

About the User's Manual

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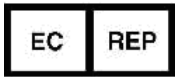
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Due to technical upgrade or special requirements from users and with the precondition that the performance of the instrument will not be lowered, some components may vary from the description of configuration in the User's Manual.



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The products herewith comply with the requirements of the Medical Device Directive 93/42/EEC



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Chapter 1 Brief introduction

1.1 Product Introduction

Thank you for your purchasing iC90, iC90 is an innovative full specification and designed to make routine fetal monitoring simple and effective at low cost. It has been designed for maximum convenience and ease of use for both the clinician and the patient, it is ideal for use in any environment ranging from community to the labor ward.

This fetal/ maternal monitor equipped with ultrasound and TOCO transducers, SpO₂ sensor, a cuff and Pregnant woman event market. The capability complies with the newest standard of the world.

- A big TFT color LCD displays the FHR, TOCO curve and maternal parameters and the monitoring states, meanwhile it has data storage and playback functions.
- The internal line thermal recorder can record FHR, TOCO, the life exceeds over 20 years.
- Advanced DSP technology, accurate and reliable.
- Multi-crystals, wide beam form, high sensitivity ultrasound transducer, 1MHz pulsed wave, low ultrasound power, safer to the fetal.
- A standard patient event marker and a clinical event marking button to separately mark clinical events.
- 3 in 1 transducers, no cable intertwining.
- Maternal SpO₂, heart rate, NIBP, ECG, RR, TEMP functions are options.
- Operate with an encoder for easy and convenient use.

Many alarm functions are included: the monitoring time over alarm, no paper alarm.

Working Principle

We know a defined frequency ultrasound will reflect when transmission through different tissues in human body, if the tissue is in quiet, then the frequency of reflecting signal is the same as the frequency of transmission signal, once the tissue is moving, the reflecting frequency will change a little, this is the so-called Doppler Effect. When we put the probe on the pregnant woman's belly, the reflecting frequency will change with the moving of fetal heart. When we get the variance of the frequency, we can get the fetal heart rate (BPM: beats per minute).

The artery oxygen saturation of SpO₂ parameter measurement function is the percentage of oxyhemoglobin in total of oxyhemoglobin and deoxyhemoglobin.

When passing two wavelengths of light, one red (660nm) and the other infrared (890nm), through body tissue to a photo detector. Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time-varying effects of the pulse) in the body tissues.

The monitor processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO₂) to identify the pulse and calculate oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen depleted blood.

NIBP MONITORING:

The patient monitor uses oscillometric principles to calculate the systolic, diastolic, and mean arterial pressure (MAP) values. The MAP is calculated as the lowest cuff pressure that provides the maximum cuff oscillations. Therefore, MAP is the largest signal received and is the most accurate reading using oscillometric methods. Systolic pressure is calculated as the cuff pressure at which an increase in cuff oscillations is perceived. The diastolic pressure is the cuff pressure when oscillations are no longer decreasing as pressure is released from the cuff.

The patient monitor first inflates the cuff to a pressure of around 20mmHg higher than the systolic pressure, then, slowly deflates the cuff. When the cuff pressure is higher than systolic pressure, the artery is blocked and there are small amplitude oscillometric waveforms. When the cuff pressure is equal to the systolic pressure, the oscillometric amplitude increases. With the decrease of the cuff pressure, the oscillometric amplitude increases. When the cuff pressure reaches a certain value, the oscillometric amplitude reaches a maximum value, then, the cuff pressure is mean arterial pressure. It is based on the changes of the oscillometric amplitude under different cuff pressure to identify mean pressure and calculate the systolic and diastolic pressure.

This antepartum monitor is suitable for use in all conventional external fetal monitoring and maternal monitoring applications.

DO NOT use this antepartum monitor for:

- underwater monitoring during labor or delivery.
- prolonged periods of time unless clinically indicated---typically antenatal tests can give a trace sufficient for interpretation in 20 to 30 minutes or less.

1.2 Safety Guide

iC90 Fetal/Maternal Monitor is Class II device in conformity with IEC60601/EN60601 requirements with protective earth .



Type BF Applied Part: F-type applied part (floating/insulated) complying with the specified requirements of IEC 60601-1 Medical Standards to provide a higher degree of protection against electric shock than that provided by Type B applied parts.



Type B Applied Part: B-type applied part complying with the specified requirements of IEC 60601-1 Medical Standards.

Important notices:

To avoid getting the potential harm, please operate this instrument complying with follows:

Warning:

ALARMS- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring is the monitor be used and closely monitored. Alarm function must be validated timely. When several devices are used on the same patient, leakage current may increase and lead to danger to the patient. Before using, please consult professional people to do leakage current test and make sure the leakage current is within safety limits. Before use the monitor, please make sure the monitor is in normal working conditions and operation environment. When using High Frequency surgical equipment, you should put the patient cables and transducers far from the surgical operation in order to reduce the hazards of burns in the event of a defect in the High Frequency surgical equipment neutral electrode connection. Check the repeatedly used accessories at regular intervals. Replace the damaged parts if necessary and dispose them as medical waste according to local governing ordinances and recycling instructions.

Warning: When the iC 90 series of fetal/maternal monitor is not used, especially no people in the field, you must not only switch off the monitor by pressing the power key at the front panel, but also power off the input switch of the AC power at the left side of the monitor, or there will be some hidden safety troubles and this is a good habit.

Press the  position downwards to switch off the power.

Press the  position downwards to switch on the power.



Fig1. Power switch (OFF)



Fig2. Power switch (ON)

Our power working mode is just like that of the power adaptor of the notebook computer, when the notebook is powered off, but the adaptor is still working at no load situation.

So you remember you must power off the switch of the monitor at the left side or the electrical outlet outside of the monitor when the monitor is not used.

Warning: It should not switch off the volume during the monitoring, no fetal heart beating sound can be heard when the fetal heart is out of the ultrasound field for the movement or dead fetus reasons, so be care the FHR displayed on the LCD may be meaningless when it happens.

Warning: Do not use iC90 in the presence of flammable gases such as anesthetic agents.

Warning: Don't throw the battery into fire, or it may cause an explosion

Warning: Don't touch the signal input or signal output connectors and patient at the same time

Caution: iC90 must be maintained by qualified engineers.

Caution: This instrument is designed to work continuously, and water drop proof type, and be care to avoid to be splashed.

Caution: Keep iC90 clean and avoid vibrating.

Caution: This instrument is in conformity with IEC60601-1-2 EMC standards. But when the electromagnetic power is very high, it will still cause interference. Please do not use mobile phone, portable communication devices, etc nearby it.

Caution: Before use the instruments, please check if there is any damage of equipment that may affect the patient's safe or the instrument performance. The recommended check period is one month or shorter. If an obvious damage is found, it should be solved before use.

Caution: the following safety check is done by the authorized person, normally one time per two years or according to test regulation by the public organization.

- ✧ Check whether there are damages in the mechanical and functions.
- ✧ Check whether the relative safety label is easy to identify.
- ✧ Check whether the function is the same as described in the user manual.

Caution: After the effective life of this instrument, Please send it back to the manufacturer according to local rules for recycling.

Caution: The battery should be get properly treatment according to local rules after the capability of battery run out.

Caution: If this instrument is to be stored for a long period of time, the battery should be removed.

Caution: The battery should be stored in a cool and dry environment.

Caution: When the battery is stored, please don't mix it with metal objects to avoid short-circuit accident.

Caution: We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable---ALAEA. This is considered to be good practice and should be observed at all times.

Caution: Don't use this instrument immediately when it is transferred from a cold environment to a warm and moisture place.

Caution: To ensure electric installation safety, the environment shall be reasonably dust free, without corrosive or combustible gas, or extreme temperature or humidity.

Caution: Please stop operating if this instrument is splashed or has water drops.

Caution: Although iC90 is robust and designed to withstand the clinical use, the unit does contain delicate components and should be treated with care. This applies especially to the transducers which should not be dropped or knocked.

Caution: The use of water based gel supplied by certificated suppliers is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty.

Caution: Excess gel should always be wiped off after use. The transducer faceplate, transducer body and main unit can be cleaned with a damp cloth impregnated with a mild disinfectant or detergent.

Caution: To assist with disinfection a soft cloth dampened with sodium hypochlorite 1000ppm may be used and the units wiped dry. Please be sure to check your local control of infection policies or any equipment cleaning procedures.

Caution: The main unit, transducers and other accessories can't be disinfected by steam.

Caution: TOCO transducer is non-waterproof type, don't use Gel and avoid any liquids into it.

Caution: The power wire should be inserted into the socket with three wires, the ground wire mustn't be emoved. Don't use the socket with bad connection.

Caution: After use, Do not wire the transducer cable together with the transducers , in case it is broken.

Caution: It should not switch off the volume during the monitoring, no fetal heart beating sound can be heard when the fetal heart is out of the ultrasound field for the movement reason, so be care the FHR displayed on the LCD may be meaningless when it happens.

Caution: The accuracy of FHR is decided by machine itself and can not be adjusted. If you are suspicious of accuracy of result, you can verify it through other devices like a stethoscope,also you can contact local distributors or manufacturers for help.

Caution: Please turn on the loudspeaker while searching for FHR,then you can make the examination after hearing the FHR clearly.

Caution: Please turn off the main power after the examination

1.3 Recommended clinical application

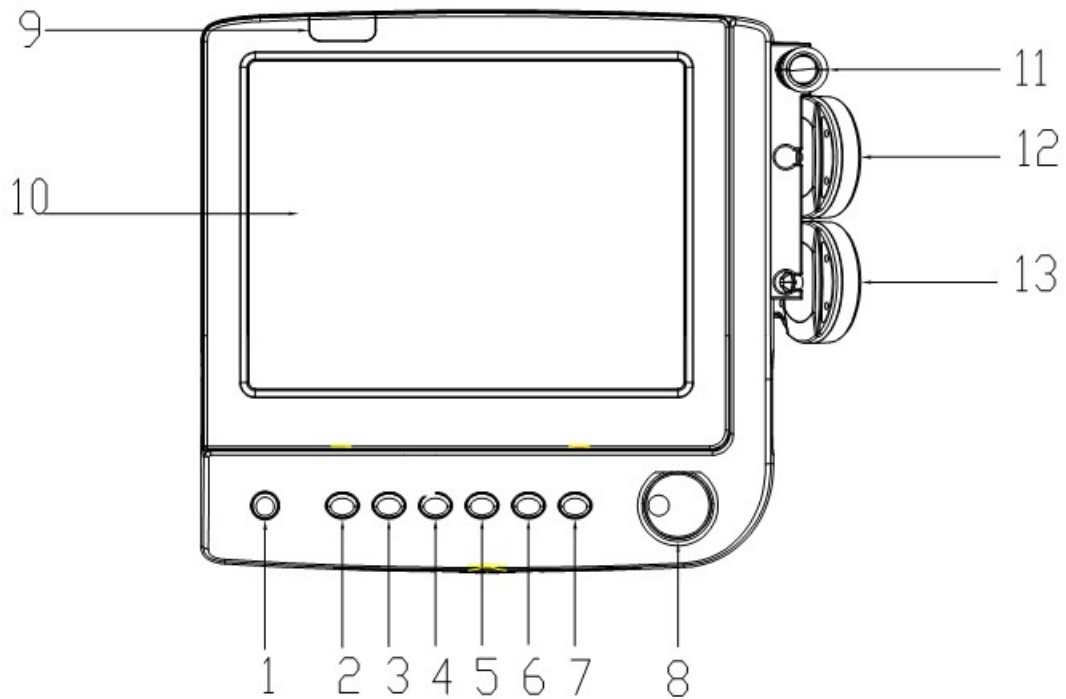
Use this antepartum monitor for:

- antenatal monitoring in any environment ranging from community to the labor ward

- hospital admission tests

Chapter 2 Product description

2.1 Main interface introduction.



- 1. POWER
- 2. NIBP start/stop
- 3. FREEZE
- 4. VOLUME DOWN
- 5. VOLUME UP
- 6. PRINTING
- 7. TOCO RESET
- 8. ENCODER
- 9. INDICATOR LAMP
- 10. TFT LCD
- 11, 12, 13: TRANSDUCERS HOLDER



2.2 Standard Configure

- Main unit.
- Adapter and power wire.
- 3 in 1 transducer (U/S, TOCO and Remote Even market),(options: maternal Spo2 sensor, blood pressure cuff).

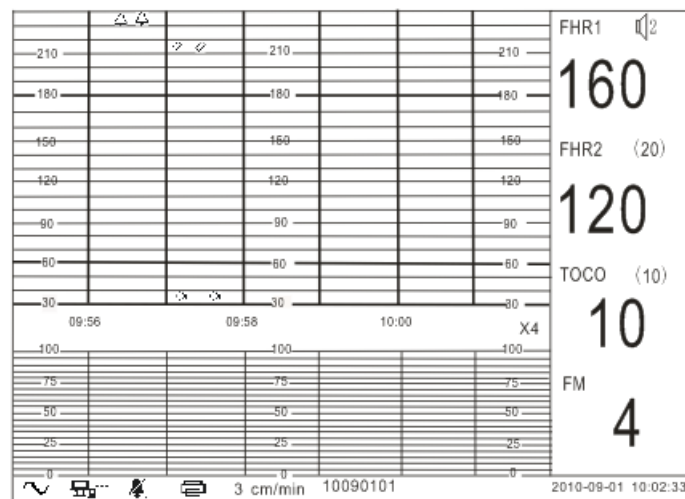
Main unit: the main unit has the LCD module, recorder and electronic circuitry-microprocessor, signal

processing, audio system, display systems and power supply. Signals from the transducers are processed and displayed on the large LCD display. And the menu can be adjust by encoder .the key on control panel can be set up the system parameter ,freeze display , adjust volume, printer control , alarm control and so on.

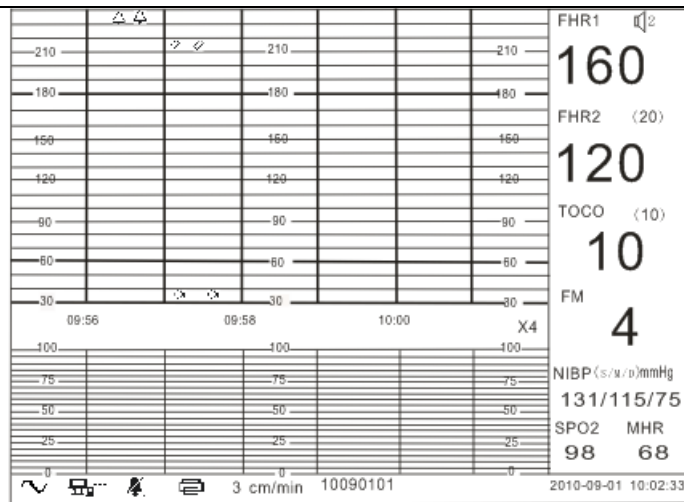
Transducer: 3-in-1 transducer (include U/S, TOCO and Remote Event marker). The transducer are held inPlace on the abdomen by elastic straps. The pregnant woman hold the marker, push the button when she feels fetal moving or uterine activity.

notice the markers  are printed on the top paper of the FHR scale. The clinical event markers (the operator using) also keep on the top of paper, the figure is 

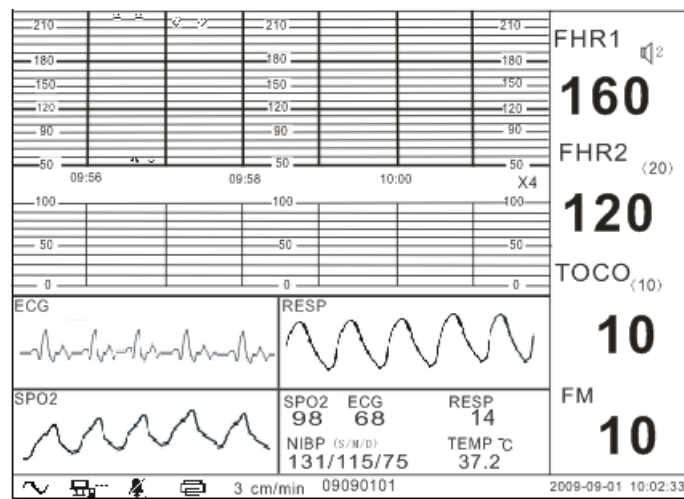
2.3 Display



The interface of 3 parameter monitor



The interface of 6 parameter monitor



The interface of 9 parameter monitor

The Figure of main screen

The bottom is the display area for the system parameters:

Date/time: The real working date and time for real-time monitoring or the stored working date for the freeze state.

PRINT SPEED: the current printer working speed, there are 3 choices:1 , 2 , 3 (unit: cm/min)



07021001: The Pregnant Woman ID, the system can produce one new ID automatically when power on, and this ID can be changed during monitoring, and has effect on the data after ID change. If alarm happens, this place will display the alarm reasons. If the FHR alarm is enabled and happened, it will display FHR ALARM. If no paper or the printer panel open or failures with the printer, it will display PRT ALARM. If monitoring time length is set, when the time is over, it will display TIME OVER.

Current status: displays the current state is monitoring mode or demo mode

Power status:  A.C. power supply,  Li-ion battery power supply


Internet connection:  means connected, if no connection, displays  .


FHR alarm status: , alarm enable,  alarm disable.


Printing status: , means printing, if no printing, displays .


X4: it means the LCD display traces speed, four choices: X1,X2,X4,X8, the fastest speed display 4 points per second.


The green strip of the FHR area means the normal range of FHR, the upper one indicates the high threshold is 160 **bpm** (Beat Per Minute) and the lower one indicates low threshold is 120 **bpm**.

The bell icon  means there was an alarm happened at that time.

The triangle icon  means there was a clinical event happened at that time.

The arrow icon  means there was a patient event happened at that time.


The TOCO reset icon  means there was a reset operation at that time.

The FAS (Fetal Acoustic Stimulator) icon  means the FAS was working at that time (FAS is an option)

The right value display area is illustrated as below:

FHR1: The fetal heart rate is displayed in (**bpm**) beats per minute. In the absence of a signal (or with a signal of poor quality) the display reads '---'

: The speaker volume, there are eight levels marked from 0 to 7

: It means the FHR alarm function is enabled
(20) It indicates the twin offset value.

TOCO: Relative strength of uterine activity. 0~100 is displayed

(10): Reference value of uterine activity, five levels are available, they are 0, 5, 10, 15, 20

FM: This is the fetal movement counting value, the movements within 5 seconds are regarded as 1 time.

NIBP, SpO2 and MHR: these are the maternal parameters display items. If no value, they will display "---".

2.4 Encoder description

ENCODER is used for setting the system parameters. At normal scanning mode, rotate it, there will be a purple rectangle at the edge of values area or system items area alternatively, pressing it will enter the correspond configuration menu, rotate it again to select the item you want to adjust. The purpose item is the selected or the result you changed.

2.5 Interface parameter description

FETAL & MOTHER MENU	
TWIN OFFSET	20
ALM_HI_LIMIT	160 bpm
ALM_LO_LIMIT	120 bpm
ALM_DELAY	15 sec
ALM_ENABLE	OFF
TOCO_REFERENCE	15
PREGNANT ID	09101101
GESTATIONAL AGE	25 W 3 D
NIBP UNIT	mmHg
NIBP INTERVAL	1 min
FM COUNT	AUTO
FM THRESHOLD	60%
FHR CHANNEL	FHR1
FHR IN CHAIN	2
COLOR	0
RETURN	

The figure of Fetal and mother menu

TWIN OFFSET: when doing twin monitoring, if the two FHR values are the similar, it is easy to be confused for displaying and printing the two curves. So we add an offset to the FHR2 (the second FHR). There are two choices, one is 0, that means no offset, the other is 20, that means a minus 20 bpm offset.

ALM HI_LIMIT: the FHR alarm upper limit, there are 4 levels: 160,170,180,190(unit bpm)

ALM LO_LIMIT: the FHR alarm lower limit, there are 4 levels: 90,100,110,120(unit bpm)

ALM DELAY: 15 seconds or 30 seconds are available, if the successive FHR time above the ALM HI_LIMIT or below the ALM LO_LIMIT exceeds this length and alarm function is enabled, then FHR alarm happens.

ALM ENABLE: on or off means enable or disable the alarm function.

TOCO REFERENCE: the TOCO reference value, it can be set with 0, 5, 10, 15, 20

PREGNANT ID: the identifier for the pregnant woman, if no setting when operating, the system will generate a pregnant ID., according to the date and time automatically.

GESTATION AGE: input the pregnant woman gestation age.

NIBP UNIT: there are two choices, one is mmHg, another KPa.

NIBP INTREVAL: the NIBP measurement interval time, 0 means manually.

FM COUNT: counting manually and counting automatically.

FM THRESHOLD: when using the automatic fetal movement counter , the system will regard there is a fetal movement when the amplitude variance is larger than this threshold.

FHR IN CHAIN: enable or disable the chain display function, with this function, we can see a longer time of monitoring from the screen, and it can help to judge the results.

RETURN: return to the normal display state.

2.6 System parameter interface

SYSTEM SETUP	
DATE(MM-DD-YY)	09-01-10
TIME	12:14:15
MONITORING LENGTH	2 min
DISPLAY SPEED	X4
DISPLAY MODE	DEMO
POWER OFF	2 min
LANGUAGE	ENGLISH
PRT SPEED	3 cm/min
PRT DENSITY	7
FHR 210 PRT POSITION	1006
FHR 90 PRT POSITION	800
TOCO 100 PRT POSITION	542
TOCO 0 PRT POSITION	100
Local Ip ADDRESS	192.168.1.2
Local PORT ID	4 0 0 0
Target Ip ADDRESS	192.168.1.161
Target PORT ID	5 0 0 0
RETURN	

The figure of System setup menu

DATE and TIME: the real date and time.

MONITORING LENGTH: it can set the monitoring time length, when the time is over, it can alarm to reminder the user.

DISPLAY SPEED: 4 levels adjustable, they are X1, X2, X4, X8.

DISPLAY MODE: 2 modes available, monitoring mode or demo mode.

POWER OFF: it can set the monitor working time, when the time is over, the system will power off automatically.

LANGUAGE: two choices: ENGLISH or CHINESE.

PRT SPEED: it can be set with 1,2,3 cm/min

PRT DENSITY: it can be increased or decreased to a suitable printing deepness effect.

This system design is suitable for many kinds of 150mm wide printing paper with different specifications.

TOCO 0 PRT POSITION: it can adjust the 0 printing position on the paper.

TOCO 100 PRT POSITION: it can adjust the 100 printing position on the paper.

FHR 90 PRT POSITION: it can adjust the 90 bpm printing position on the paper.

FHR 210 PRT POSITION: it can adjust the 210 bpm printing position on the paper.

IP ADDRESS: Internet IP Address.

IP PORT: Internet IP Port.

RETURN: return to the normal state.

Setting operation :

When the curve scrolls (figure 1), Rotate the encoder, there will have a thick wireframe in the values display area or system items area, press the encoder, enter to fetal and pregnant parameter interface, Rotate the encoder again to select the item you want to adjust .the purple item is the selected or the result you changed. Press the encoder again, enter the adjustment state, encoder the encoder again ,you can adjust it .After setting ,press the encoder to confirmed it ,then rotate the encoder to choose returning ,it will return the normal display.

Returning operation:

Under the selection status, select the **RETURN, press the encoder**, it will return the normal display.

2.7 Key description



Pressing this key, the system enters the freeze state, press it again, the freeze state will be cancelled .

Under the freeze state, if you want to enter the system manual, you must unfreeze first.

▲ and ▼ When at freeze state, it can be used to review the past date backward and forward.

When at display state, it can be adjust the volume at the main screen



Press this key at any time if the recording is needed and press it again to stop the recording.

The

LCD right corner will display PRINTING.

When the alarm function is enabled (there is a yellow alarm bell beside the fetal heart rate value), when there is an FHR alarm, an alarm bell icon will be displayed at the curve area, meanwhile an alarm sound can be heard, this alarm can be cancelled by pressing any key. When an alarm is happening, the alarm reason can be displayed at the right bottom area of the LCD, totally there are three alarm reasons: FHR alarm, monitoring time over and printer alarm.



Set the uterine pressure value to the preset value, this key is often used when begin to monitor

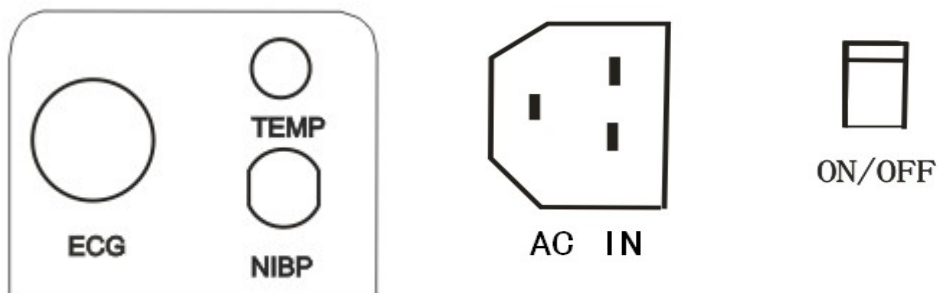


measure the mother NIBP



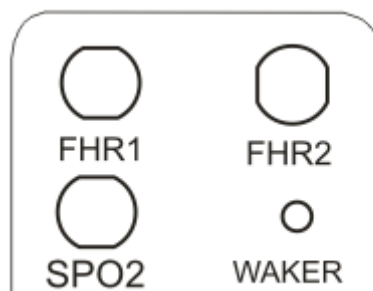
When at the occasion of twin monitoring, Press this button to for select which heart beat sound will be monitored.

2.8 Right and left panel description



the left side panel

- ECG: maternal ECG socket
- TEMP: maternal temperature probe socket.(option)
- NIBP: maternal NIBP cuff input.(option)
- AC IN: AC power input jack adapter ouput socket
- ON/OFF: power switch



the right side panel

FHR1: The socket of 3 in 1 transducer

FHR2: The second ultrasound transducer socket when doing twin monitoring(option)

SpO2: Maternal Spo2 socket(option)

WAKER: Fetal acoustic stimulator (FAS) socket(option)



backside board

NET: network socket of central station

USB: retained.

RS232: retained.

Chapter 3 Set up the iC90

This section shows you how to:

- unpack
- connect power
- Load paper
- set up the unit for use

3.1 Unpacking the units

3.1.1 Carefully remove the main unit and accessories from the carton.

3.1.2 Check that the content of the carton corresponds with the list below and that all items are undamaged .

- ◆ 1 main unit of fetal monitor
- ◆ 3 in 1 transducer(ultrasound transducer ,contraction transducer, remote event marker)
- ◆ 2 transducer belts
- ◆ 1 mains power cord and adaptor
- ◆ 2 paper pads
- ◆ Warranty card
- ◆ 1 250ml bottle of gel
- ◆ Use's manual
- ◆ One Spo2 sensor(option)
- ◆ One blood pressure cuff(option)

3.2 Connect power

This fetal monitor uses 110v~220v \pm 20%AC or Li-ION battery inside.

3.2.1 If using AC, connect power cable to the monitor..

3.2.2 Switch the unit on by pressing the POWER switch at the front panel of the unit.

3.3 Load the paper

When you take delivery of this fetal monitor, you need to insert paper as following:

3.3.1 Open the front panel of the printer, open the uppermost page of one pack of paper from inside to outside, make FHR grids on the left side, TOCO grids on the right side.

3.3.2 Pull out the paper, make sure the both sides are paralleled with the printer Panel side.

3.3.3 Close the front panel of the recorder

3.4 Set up the menu

3.4.1 Set up the date/time

3.4.1.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.1.2 Rotate the encoder, choose the **DATE or TIME**, press the encoder again , then enter the adjustment state, rotate the encoder to adjust the value.

3.4.1.3 After set up, press the encoder to confirmed it, then it will back to the normal display by pressing any key.

3.4.2 Set up the monitoring time length

3.4.2.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.2.2 Rotate the encoder ,choose the **MONITORING TIME LEN**, press the encoder again ,then enter the adjustment state, rotate the encoder to set up the monitoring time .0 means no this function

3.4.2.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.3 Set up the display speed

3.4.3.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.3.2 Rotate the encoder, choose the **DISPLAY SPEED**, press the encoder again, enter the adjustment state. Rotate the encoder, there will have X1, X2, X4, X8 for choice After set up, press the encoder to confirm it , then it will back to the normal display by pressing any key.

3.4.4 Set up the display mode

3.4.4.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.4.2 Rotate the encoder, choose the **DISPLAY MODE**, press the encoder again, enter the adjustment state. Rotate the encoder to choose monitoring mode or demo mode.

3.4.4.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.5 Set up the working time

3.4.5.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to

enter the **SYSTEM SET UP MENU**

3.4.5.2 Rotate the encoder, choose the POWER OFF, press the encoder again, enter the adjustment state. Rotate the encoder to set up the working time.

3.4.5.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.6 Set up the printing speed

3.4.6.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.6.2 Rotate the encoder, choose the PRT SPEED, press the encoder again, enter the adjustment state.

3.4.6.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.7 Set up the printing density

3.4.7.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**.

3.4.7.2 Rotate the encoder, choose the PRT DENSITY, press the encoder again, enter the adjustment state, it can be increased or decreased to a suitable printing effect.

3.4.7.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.8 Set up the Printing Position

3.4.8.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**.

3.4.8.2 Rotate the encoder, choose the printer adjustment items, there will have for items for you choose, TOCO 0 PRT POSITION, TOCO 100 PRT POSITION, FHR 90 PRT POSITION, FHR 120 PRT POSITION, pressing the encoder again to enter the adjustment .the printer will be working at the same time when you adjust it.

3.4.8.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.9 Set up the Alarm HI_LIMIT and LO_LIMIT

3.4.9.1 Rotate the encoder, move the purple frame to values area. Press the encoder to enter the **FETAL & MOTHER MENU**.

3.4.9.2 Rotate the encoder, choose the **ALM HI_LIMIT or ALM LO_LIMIT**, press the encoder again, enter the adjustment state, rotate the encoder to adjust it .

3.4.9.3 After set up, press the encoder to confirm it, then it will back to the normal display by

pressing any key.

3.4.10 set up the FHR alarm enable

3.4.10.1 Rotate the encoder, move the purple frame to values area. Press the encoder to enter the **FETAL & MOTHER MENU**.

3.4.10.2 Rotate the encoder, choose the **ALM ENABLE** press the encoder again, enter the adjustment state, ON or OFF for you choice.

3.4.10.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.11 set up the Alarm Delay

3.4.11.1 Rotate the encoder, move the purple frame to values area. Press the encoder to enter the **FETAL & MOTHER MENU**.

3.4.11.2 Rotate the encoder, choose the **ALM DELAY** press the encoder again to enter the adjustment state, then rotate the encoder to adjust it.

3.4.11.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.12 set up the TOCO reference

3.4.12.1 Rotate the encoder , move the purple frame to values area. Press the encoder, it will enter the **FETAL & MOTHER MENU**.

3.4.12.2 Rotate the encoder, choose the **TOCO REFERENCE** press the encoder again, enter the adjustment state, then ,Rotate the encoder will change it .Normally ,set it with 10 .

3.4.12.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.13 Set up the pregnant woman ID, and age

3.4.13.1 Rotate the encoder, move the purple frame to values area. Press the encoder, it will enter the **FETAL & MOTHER MENU**.

3.4.13.2 Rotate the encoder, choose the **PREGNANT ID** or **GESTAION AGE**, press the encoder Again to enter the adjustment state, then rotating the encoder will change the ID and age.

3.4.13.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.14 Set up the LANGUAGE

3.4.14.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.14.2 Rotate the encoder, choose the **LANGUAGE**, press the encoder again, enter the

adjustmentState, only CHINESE or ENGLISH can be selected.

3.4.14.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.15 Set up the Ip address

3.4.15.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.15.2 Rotate the encoder, choose the Ip address, press the encoder again, enter the adjustment state, there are four items divided by dot symbol, the range for every item is from 0 to 255.

3.4.15.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.16 Set up the PORT ID

3.4.16.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **SYSTEM SET UP MENU**

3.4.16.2 Rotate the encoder, choose the PORT ID item, press the encoder again, enter the adjustment state,

The range is 0 to 4000.

3.4.16.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.17 Set up the TWIN OFFSET

3.4.17.1 Rotate the encoder, move the purple frame to values area. Press the encoder to enter the **FETAL & MOTHER MENU.**

3.4.17.2 Rotate the encode , choose the TWIN OFFSET item, press the encoder again, enter the adjustment state, rotate the encoder to adjust it, There are two choices, one is 0, that means no offset, the other is 20, that means a minus 20 bpm offset.

3.4.17.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.18 Set up NIBP UNIT

3.4.18.1 Rotate the encoder, move the purple frame to values area. Press the encoder, it will enter the **FETAL & MOTHER MENU.**

3.4.18.2 Rotate the encoder, choose the **NIBP UNIT**, press the encoder again, enter the adjustment state,

You can select mmHg or KPa as needed.

3.4.18.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.19 Set up NIBP INTERVAL

3.4.19.1 Rotate the encoder, move the purple frame to values area. Press the encoder, it will enter the **FETAL & MOTHER MENU**.

3.4.19.2 Rotate the encoder, choose the **NIBP INTERVAL**, press the encoder again, enter the adjustment state, You can select NIBP measurement interval, the unit is minute, 0 means take measurement

manually, others mean the time interval when doing NIBP measurement automatically.

3.4.19.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.20 Set up FM COUNT

3.4.20.1 Rotate the encoder, move the purple frame to values area. Press the encoder, it will enter the **FETAL & MOTHER MENU**.

3.4.20.2 Rotate the encoder, choose the **FM COUNT**, press the encoder again, enter the adjustment state, You can select AUTO or MANUALLY, when AUTO is selected, the FM counting will be done automatically, if MANUALLY is selected, the FM counting is added one when the marker is

pressed one time, the pressing times with 5 seconds is only regarded as one time.

3.4.20.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.21 Set up the FM THRESHOLD

3.4.21.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **FETAL & MOTHER MENU**

3.4.21.2 Rotate the encoder, choose the **FM THRESHOLD** item, press the encoder again, enter the adjustment state, there are 8 levels of thresholds, from 10% to 80%, when the fetal movement value is larger than this level, it will be regarded as one times of fetal movement event.

3.4.21.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.22 Set up the FHR CHANNEL

3.4.22.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **FETAL & MOTHER MENU**

3.4.22.2 Rotate the encoder, choose the **FHR CHANNEL** item, press the encoder again, enter the

adjustment state, there are two choices, FHR1 and FHR2, when FHR1 is selected, the sound from speaker is from FHR1 channel, the same is for FHR2.

3.4.22.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

3.4.23 Set up the FHR IN CHAIN

3.4.23.1 Rotate the encoder, move the purple frame to system items area. Press the encoder to enter the **FETAL & MOTHER MENU**

3.4.23.2 Rotate the encoder, choose the **FHR IN CHAIN** item, press the encoder again, enter the adjustment state, you can select enable or disable this function, if ON is selected, then the display time length will be extended twice the old length, it is convenient to observe the more time of monitoring process.

3.4.23.3 After set up, press the encoder to confirm it, then it will back to the normal display by pressing any key.

Chapter 4 Operating instruction

4.1 Preparation for use

Insert the 3 in 1 transducer, Spo2 sensor, blood pressure cuff into the sockets on the right side, press the Switch on the front panel several second, the LCD displays should illuminate.

4.2 FHR Monitoring

4.2.1 Determine fetal position by palpation

4.2.2 Apply gel to the center of the ultrasound transducer face.

4.2.3 Place the transducer on the abdomen ensuring that the gel makes good contact between the skin and the transducer. The best signal will be achieved by positioning the transducer over the fetus's upperback over the left scapula. Adjust the position slowly until the best signal is obtained.


4.2.4 When the fetal heartbeat is heard, keep the transducer in position and move one end of the belt into position.

4.2.5 Reposition the transducer to obtain a good fetal heart beat signal. An indication of this is given by the signal quality indicator.

4.3 TOCO monitoring

4.3.1 Position the TOCO transducer over the fundus of the uterus.

4.3.2 With the transducer still in position, move one end of the belt into position over the transducer, Meanwhile maintain belt tension.

4.3.3 Once satisfied with the transducer position and belt tension, set the contractions read-out to reference value by pressing . The TOCO display should respond to contractions and maternal breathing.

4.4 Pregnant woman Spo2 and HR monitoring

Warning: During MRI scan, SpO2 sensor may cause serious burnt. To minimize this risk, ensure the cable position will not make a circuit. If the sensor doesn't work well, remove it from patient immediately.

Warning: Do not apply the SpO2 sensor to an extremity where there is arterial catheter or injection tube.

Warning: Make sure the light emitting part and light detecting part face each other. All the emitting lights should get through patient tissue.

Warning: During prolonged monitoring, check and change the sensor position regularly in order to avoid damage to the patient's skin. Special patients need special treatment.

Caution: SpO₂ sensors are precise and fragile and shall be handled with great care. We are not responsible for the damage caused by negligent use.

Caution: The infusing dye may cause wrong reading.

Caution: Outside interference: strong ambient light and patient motion may impact measurement of blood oximetry.

Note: Make sure the sensor is applied to a region of arterial blood flow.

Note: Make sure there is no extreme motion.

Note: Make sure the skin where the sensor is applied is neither too thick nor too thin.

Note: Make sure there is no strong ambient light coming into the sensor. Cover the attaching part with non-transparent material.

Note: Keep the power cord away from the sensor transducer.

4.5 NIBP monitoring

4.5.1 Select proper sizes of cuffs for different patients in accordance with the limb sizes

Caution: If the cuff is too small or too tight, the measured blood pressure value will be higher than real value. If the cuff is too large or too loose, the measured blood pressure value will be lower than real value.

- (1) Make sure the cuff is completely deflated.
- (2) If possible, measure NIBP on the left arm and roll up sleeves.
- (3) Place the cuff on the arm, 2-5cm above the elbow. Make sure the hose is not kinked or obstructed.
- (4) Connect the cuff to the monitor.
- (5) Make sure there is no block between the monitor and the hose.
- (6) Selecting the NIBP patient mode: Setting the NIBP patient mode to adult or neonate.
- (7) The patient's arm shall be at the same level as the heart with the center of the palm upward.
- (8) Press the blood pressure start key and start measuring blood pressure.

Caution: Do not place the cuff on a position where skin or tissue is damaged.

Caution: Do not place the cuff on an extremity where infusion is being done.

Caution: Make sure there is no external pressure on the cuff during measurement.

Warning: Check patients carefully before doing NIBP measurement. Do not perform NIBP measurement if patient's condition does not permit.

4.5.2 The following circumstances may affect the measurement results:

- (1) patient motion
- (2) rapid change in pressure
- (3) shock or hypothermia

Caution: Do not measure other parameters (e.g. SpO₂) on the same extremity.

Caution: For patient who suffers from trembling or epilepsy, the readings may be distorted.

Caution: Do not measure patient's blood pressure repeatedly in a prolonged during of time.

Note: Arrhythmia may increase the NIBP measurement time.

Note: After power off, please remove the cuff.

4.5.3 NIBP Cuff cleaning and maintenance.

Note: Clean the reusable cuff each time after use with mild soap water.

Caution: If possible, please always abide by the instructions provided together with the cuff. The information listed in this chapter can only be treated as general cleaning guidance when no other specific method can be obtained.

Caution: Do not let liquid enter into the NIBP connector because it will damage the equipment. Please make sure that whenever you clean the cuff, do not let liquid enter the tube and being absorbed by the equipment.

4.5.4 Clean reusable NIBP cuff

Steps:

- (1) Remove the bag.
- (2) Clean the cuff in detergent.
- (3) Dry the cuff in the air.
- (4) Put the cuff back in the bag.

Caution: The cuff cannot be dry-cleaned.

4.5.5 The means of Avoid intercrossing infection through cuff

- (1) Remove the rubber bag inside.
- (2) Sterilize with normal method. Choose gas, radiation or detergent (acetone 70% or ethanol 70%) disinfections.
- (3) If you choose detergent, make sure the cuff dries completely.
- (4) Put the bag back into the cuff.

4.5.6 Put the rubber bag back

- (1) Roll up the bag from the hose.
- (2) Put the bag, first the hose into the mouth at the short end of the cuff.
- (3) Push the hose and let it get through the longer end of the cuff.
- (4) Grasp the hose and the cuff and shake until the bag returns to initial position.
- (5) Check the cuff and the hose. In case there is any damage, do not use it again.

4.6 ECG MONITORING

4.6.1 General Information

L8 monitors patient's ECG activities and presents in the form of continuous waveform and heart rates. It is necessary to do sufficient preparations before monitoring in order to get accurate readings.

The patient cables consist of the main cable (connected to the patient monitor) and the leadwires (connected to the patient).

Warning: At ECG receptacle, we can see  label, which indicates that the signal input part is highly insulated

4.6.2 Before Monitoring

4.6.2.1 Skin Cleaning

The ECG signal displayed on the monitor is decided by the signal quality collected by ECG electrodes. In order to get clear signal, it is necessary to clean the skin before. We recommend the following:

- (1) Clean the skin with soap water or pure alcohol .
- (2) Apply electrodes when skin is completely dry.

4.6.2.2 Preparation for monitoring

- (1) Select correct electrodes
- (2) Connect electrodes to leadwires.
- (3) Attach electrodes to the patient correctly.
- (4) Plug the ECG cable into the ECG receptacle on the side panel of the monitor.

Warning: When connecting the electrodes or patient cable, make sure the other conducting part or earth is not connected. Particularly make sure all ECG electrodes are attached to the patient and prevent them from getting in contact with other conducting part or earth.

4.6.3 Attaching ECG Electrodes

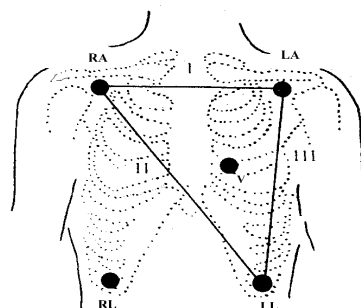
4.6.3.1 Leadwires and Color

Europe and USA have different standards on the descriptions, codes and color for five leads.

Lead	USA	Europe		
Location	lead name	color	lead name	color
Right Arm	RA	white	R	red
Left Arm	LA	black	L	yellow
Left Leg	LL	red	F	green
Right Leg	RL	green	N	black
Chest	V	brown	C	white

4.6.3.2 Five-lead ECG electrodes locations

- RA-under the right collarbone
- LA- under the left collarbone
- LL-on the left lower belly
- RL-on the right lower belly
- V –on the chest



Three lead electrode locations are shown as the triangle.

Caution: All leads must be attached to the patient.

Note: Disposable electrodes shall be disposed of in accordance with the local regulations.

4.6.3.3 Setup

ECG Lead: Select II leads, that means positive lead is LL(left leg) and negative lead is RA(right arm), and the ECG signal between them is displayed on the LCD.

ECG Gain: Select constant gain to get ECG waveform with enough amplitude .

ECG Mode: Monitoring mode, that means displaying the waveform where interference has been filtered.

Priority HR/PR: ECG, SpO2, NIBP

4.6.4 Precautions

Warning: this monitor is not intended to use with a defibrillator or a HF equipment, don't use it when the equipment will be working.

Warning: Ensure conductive parts including electrodes of the patient cable do not come into contact with any conductive surfaces or earth parts.

Warning: Do not use the patient monitor during MRI.

Caution: Using electrodes of dissimilar metal materials may cause the electrodes over polarization or accelerated polarization.

Caution: Leads and cables should be away from patient's throat.

Caution: Many parts of the device connecting together may increase leakage current and result in hazard.

4.6.4.1 How to select and use ECG electrodes correctly?

Besides recommended Ag-AgCl electrodes, we recommend to change the electrode at least every 48 hours. Please discard used electrodes properly.

4.6.4.2 What negative effects may occur if the monitor is used with pacemaker?

When monitor is used with pacemaker, the pulse of pacemaker may be taken as QRS wave and some pacemaker may result in inaccurate respiration impedance or arrhythmias. Doctors shall keep close to the patient with pacemaker and make right decisions.

4.6.4.3 How to select ECG cable?

ECG cable is only intended for connecting the accompanying ECG cable, no other conductor or earth shall be connected to it. Check the ECG cable regularly. Replace it immediately when any damage is found.

4.6.4.4 How to reduce leakage current when several machines are used at the same time?

When several devices are being used on the same patient at the same time, leakage current may accumulate. Before connecting the devices, leakage current test shall be done by qualified personnel. If there is any doubt, please consult the manufacturer.

4.6.4.5 When will wrong measurement occur?

When pacemaker or other devices are being used on the same patient at the same time, or there is VPC problem, wrong measurement may arise. After the patient's death, ECG signal still exists. Medical patients shall keep close to it and give right diagnosis.

4.6.5 Cleaning and Maintenance

Caution: Please always obey the detailed instructions supplied together with the transducer, which are more updated than the information here. The following instructions shall be treated as general guidance when there is no specific method. When the cable is found worn out or damaged, please replace the cable at once.

4.6.5.1 ECG cable cleaning

In order to keep the cable dust-free, please clean it with clean cloth immersed in mild soap water or any of the following recommended liquids.

If there is any damage or other quality problem, do not use for monitor again.

Recommended detergent and labels:

Soap	mild soap
Tensides	Alconox (for dish cleaning)
Ammonia	diluted ammonia<3% (for window cleaning)
Ethanol	70%(for window cleaning)

4.6.5.2 ECG cable disinfection

In order to avoid long-term damage to the cable, we recommend that you only disinfect the cable when it's necessary according to your hospital regulations. Do clean it first.

Recommended detergent:

Ethanol 70% ; Isopropyl alcohol 70% ; Clidex

Caution: Do not autoclave the cable.

4.6.6 Troubleshooting

4.6.6.1 Inaccurate Heart Rate

- (1) check patient's ECG signal
 - a. check /adjust lead placement
 - b. check/clean the patient's skin
 - c. check/replace ECG electrodes
- (2) check if ECG waveform amplitude is normal.

4.6.6.2 No ECG waveform

After leadwires are connected but there is no ECG waveform.

- (1) Check if the electrodes are in good contact with the patient and if the leadwires are open.
- (2) Check all the external connection of the ECG leadwires.
- (3) Check the ECG electrodes. Prolonged placement of electrodes may result in polarized voltage and the electrodes shall be replaced.

4.6.6.3 ECG baseline shift

ECG scan baseline is not stable on the display.

- (1) check if the working environment is too humid and if the machine has moisture inside. If yes, keep the machine on for 24 hours and keep the ambient environment dry.
- (2) Check the electrode quality and if the skin where the electrode placed is clean.

4.7 RESPIRATION and TEMPERATUR MONITORING

4.7.1 General Information

Thoracic impedance method is used in monitoring patient's respiration. Respiration rate and waveform can be displayed on screen.

Monitor can measure adult temperature. The temperature value is displayed on the bottom part of screen.

Warning: TEMP socket is labeled with , showing the signal input part is insulated

Caution: Please use accessories recommended by the manufacturer only.

4.7.2 Temperature Monitoring

Warning: Keep the skin-surface temperature probe tightly to the skin.

(1) Insert the temperature probe into the temperature socket in the side panel.

(2) Start to monitor patient's temperature.

Warning: Before performing temperature measurement, do not get the temperature probe close to heat source. If it has been close to a heat source, then let it cool down for 5 minutes before performing measurement.

Caution: It takes about 3 minutes for the patient monitor to display stable reading.

4.7.3 Respiration Monitoring

The patient monitor measures respiration through the change of impedance and displays the respiration waveform and respiration rate on the screen. When the ECG electrode is placed on the arm, it is impossible to monitor impedance respiration.

Note: Electrodes must be placed in proper positions.

Caution: Patient motion may result in respiration measurement error.

4.7.3.1 Precautions

Warning: The patient monitor is not intended for use during MRI scan.

Caution: Clean the probe surface before and after each use.

Caution: Check the temperature probe each time before use. Please replace it immediately if any damage is found.

Factors which may impact the measurement:

(1) Temperature probe is not placed in a proper position.

(2) Heat balance is not achieved. Partial of the heat dissipated.

(3) Patient temperature fluctuates.

Respiration signal too low:

If the respiration waveform on the screen is very small, please check the electrodes quality and positions. Make sure the skin is clean and in good contact with the electrodes.

4.7.3.2 Cleaning and Maintenance

Temperature probe is used in close contact with patient. So it shall be cleaned each time after use.

Caution: Do not steam or autoclave the probe.

- (1) Hold the pointed part with one hand and use the other hand to wipe downward toward the connecting component with wet soft cloth.
- (2) Dry the probe with soft cloth and let it dry completely.
- (3) Check the probe. Do not use it for measurement if there is damage or quality problem.

Caution: Use soft cloth damped in soap water to clean the probe. Do not let liquid enter into the Temperature connector.

Note: Disinfect the probe periodically. Sterilize with ethylene oxide.

Caution: Do not heat the probe over 100°C(212°F). The range during short time is 80°C(176°F)~100°C(212°F).

4.8 Printing

When you need recorder the value and curve , press the printer key . the right side of LCD will display printing . means it starts print. Press the printer key in any time, the printer will be stop. When under the freeze state, it will print the current value on the LCD.

4.9 After use

WHEN THE EXAMINATION IS FINISHED ,DO THE FOLLOWING:

- 4.7.1 Switch off the iC90
- 4.7.2 Detach the transducers from the pregnant woman and store it safely, clear the gel on abdomen and transducer
- 4.7.3 Refer to the cleaning section for further instructions on cleaning the monitor

Chapter 5 Care of iC90

5.1 Handling

Although this monitor is robust and designed to withstand the clinical use, the unit does contain delicate components and should be treated with care. This applied especially to the transducers which should not be dropped or knocked

5.2 Except the cleaning, this fetal monitor needn't any other maintenances

Keep the instrument clean, no any dust. Can be clean it with a dry and soft cloth. If necessary, to clean it use a damp cloth impregnated with a mild detergent.

Use a soft damp cloth to clean the excrescent Gel on the transducer. And the transducer just be cleaned by water and soap.

Caution: Do not use strong solvents such as acetone.

Caution: forbid to use friction material (such as steel wire and silver polish)

Caution: do not immerse instrument in any liquid.

Caution: do not put any liquid on the instrument when cleaning.

Caution: do not leave any cleaning liquid on the instrument surface.

Caution: to clean the transducer surface, can be use the alcohol which density is 70% or isopropyl alcohol, air dry or clean and dry cloth to clean.

5.3 Disinfection

As above described way to clean the instrument appearance and transducer, then use the alcohol which density is 70% or isopropyl alcohol to clean the transducer surface.

Then use a dry and soft cloth to clean the liquid leaved on the instrument.

Caution: Do not use low-temperature steam or other sterilization way for instrument and transducer.

5.4 Clean the printer

The thermal printer can work exceed 20 years. But printing paper and operation environment will affect its capability. If the printing content is not clear, you should clean the print head as following:

5.4.1 Power off iC90

5.4.2 Open the front panel of printer

5.4.3 Moving the cotton swab wetted with alcohol at the printer head thermal area from left to right smoothly(a thin black thermal line can be seen at the printer head) to clean the printer head thermal line area, after finished for several minutes, power on iC90 to confirm.

5.4.4 If the content is not clear yet, do the step 3 repeatedly.

5.5 Ordering information

Accessories below are supplied or approved by Biocare

accessories Biocare series NO.

Gel (250g one bottle) iC90 -14101

Printer paper iC90 -14110

Chapter 6 Troubleshooting

iC90 had been designed to a high level of quality and reliability, if you meet some problems, please check it below is the table which list some possible solutions

symptom	possible causes	remedy
No display when unit switched on.	No mains power or connection badly.	Check adapter and power wire .
Abnormal FHR value	Transducer connects with main unit badly. No find the fetal heart, the transducer place isn't correct. No gel or little gel . fetal/maternal activity. The transducer is broken.	Reconnect the ultrasound transducer. Readjust the ultrasound transducer Add gel. When no activity, readjust the ultrasound transducer . Replace the ultrasound transducer.
Abnormal TOCO value	Transducer connects with main unit badly The transducer place isn't correct. No reference reset No contraction	Reconnect the ultrasound transducer Readjust the ultrasound transducer Reset the TOCO value Waiting the contractions appears.
Press the Toco transducer, the Toco value changes a little only.	The initial output value should be readjusted. Toco transducer broken	Readjust the inner potentiometer inside the transducer Replace the toco transducer
Press the marker, no icon is displayed and printed	Bad marker.	Confirmed using a multimeter.
no sound from speaker	Volume is too low	adjust volume
Printer is working ,but no FHR curve, toco curve on paper. or the FHR curve and TOCO curve is not in right area.	The paper thermal side is opposite Or right side and left side is opposite	Reload the paper with the thermal side facing the printer head
Print unclearly or some parts can't be printed out	Light printing deepness Unqualified paper Dirty printer head.	Adjust the printer deepness. Replace the paper. Clean the printer head

paper goes with alias Printing data position error	Paper is not loaded at its place. Using other brand printer paper Printing position is not calibrated.	Reload the paper Replace with qualified paper readjust the printing data position according to this manual.
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Chapter 7 Warranty and maintenance

Our company treat all clients equally, all products have one year warranty, but we will keep the maintenance after one year.

About the after-sale service, maintenance and any other problem relative with the products from our company ,please contact with us.

In case that you want to return this product ,please disinfect it with local disinfection procedure , and supply relevant document to describe the problem. Also please pack this document together with monitor.

Attention: our company won't take any responsibility for error of this user manual, or the direct or indirect damage as this manual supplied.

Our company has copyright of this manual, No part can't photocopied, copied, and translated it into other languages without the prior written consent.

Our company reserves the right to revise and amend it at any time without prior notice.

Warning: This instrument is use for clinic application, not use for treatment. if you are suspicious of accuracy of result ,you can verify it through other devices like a stethoscope.

Explaining the label:

Warning: you should know the information to avoid the potential hurt to the patient and doctor.

Caution: you should know this information about how to protect the instrument.

Note: you should know this important information.

IPX1: closed instrument with water drop proof function.

SN

Manufacture's serial number.



Refer the files attached.



Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive).

Chapter 8 Technical Date

iC 90 fetal/maternal monitor

Fetal Heart Rate:

Transducer: Multi-crystals, pulsed doppler , high sensitively

Strength: <5mW/cm²

Working frequency: 1.0MHz

Signal processing: special DSP system and modern recognition.

Measurement range: 50~210 bpm

Alarm Range:

High limit: 160,170,180,190 bpm

Low limit: 90,100,110,120 bpm

Maximum audio output power : 1.5 Watt

Toco:

Measurement range: 0~100 units

Maternal SpO2 measure:

Measure scope : 70%~99%。

Measure accuracy: ±3%

Pregnant HR Measure:

Measure scope: 30bpm~240bpm

Measure accuracy: ±2 bpm

NIBP measure:

a) NIBP-SYS (6.7~32.0Kpa)(50~240mmHg)

b) NIBP-DIA (3.4~26.6Kpa)(25~200mmHg)

c) NIBP-MEAN(2.0~24.0ka)(15~180mmHg)

NIBP Accuracy: ±1.1kPa (±8mmHg) or ±5% of the results, take the bigger one.

Maximum Mean error : ±5mmHg

Maximum Standard deviation 8mmHg

Pulse Rate Accuracy: Maximum Mean error : ±2bpm

Measure accuracy: ±2 bpm or ±5% of the results, take the bigger one.

Measure mode: Manual

ECG

CMRR: ≥ 90 dB

Heart Rate Measurement and Alarm Range: 15-300bpm

Accuracy: ± 1 bpm

Heart Rate Average: 8 beats

Lead Selection: II

Input: 5-lead ECG cable

Sweep Speed: 25 mm/s

Amplitude Selection: $\times 1/4$, $\times 1/2$, $\times 1$, $\times 2$, $\times 4$

Frequency Response:

Monitoring: 0.5 to 35Hz (+0.4dB, 3.0dB)

Defibrillation Protection: 5kV test

Recovery Time Following Defibrillation: Less than 5 seconds

Temperature:

Measurement and Alarm Limit: 0-50°C

Probe: Skin surface

Unit: Celsius/Fahrenheit

Accuracy: $\pm 0.1^\circ\text{C}$ (25°C ~45°C), $\pm 0.2^\circ\text{C}$ (0°C ~25°C or 45°C ~50°C)

Resolution: 0.1°C

Respiration

Measurement Mode: Thoracic Impedance

Respiration Rate: 0-150 bpm

Waveform Display Speed: 25mm/s

Display:

The LCD displays FHR, TOCO, FM , maternal parameters ,time, date, volume and so on,

It can store and playback the data.

Power: a.c.100-240v, 50/60Hz or 16.8v Li-ION battery

Power Consumption: < 20W

Dimension: 350W×320D×85H (mm)

Net weight:3.5kg

Environment

Working environment: Temperature: +5°C ~ +40°C

Humidity: < 85%

Atmospheric pressure: 86kPa ~ 106kPa

Transport and storage temperature: Temperature: -10°C ~ +55°C

Humidity: < 93%

Atmospheric pressure: 86kPa ~ 106kPa

Transducer Acoustic Output:

Under the requirements laid down in IEC 1157, 1992, the peak negative acoustic Pressure does not exceed 1Mpa. The output beam intensity does not exceed 20mW/cm² and the spatial-peak temporal-average intensity does not exceed 100mW/cm²

GEL:

Viscous aqueous non-sensitizing , hypo-allergenic and non-irritating to skin. Indefinite shelf life, Bacteriostat (not sterile).

Annex EMC-Guidance and Manufacturer's Declaration

D.1 Guidance and manufacturer's declaration-electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The iC 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the iC 90 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The iC 90 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	


D.2 Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT and

SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The iC 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the iC 90 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5% UT for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iC 90 requires continued operation during power mains interruptions, it is recommended that the iC 90 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

D.3 Guidance and manufacturer's declaration – electromagnetic immunity –for EQUIPMENT and

SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The iC 90 is intended for use in the electromagnetic environment specified below. The customer or the user of the iC 90 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the iC 90, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

D.4 Recommended separation distances between portable and mobile RF communications equipment and

the EQUIPMENT or SYSTEM – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the iC 90			
The iC 90 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iC 90 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iC 90 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



In order to protect your right for repair service, please take a few moments to fill out the warranty card below:

Warranty Card

Product		
Model		
SN:		
Date of purchase		
Warranty period		
Customer	Name	
	Tel.	
	Fax	
	Add.	
Information source	<input type="checkbox"/> Internet <input type="checkbox"/> Exhibitions <input type="checkbox"/> Magazines <input type="checkbox"/> Recommended by salesperson <input type="checkbox"/> others	
Comments		

