EDAN INSTRUMENTS, INC.

CADENCE II

Fetal Monitor

Service Manual

Manual Ver: V1.1
Release Date:Mar.2005
Part Number: MS1-17567-V1.1

Copyright

Attention

Edan Instruments, Inc. (hereinafter called EDAN) makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. EDAN assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

No part of this document may be photocopied, reproduced or translated to another language without prior written consent of EDAN.

The information contained in this document is subject to change without notice.

Responsibility of the Manufacturer

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

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

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

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

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.

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.

Warranty

EDAN warrants that the CADENCE Ⅱ Fetal Monitor we sell is free from defects in materials and workmanship. In the status of normal operation and maintenance, if EDAN receives notice of such defects during the warranty period that begins on the date

of shipment, EDAN shall, at its option, either repair or replace hardware products which prove to be defective.

EDAN software and firmware products which are designated by EDAN for use with a hardware product, when properly installed on that hardware product, are warranted not to fail to execute their programming instructions due to defects in materials and workmanship. If EDAN receives notice of such defects during the warranty period that begins on the date of shipment, EDAN shall repair or replace software media or firmware which do not execute their programming instructions due to such defects. But EDAN doesn't warrant that operating of the hardware, software, or firmware shall be uninterrupted or free from error.

This unit has no parts can be repaired by users themselves. The equipment 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.

The warranty period for this main unit is two years, and one year for transducers, etc. accessories (from the date of purchasing). EDAN's obligation under this warranty is limited to repairing, at EDAN's option, any part which upon EDAN's examination proves defective. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge.

Notes:
EDAN's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution upon it of parts or accessories not approved by EDAN or repaired by anyone other than EDAN authorized representative.

This warranty shall not extend to any instrument which has been subjected to misuse, negligence or accident; any instrument from which EDAN's original serial number tag or product identification markings have been altered or removed, or any product of any other manufacturer.

Using This Label Guide

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

⚠**WARNING**⚠

A **WARNING** label advises against certain actions or situations that could result in

personal injury or death.

◇**CAUTION**◇

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

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

Table of Contents

Chapter 1 Overview

1.1 Product Information

CADENCE Ⅱ provides accurate and reliable monitoring information, using non-invasive ultrasound Doppler, external TOCO technique.

RS-485/RS-232 communication port is built, the monitor can be connected with MFM-CNS central monitoring system via this port. The monitor can be connected to wireless network module via a DB9 interface, and the wireless network module will complete the data switch of the monitor and the MFM-CNS central monitoring system.

The data collected and stored by the CADENCE Ⅱ Fetal Monitor can be analyzed and printed by the CADENCE Insight software running on PC or MFM-CNS Obstetrical Central Monitoring System (CareVista) (Refer to **MFM-CNS Obstetrical Central Monitoring System (CareVista) User Manual** and the relevant information of wireless network module).

CADENCE Ⅱ adopts 5.7 " LCD, and the collected data, trends, and monitoring parameters are displayed at the same screen. A built-in thermal recorder is used to record the monitoring information.

1.2 Technical Specifications

(1) Safety

The CADENCE Ⅱ Fetal Monitor is designed to comply with the international safety requirements IEC 60601-1 for medical electrical equipment. It is class I equipment.

(2) Size and Weight

Size (Monitor)   330 (L) x 270 (W) x 100 (H) mm

Weight (Monitor)   About 3.5 kg

(3) Environment

Working   Temperature: 5℃-40℃
                        Humidity: < 80%
                        Atmospheric Pressure: 86kPa-106kPa

Transport and Storage   Temperature: -20℃-55℃
                        Humidity: < 93%
                        Atmospheric Pressure: 86kPa-106kPa

Power Supply: 100-240V AC, 50/60Hz
                        Pmax = 60VA

	Fuse T1.6AL
BATTERY	16.8V 6000mAh 3X4 encapsulation

(4) Display

Backlight: Cold cathode fluorescent

Active Area: 103.0(W) x 79.0(H) mm (320 x 240 dots)

Resolution: 85 dots per inch

(5) Recorder

Paper Width:	112mm
Effective Printing Width	104mm
Printing Speed	1cm/min, 2cm/min, 3cm/min optional
FHR Printout Width	7cm
FHR Scaling	30 bpm/cm
TOCO Printout Width	3.4cm
TOCO Scaling	25%/0.85cm
Accuracy of Data	$\pm$5% (X axis)
Accuracy of Data	$\pm$1% (Y axis)
Record Message	Data,time,TOCO type, paper speed,FHR type,bed NO.,ect
Paper	Z-fold, thermal

(6) Ultrasound Channel

Technique	Peak-peak detection technique and autocorrelation
Pulse Repetition Rate	3.2KHz
Pulse Duration	114us
Nominal Frequency	2.0MHz
Ultrasound Frequency	2.0MHz$\pm$10%
Acoustic pressure	P- <1 MPa
Output beam intensity	I_{ob}<20 mW/cm^2
Intensity	Ispta<100mW/cm^2
FHR Range	50-210 bpm
Resolution	1 bpm
Accuracy	$\pm$2 bpm
Leakage	<10uA@264VAC applied to transducer
Dielectric Strength	>4KV RMS
FHR Range	50-210bpm(international standard)
	30-240bpm(USA standard)

(7) Contraction

Internal IUP (optional)

Pressure Range (IUP): 0-100mmHg

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

Leakage: <10 uA @ 264 VAC applied to transducer

Dielectric Strength: >4 kV RMS

(8) DECG (optional)

Technique: Peak-peak detection technique

FHR Range: 50-210bpm (international standard)

        30-240bpm (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: <10 uA @ 264 VAC applied to transducer

Patient Leakage Current: <10uArms@220V/50Hz

Patient Auxiliary Current: <0.1uA(dc)

Dielectric Strength: 4000Vrms

Calibration Signal Input: 1mv

(9) Fetal Movement Marker

Manual fetal movement mark

(10) AFM

Technique: Pulsed Doppler ultrasound

Range: 0-100 (%)

Resolution: 1%

Gain Control: Manual/ Automatic

1.3 Fetal Monitor Operation Principle

The first and the second generation fetal monitors used previously detect FHR with high frequency continuous ultrasonic waves. Continuous ultrasonic waves can't control distance gate, and easy to be interfered by other movement organ and adult trunk blood vessel movement signal. The fetus suffers more ultrasonic radiation than pulsed wave. The third generation fetal monitor adopts low frequency pulsed wave ultrasound, The ultrasonic signal controlled by Doppler gate transmits pulsed waves with specific frequency to fetal heart, and it's hard to be interfered.
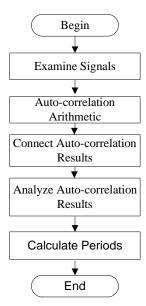
The first and the second generation fetal monitors calculate FHR by measuring the interval time of Doppler signal peak values. While modern fetal monitor calculates FHR using digital signal processing auto-correlation arithmetic. Auto-correlation operation creates characteristic parameter via processing Doppler echo signal. Comparing new characteristic parameter created by new signal with the former one, and obtain the data of FHR display and recorder updating. Auto-correlation operation decreases additional artificial signal effectively, and only extracts effective echo signal that can deduce FHR. The detection of external TOCO is obtained by indirect measurement via displacement transducer (TOCO) binding at maternal abdominal wall.

Operation Principle of Ultrasound Doppler FHR Monitoring

Ultrasound transducer is made up of a group of quincunx multi-wafer piezoelectricity transducers. The CADENCE II ultrasound transducer is made up of nine pieces of piezoelectric crystals with uniform distributed eight pieces constituting a circle, and one lying at the center of a circle. Transducer transmits / receives switch under the control of transmitting / receiving timing pulse given by system timer. Receiver will be closed during transmitting. It can receive Doppler frequency shift information of fetal heart when

transducer is in the proper place. Magnify and filter f0±fd Doppler frequency shift ultrasound echo received by hardware system, then demodulate it, the (f0±fd)- f0＝±fd signal is obtained. After the signal is filtered by Doppler frequency shift filter, it is rectified in full wave, and low-pass filtered. The envelope signal of Doppler frequency shift is extracted, and sent to multi-channel strobe. It will become digital signal via A/D transform. FHR is obtained by DSP auto-correlation operation. The Doppler audio is not real sound, but an imitative sound caused by Doppler frequency shift change brought by movement object. The FHR signal range is 50-210BPM.

FHR signal processing flow is as follows.

```
            ( Begin )
               ↓
      ┌─────────────────────┐
      │   Examine Signals   │
      └─────────────────────┘
               ↓
      ┌─────────────────────┐
      │   Auto-correlation  │
      │     Arithmetic      │
      └─────────────────────┘
               ↓
      ┌─────────────────────┐
      │ Connect Auto-correlation │
      │       Results       │
      └─────────────────────┘
               ↓
      ┌─────────────────────┐
      │ Analyze Auto-correlation │
      │       Results       │
      └─────────────────────┘
               ↓
      ┌─────────────────────┐
      │  Calculate Periods  │
      └─────────────────────┘
               ↓
            (  End  )
```
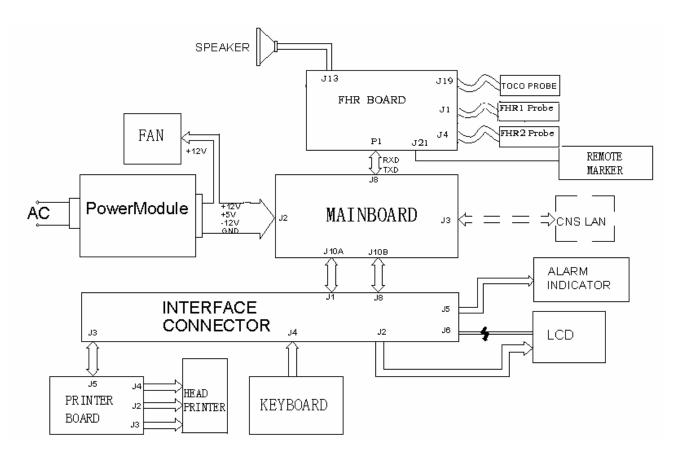
TOCO Measurement Operation Principle

External TOCO measurement sub system uses the strain gauge bridge. When strain gauge suffers pressure, the bridge connection will lose balance, and produces an output signal. The pressure changes very slowly, so a low-pass filter is set to filter noise signal. It will change into digital signal via A/D, and its relevant value is computed by DSP. We take 100 gram forces as 100 units, pressure measured by TOCO is contact force sensor processing.

1.4 Function Modules

CADENCE II Monitor obtains accurate and reliable parameters, e.g. FHR and maternal uterine activity, etc. by using pulsed Doppler ultrasound, external TOCO, etc. invasive detection technology and device. The structure of CADENCE Series may be different

according to different configuration. The basic parts of the monitor include: pulsed wave ultrasound transducer, external TOCO transducer, Manual fetal movement mark, Fetal monitor board, mainboard, built-in thermal printer module, power supply module, and

Structure Diagram

1.3.1 Power Supply Board

power module is designed according with IEC 60601-1, which can offer DC power as +12V@1.5A,-12V@0.5A, and +5V@1.5A; The definitions of its power input, and output jacks are as follows:

P4 is power switch ；P8 is Battery supply input jack.

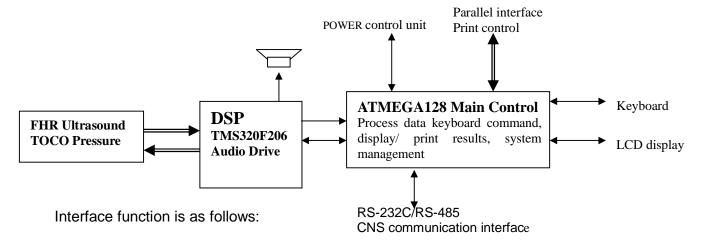Definitions for power supply input jack pins:

PIN No.	Function Description
PIN1 (brown), PIN3 (blue)	A.C. supply input pin
PIN2	Null

Definitions for power supply output jack pins:

PIN No.	Function Description
PIN1(yellow)	D.C. supply output pin: VDD (+12V)
PIN2 (red)	D.C. supply output pin: Vcc (+5V)
PIN3	Null
PIN4、PIN5 (black)	Earth: 0V
PIN6 (blue)	D.C. supply output pin: VEE (-12V)

1.3.2 Mainboard

Mainboard includes key input control, LCD display, process print, audio alarm and led indicate light alarm, data memorize and recall , time and date management, communication with the internal modules ,ect.

Interface function is as follows:

Define interface:

Parallel Interface 1: send out command (ESC protocol) to thermal printer for printing via print interface.

Serial Interface 2: send out command to LCD display module for data display, and receive keyboard command.

Serial Interface 3: communicate with central station. Transmit data and receive command from central station.

Definitions for each jack pin on the mainboard are as follows:

Definitions for power supply jack J2 pins:

PIN No.	Function Description
PIN1	VCC
PIN2	Earth: 0V
PIN3	Earth: 0V

PIN4	Earth: 0V
PIN5	VDD
PIN6	VEE

Definitions for 50Pin jack J10 pins:

PIN No.	Function Description
PIN1	VO
PIN2	AA0
PIN3	WR
PIN4	RD
PIN5	LCDAD0
PIN6	LCDAD1
PIN7	LCDAD2
PIN8	LCDAD3
PIN9	LCDAD4
PIN10	LCDAD5
PIN11	LCDAD6
PIN12	LCDAD7
PIN13	LCDCS
PIN14	LCDRST
PIN15	LCDVEE
PIN16	Earth: 0V
PIN17	PD0
PIN18	PD1
PIN19	PD2
PIN20	PD3
PIN21	PD4
PIN22	PD5
PIN23	PD6
PIN24	PD7
PIN25	/ACK
PIN26	PE
PIN27	/STB
PIN28	/ERR
PIN29	BUSY
PIN30	VCC
PIN31	Earth: 0V
PIN32	VCC
PIN33	ALARM_G
PIN34	VCC
PIN35	ALARM_R
PIN36	Earth: 0V
PIN37	POWER_LED
PIN38	Earth: 0V
PIN39	VDD
PIN40	Earth: 0V
PIN41	K0
PIN42	K5
PIN43	K1
PIN44	K6
PIN45	K2

PIN46	K7
PIN47	K3
PIN48	K8
PIN49	K4
PIN50	K9

Definitions for J1 JTAG

PIN No.	Function Description
PIN1	TCK
PIN2	Earth: 0V
PIN3	TDO
PIN4	VCC
PIN5	TMS
PIN6	NRESET
PIN7	VCC
PIN8	NULL
PIN9	TDI
PIN10	Earth: 0V

Definitions for J3 RJ-45

PIN No.	Function Description
PIN1	T1OUT
PIN2	R1IN
PIN3	Earth
PIN4	TA
PIN5	TB
PIN6	RA
PIN7	RB
PIN8	485EN

Definitions for J5 RS-232

PIN No.	Function Description
PIN1	Earth
PIN2	T1OUT
PIN3	R1IN
PIN4	Earth
PIN5	Earth
PIN6	TA
PIN7	TB
PIN8	RA
PIN9	RB

Definitions for J4 FSPO2

PIN No.	Function Description
PIN1	FSPO2RXD
PIN2	FSPO2TXD
PIN3	VCC
PIN4	Earth: 0V
PIN5	VDD
PIN6	Earth: 0V
PIN7	VEE

Definitions for J6 POWER COM

PIN No.	Function Description
PIN1	BATTXD
PIN2	BATRXD
PIN3	Earth: 0V
PIN4	POWER_LED
PIN5	NULL
PIN6	NULL

Definitions for J8 FM

PIN No.	Function Description
PIN1	VCC
PIN2	VCC
PIN3	Earth: 0V
PIN4	VDD
PIN5	Earth: 0V
PIN6	VEE
PIN7	FHRTXD
PIN8	FHRRXD
PIN9	Earth: 0V

Definitions for   J9 DECG

PIN No.	Function Description
PIN1	DECGRXD
PIN2	DECGTXD
PIN3	VEE
PIN4	Earth: 0V
PIN5	VDD
PIN6	VDD
PIN7	Earth: 0V
PIN8	VCC

Definitions for   J7 CON6

PIN No.	Function Description
PIN1	VCC
PIN2	Earth: 0V
PIN3	CTCK
PIN4	CTDO
PIN5	CTDI
PIN6	TMS

1.3.3 fetal monitor Board

Fetal monitor board includes ultrasound channel signal processing, AFM channel signal processing, pressure channel signal processing, Doppler audio signal processing, DSP ultrasound and pressure data processing, general alarm audio signal, communication with main board.

Definitions for each jack pin on the fetal monitor Board are as follows:
Definitions for J1 CON4 PINS

PIN No.	Function Description
PIN1	FHR1
PIN2	FHR1P
PIN3	FHR1P
PIN4	VDD2

Definitions for J4 CON4 PINS

PIN No.	Function Description
PIN1	FHR2
PIN2	FHR2P
PIN3	FHR2P
PIN4	VDD2

Definitions for P1 POWER

PIN No.	Function Description
PIN1	+5V
PIN2	+5V
PIN3	Earth: 0V
PIN4	+12V
PIN5	Earth: 0V
PIN6	-12V
PIN7	RXD
PIN8	TXD
PIN9	Earth: 0V

Definitions for J19 TOCO

PIN No.	Function Description
PIN1	E3
PIN2	E2
PIN3	E4
PIN4	E1
PIN5	TOCOP
PIN6	Earth: 0V

Definitions for J7 HEADER3

PIN No.	Function Description
PIN1	TDI1
PIN2	TDI
PIN3	TDI2

Definitions for J8 HEADER3

PIN No.	Function Description
PIN1	TDO1
PIN2	TDO
PIN3	TDO2

Definitions for J22 EVENT_MARKER

PIN No.	Function Description
PIN1	Earth: 0V
PIN2	EVENT_MARKER

Definitions for J21 FETAL_MARKER

PIN No.	Function Description
PIN1	Earth: 0V
PIN2	FETAL_MARKER

Definitions for J16 CPLD_JTAG

PIN No.	Function Description
PIN1	VCC
PIN2	Earth: 0V
PIN3	CTCK
PIN4	CTDO
PIN5	CTDI
PIN6	CTMS

Definitions for J13   AUDIO OUTPUT

PIN No.	Function Description
PIN1	OUT+
PIN2	OUT-

1.3.4 Print Control Board

Record Paper Width: 112mm

Effective Printing Width: 104mm

Dot/Line: 832/mm

Resolution: 8dots/mm

Working Voltage: 5V

Working Circuit: Printhead: 3.4A(Max), 0.9A(Ave)

               Electrical Machine: 2.4A(Max), 0.5A(Ave)

Life: MTBF 5*10EXP (7)

    50Km

Connect with mainboard by CENTRONIX interface to finish detection of driving, paper empty or not, and the status of printhead.

Definitions for print board 20P interface jack J5 pins:

PIN No.	Function Description
PIN1	STROBE
PIN2	DATA0
PIN3	DATA1
PIN4	DATA2
PIN5	DATA3
PIN6	DATA4
PIN7	DATA5
PIN8	DATA6
PIN9	DATA7
PIN10	ACK
PIN11	BUSY
PIN12	PE
PIN13	ERROR
PIN14	Power supply: +12V
PIN15	GND
PIN16	Vp
PIN17	GND
PIN18	Vp
PIN19	GND
PIN20	Vp

1.3.5 the interface board

The interface board implement communication between the mainboard and the print control board and the display screen.The DC-AC inverter for 2-cold cathode fluorescent lamps support wide range of CCFL devices and are characterized by highly stable output current.
Definitions for each jack pin on the interface board are as follows:

Definitions for J1 2005S30P

PIN No.	Function Description
PIN1	VO
PIN2	AA0
PIN3	WR
PIN4	RD
PIN5	AD0
PIN6	AD1
PIN7	AD2
PIN8	AD3
PIN9	AD4
PIN10	AD5
PIN11	AD6
PIN12	AD7
PIN13	LCDCS
PIN14	LCDRST
PIN15	LCDVEE
PIN16	Earth: 0V
PIN17	PD0
PIN18	PD1
PIN19	PD2
PIN20	PD3
PIN21	PD4
PIN22	PD5
PIN23	PD6
PIN24	PD7
PIN25	/ACK
PIN26	PE
PIN27	/STB
PIN28	/ERR
PIN29	BUSY
PIN30	VCC

Definitions for J2 LCM

PIN No.	Function Description
PIN1	Earth: 0V
PIN2	VCC
PIN3	VO
PIN4	AA0
PIN5	WR
PIN6	RD
PIN7	AD0
PIN8	AD1
PIN9	AD2
PIN10	AD3
PIN11	AD4
PIN12	AD5
PIN13	AD6
PIN14	AD7
PIN15	LCDCS
PIN16	LCDRST
PIN17	LCDVEE
PIN18	Earth: 0V

Definitions for J3 PRINTER 20PINS

PIN No.	Function Description
PIN1	/STB
PIN2	PD0
PIN3	PD1
PIN4	PD2
PIN5	PD3
PIN6	PD4
PIN7	PD5
PIN8	PD6
PIN9	PD7
PIN10	/ACK
PIN11	BUSY
PIN12	PE
PIN13	/ERR
PIN14	VDD
PIN15	Earth: 0V
PIN16	VCC
PIN17	Earth: 0V
PIN18	VCC
PIN19	Earth: 0V
PIN20	VCC

Definitions for J4 KEYBOARD

PIN No.	Function Description
PIN1	VCC
PIN2	K1
PIN3	K0
PIN4	K3
PIN5	K4
PIN6	K5
PIN7	K6
PIN8	K7
PIN9	K8
PIN10	K9
PIN11	K2
PIN12	Earth: 0V
PIN13	POWER_LED

Definitions for J6 CON4

PIN No.	Function Description
PIN1	VFL1
PIN2	NULL
PIN3	NULL
PIN4	VFL2

Definitions for J5 2510S-3P

PIN No.	Function Description
PIN1	ALARM_G
PIN2	Earth: 0V
PIN3	ALARM_R

Definitions for J8　2005S20P

PIN No.	Function Description
PIN1	Earth: 0V
PIN2	VCC
PIN3	ALARM_G
PIN4	VCC
PIN5	ALARM_R
PIN6	Earth: 0V
PIN7	POWER_LED
PIN8	Earth: 0V
PIN9	VDD
PIN10	Earth: 0V
PIN11	K0
PIN12	K5
PIN13	K1
PIN14	K6
PIN15	K2
PIN16	K7
PIN17	K3
PIN18	K8
PIN19	K4
PIN20	K9

TOCO Transducer

External TOCO transducer uses 4 pieces of strain gauges to form full-bridge. When strain gauge is balanceable, the bridge is balanceable, and no output. When strain gauge suffers the pressure, the bridge will lose balance, and produce an output signal.

Relevant contact force measurement range: 135g force, 100 units. The maximum measurement is 600g.

Ultrasound Transducer

Central Frequency: 2MHz, 9 wafer structure

Fetal Movement Marker

Fetal movement marker inside is a vernier switch and equal to a key.

Chapter 2 Inspection of the Monitor

2.1 System Inspection

2.1.1 Appearance, and Packing Inspection

Take the monitor out of packing carton, then check its surface. If it has scratching or stain, please contact your local distributor or us. Check if the six screws (three on left side, and three on right side) used to fix are screwed down.

Open the packing carton of the accessories, it may include user manual, TOCO transducer, ultrasound transducer, marker, power cord, coupling gel (one bottle), earth wire, abdomen belt, intrauterine pressure cable, fetal ECG lead cable, disposable fetal spiral electrode, disposable intrauterine pressure catheter, disposable attachment pad, etc. Please check the completeness and condition of damaging. If you find any abnormality, please contact your local distributor or us.

2.1.2 Power On Inspection

Insert the mains cable connector into the power socket (see Figure 2-1), insert the other end of the power cord into the hospital private power supply (100-240V AC, 50/60 Hz) output socket. Connect transducers, connectors, and event marker to sockets at the front panel, see Figure 2-2 for the connection position.

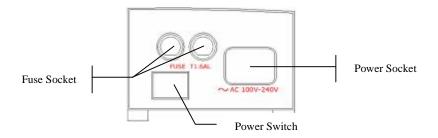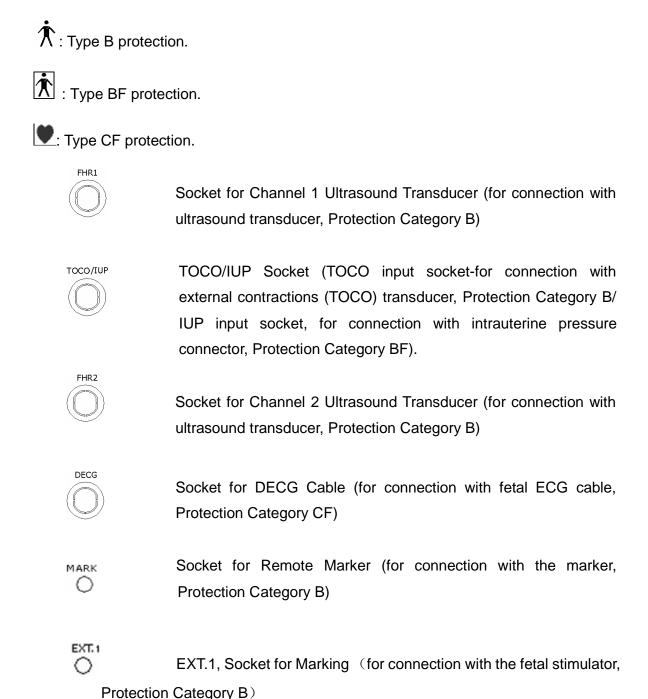Figure 2-1 Sockets on the right side of the monitor

Figure 2-2 Sockets at the front panel of the monitor
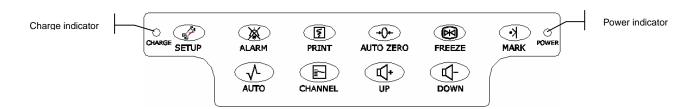

⚠: Attention, consult accompanying documents.

Only use accessories from EDAN or approved by EDAN.

🕴 : Type B protection.

🧍 : Type BF protection.

♥ : Type CF protection.

FHR1

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

TOCO/IUP

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).

FHR2

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

DECG

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

MARK

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

EXT.1

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

Note: Please pay attention to the direction when connecting transducer(s), and connector(s) to main.
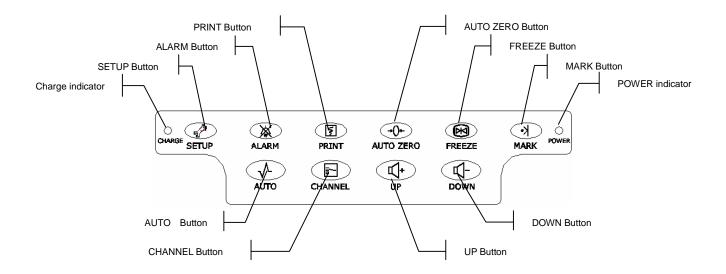
Turn the power switch ON, you can hear the short sound of "Do", and see that the power on LED indicator on the right side of the front panel is lit (see Figure 2-3 for the position of Power ON indicator). The numeral LED will flash in red color and green color to test it. At the same time, the system will print a test baseline.

Figure 2-3 Position of power on indicator

2.1.3 Control Panel

There are several keystrokes with different functions on the front panel of the monitor. The diagram is showed as Figure 2-5, and their primary functions are as follows:

Figure 2-5 keystrokes

(1) SETUP

Function: Set menu item

Press this key to enter the menu interface. To move cursor among the menu items up and down by pressing the UP / DOWN key. When the cursor is moved to the menu item to be executed/ revised, this item will be encircled by a pane. Press the CHANNEL key to execute relevant function or press the CHANNEL key, and this item will display reversed, then press the UP / DOWN key to revise the relevant content, and press the CHANNEL key to confirm.

Press this key again to enter the next menu page, till return to the main interface.

Press the key to return to the main interface quickly under the status of menu.

（2） ALARM

Function: Disable/Enable alarm

Press this key, the system accesses alarm pause status. But the alarm information will be displayed, and the alarm indicator flashes continuously. Press this key again, the system terminates alarm pause status and returns to normal monitoring status, then the alarm sound resumes.

There are two alarm levels available at the monitor, middle-level alarm and low-level alarm.

Middle-level alarm means serious warning.

Low-level alarm is a general warning.

The precedence of alarm level is middle-level alarm higher than low-level alarm. If the two kinds of alarm levels exist simultaneously, the alarm sound is that of middle-level alarm.

When alarm occurs, the monitor may raise the user's attention in at least three ways, which are audio prompt, visual prompt and description.

Screen Display
When an alarm occurs, the alarm message will be displayed at the top left corner of the monitoring screen in red. The alarm message will be displayed in turn when more than one piece of alarm appears.

Alarm Indicator

Alarm indicator flashes in orange with low frequency of 0.5Hz at middle-level alarm. Alarm indicator lights on in orange at low-level alarm.

Alarm Sound

If the alarm is not muted, the system will give out relevant alarm sound. Alarm with different level has different alarm sound. If the alarm sound is "Do-do-do", the alarm level is middle. If the alarm sound is "Do-", the alarm level is low.

⚠**WARNING**⚠: Do not disable the sounds if endangering the patient's safe.

Notes: ① The alarm description can never be paused or cancelled.

② The alarm sound is that of the higher level when more than one kind of alarm level exists.

When an Alarm Occurs:

Z   Check the patient's condition;

Z   Identify the cause of the alarm;

Z   Silence the alarm, if necessary;

Z   When cause of alarm has been over, check if the alarm is working properly.

(3) PRINT

Function: Enable/Disable printing

Press this key a second later to start printing. If the system is at the status of playback, press this key to print quickly the selected paragraph, i.e. 20 minutes from the left of the current screen. Or else, press this key to print from current data by paper advance speed set; If feeding paper when out of paper, the recorder will print from the data that it is out of paper.

The following reasons may cause the failure of printing:

Z Just press the PRINT key to end printing, the last row output hasn't been completed.

Z The ultrasound transducer or DECG cable connector is off.

Z Recorder is out of paper.

Z Recorder failure.

Press this key again a second later to stop printing.

（4） AUTO ZERO

Function: TOCO zero

Adjust the external TOCO contractions trace/value to preset unit (external monitoring contractions) or adjust the IUP trace/value to reference point 0 (internal monitoring contractions).

(5) FREEZE

Function: Freeze

Press this key at the main interface, the UP / DOWN key can be pressed to play back automatically. Press the DOWN key to play back forward. Press the DOWN key continuously to play back forward quickly till the speed is the fastest. If press the UP key at this time, the speed of playback is decelerated till slowest. Press the UP key to play back backward. Press the UP key continuously to play back backward quickly till the speed is the fastest. If press the DOWN key at this time, the speed of playback is decelerated till slowest. After stopping playing back, press the FREEZE key to return to the real-time monitoring status. Press the FREEZE key to stop playing back during playback automatically. Press the PRINT key to print the CTG trends of current 20 minutes from the left of the screen.

Notes: ① The process of automatic playback does not bear the limit of returning to the main interface 30 seconds later.

② The longest automatic playback time is 12 hours.

(6) MARK

Function: Record event at the trace.

If the physician wants to make a label for patient event under monitoring status, who may press this key to mark. At the moment, the symbol "↓" of label will be displayed at the CTG trend and printed on the record paper.

Under the status of load, an abnormal audio will be given out when pressing this key, and no function is executed.

(7) AUTO

Function: Under the status of non-auto monitoring, press this key at the main screen to begin auto monitoring. Auto monitoring will execute the function of TOCO zero/ FM zero/adjusting audio volume, etc. automatically according to user settings, and stop monitoring automatically when monitoring time reaches the time of auto stop.

If the auto monitoring time is not set, the auto monitoring will continue till the monitoring is over.

If the system is under the status of auto monitoring, press this key, an abnormal audio will be given out, and no function is executed.

Press this key to return to the main interface quickly under the status of menu.

(8) CHANNEL

Function: ① Press the key to select fetal heart audio channel, the default fetal heart audio channel is US1. ② When the cursor is moved to the menu item to be executed/ revised, this item will be encircled by a pane. Press this key to execute relevant function or press this key, and this item will display reversed, then press the UP / DOWN key to revise the relevant content, and press this key to confirm.

(9) UP

Function: ① Increase the fetal heart audio volume of the channel selected; ② Press the FREEZE key under the monitoring mode, then press this key to play back backward; ③ Press this key to move the cursor downward among the menu items after entering the menu interafce. ④ Adjust the values of items in menu.

(10) DOWN

Function: ① Decrease the fetal heart audio volume of the channel selected; ② Press the FREEZE key under the monitoring mode, then press this key to play back forward; ③ Press this key to move the cursor upward among the menu items after entering the menu interafce. ④ Adjust the values of items in menu.

2.1.4 Indicator

Figure 2-6 Display area diagram
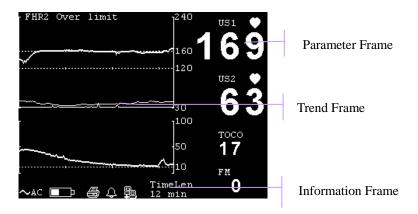
Table 2-7 Indicator description

Indicator	Status of Indicator	Meaning
FHR Indicator (including channel 1 and channel 2)	Green and twinkle	Fetal heart signal quality is optimal
	Orange and twinkle	Fetal heart signal quality is unacceptable
	Off	Ultrasound transducer is off
DECG Indicator	Green and twinkle	DECG signal quality is optimal
	Orange and twinkle	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 twinkle	No paper or recorder error
	Off	Disable printing
Alarm Indicator	Green	Enable audio alarm
	Red and twinkle	Alarm
	Off	Disable audio alarm
POWER Indicator	Green	Power on
	Off	Power off
Charge Indicator	Green	Charging
	Off	No battery or electric charge is full

2.1.5 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 trend, etc. will be recorded at the beginning of the paper. The offset of FHR2/DECG pattern is –20bpm means that FHR2/DECG pattern is 20bpm lower than its actual position, so

20bpm should be added when calculating the numerical value of FHR2/DECG. After printing the information mentioned above, "FHR1", "FHR2"/"DECG" will be recorded above the relevant trends. In the process of later printing, the recorder will print system time once every 10 minutes and "FHR1", "FHR2"/"DECG" once every 8 minutes (see Figure 2-8).

If pressing AUTO ZERO key, the symbol of TOCO zero is printed. If the MARK key is pressed, the marking 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 can not be changed in the process of printing.
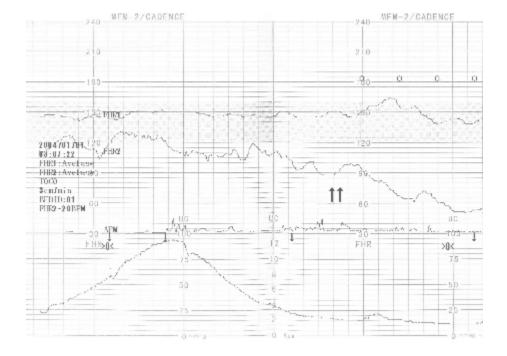
Figure 2-8 An example of printing pattern

🔔**:** Indicates the alarm status information of monitoring.

↑ : Indicates the fetal movement.

↓ : Indicates the event mark.
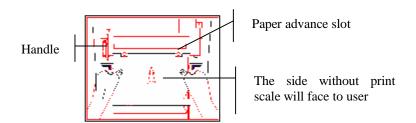
>0< **: Indicates the information of auto zero.**

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 key to continue. The current printing data will lose when ultrasound transducer or DECG cable connector falls off, or power off.

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 2-9) and the paper will go out from the notch automatically.

Figure 2-9 Diagram of feeding paper

Handle

Paper advance slot

The side without print scale will face to user
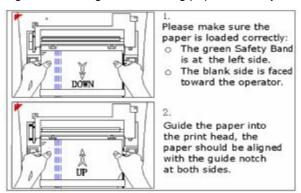
④ Adjust the paper length by the gear beside the handle if required.

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 (There is a pull-paper bar within the recorder, which is used to pull paper easily).

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 2-10 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.
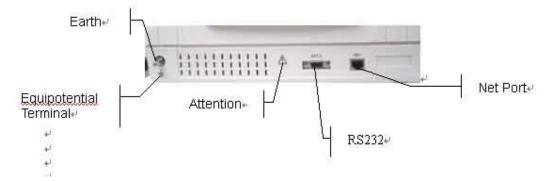
Removing Paper Jam

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:

Z   Cut the record paper from the paper notch edge.

Z   Open the door of recorder, and revolve the left gear of the recorder.

Z   Pull the paper from below.

2.1.6 Networking Function

Connect RS-485/232 socket of the monitor (see Figure 2-11) to network cable, the data will be transmitted automatically. Refer to *MFM-CNS Obstetrical Central Monitoring System (Carevista) User Manual* for details.

Figure 2-11 CADENCE II   Fetal Monitor rear panel

2.1.7 Connecting with Personal Computer (PC)

Connect RS-485/232 socket of the monitor (see Figure 2-13) with PC via special RS-232 cable provided by EDAN. Refer to **CADENCE Insight User Manual.**

Chapter 3 Installing the Monitor

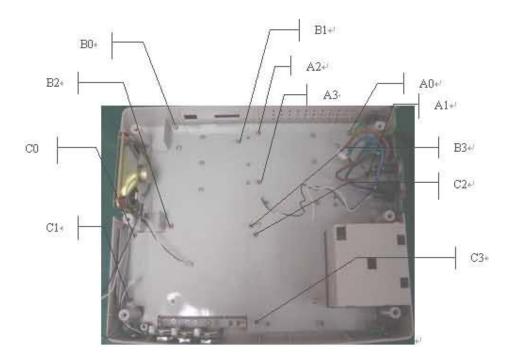Figure 3-1   overview of the back panel and the position of   the screws which fixup the functional boards

Table 3-1

The position	The type of the screws	Functional board
A0, A1, A2, A3	M3X5	The power board
B0, B1, B2, B3	Bulletheaded M3X6	The main board
C0, C1, C2, C3	Bulletheaded M3X6	The fetal monitor board

NOTE: use the screws to fixup the functional board according to the position

3.1 Installing Power Supply Board

Figure 3-2 the power board
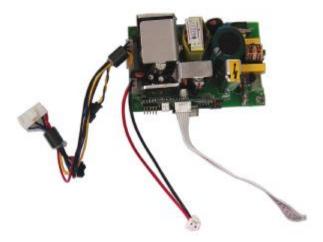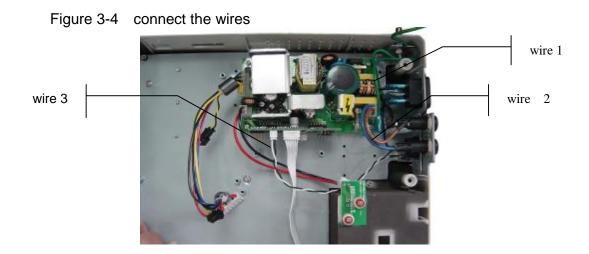
Figure 3-3 fixup the power board on the back panel

NOTE: connect the three wires with the power supply board as showing in figure 3-4

Figure 3-4　connect the wires

wire 1

wire 3

wire　2

3.2 Installing main board

Figure 3-5 The main board

20 pins socket connecting with the interface board

30 pins socket connecting with the interface board

The 6pins socket connecting with the power line
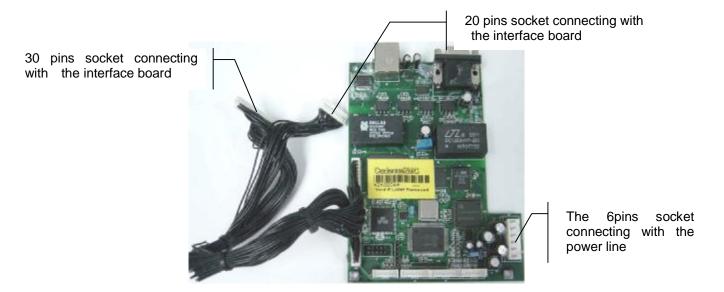
Figure 3-6 setting the main board on the back panel

3.3 Installing Fetal monitor Board

Figure 3-7 the fetal monitor board

Figure 3-8 fixup the fetal monitor board

The socket connecting the marker with fetal monitor board

The wire connecting the fetal monitor board with the main board

The wire of the marker

The socket connecting the soundspeaker with the fetal monitor board

Figure 3-9   the back panel with the functional board

The power wire connecting with the battery

NOTE: The power wire connect with the battery via battery bd.

3.4 Installing   battery

Figure3-10   the battery

Figure 3-11 Installing the battery

connect the wires   place the battery   close the door of the battery

Note: reverse the back panel ,you can see the door of the battery.
.

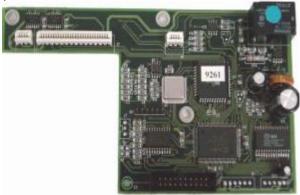# 3.5 Installing the print board

Figure 3-12 the print board
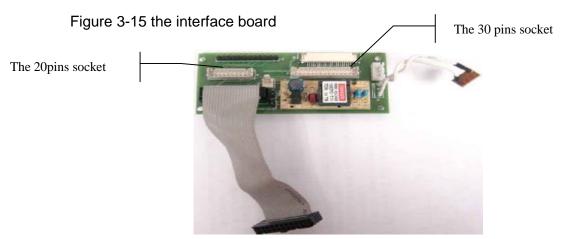
Figure 3-13   setting the print board

connecting the wires   fixup the board

3.6 installing the interface board

Figure 3-15 the interface board

The 30 pins socket

The 20pins socket

NOTE: connecting the 20pins and 30pins sockets with correspondings in the figure3-5 after setting the inteface board.
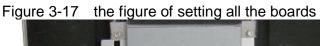
Figure 3-16 connecting the wires

Figure 3-17　　the figure of setting all the boards

Figure 3-18 close the up panel and the down panel

NOTE: removing the monitor is the opposite operation of the installing .

3.7 Troubleshooting

3.7.1 Monitor Failure

Phenomenon	Possible Cause	Solution
Power on, LCD has no display, and the power indicator is off, the fan doesn't run.	①Fuse is damaged	①Change fuse
	②Power supply has a failure	②Change power supply
	③Other parts has a short circuit	③Confirm short circuit parts
Power on, LCD has no display, but the power indicator is on, and the fan runs normally.	① Mainboard has a failure	①Confirm if the display is fail
	② Connector has a failure	②Check interface board,and the connector
A certain operation or measurement function is invalid	①Mainboard or relevant part is damaged	①Check mainboard and relevant part
Faculative down	① Electrified wire netting is interfered strongly at a moment.	① Check power supply and earth system
	② Bad power supply performance	②Change power supply
	③ Bad mainboard performance	③Change mainboard
	④ Bad power supply, mainboard, display connecting	④Change or repair connector

3.7.2 Operation, Recorder, or Networking Failure

Phenomenon	Possible Cause	Solution
Button is disabled	① keyboard is damaged	①Change keyboard
	②keyboard connecting has a failure	②Change or repair keyboard wire
Hoarse sound or no sound	① Mainboard has a failure	①Change mainboard
	②Loudspeaker or wire has a failure	②Change loudspeaker or cable
Recorder does not work	①Recorder is out of paper or paper jam	①feed paper or remove paper jam
	②Recorder failure	②Change recorder
	③Recorder connecting has a failure	③ Change or repair recorder connecting
Slantwise recorder paper advancing	Improper recorder installation, or locating	Rectify installation of recorder
Network does not work	①Network failure ②Mainboard failure	①Check and repair network cable ②Change mainboard

3.7.3 Display Failure

Phenomenon	Possible Cause	Solution
Power on, the power is normal but no display, or improper flashes	①LCD is damaged	①Change LCD
	②Bad LCD connecting	② Repair or change connection wire
	③Mainboard is damaged	③Change mainboard
	④interface board is damaged	④Change interface board
LCD character has error displays	Invalid LCD numeral tube	Change LCD

3.7.4 Power Supply Board Failure

Phenomenon	Possible Cause	Solution
The fuse burns when power on	① Short circuit of power supply or other parts	Remove a part load, and check again
Disconnect all loads, but the fuse still be burned	② Power failure Network power specification doesn't fit	Change power supply Quit till the network power is solved
The fuse is burned when connecting some a part	The part is in the status of short circuit.	Change the parts
Power indicator is on, but the fan doesn't run, the measurement isn't normal	+12Vd.c. supply is damaged	Change power supply

3.7.5 Monitoring Parameter Failure

Phenomenon	Possible Cause	Solution
Abnormal FHR display	① Bad connecting of transducer.	①Change transducer
	②Display has a failure	②See display failure solution
	③ The mainboard has a failure (FHR1 or FHR2 has no display)	③Change mainboard
Abnormal TOCO display	① Bad connecting of transducer.	①Change transducer
	② Display has a failure	②See display failure solution
	③ Mainboard has a failure	③Change mainboard
Lower heart beat or no sound	① Mainboard has a failure	①Change mainboard
	② Transducer has a failure	②Change transducer
	③Loudspeaker has a failure	③Change loudspeaker

Inaccurate measurement value	① Mainboard has a failure	①Change mainboard
	② Transducer has a failure	②Change transducer

Chapter 4 Packing of the Monitor

This chapter describes the packing of the monitor, configuration, and important notes.

4.1 Checking Before Packing

Take the monitor out of packing carton, then check if the six bolts (three on left side, and three on right side) used to fix are screwed down.

Open the packing carton of the accessories, Please check the accessories comparing with packing list, and check if they match with each other.

4.2 Preparation Before Power On

Proper transducer connections must be checked before power on. Environment temperature of the monitor and transducer should be the same with room temperature. The power supply should meet the requirement of the user manual. The operation of the device should be far away from the stronger electromagnetic field, in order not to influence the measuring accuracy caused by eradiating or interfering.

4.3 Power On

Please check if the earthing is reliable, and if the power cord is good in order to prevent short circuit from damaging the monitor before power on. Connect well with power cord, then press the power switch showed in Figure 2-1 to turn on the power of the monitor

4.4 Notes

Please check if the relevant label is clear, and ask the user to get familiar with the basic operation of the monitor in order not to influence the effect of the monitor or damage the device by misuse.

Chapter 5 Monitoring

5.1 Ultrasound Monitoring of FHR

The 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 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 US1 speaker volume well.

Attach the buckle of the ultrasound transducer to the belt.

Apply aquasonic coupling medium 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 pregnant woman monitored in the comfortable situation, and the fetal heart rate value and trend will be showed 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 US2 speaker volume well so that the second heart sounds can be heard.

Apply aquasonic coupling medium to the face of the transducer.

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

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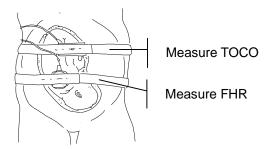
The elasticity of belt can be adjusted, which make the pregnant woman monitored in the comfortable situation. Also verify the position of transducer one has not changed.

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

④ **Monitor Adjustments**

Readjust the volume settings for the desired loudness.

Figure 5-1 Ultrasound transducer & TOCO transducer positioning

Measure TOCO

Measure FHR

◇**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.
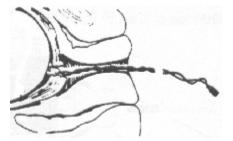
Parts Required

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 on the monitor.

⑦ Check the 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 DECGAntiArt at the menu is set to ON). 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 (The DECGAntiArt at the menu is set to OFF). 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.

Z Shave hair from sites, if necessary.

Z Wash sites thoroughly with soap and water (Never use ether or pure alcohol, because this increases skin impedance).

Z 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 trend is –20bpm. –20bpm means that FHR2/DECG trend is 20bpm lower than its actual position, so 20bpm should be added when calculating the numerical value of FHR2/DECG.

③ If two ultrasound channels are used to monitor the twins, only the audio signals of one fetus can be heard. Press the CHANNEL key to hear the audio signals of the other fetus.

④ If one ultrasound channel and one DECG channel are used to monitor the twins, the audio signals of twins can be heard simultaneously.

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.

Check for the proper setting for TOCO baseline. Adjust when needed.

② Acquiring Uterine Activity Data

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

Do not use 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 key 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 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 ② Reusable intrauterine pressure cable

Operation Procedure

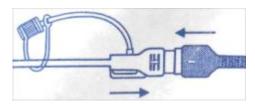Read **Directions for Use of Disposable Saflex™ IUPC** before monitoring.

① Perform a complete clinical exam to insure ruptured membranes and adequate dilation. Do not insert the intrauterine pressure catheter if placenta previa or unknown uterine haemorrhage.

② Insert intrauterine pressure catheter according to **Directions for Use of Disposable Saflex™ IUPC**.

③ Zero the monitor by pressing the AUTO ZERO key, and the display and trace are both "0".

④ Wash timely during monitoring. A spike on the tracing is in response to the washing.

Directions for Use of Disposable Saflex™ IUPC

(1) Preparation and Set Up

① Gather supplies: Saflex™ IUPC, and reusable cable.

② Plug the reusable cable connector into the TOCO/IUP socket on the monitor.

③ Open the sterile Saflex™ IUPC package.

④ To zero the system, connect the catheter to the reusable cable (see Figure 5-3) and adjust monitor to zero.
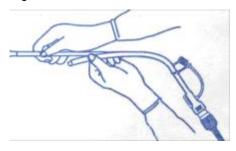
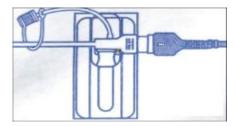Figure 5-3 Connect catheter to cable

(2) Insertion and Application

① Using aseptic technique, remove the catheter from the package.

② Perform vaginal exam to insure ruptured membranes and adequate dilation.

③ 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.

④ 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 Saflex™ logo on the catheter meets the end of the introducer.

⑤ Remove the introducer by carefully sliding it back out of the vagina along the catheter. When the introducer is completely out of the vagina, twist it away from the catheter beginning at the proximal end. Peel the introducer away from the patient (See Figure 5-4).

Figure 5-4 Remove introducer

⑥ Remove the adhesive pad liner and adhere the pad to the patient's skin. Secure catheter using attachment system (See Figure 5-5).
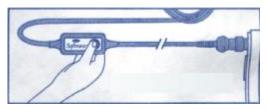
Figure 5-5 Secure adhesive pad to mother

⑦ Ask the mother to cough. A spike on the tracing in response to the cough indicates proper positioning and function of the Saflex™ IUPC.

(3) Rezeroing the System

If rezeroing of the Saflex™ system is required during use, follow this procedure.

① With the catheter connected to the cable; Press and hold the blue button on the reusable cable (See Figure 5-6).

Figure 5-6 Rezeroing the system

② Adjust the monitor to zero.

③ After releasing hand from monitor, release the blue button on the cable and resume monitoring.

To Check Cable Function

If cable performance is in question, follow this procedure:

① Disconnect the catheter from the cable and plug the cable end into the in-line cable test port (See Figure 5-7).

Figure 5-7 Cable check

② Press and hold the blue button on the cable. Adjust the monitor to zero.

③ After releasing hand from monitor, release the blue button on the cable.

A reading of 40-60mmHG on the monitor indicates the cable is functioning. If this reading is not obtained, replace the cable.

⚠ WARNING ⚠ : **Before insertion, placental position should be confirmed, amniotic membranes adequately ruptured and sufficient cervical dilatation assured.**

⚠WARNING⚠: **Do not insert the introducer beyond the cervical OS. Attempt to insert the catheter opposite the placental site. Use caution when uterine infection is present.**

⚠WARNING⚠: **If resistance is met at any time during insertion, withdraw the catheter slightly and attempt insertion at a different angle. Forced insertion may result in patient discomfort or injury.**

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

◇CAUTION◇**: 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 Saflex™ IUPC is dependent on the skill of the clinician who applies /use it.**

◇CAUTION◇**: Read** Directions For Use of Disposable Saflex™ 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.**

5.5 Remote Patient Marker Recording of Fetal Movement

Insert the marker cable of fetal movement into its socket. When FHR is monitored, the mother takes the event 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 shown at the display screen and 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 ultrasound 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 cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor.

② Many cleaners 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 parts of the monitor into any liquids.

⑥ Avoid pouring liquids on the monitor while cleaning.

⑦ Don't remain any cleaning solution on the surface of the monitor.

6.2.1 Cleaner

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 Transducer

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℃.

② Do not autoclave the transducers and cables or heat them above 70℃.

6.3.1 Cleaning of TOCO Transducer

To clean a TOCO transducer:

① Wipe the transducer with a cloth.

② Clean the transducer with a cloth soaked in a solution of soap and water, or a cleaning solution. Do not immerse the transducer in the solution. Use only the following cleaning solutions:

    Z BURATON LIQUID

    Z MIKROZID

    Z ETHANOL 70%

    Z SPORACIDIN

    Z CIDEX

    When using a cleaning solution, follow the manufacturer's directions carefully to avoid damaging the transducer.

③ Wipe the transducer with a cloth damped with water.

④ Wipe the transducer with a clean, dry cloth to remove any remaining moisture.

6.3.2 Cleaning of Ultrasound Transducer

To clean an ultrasound transducer:

① Wipe the transducer with a cloth.

② Immerse the transducer in a solution of soap and water, or a cleaning solution. Use only the following cleaning solutions:

- **Z** BURATON LIQUID
- **Z** MIKROZID
- **Z** ETHANOL 70%
- **Z** SPORACIDIN
- **Z** CIDEX

When using a cleaning solution, follow the manufacturer's directions carefully to avoid damaging the transducer.

③ Rinse the transducer with water.

④ Wipe the transducer with a clean, dry cloth to remove any remaining moisture.

6.3.3 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℃.

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 cleaners 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℃;

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.