EDAN INSTRUMENTS, INC.

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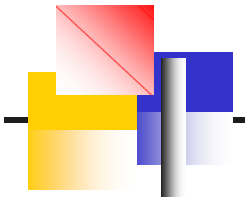

CADENCE

Fetal Monitor

User Manual

Manual Ver.: 1.6
Release Date: Aug. 2008
Part No.: MS1R-02284-V1.6

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Responsibility of the Manufacturer

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

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

NOTE: This device is not intended for home use.

⚠WARNING⚠: This device is not intended for treatment.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other

information to help qualified technician to maintain and repair some parts, which EDAN 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 a procedure.

Table of Contents

Chapter 1 Safety Guidance

1.1 Instruction for the Safe Operation

- The CADENCE Fetal Monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The CADENCE Fetal Monitor operates within specifications at ambient temperatures between 5°C and 40°C. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cm) clearance around the instrument for proper air circulation.
- The user must check 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.
- The monitor must be serviced only by authorized and qualified personnel. EDAN 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 periodic 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 protective categories against electric shock of the patient connections are:

 1) FHR1 2) FHR2 3) TOCO 4) MARK 5) FS

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

 IUP

This symbol indicates that the instrument is IEC/EN 60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock.

 DECG

This symbol indicates that the instrument is IEC/EN 60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock.

- The monitor described in this user manual is not protected against:

a) The effects of defibrillator shocks

b) The effects of defibrillator discharge

c) The effects of high frequency currents

d) The interference of electrosurgery equipment

1.2 Ultrasound Safety Guide

Z Fetal Use

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

Z Instructions for Use in Minimizing Patient Exposure

The acoustic output of CADENCE 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. The exercising of clinical judgment in the monitoring of low risk patients will avoid unnecessary insonation.

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 CADENCE Fetal Monitor 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**⚠: Disconnect power cord before changing fuse. Replace with the same rating and type only.

⚠**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 device should be installed by a qualified service engineer.

⚠**WARNING**⚠: **SHOCK HAZARD**-Do not remove the top panel covers during operation or while power is connected. Only authorized service personnel could remove the unit cover.

⚠**WARNING**⚠: Only connect the device to EDAN supplied or recommended accessories.

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

⚠**WARNING**⚠: Do not apply this monitor and other ultrasonic equipment simultaneously on the same patient, in case of the possible hazard caused by leakage current superposition.

⚠**WARNING**⚠: The fetal spiral electrode and intrauterine pressure catheter are disposable, and single use only-discard after use.

⚠**WARNING**⚠: The fetal spiral electrode should be removed from the patient before performing any electrosurgical procedure.

⚠**WARNING**⚠: The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.

⚠ **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/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. 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 valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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: Sterility can not be guaranteed if package of fetal spiral electrode is broken or opened.

CAUTION: Fetal spiral electrode is sterilized by gamma radiation. Do not re-sterilize.

CAUTION: Do not autoclave or gas sterilize the monitor, or any accessory.

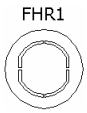
CAUTION: Turn off the system power before cleaning.

CAUTION: When washing the belts, the water temperature must not exceed 60℃.

CAUTION: **Electromagnetic Interference**-Ensure that the environment in which the fetal monitor is installed is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.

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

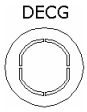
1.4 Definitions and Symbols



Socket for Channel 1 Ultrasound Transducer (for connection with ultrasound transducer, Protection Category B)

TOCO/IUP Socket (TOCO input socket-for connection with external contractions (TOCO) transducer, Protection Category B/ IUP input socket, for connection with intrauterine pressure connector, Protection Category BF).

Socket for Channel 2 Ultrasound Transducer (for connection with ultrasound transducer, Protection Category B)



Socket for DECG Cable (for connection with fetal ECG cable, Protection Category CF)

Socket for Remote Marker (for connection with the marker, Protection Category B)

EXT.1, Socket for Marking (for connection with the fetal stimulator, Protection Category B)

Power Socket

Fuse Socket

DB9 interface (for connection with wireless network module)

RJ45 Interface

Equipotential Grounding System

Attention, Consult Accompanying Documents

Type B Applied Part Symbol

Type BF Applied Part Symbol

Type CF Applied Part Symbol

This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

This symbol consisting of two parts, see below.

It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

It indicates that the equipment is put on the market after 13 August 2005.

P/N

Part Number

Serial Number

Date Of Manufacture

Manufacturer

Authorized Representative in the European Community

Recycle

Rx Only

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Chapter 2 Introduction

The CADENCE Fetal Monitor can provide different configurations according to different user requirements, FHR1 (US1), FHR2 (US2, optional), TOCO, MARK (remote marker), AFM (automatic fetal movement mark, optional), FS (fetal stimulator, optional), DECG (direct fetal ECG, optional), and IUP (intra-uterine pressure, optional). The user can select the monitors according to requirements.

Note: This user manual is written to cover all options. Therefore, your model may or may not have some of the parameters and functions described, depending on what was ordered. See ***FS-1 Fetal Stimulator User Manua***l for detailed information of fetal stimulator.

2.1 Intended Use

CADENCE Fetal Monitor can acquire fetal heart rate (FHR1 of channel 1/FHR2 of channel 2), maternal uterine contraction (TOCO, abdomen pressure) when pregnancies over 28 weeks. The CADENCE Fetal Monitor can be used for monitoring fetal heart rate during the antepartum period for NST (Non-stress Test) and CST (Contraction Stress Test).

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

CADENCE Fetal Monitor is a complete monitoring system for use during the management of labor (IUP and DECG as options). It provides accurate and reliable monitoring information, offering non-invasive ultrasound, external TOCO facilities, DECG (direct fetal ECG), and Intra-uterine Pressure (IUP) measurements.

2.2 General Information

CADENCE Fetal Monitor provides accurate and reliable monitoring information, using non-invasive ultrasound Doppler, external TOCO technique, and direct fetal ECG technique.

RJ45 interface is built, and the monitor can be connected with MFM-CNS Obstetrical Central Monitoring System via it. The monitor can be connected to the wireless network module via a DB9 interface, and the wireless network module will complete the data transmission of the monitor and the MFM-CNS Obstetrical Central Monitoring System.

The data collected and saved by the CADENCE Fetal Monitor can be analyzed and printed by the CADENCE Insight software running on PC.

2.3 Features

- Basic function: FHR1 (channel 1), FHR2 (channel 2, optional), TOCO, IUP (optional), DECG (optional)
- Automatic fetal movement mark (optional)
- Nine crystals broad band pulsed wave transducer
- High brightness bi-color numerical LED display
- Built-in long life thermal recorder
- Advanced autocorrelation digital signal processing technique
- Signal quality indicator and alarm function

- TOCO zero
- Recorder can be stopped by the user programmable timer
- Built-in DB9/RJ45 interface
- DECG arrhythmia logic judgment
- DECG range optional
- Wireless network module optional
- Vibrating operation marks can be recorded on CTG trends (when connected with a fetal stimulator by an audio cable, optional, the dual configuration hasn't this option)
- Lightweight, compact size

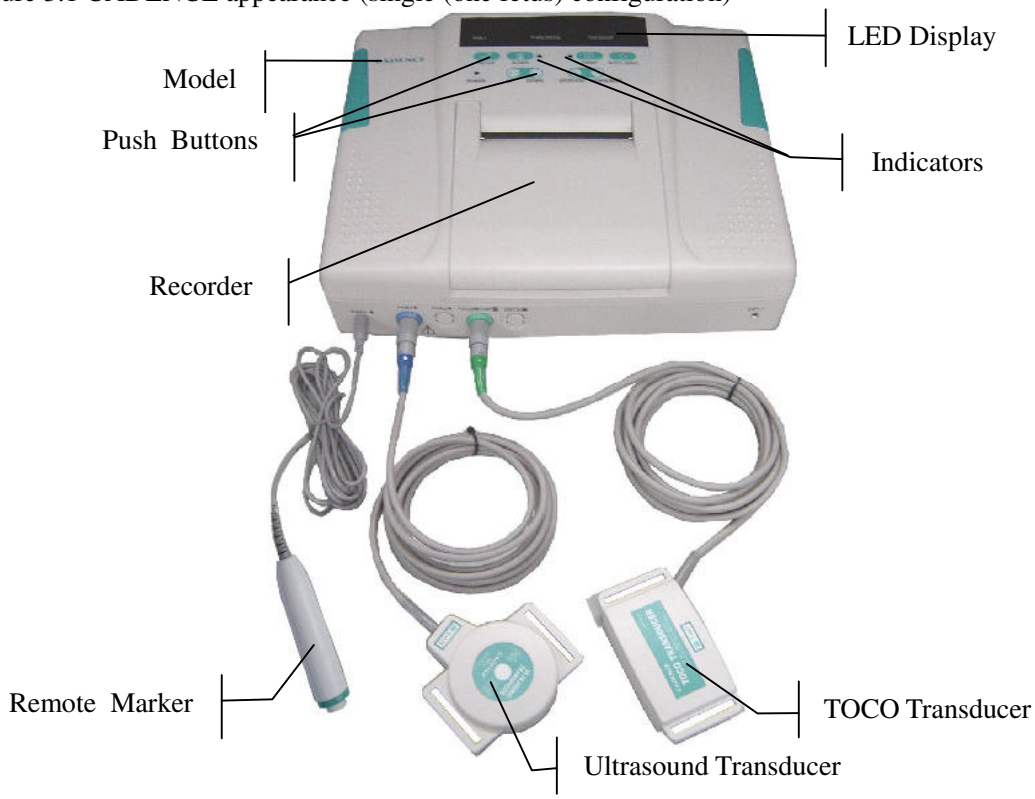
2.4 Ordering Information

Accessories supplied or approved by EDAN can be used with the CADENCE Fetal Monitor. See the following table for details.

Accessory (Spare Part)	**Manufacturer and Part Number**
Ultrasound Transducer	EDAN, MS3-01913
TOCO Transducer	EDAN, MS3-01916
Remote Marker	EDAN, MS3-107673
Fetal Stimulator	EDAN, MS9-17660
Thermosensitive Paper	EDAN, MS1-01921
Belt	EDAN, MS1-02264
Aquasonic Coupling Gel (0.25ltr bottle)	Parker Aquasonic 100, 01943 or M50-78001
Fuse T1.6AL 250V	EDAN, M21-64010
Intrauterine Pressure Cable Connecting Wire	EDAN, MS1-104151
Intrauterine Pressure Cable	EDAN, MS1-104152
Disposable Intrauterine Pressure Catheter	TYCO, 40000021/MS1-104153
Fetal ECG Cable	EDAN, MS2-12148
Disposable Fetal Spiral Electrode	TYCO, 31479549/MS0-02145
Disposable Electrode	TYCO, 50000095/MS0-02146

Chapter 3 Monitor and Accessories

Figure 3.1 CADENCE appearance (single (one fetus) configuration)

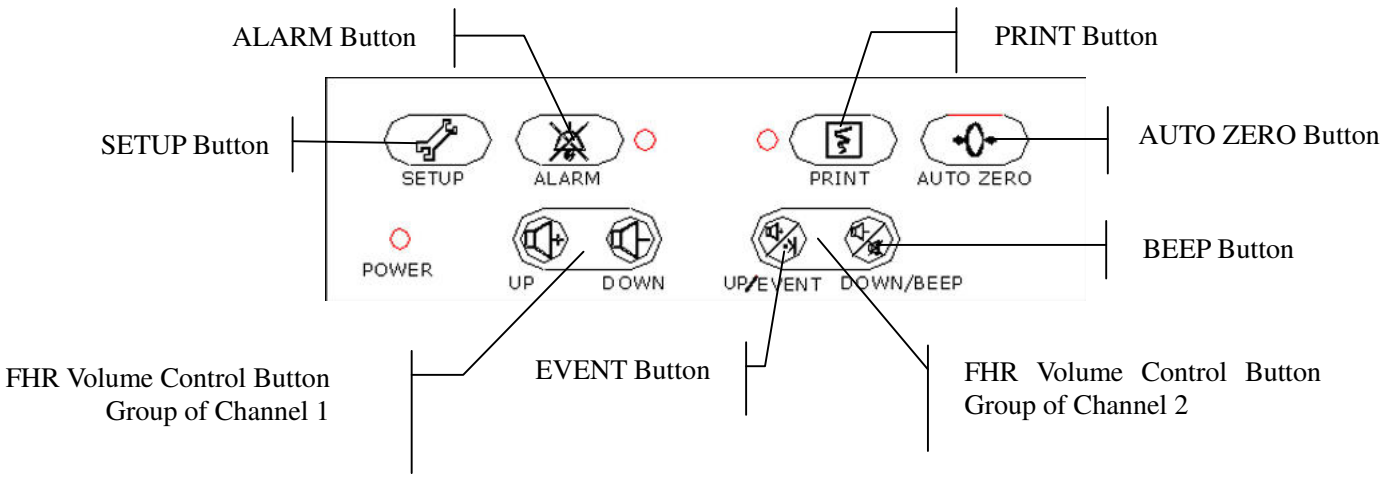


3.1 Monitor

3.1.1 Push Buttons

There are several push buttons with different functions on the front panel of the monitor. The diagram is shown as Figure 3.2, and their primary functions are as follows:

Figure 3.2 Push buttons

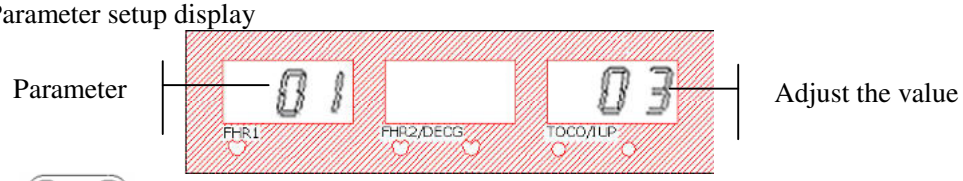


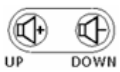
(1) SETUP Button 

Function: Press the button to enter setup mode, the numerical LED display is in red color. The color of the numerical LED may be red or green. While the monitor is in the setup mode, the numerical LED is all red; while the monitor is in the monitoring mode without physiological parameter alarm, the numerical LED is green, but if parameter such as FHR is in alarm situation, the color of the alarmed parameter is displayed in red until the alarm disappears.

Pressing this button will activate the function of setting parameters step by step (such as bed No., printing speed, system date, time, etc).
Press the button to enter setup mode, the first showing is as follows:

Figure 3.3 Parameter setup display



Then press 

to adjust the value up or down.
The parameters and the adjustable ranges are given in the following table.

Table 3.1 Parameters and adjustable values

Parameter	Meaning	Adjustable Value
01	Bed No.	1-32 adjustable
02	Printing Speed	1 (1cm/min), 2 (2cm/min), 3 (3cm/min) optional
03	Year	0-99 (i.e.: 2000-2099) adjustable
04	Month	1-12 adjustable
05	Day	1-31 adjustable
06	Hour	0-23 adjustable
07	Minute	0-59 adjustable
08	Second	0-59 adjustable
09	Upper Limit of Alarm	160bpm-180bpm adjustable; the default is 160bpm, and the interval is 10bpm.
10	Lower Limit of Alarm	90bpm-120bpm adjustable; the default is 120bpm, and the interval is 10bpm.
11	Alarm Delay	10-40 (seconds) adjustable; The default is 30 seconds, and the interval is 5 seconds.

Parameter	Meaning	Adjustable Value
12	AFM Gain	1-4 adjustable; The default is 3, and the interval is 1
13	AFM Threshold	0-100 adjustable; The default is 30, and the interval is 10
14	Printing Timer	0-60 (minutes) adjustable. The default is 0 minute, and the interval is 10
15	FHR2/DECG Printing Trace Offset	0-2 adjustable; 0: no offset, 1: +20bpm, 2: -20bpm, and the default is 0
16	Record Paper Type	1, 2 optional; 1: international standard record paper, and the range is 50bpm-210bpm, 20bpm/cm, 2: USA standard record paper, and the range is 30bpm-240bpm, 30bpm/cm; The default is 2
17	Network Protocol	0, 1, 2 are optional. 0: RS485 network protocol V1.0; 1: RS485 network protocol V1.1; 2: Insight protocol V1.2. The default is 1
18	Device Configuration	0, 1, 2 optional; 0: single, 1: dual, 2: IUP and DECG. The default is 0
19	DECG Calculation Mode	1, 2 optional; 1: Transient calculation mode, 2: Twice average calculation mode. The default is 1
20	DECG Range	1, 2 optional; 1: 50bpm-210bpm, 2: 30bpm-240bpm. The default is 2
21	DECG Arrhythmia Logic Judgment	1, 0 optional; 1: Enable DECG arrhythmia logic, ±25bpm anti-artificial, 0: Disable DECG arrhythmia logic. The default is 1
22	ECG Leads Selection	1, 2, 3 optional; 1: Lead-I, 2: Lead-II, 3: Lead-III. The default is 2

Note: The parameter 16 to 18 are only be set by the manufacturer or service engineer, and can not be operated by the user.

Press **AUTO ZERO** button to exit from the setting quickly.

Note: When no operation happened within 30 seconds in the setup mode, the monitor will be switched to the monitoring status of displaying FHR1, FHR2/DECG, and TOCO/IUP automatically.

(2) ALARM Button 

Function: Enable/Disable audio alarm when FHR is in alarm situation.

Power on, the alarm indicator status is shut off, no audio alarm.

Press the button to enable audio alarm, the alarm indicator will become green, when FHR (FHR1/FHR2/DECG) is in alarm situation, alarm sound “Di, Di, Di” appears and alarm indicator becomes red and flash.

Press the button again to silence audio alarm, the alarm indicator is shut off. When FHR (FHR1/FHR2/DECG) is in alarm situation, alarm sound does not appear, but alarm indicator becomes red and flash. When alarm condition disappears, the alarm indicator will be off.

When FHR (FHR1/FHR2/DECG) is less than the lower limit or higher than the upper limit of alarm over the time of alarm delay, alarm signal will be given out.

(3) PRINT Button 

Function: Enable/Disable printing.

Power on, the print indicator status is shut off after self-test, and no printing.

When pressing the **PRINT** button, the print indicator will be green and the recorder works. If print indicator is still off, and the recorder gives out alarm audio, the printing function can not be executed and the operation is failed.

The following reasons may cause the failure of printing:

- The monitor is still in the process of self-test, and the test baseline printing has not been finished. After the recorder has finished printing test baseline, it begins to print by pressing the **PRINT** button.
- Just press the **PRINT** button to end the printing, the last row output hasn't been completed.
- The ultrasound transducer or DECG cable connector is off.
- Recorder is out of paper.
- Recorder failure.

When pressing the **PRINT** button once more, the print indicator will be off and the recorder will stop working (at the moment, the recorder may reset after outputting the last row).

(4) AUTO ZERO Button 

Function:

1) Adjust the external TOCO contractions trace/value to reference point 10 (external monitoring contractions) or adjust the IUP trace/value to reference point 0 (internal monitoring contractions) when the system is not in the status of setting.
2) Exit from the setting quickly when the system is in the status of setting.

When in the status of monitoring, after pressing the **AUTO ZERO** button, the symbol "0" will be printed at the trace.

(5) Volume Control Button Group 

Function:

1) For dual configuration, press one of the two buttons to select fetal heart audio channel (press 

to select fetal heart audio coming from channel 1, press 

to select fetal heart audio coming from channel 2, the default fetal heart audio is that of channel 1).
2) Press 

(dual configuration) to adjust the volume of the loudspeaker up or down (0-10 levels adjustable).
3) When in the setup mode, press 

to adjust the value of parameter selected.

Up: press to increase the sound level or the value of parameter selected.

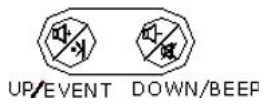
Down: press to decrease the sound level or the value of parameter selected.

Notes:

1) When volume has reached to its limit, press **up** or **down**, a high frequency "Di" will

be given out.

2) Do not press any button continuously, otherwise, uncertain result will happen.
3) Press any button, if succeed, the speaker will make a sound of "Do"; If failed, the speaker makes no sound.
4) For single configuration, the **Volume Control Button Group of Channel 2** does not work.
5) For dual configuration, when one **Volume Control Button Group** is pressed, the other fetal audio channel will be mute automatically.

(6) EVENT Button (Optional) 

UP/EVENT Button Function: Record event at the trace.

If the physician wants to make a label for patient event, he/she may press this button to mark. At the moment, the symbol "↓" will be printed on the record paper.

(7) BEEP Button (Optional) 

DOWN/BEEP Button Function: Enable/Disable DECG sound.

3.1.2 Indicators

Figure 3.4 Indicators

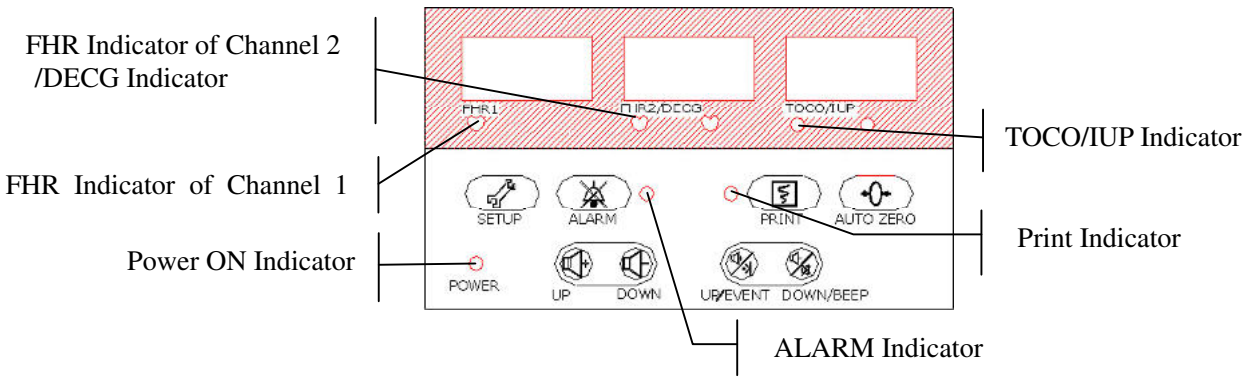


Table 3.2 Indicator description

Indicator	Status of Indicator	Meaning
FHR Indicator (including channel 1 and channel 2)	Green and flash	Fetal heart signal quality is optimal
	Orange and flash	Fetal heart signal quality is unacceptable
	Off	Ultrasound transducer is off
DECG Indicator	Green and flash	DECG signal quality is optimal
	Orange and flash	DECG signal quality is unacceptable
	Off	DECG cable connector is off

TOCO Indicator	Green	TOCO pressure is at the range from 0 to 100
	Orange	TOCO pressure equals to 0 or is over 100
	Off	TOCO transducer is off
IUP Indicator	Green	Intrauterine pressure is at the range from 0 to 100
	Orange	Intrauterine pressure equals to 0 or is over 100
	Off	Intrauterine pressure connector is off
Print Indicator	Green	Enable printing
	Green and flash	No paper or recorder error
	Off	Disable printing
Alarm Indicator	Green	Enable audio alarm
	Red and flash	Alarm
	Off	Disable audio alarm
Power ON Indicator	Green	Power on
	Off	Power off

3.1.3 Recorder

If the transducers and connectors are connected well, press 

to print. The date, time, FHR type, TOCO type, paper speed, bed No., and the offset of FHR2/DECG trace, etc. will be printed at the beginning of the paper. The offset of FHR2/DECG trace is the preset FHR2/DECG printing trace offset (-20bpm, 0bpm or 20bpm), which means that FHR2/DECG trace is 20bpm lower than its actual position, or actual position, or 20bpm higher than its actual position, so 20bpm should be added, unchanged, 20bpm should be subtracted when calculating the numerical value of FHR2/DECG. After printing the information mentioned above, “FHR1”, “FHR2”/“DECG”, “AFM”, “TOCO ext”/“TOCO int” will be printed at the relevant trace. In the process of later printing, the recorder will print system time once every 10 minutes and “FHR1”, “FHR2”/“DECG”, “AFM”, “TOCO ext”/“TOCO int” once every 8 minutes (see Figure 3.5 and Figure 3.6).

FHR2/DECG trace is a broad one.

If pressing the **AUTO ZERO** button, the symbol of TOCO zero is printed. If the **EVENT** button is pressed, the symbol of “↓”will be printed at the trace. If alarm occurs, the symbol “” will be printed at the trace.

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

Note: The printing speed and FHR2/DECG printing trace offset can not be changed in the process of printing.

Figure 3.5 An example of printing pattern (USA standard record paper)

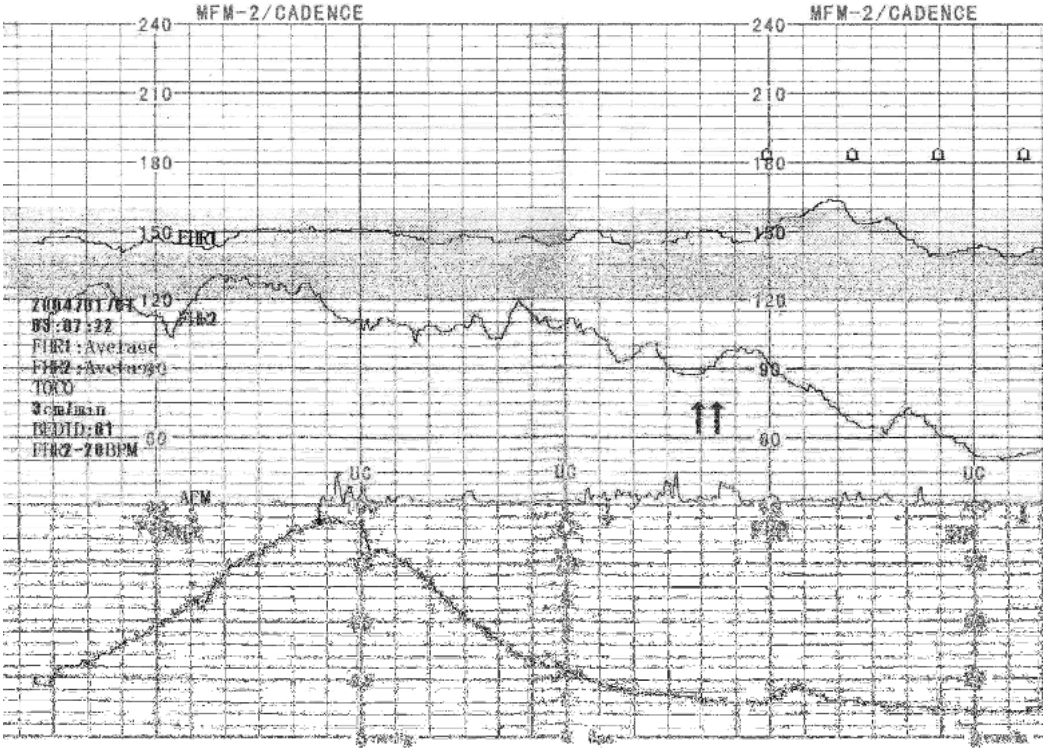
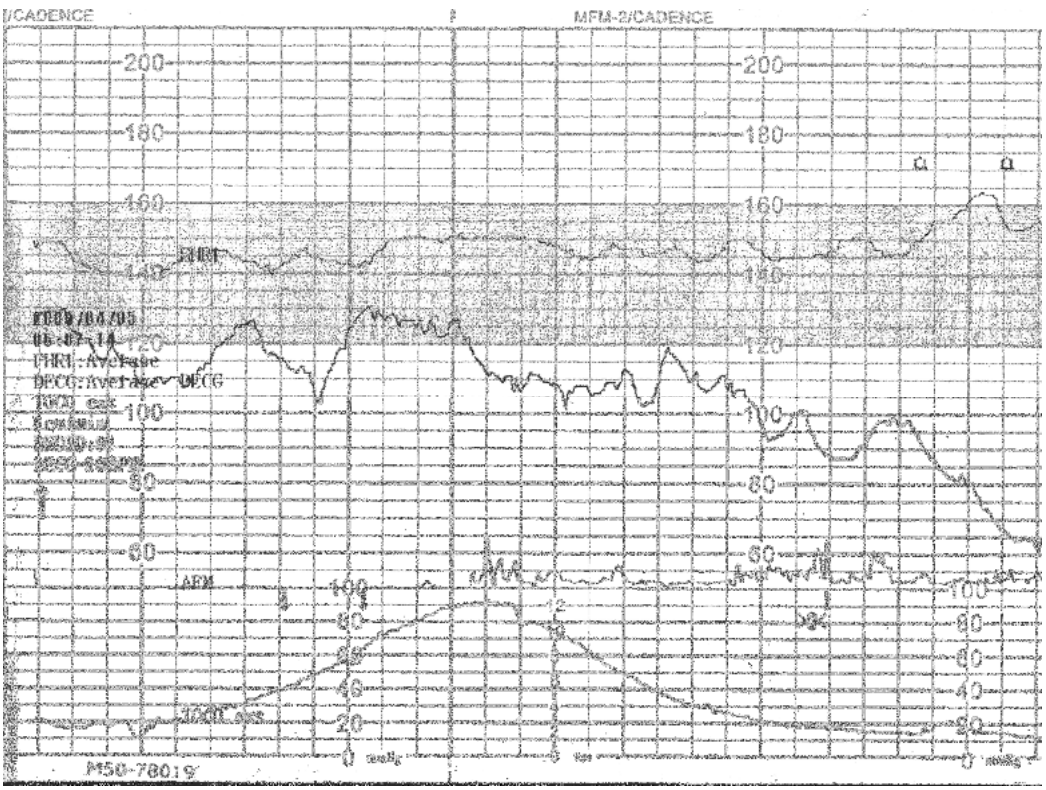


Figure 3.6 An example of printing pattern (international standard record paper)



: Indicates the alarm status information of monitoring.

: Indicates the fetal movement event marked by the patient.

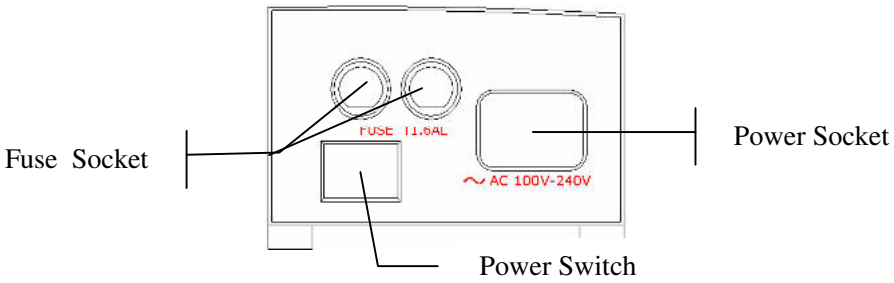
: Indicates the event marked by the physician.

: Indicates the information of TOCO zero.

Note: When paper is used up, the recorder will stop printing and the data of waiting printing will be kept in the memory. After feeding paper again, you can press the **PRINT** button to continue. The current printing data will lose when ultrasound transducer or DECG cable connector falls off, or power off.

3.1.4 Sockets on the Right Side of the Monitor

Figure 3.7 Sockets on the right side of the monitor



Power Switch (O/1): A.C. mains On/Off switch. O=Off, 1=On
Fuse Specification: Size: Φ5mm*20mm Model: T1.6AL 250V

Power Socket: Input socket for the A.C. mains supply

Rated A.C. supply voltage is a.c. 100V-240V.

~ : Alternating current

3.2 Transducers and Cables

The ultrasound transducer(s) and TOCO transducer, IUP cable connector, DECG cable connector, and remote marker are attached to the front panel of the monitor. Each cable has a tab located on the connector housing to insure proper insertion into the appropriate socket on the monitor.

3.2.1 Ultrasound Transducer

This multi-crystal, broad beam ultrasound transducer is used for monitoring fetal heart rate (FHR). The ultrasound transducer operates at a frequency of 2.0MHz. Put the ultrasound transducer on maternal abdomen to transmit lower energy ultrasound wave to fetal heart, then receive the echo signal from it.

Figure 3.8 Ultrasound transducer

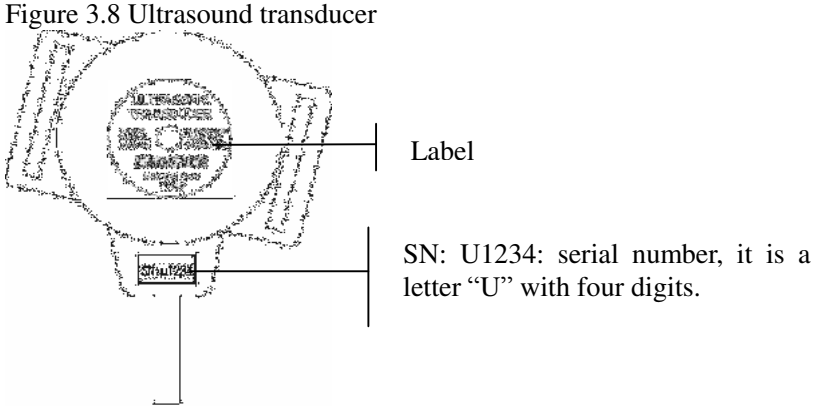


Figure 3.9 Label of ultrasound transducer

The main information on the label is as follows.

PM 2.0: P means pulsed wave, M means multicomponent, 2.0 means central frequency is 2.0 MHz.

MS3-01913: EDAN part number for the ultrasound transducer.

A1: Version number for the ultrasound transducer.

DO NOT IMMERSE IN WATER, CLEAN WITH SOAP AND WATER ONLY: the CAUTION message.

3.2.2 TOCO Transducer

This transducer is a tocotonometer 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.

Figure 3.10 TOCO transducer

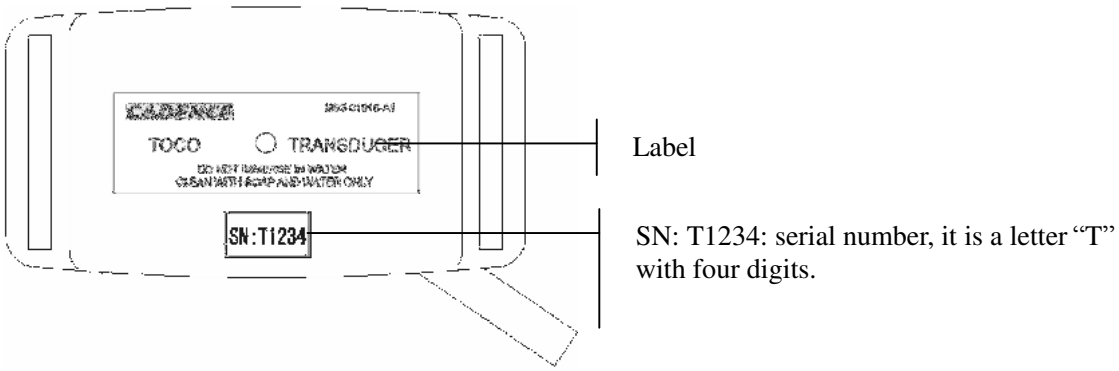


Figure 3.11 Label of TOCO transducer

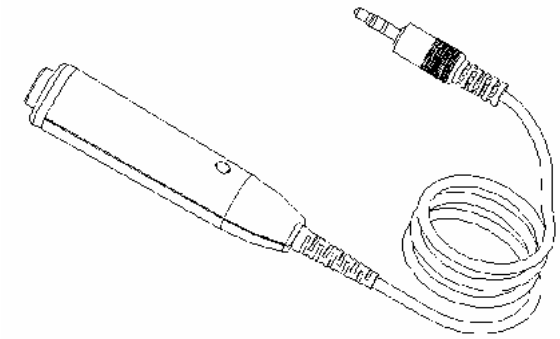
The main information on the label is as follows.

MS3-01916: EDAN part number for the TOCO transducer.
A1: Version number for the TOCO transducer.
DO NOT IMMERSE IN WATER, CLEAN WITH SOAP AND WATER ONLY: the CAUTION message.

3.2.3 Remote Marker

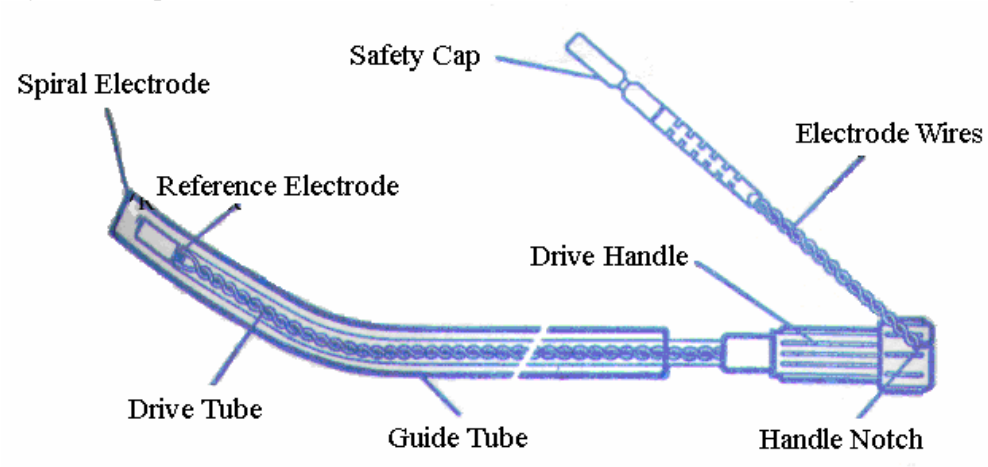
The remote marker is a hand-held switch operated by patient, shown here. The mother is normally instructed to push down this switch when feeling fetal movement. The remote marker will add an event mark to the record paper.

Figure 3.12 Remote marker



3.2.4 Fetal Spiral Electrode

Figure 3.13 Spiral electrode



Chapter 4 Getting Started

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. Keep the package for possible future transportation or storage. Check the components according to the packing list.

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

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

4.2 Connect the Power Cable

- Make sure the AC power supply of the monitor complies with the following specification: a.c.100V-240V, 50/60 Hz.
- Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor (see Figure 3.7). Connect the other end of the power cable to a grounded 3-phase power output special for hospital usage.
- Connect to the ground wire if necessary.

4.3 Connect with Network

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

4.4 Connect with PC

Connect RJ45 interface of the monitor with PC via special RS232 cable provided by EDAN.

4.5 Connect with Wireless Network Module

Connect the DB9 interface of the monitor with one end of RS232, and connect the DB9 interface of the wireless network module with the other end of RS232. When CADENCE Fetal Monitor and the MFM-CNS Obstetrical Central Monitoring System work, the wireless network module will complete the transmission of data between them.

4.6 Feeding Paper and Removing Paper Jam

Feeding Paper

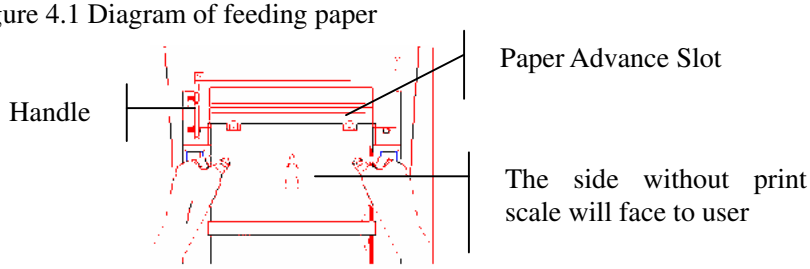
If the paper is used up or paper jam happens, you have to feed paper into the recorder, the operation procedure is as follows:

1) Push the  position simultaneously on both sides of the recorder cover to open it.
2) Take out the “Z” type thermosensitive paper from the wrapper. Put the green safety band to

the left and the face of the paper downward. Put the paper into the box.

3) Feed the record paper into the slot of the recorder (Figure 4.1) and the paper will go out from the notch automatically.

Figure 4.1 Diagram of feeding paper



4) Adjust the paper length by the gear beside the handle if required.

5) If the paper is slantwise, you must pull the handle up and push the gear to force the paper out, push the handle down and feed paper again.

6) After closing the cover, make sure that the paper can go out from the paper notch.

Notes:

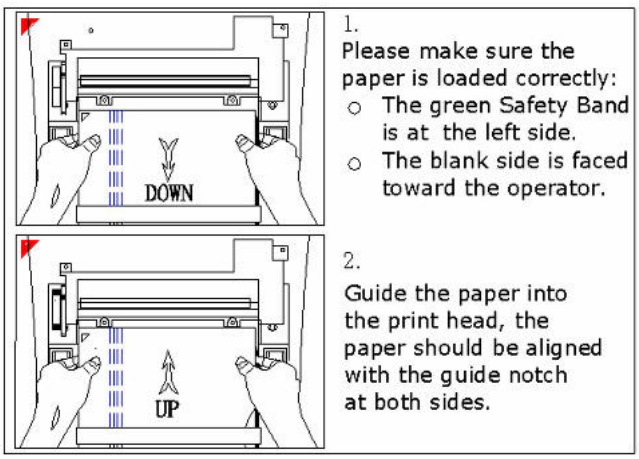
1) When feeding paper, the black handle must be down. If jam happens, pull up the handle first, and push the gear to force the paper out. Then feed the paper again.

2) The paper going out from the notch should be aligned, otherwise, the data will be inaccurate or paper jam will happen.

3) Only use EDAN approved paper to avoid poor printing quality, deflection, or paper jam.

4) The printing function can't be executed when ultrasound transducer or DECG cable connector falls off.

Figure 4.2 Diagram of feeding paper correctly



Note: Be careful when inserting paper. Avoid damaging the thermosensitive print head. Unless inserting paper or shooting troubles, do not leave the recorder door open.

Removing Paper Jam

When the recorder functions or sounds improperly, open the recorder door to check for a paper jam. Removing the paper jam in the following way:

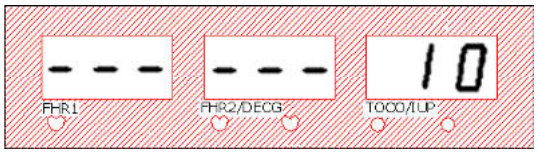
- Cut the record paper from the paper notch edge.
- Open the door of recorder, and revolve the left gear of the recorder.
- Pull the paper from below.
- Reload the paper.

4.7 Power on the Monitor

⚠**WARNING**⚠: If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.

Turn the power switch ON, you can hear the short sound of "Do", and see that the power ON indicator is lit. The numeral LED will flash in red color and green color to test it. At the same time, the system will print a test baseline. About ten seconds or so, the system will enter monitoring screen after self-test, and you can perform normal monitoring now.
After self-test, the numeral LED will display as Figure 4.3 (dual configuration).

Figure 4.3 Numeral LED display status after self-test (external TOCO)



4.8 Connect Transducers and Cables

Prior to every time use, check for visible damages of the transducers and cables. If damage is found, replace them at once.

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

Note:

1) Only connect the transducers and cables supplied by EDAN to the monitor.

2) Place the arrow symbol on the transducer connector on top when connecting them to the monitor.

3) Be gentle when connecting and using transducers to avoid mechanical damage to them.

Chapter 5 Monitoring

5.1 Ultrasound Monitoring of FHR

Ultrasound monitoring 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.

Ultrasound monitoring can be used for antepartum monitoring.

Parts Required

1) Ultrasound transducer 2) Aquasonic coupling gel 3) Belt

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 is properly connected.

Set the current heart rate channel to US1, 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.

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 in the screen.

3) Acquiring Twins' Heart Rates Signal

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

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

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

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 second fetal heart is heard.

The elasticity of belt can be adjusted, which make the patient monitored in the comfortable situation. Also verify the position of transducer one has not changed.

Verify the monitor is displaying fetal heart rate values for both fetuses.

The signal quality can be reflected by the color of fetal signal quality indicator

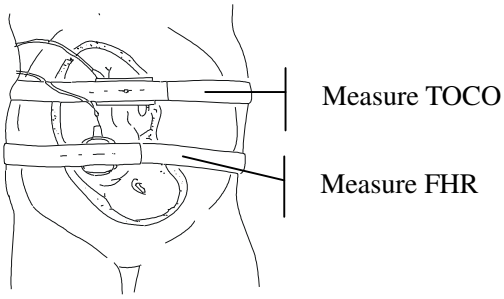
Good: green and flash

Poor: orange and flash

4) Monitor Adjustments

Readjust the volume settings for the desired loudness.

Figure 5.1 Ultrasound transducer & TOCO transducer positioning



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

Notes:

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.

5.2 Fetal ECG Electrode Monitoring of FHR

Contraindications

The fetal spiral electrode can be used when amniotic membranes adequately ruptured and sufficient cervical dilatation assured. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique.
The fetal spiral electrode should not be applied to the fetal face, fontanels or genitalia.
Do not apply when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. Application when fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhea is not recommended but may be acceptable if a clear benefit to the fetus or mother can be established.

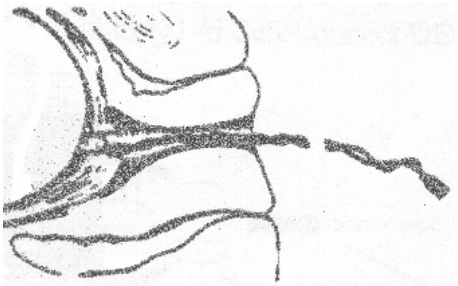
Parts Required

1) Fetal ECG cable 2) Disposable fetal spiral electrode 3) Attachment pad

Operation Procedure

1) Perform a vaginal examination and clearly identify the fetal presenting part. Using a sterile technique to attach the fetal spiral electrode to the fetal presenting part as described in the **Directions for Use of Fetal Spiral Electrode** at this section.

Figure 5.2 Connection for fetal spiral electrode



⚠**WARNING**⚠: Do not plug the fetal spiral electrode wire into the power socket.

2) Fix an attachment pad at fetal ECG cable.
3) Thoroughly clean is on patient's thigh and ensure that it is dry. Remove the release liner from the back of the pad. Place the pad on maternal thigh and press firmly in place (Read **Prepare the Patient's Skin Prior to Placing Electrodes** at this section first).
4) Connect fetal spiral electrode with fetal ECG cable.
5) Switch on the power of the monitor.
6) Insert connector of fetal ECG cable into the DECG socket at the monitor.
7) Check setup of DECG arrhythmia logic.

The transient heart rate change that equals to or is greater than±25bpm is not recorded when enabling the DECG arrhythmia logic. The recording will resume when beat drops within the limits.

The monitor will display all the recorded fetal heart beats when disconnecting DECG arrhythmia logic. If you have doubts about arrhythmia of the fetus, disconnect the DECG arrhythmia logic.

Prepare the Patient's Skin Prior to Placing Electrodes

The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

Detach Fetal Spiral Electrode

To detach the fetal spiral electrode, rotate it counterclockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin.

⚠**CAUTION**⚠: Do not mistake the higher maternal heart rate for fetal heart rate.

Notes:
1) If the DECG arrhythmia logic is disconnected during monitoring, remember to connect it later.
2) If there is any doubt as to the presence of a fetal heart signal with ECG, check with the ultrasound transducer on the mother or with a separate diagnostic instrument. The presence of an audible Doppler heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of fetal life.
3) After connection of electrodes a few minutes should be allowed for stabilization of the electrode and fetal tissue. It is essential that the ECG signal electrode is in good contact with the fetal presenting part.

Directions for Use of Fetal Spiral Electrode

1) Remove from package, leaving the electrode wires locked in the handle notch.
2) Gently form the guide tube to the desired angle.
3) With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.
4) Holding the drive handle, ensure the spiral electrode is retracted approximately one inch (2.5 cm) from the distal end of the guide tube.
5) Place the guide tube firmly against the identified presenting part.
6) Maintain pressure against the fetal presenting part with guide and drive tubes. Turn the drive tube by rotating the drive handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the drive handle indicates attachment. This will usually occur after one complete rotation.
7) Release the electrode wires from the handle notch and straighten them. Slide the drive and guide tubes off the electrode wires.
8) Insert the safety cap into fetal ECG cable.

5.3 Dual Heart Rate Monitoring

Simultaneous monitoring of twins using two ultrasound channels (see section 5.1 for the operation) or using one ultrasound channel (see section 5.1 for the operation) and the DECG (during labor) channel (see section 5.2 for the operation).

Notes:
1) The monitoring results are two different fetal heart rates. If the two channels record the same fetal heart rate, one ultrasound transducer must be moved till the second fetal heart rate is found.
2) In order to distinguish the two fetal heart rates recorded by different channels, the offset of FHR2/DECG trace is the printing trace offset preset.
3) If two ultrasound channels are used to monitor the twins, only the audio signals of one fetus can be heard. The audio signal for each fetus can be heard by selecting the appropriate channel with the **Volume Control Button Group**.
4) If one ultrasound channel and the DECG channel are used to monitor the twins, only the volume of channel 1 FHR can be adjusted.
5) Avoid mistaking maternal heart rate for the fetal heart rate.

5.4 Monitoring Uterine Activity

Use a TOCO transducer to external measure uterine activity, or use an intrauterine pressure catheter to internal measure uterine activity (Only ruptured membranes and adequate dilation can the internal contractions be monitored).

5.4.1 Monitoring Contractions (External)

Monitoring of the external contractions is obtained through TOCO transducer on abdominal wall.

Parts Required

1) TOCO transducer 2) Belt

Operation Procedure

1) Preparing the Monitor

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

Check the TOCO transducer to verify proper attachment to the monitor.

2) Acquiring Uterine Activity Data

Place another belt around the abdomen. Attach the buckle of the TOCO transducer to the belt.

Do not use aquasonic coupling gel. Wipe off any gel present on abdomen around this area.

Fix the transducer. The transducer is retained on the midline half-way between the mother's fundus and the umbilicus (see Figure 5.1 for the positioning of the external TOCO).

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. If the belt is over tightened, the contraction peaks may have a flat-top at less than 100 on the TOCO scale. If the belt is under tightened, the position of the transducer may wander and cause unusable readings. Readjust the belt pressure as needed.

3) Monitor Adjustments

Press the **AUTO ZERO** button to adjust the value to the baseline. This should be done during non-contraction intervals.

⚠**WARNING**⚠: Under no circumstances are transducers to be used to monitor patients under water.

Notes:

1) Do not use aquasonic coupling gel on the TOCO transducer or transducer contact area.
2) Check the function by TOCO transducer, and observe the change of relevant value.

5.4.2 Monitoring Contractions (Internal)

Parts Required

1) Disposable intrauterine pressure catheter ACCU-TRACE™ IUPC ("IUPC" for short)

2) Reusable intrauterine pressure connecting cable ("connecting cable" for short)

3) Reusable intrauterine pressure cable ("IUP cable" for short)

Directions for Use of IUPC

Preparation

1) Gather supplies: ACCU-TRACE IUPC, reusable cable, and amniounfusion supplies if needed.
2) Open the sterile ACCU-TRACE IUPC package.

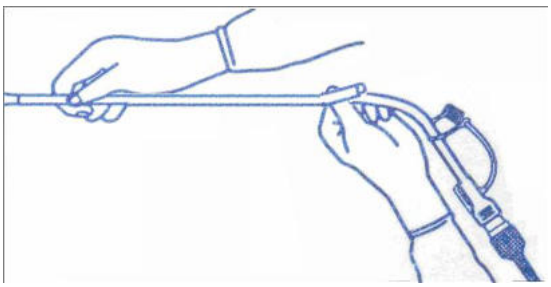
Insertion

NOTE: This product is designed for use with the introducer.

3) Using aseptic technique, remove the catheter from the package.
4) Perform vaginal exam to insure ruptured membranes and adequate dilation.
5) Advance the catheter tip to the cervical os along the examination hand, using the hand as a guide. Do not advance the introducer through the cervix.
6) Continue to gently advance the catheter tip through the cervical os and feed the catheter into the intra-amniotic cavity until the 45cm mark is at the introitus. If the 45cm mark is not clearly visible, stop advancing when the ● symbol on the catheter meets the introducer.

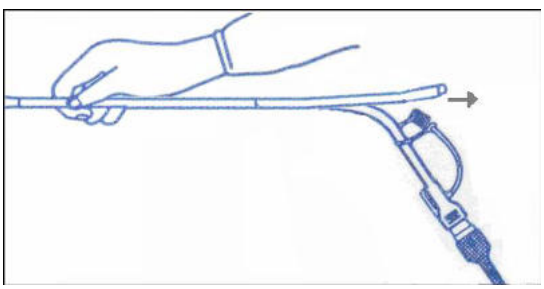
   NOTE: For easier insertion, do not twist the catheter in the introducer.
7) The IUPC may spontaneously fill with amniotic fluid. This can be seen in the clear lumen of the catheter. The filter cap will prevent the amniotic fluid from leaking.
8) Slide the introducer out of the vagina along the catheter. When the introducer is completely out of the vagina, slide thumb between catheter and introducer tab, which will begin to separate the introducer from the catheter. (See figure 5-3)

Figure 5-3 Separate the introducer



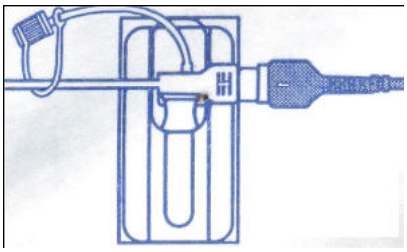
9) Anchoring the catheter in place with one hand, pull the introducer straight back off the catheter. (See figure 5-4)

Figure 5-4 Remove the introducer



10) Remove the liner from the adhesive pad, then adhere the pad to the patient's skin. Secure the catheter by placing the catheter attachment strap to the adhesive pad. (See Figure 5-5).

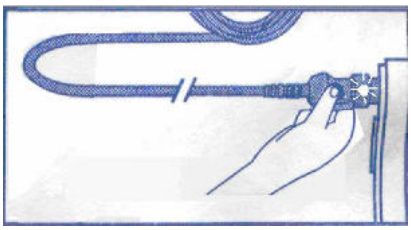
Figure 5-5 Secure the adhesive pad to mother



Rezeroing the System During Monitoring

1) With the catheter connected to the IUP cable, momentarily pressing the re-zero button on the pressure cable (See Figure 5-6). The green light on the cable will flash for five seconds.

Figure 5-6 Rezeroing the system



2) During this five seconds, adjust the monitor to zero by pressing **AUTO** key.

⚠WARNING⚠:

Z Before insertion, placental position should be confirmed, amniotic membranes adequately ruptured and sufficient cervical dilatation assured.

Z Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use with caution when uterine infection is present.

Z If resistance is met at any time during insertion, withdraw the catheter slightly and try at a different angle. Forced insertion may result in patient's discomfort or injury.

◈CAUTION◈:

Z Since procedures vary according to hospital needs/ preferences, it is the responsibility of the hospital staff to determine exact policies and procedures for both monitoring and amnioinfusion. The safe and effective use of the IUPC depends on the skill of the clinician who applies /use it.

Z Read *Directions For Use of Disposable IUPC* prior to insertion. The Product has been sterilized by gamma radiation and is sterilized and non-pyrogenic unless package is broken or open. Do not re-sterilize it.

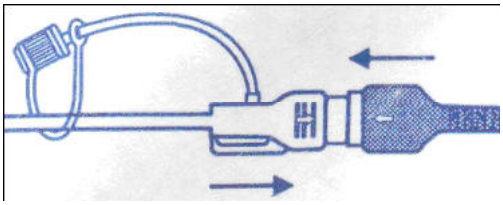
NOTE:

Refer to the instruction on the package for more information about using the IUPC.

Operation Procedure

1) Insert IUPC using the procedure described in s ***Directions For Use of Disposable IUPC***.
2) Connect the IUPC to the IUP cable. (See figure 5-7)

Figure 5-7 Connect catheter to pressure cable



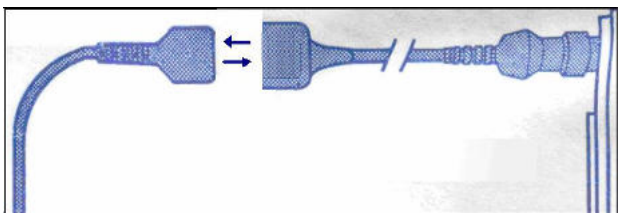
3) Connect the IUP cable to the connecting cable. (They might have already been well connected in the package.)
4) Plug the connecting cable to the TOCO/IUP socket of the monitor.
5) Momentarily pressing the re-zero button on the IUP cable. The green light on the cable will flash for five seconds. During this time, zero the monitor by pressing the **AUTO** key. Make sure the display value and trace are both "0".
6) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
7) Wash timely during monitoring. A spike on the tracing will respond to the washing.

Checking Intrauterine Pressure Cable Function

To test an IUP cable's function:

1) Disconnect the catheter from the cable. Insert the cable check plug into the catheter end of the cable. (See Figure 5-8).

Figure 5-8 Test the Pressure Cable



2) Verify that the green light is continuously lit (no flashing).
3) If the light does not illuminate, replace the cable.

NOTE: If the light is flashing, verify that the cable check plug is inserted completely into the cable.

⚠WARNING⚠:

The cable test function is not meant to check the accuracy of the system, only to confirm cable function.

5.5 Remote Marker Recording of Fetal Movement

Insert the remote marker cable into its socket. When FHR is monitored, the mother takes the remote maker in her hand. She operates the hand-held remote marker press-switch when sensing fetal movement. At the moment, the symbol "↑" of fetal movement will be printed on the record paper.

5.6 After Monitoring

Operation after Monitoring

1) Remove transducers, electrodes, etc. from patient. Wipe transducer with a soft cloth to remove remaining aquasonic coupling gel.
2) Tear the paper at the folding place.
3) Switch off the power of the monitor.

Chapter 6 Maintenance, Care and Cleaning

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.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

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

6.2 Care and Cleaning of Monitor

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

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

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

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

CAUTION:

1) Although the monitor is chemically resistant to most common hospital cleansers and non-caustic detergents, different cleansers are not recommended and may stain the monitor.
2) Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.

3) Don't use strong solvent, for example, acetone.
4) Never use an abrasive such as steel wool or metal polish.
5) Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.
6) Avoid pouring liquids on the monitor while cleaning.
7) Don't remain any cleaning solution on the surface of the monitor.

Cleanser

The following cleaning solutions are recommended for monitor and accessories:

	Soft Soap	Tensides	Ethylate	Acetaldehyde
Monitor	√	√	√	√
Ultrasound Transducer	√	√	√	√
TOCO Transducer	√	√	√	√
Belt	√	√	√	√
Remote Marker	√	√	√	√
Intrauterine Pressure Cable	√	√	√	√
Fetal ECG Cable	√	√	√	√

Notes:

1) The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
2) EDAN has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

6.3 Care and Cleaning of Accessories

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**◈:

1) Be sure that the cleaning solutions and transducers do not exceed a temperature of 45°C.
2) Do not autoclave the transducers and cables or heat them above 70°C.

6.3.1 Cleaning of Transducers

Follow these steps to clean a transducer:

1) Clean the transducer with a cloth soaked in a solution of soap and water, or a cleaning solution. Do not immerse the transducer in the solution. Use only the following cleaning solutions:
   - BURATON LIQUID
   - MIKROZID
   - ETHANOL 70%
   - SPORACIDIN
   - CIDEX

   When using a cleaning solution, follow the manufacturer's directions carefully to avoid damaging the transducer.
2) Wipe the transducer with a cloth damped with water.
3) Wipe the transducer with a clean, dry cloth to remove any remaining moisture.

6.3.2 Cleaning of Fetal ECG Cable

The fetal ECG cables must never be immersed, soaked, or cleaned with harsh chemicals. The recommended cleaning method of the cables is a cloth wipe using ordinary alcohol-free hand soap or USP green soap tincture. After cleaning the cables, they should be wiped with water using a clean damp cloth and then with a clean dry cloth.
Do not autoclave, Ethylene Oxide (EtO), or stem sterilize the fetal ECG cables.

6.4 Cleaning of Recorder

The recorder platen, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when traces become faint).

To do this:

1) Clean the recorder platen with a lint-free cloth and soap/ water solution.
2) With the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.
3) Check the paper sensing mechanism is free of dust.

6.5 Cleaning of Belt

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

6.6 Sterilization

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

	Ethylate	Acetaldehyde
Monitor	√	√

Ultrasound Transducer	√	√
TOCO Transducer	√	√
Intrauterine Pressure Cable	√	√
Fetal ECG Cable	√	√

CAUTION

1) Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.
2) Do not let liquid enter the monitor.
3) No part of this monitor can be subjected to immersion in liquid.
4) Do not pour liquid onto the monitor during sterilization.
5) Use a moistened cloth to wipe up any agent remained on the monitor.

6.7 Disinfection

To avoid extended damage to the equipment, disinfection is only recommended when stipulated as necessary in the hospital maintenance schedule. Disinfection facilities should be cleaned first.
Do not use Povodine®, Sagrotan®, Mucovit® or strong solvent.

Do not use strong oxidant, for example, bleaching powder.

Do not use bleaching powder with sodium hypochlorite.

Do not use sterilant with iodide.

Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.

Do not use EtO gas or formaldehyde to disinfect the monitor, transducer, and cable.

WARNING: Do not autoclave the transducers, or heat them.

CAUTION: Check carefully after cleaning, sterilization, or disinfection of monitor and accessories. If aging and damage are found, please do not use them to monitor.

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

6.8 Care of Record Paper

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°C;
Do not exceed a relative 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.

Appendix 1 Product Specifications

A1.1 Monitor

Physical Characteristics

Dimensions: 330mm x270mm x100mm

Weight: 3.5 kg or so

Safety

Comply with: IEC/EN 60601-1, IEC/EN 60601-1-2

Anti-electric Shock Type: Class I equipment without internal power supply

Anti-electric Shock Degree:

FHR1, FHR2, TOCO, MARK, FS	B
IUP	BF
DECG	CF

Degree of Protection against Harmful Ingress of Water: Non-protected

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

Disinfection/Sterilizing Method: Refer to this user manual for details

EMC: Group I Class A

Working System: Continuous running equipment

Power Supply

Working Voltage: a.c.100V-240V

Line Frequency: 50/60Hz

Pmax = 60VA

Fuse: T1.6AL 250V

Environment

Transport and Storage

Temperature: -10°C~55°C

Relative Humidity: ≤93%

Atmospheric Pressure: 700hPa-1060hPa

Working

Temperature: 5°C~40°C

Relative Humidity: ≤80%

Atmospheric Pressure: 860hPa-1060hPa

Display	Three digits bi-colors (Green/Red) numerical LED display FHR (FHR1/FHR2) Three digits bi-colors (Green/Red) numerical LED display TOCO/IUP Three digits bi-colors (Green/Red) numerical LED display DECG One printing status LED (Green) One power status LED (Green) One audio alarm LED (Green/Red) One/Two FHR signal quality indicator LED (Green/Orange) One TOCO/IUP signal quality indicator LED (Green/Orange) One DECG signal quality indicator LED (Green/Orange)
Printing	Record Paper: Z-fold, thermal Printing Width: 112mm Effective Printing Width: 104mm Paper Advance Speed: 1cm/min, 2cm/min, and 3cm/min optional FHR/DECG Printout Width: 7cm (USA standard) /8cm (international standard) FHR/DECG Scaling: 30bpm/cm (USA standard)/20bpm/cm (international standard) TOCO/IUP Printout Width: 3.4cm (USA standard)/2.4cm (international standard) TOCO/IUP Scaling: 25%/0.85cm (USA standard)/ 25%/0.6cm (international standard) Data Accuracy: ±5% (X axis), ±1% (Y axis) Record Message: Date, time, TOCO type, paper speed, FHR type, bed No., etc.
Signal Interface	RS485/RS232 interface
Ultrasound	Technique: Pulsed Doppler and autocorrelation Pulse Repetition Rate: 3.2KHz Pulse Duration: 114μs Nominal Frequency: 2.0MHz Ultrasound Frequency: 2.0MHz±10% P- <1MPa I_{ob}<10mW/cm^2 *I*spta<100mW/cm^2 FHR Range: 50bpm-210bpm Resolution: 1bpm Accuracy: ±2bpm Earth Leakage Current: <10 uA @ 264 VAC applied to transducer Dielectric Strength: >4000Vrms

DECG

Technique: Peak-peak detection technique
FHR Range: 50bpm-210bpm (international standard)
30bpm-240bpm (USA standard)
Artifact Elimination > ±25bpm changes are ignored
Resolution: 1bpm
Accuracy: ±1bpm
Input Impedance: >10M (differential, dc to 50/60Hz)
Input Impedance: >20M (Common mode)
CMRR: >110dB
Noise: <4uVp
Skin Voltage Tolerance: ±500mV
Fetal Input Voltage Range: 20uVp to 3mVp
Earth Leakage Current: <10uA @ 264 VAC applied to transducer
Patient Leakage Current: <10uArms@220V/50Hz
Patient Auxiliary Current: <0.1uA(dc)
Dielectric Strength: 4000Vrms
Calibration Signal Input: 1mv

Contraction

Internal IUP
Pressure Range (IUP): 0mmHg-100mmHg
Sensitivity: 5uV/V/mmHg
Non-linear Error: ±1mmHg
Resolution: 1%
Zero Mode: Automatic/Manual

External TOCO
TOCO Range: 0%-100%, 135g strength corresponding to 100%
Sensitivity: 3.7uV/V/mmHg
Non-linear Error: ≤ ±10%
Resolution: 1%
Zero Mode: Automatic/ Manual
Earth Leakage Current: <10 uA @ 264 VAC applied to transducer
Dielectric Strength: >4000Vrms

AFM

Technique: Pulsed Doppler ultrasound
Range: 0%-100%
Resolution: 1%

Mark

Manual fetal movement mark

FHR Alarm When FHR (FHR1/FHR2/DECG) is less than the lower limit or higher than the upper limit of alarm over the time of alarm delay, the monitor will give out audio and LED flashing alarm signal.

A1.2 Transducers and Cables

Ultrasound Transducer
System: Pulsed Doppler
Weight: 160g
Cable Length: 2.5m
Dimension: 90mm×65mm
Latex free

TOCO Transducer
System: Passive straingauge
Weight: 150g
Cable Length: 2.5m
Dimension: 102mm×50mm
Latex free

Remote Marker
Length: 2.5m
Weight: 56g

A1.3 Acoustic Output Reporting Table

Acoustic Output Reporting Table for Track 1

Non-Autoscanning Mode

Transducer Mode：Cadence U1752, U2291, U2318

Operating Mode：Pulsed sinusoid, 2MHz

Application(s)：Fetal heart monitoring

Acoustic Output			**MI**	**$I_{SPTA.3}$** (mW/cm^2)	**$I_{SPPA.3}$** (W/cm^2)
Global Maximum Value			6.6623E-02	2.6642E+01	2.3909E-01
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		9.4220E-02		
	W_0 (mW)			6.972	6.972
	f_c (MHz)		2.000	2.000	2.000
	Z_{sp} (mm)		30.23	30.23	30.23
	Beam dimensions	x_{-6} (mm)		4.829	4.829
		y_{-6} (mm)		4.813	4.813
	PD (μsec)		1.129E+02		1.129E+02
	PRF (Hz)		9.960E+02		9.960E+02
	EBD	Az. (cm)		1.200 (dia)	
		Ele.(cm)		1.200 (dia)	
Operating Control Conditions	No operator adjustable controls				

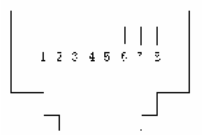
Appendix 2 Signal Input/Output Connector

Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. 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 valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

RJ45/DB9 Interface

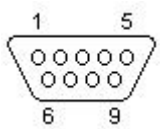
(1) RJ45 Interface

RJ45 interface is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Pin	Signal	Input/Output
1	TX	Output
2	RX	Input
3	0V Ref.	
4	TA	Output
5	TB	Output
6	RA	Input
7	RB	Input
8	485EN	Input

(2) DB9 Interface



Pin	Signal	Input/Output
1	+5V	Output
2	RX	Input
3	TX	Output
4	485EN	Input
5	0V Ref.	
6	TA	Output
7	TB	Output
8	RA	Input
9	RB	Input

Appendix 3 Troubleshooting

A3.1 No Display

Symptom	Possible Cause	Solution
Power ON indicator is off	Power cable is loose	Tighten it and check the fuse

A3.2 Noise

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

A3.3 Recorder Error

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
	Ultrasound transducer or DECG cable connector is off	Connect with ultrasound transducer or DECG cable connector

A3.4 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 till the signal indicator is green
	Loose belt	Tighten 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
Signal indicator is orange continuously	Improper position of ultrasound transducer	Change the position of ultrasound transducer till the signal indicator is green
	FHR is less than 50bpm	No
Doubtful FHR	Record maternal 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 paper recommended by manufacturer

A3.5 Fetal ECG Electrode Monitoring of FHR

Symptom	Possible Cause	Solution
Inconstant trace Inconstant display	No ECG signal	Use a new spiral electrode
	Bad contact of reference electrode and patient	Use a new spiral electrode
Inconstant trace	The ECG cable has not been fixed firmly.	Fix an attachment pad at the fetal ECG cable
Signal indicator is orange continuously	Fetal arrhythmia	Insure that DECG arrhythmia logic has been disconnected

A3.6 Monitoring Contractions (External)

Symptom	Possible Cause	Solution
Worse trace quality or fluctuant TOCO baseline	Too tight or too loose belt or no elasticity	Ensure the 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 averaged value.	Insure favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.7 Monitoring Contractions (Internal)

Symptom	Possible Cause	Solution
No trace	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	"Dry" environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system
The trace is a beeline	The connector failure	Move or contact catheter. If trace no fluctuation, change intrauterine cable

Appendix 4 EMC Information – Guidance and Manufacture's Declaration

A4.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Cadence Fetal Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the Cadence Fetal Monitor should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Cadence Fetal Monitor 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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The Cadence Fetal Monitor is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

A4.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *Cadence Fetal Monitor* is intended for use in the electromagnetic environment specified below. The customer or the user of *Cadence Fetal Monitor* 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	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2V for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz, 60Hz) magnetic field IEC61000-4-8	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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Cadence Fetal Monitor* requires continued operation during power mains interruptions, it is recommended that the *Cadence Fetal Monitor* be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

A4.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacture's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Cadence Fetal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Cadence Fetal Monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>$3V_{rms}$

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Cadence Fetal Monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

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

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

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

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

A4.4 Recommended Separation Distance

Recommended separation distances between portable and mobile RF communications equipment and the *Cadence Fetal Monitor*

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**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.

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