface of the Remote Marker with a medical brush dipped in disinfectant (no liquid drips from the brush) for one minute.

③ Gently wipe surfaces of the the Remote Marker twice (30 seconds each time) with a medical gauze dipped in disinfectant, then wipe it with a medical gauze dipped in clean water for 45 seconds, finally wipe dry with a clean soft cloth.

④ After the disinfection steps are complete, inspect its surface visually, if residues or stains are found, please repeat the above steps.

CAUTION:

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

② Do not use bleaching powder containing chlorates on any parts of the monitor.

③ Do not disinfect the accessories with autoclave、gassing、formaldehyde process or radiation.

④ Check carefully after cleaning or disinfect ion of 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.

Note: The periods of cleaning and disinfect are once per month.

Warning: After cleaning and disinfect, must do boot-strap check up, insuring without bad circumstance as black screen or fuzzy screen, probe fever and so on.

6.6 Maintenance of battery

◆Built-in rechargeable lithium battery. It has a automatic charge and discharge monitoring system, when there is AC, the battery will be charged automatically. Under "ON" state, the current battery state will be displayed on top right corner of LCD, it is four grids for fully charged and the icon changes in sequence (1 ~ 4) while charging, it need about 8 h for fully charged after

fully discharged.

◆The device can be used continuously for 3 h after fully charged. When the battery power is too low to operate, please cut off the power to avoid permanent damage to battery due to over-discharge.

◆Recharge the battery soon after the over-discharge. The device should be recharged every three months when it is not used for some time. It can extend the battery life following this guidance.

◆The battery is a consumable. After fully charged, if it is used up when only using for less than 10 minutes or it can not be charged, please replace the battery. Then please contact the dealer or manufacturer to replace.

Note:

- Read the Operation Manual and Safety Instruction for Use carefully before using the rechargeable lithium ion battery (referred to as "lithium battery" hereinafter).
- This lithium battery is for use with the Instrument only.
- The lithium battery can only be charged in the Instrument.
- Do not reverse the polarity of the lithium battery.
- Do not directly connect the positive and negative electrodes of the lithium battery with wires or other metal objects to cause short circuit.
- The cycle life of a lithium battery is 300 times, which may be shortened by improper use. It is recommended to replace the lithium battery in time when it goes through more than 300 times of charge and discharge cycle, otherwise, it may cause safety risks such as heat and liquid leakage, and functional failure or decline.
- Do not heat lithium battery or throw them into fire.
- Do not immerse lithium battery in water, beverages or other liquids.
- Do not use or leave lithium battery at high temperatures (45°C+ during charging and 55°C+ during discharging, such as directly under sunlight or in an extremely hot car), otherwise the battery may occur overheating, burning or functional failure, with its service life shortened or its performance weakened.
- Do not place lithium battery near microwave equipment or other cooking appliances, as liquid leakage, heat generation, smoking and burning may occur when the lithium battery is heated or subjected to strong electromagnetic radiation.
- Avoid behaviors that may cause excessive mechanical shock to lithium battery, such as hitting, throwing and trampling.
- Do not directly weld lithium battery.
- Do not mix the lithium battery with those of other specifications and models.

- Do not use lithium battery with obvious scratches or severe deformation.
- Keep lithium battery away from children.
- In case any abnormality, such as peculiar smell, heat generation, discoloration and deformation, occurs in the use or storage of the lithium battery, or any abnormal phenomenon appears during charging, power off the instrument and remove the lithium battery immediately. In such cases, the battery must be disused, otherwise, it may result in heat generation, smoking, and burning and other accidents.
- Do not touch the leaking lithium battery. In case the electrolyte enters eyes accidentally, do not rub, rinse the eyes with clean water immediately, and visit hospital for treatment to avoid harm to eyes.
- If the instrument is only powered by lithium battery, do not replace the battery while the instrument is running.
- Excessively high internal temperature of the instrument may disrupt the charging of the lithium battery. In such case, place the instrument at room temperature and keep it away from heat sources or direct sunlight. The battery will resume charging when the temperature is normal.
- Lithium battery shall be charged, used and stored in places far away from static electricity. Waste lithium battery shall be disposed properly in an environment-friendly way in accordance with local regulations).
- Do not replace the battery by yourself. If you need to do so, contact Contec or a service personnel with relevant qualifications authorized by Contec for replacement.

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 1 Product Specification

A1.1 Monitor

Physical Characteristics

Size: 320 mm (length) × 260 mm (width) × 90.5 mm (height)

Weight: about 3 kg

Security: The Monitor obey the following norms and standards: IEC 60601-1、IEC 60601-1-2、IEC60601-2-37

Anti-shock types: Facilities I

Anti-electric Shock Degree: B type

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

Main unit waterproof grade:: IPX0

Applied part waterproof grade: IP22

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

Not intended use in an oxygen rich environment

Electromagnetic Compatibility: Group I Class A

Mode: Continuous work

Power Supply

Working Voltage: AC 100 V ~ 240 V

Frequency: 50 Hz/60 Hz

lithium battery: 7.4 V; 5000 mAh

P＜60 VA

Environment

Transport and storage

Temperature: -20 °C ~55 °C

Relative Humidity: ≤ 95%

Atmospheric pressure: 500 hPa ~ 1060 hPa

Working environment

Temperature: 5 °C~ 40 °C

Relative Humidity:15%~85％

Atmospheric pressure: 700 hPa ~ 1060 hPa

Display

Dimensions: 8.0 "color LCD display, folding 60 degree

Display Content: bed No., pregnancy weeks, age, paper speed, date, time , volume, reminder 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: 112 mm

Valid Print Width: 104 mm

Paper output speed: 1 cm/min、2 cm/min、3 cm/min(optional)

Data Precision: 5%

Record Content: hospital , bed No. ,name, pregnancy weeks, patient No., paper speed, date, time , FHR data and wave, Contraction data and wave, Fetal move times and mark etc.

Net Interface: RJ 45

Battery type: rechargeable batteries

Ultrasound probe:

Nominal Frequency: 1.0 MHz

Work Frequency: 1.0 MHz±10%

Negative peak sound pressure : p_{-}＜1 MPa

Output beam intensity : I_{ob}＜20 mW/cm^2

The peak time space peak intensity: I_{spta}＜100 mW/cm^2

The average time space peak intensity: I_{sata}＜10 mW/cm^2

FHR Rang: 50 BPM~240 BPM

Resolution: 1 BPM

Accuracy: ±2 BPM

Note: In all working application modes, mechanical index: MI<1, thermal index: TI<1.

TOCO

TOCO range: 0～100%

Resolution: 1%

Nonlinear error: ＜±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 of FHR wave display section.

FHR Reminder:

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

A1.2 Transducers

(1) Ultrasonic Transducer

System: Pulsed Doppler

Dimension: 92 mm × 76 mm

(2) TOCO Transducer

System: Passive Strain gauge

Dimension: 92 mm × 76 mm

(3) Remote Marker

Length: 130 mm

A1.3 List

List of Accessories

Name	Quantity	Model	Description	Remarks	Manufacturer
Fetal Monitor three in one probe	1	MPM1B30	Repeatable	Standard	Contec Medical Systems Co., Ltd.
Fetal Monitor separate ultrasonic probe	1	MPM1B21		Optional	

Packing List

Name	Quantity	Description	Remarks
Record Paper	2	Disposable	Standard
Power supply line	1	Repeatable	Standard
Abdomen belt	2	Repeatable	Standard
Earth line	1	Repeatable	Standard
User manual	1	Repeatable	Standard
Fetal Monitor three in one probe	1	Repeatable	Standard
Fetal Monitor separate ultrasonic probe	1	Repeatable	Optional

A1.4 Symbols

Your device may not contain all the following symbols.

	Attention! Please read the accompanying file (the user manual).		
FHR1	Ultrasonic Channel I	FHR2	Ultrasonic Channel II
MARK	Fetal Movement Marker	AC	Alternating current
TOCO	Uterine systolic pressure	P/N	Part number
	ON/OFF	IP22	Probe waterproof grade
	General warning sign		Alternating current
	Internet access		MENU
	Humidity limitation		ZERO
	Reminder button		Volume down
	PRINT button		EVENT
	Volume up		Date of manufacture
	Lock		This way up
	Equipotential		Fragile, handle with care
	Authorized representative in the European Union		Keep dry
	Serial number		Stacking layers limit
	Manufacturer		Batch code
	Atmospheric pressure limitation		Temperature limitation

	This symbol indicates that the instrument is IEC 60601-1 type B Applied part. Type B protection means that these patient connections will comply with permitted leakage currents, dielectric strengths and protective earthing limits of IEC 60601-1.
MD	Medical device identification
CE 0123	Medical Device complies with Directive 93/42/EEC
	Waste disposal mark, this symbol indicates that the waste of electrical and electronic equipment can not be disposed as an unclassified municipal waste and must be recovered separately.

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.

Power interruption

The device has a built-in lithium battery, when the power supply is interrupted unexpectedly, it will switch to battery-operated automatically, low battery indication will appear when the battery power is low, and the device will automatically switch to mains when it is restored. No need for any operation.

1 The screen not display

Shut off the power; pull out the power cord, to check the electrical current goes through the socket, and the power cord connects with the equipment properly.

2 Noises

Symptom	**Possible Cause**	**Solution**
Noise	Too high volume sets	Adjust the volume down
	Interfered by handset or other 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 ultrasound transducer
	The ultrasound transducer is not placed well on the abdomen, and the mixed noise has been recorded	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 favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

Attachment 3 Acoustic Output Reporting Table

Transducer Model: PM1.0(for FHR1) Operating Mode: PW Mode Working Frequency:1.0MHz

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.024	0.003		0.025		N/A
Index Component Value				0.003	0.001	0.025	0.014	
Associated acoustic parameters	$p_{r,a\ at\ z_{MI}}$	MPa	0.024					
	P	mW		2		2		N/A
	$P_{1\times1}$	mW		0.637		0.637		
	Z_s	cm			1.8			
	Z_b	cm					1.8	
	Z_{mi}	cm	1.8					
	$Z_{pii,a}$	cm	1.8					
	f_{awf}	MHz	1.00	1.00		1.00		N/A
Other information	prr	Hz	1282					
	Srr	Hz	1					
	n_{pps}		1					
	$I_{pa,a}$ at $z_{pii,a}$	W /cm^2	0.001					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	mW /cm^2	0.324					
	I_{spta} at z_{pii} or z_{sii}	mW /cm^2	0.282					
	p_r at z_{pii}	MPa	0.025					
Operating control	Focus(mm)		Fixed	N/A	Fixed	N/A	Fixed	N/A

conditions	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	1.00	N/A	1.00	N/A	1.00	N/A

Transducer Model: PM1.0(for FHR2) Operating Mode: PW Mode Working Frequency:1.0MHz

Index label			**MI**	**TIS**		**TIB**		**TIC**
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.024	0.003		0.025		N/A
Index Component Value				0.003	0.001	0.025	0.014	
Associated acoustic parameters	$p_{r,a\ at\ z_{MI}}$	MPa	0.024					
	P	mW		2		2		N/A
	$P_{1\times1}$	mW		0.637		0.637		
	Z_s	cm			1.8			
	Z_b	cm					1.8	
	Z_{mi}	cm	1.8					
	$Z_{pii,a}$	cm	1.8					
	f_{awf}	MHz	1.00	1.00		1.00		N/A
Other information	prr	Hz	1282					
	Srr	Hz	1					
	n_{pps}		1					
	$I_{pa,a}$ at $z_{pii,a}$	W /cm^2	0.001					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	mW /cm^2	0.324					
	I_{spta} at z_{pii} or z_{sii}	mW /cm^2	0.282					

	p_r at z_{pii}	MPa	0.025					
Operating control conditions	Focus(mm)		Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)		Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)		1.00	N/A	1.00	N/A	1.00	N/A

Attachment 4 Guidance and manufacture's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

WARNING:

●The ME EQUIPMENT or ME SYSTEM is suitable for professional medical staff in hospital, clinic and other professional medical institutions.

●Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

●Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

●Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

●Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

●Devices or systems should not be used when they are close to or stacked with other equipment, if necessary, please observe and verify that they can operate normally in the configurations.

●Electromagnetic fields can affect the performance of the device, so other equipment used near the equipment must meet the appropriate EMC requirements. Mobile phones, X-rays, or MRI devices are possible interference sources, as they emit high-intensity electromagnetic radiation.

Basic performance of electromagnetic compatibility: The error of fetal heart rate measurement is not more than ±2 times /min.

Cable listing:

NO.	Name	Typ	cable	Cable shielded
1	Power input	AC	1.8m	unshielded
2	Fetal monitor three in one probe cable	PC	2.6m	shielded

3	Fetal monitor separate ultrasonic probe cable	PC	2.5m	shielded

Table 1: Electromagnetic emission

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table 2: Electromagnetic immunity 1

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Table 3: Electromagnetic immunity 2

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					

	1720	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 –5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Attachment 5 Security function verification

1. Human user identification and authentication

After the monitor is powered on, enter the login verification on/off setting interface by following steps:

(1) Press the MENU key on the key panel to enter the menu setting interface;

(2) Choose SYSTEM SET-->MAINTAIN-->ENTER USER MAINTENANCE, and enter password 7718 to enter the user maintenance menu;

(3) Change VALIDATE LOGON to "ON" and restart the monitor;

(4) You need to enter the account and password to log in (default administrator account admin, password 7718).

2. Software process and device identification and authentication

After the monitor is powered on, connect one end of the network cable to the network port of the monitor and the other end to the network port of the computer. The icon at the top of the interface changes from  to  . After the network cable is disconnected, the icon at the top of the interface changes from  to  .

3. Account management

After logging in to the administrator account, you can add, delete, and view common users under the User Maintenance menu, and change the password.

4. Strength of password-based authentication

(1) When the default admin administrator account changes its password or the password of a common user, the system identifies the password strength. The password consists of a combination of letters and numbers, and the minimum number of digits is 8. If the password is less than eight digits, the system displays a warning message indicating that the minimum length of the password is 8 digits . The minimum password length is eight digits. If the password is only letters or only numbers, the system displays a warning message indicating that the password is weak,it is recommended to change it to a combination of letters and numbers.

(2) Each time the monitor is powered on, the system first identifies the password strength after the user enters the account and password. If the password strength is weak, the dialog box "Password

strength is weak, please contact the administrator to change the password" is displayed.

5. Unsuccessful login attempts

After the monitor is powered on, if the system login verification is enabled, for all accounts, the login fails for more than 10 times, the password of this account will be locked, and you cannot log in to this account within 30 seconds. The account will be automatically unlocked after 30 seconds to log in again.

6. System use notification

After the monitor is powered on, if the system login verification is enabled, the system login screen will prompt "Unauthorized use of the system is prohibited, otherwise criminal and/or civil penalties will be imposed".

7. Session lock

After the monitor is powered on, the session screen lock duration can be set in user maintenance if the administrator logs in or does not log in with system verification. (default is close, the session screen lock duration can be set to 10min, 20min.40min.60min.120min).

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment