EDAN INSTRUMENTS, INC.

M3B
Vital Signs Monitor

Service Manual
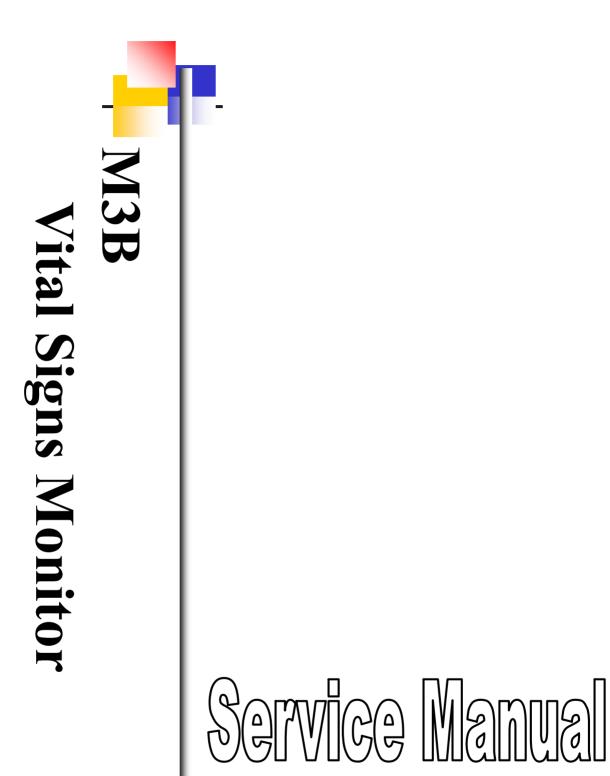
Manual Ver: V1.0

Release Date: Aug. 2008

Part Number: MS1R-109455-V1.0

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Responsibility on the Manufacturer Party

EDAN is responsible for safety, reliability and performance of this equipment only in the condition that:

- All installation, expansion, change, modification and repair of this equipment are conducted by EDAN qualified personnel; and,
- Applied electrical appliance is in compliance with relevant National Standards; and,
- The monitor is operated under strict observance of this manual.

NOTE：
This equipment is not intended for family usage.

⚠ **WARNING** ⚠：
This monitor is not a device for treatment purpose.

I

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.

Revision History

This service manual shall be revised whenever changes in regulatory requirements dictate.

Date	ECO	Version	Revision history
5th Aug. 2008		V1.0	1st edition

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1 Introduction

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1.1 General Information

M3B Vital Signs Monitor (hereinafter called monitor) monitors parameters such as CO_2 and SpO_2, and is adaptable to adult, pediatric, and neonatal in a hospital environment and during patient transport both inside and outside hospitals. The user can select different parameters configuration according to different requirements in clinic, hospital or operating room.

The monitor centralizes the function of parameter measurement modules, display, record and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the LCD display screen, SpO_2 waveform, CO_2 waveform and all the monitoring parameters can be displayed clearly.

M3B monitor is a user-friendly device with operations conducted by a few buttons on the front panel. Refer to Button Functions for details.

Figure1-1 M3B Vital Signs Monitor

M3B Vital Signs Monitor can monitor:

SpO_2: Arterial oxygen saturation (SpO_2);

Pulse Rate (PR);

SpO_2 PLETH (Plethysmogram);

CO_2: End Tidal CO_2 ($EtCO_2$);

Inspired Minimum CO_2 ($InsCO_2$);

Air Way Respiration Rate (AwRR).

M3B monitor provides extensive functions as visual and audible alarm, net connection, nurse call, recorder and storage for trend data, SpO_2/CO_2 measurements review, net connection, nurse call, alarm events and so on. The recorder, wireless net connection and mobile storage are optional functions for monitor.

1.2 Screen Display

M3B monitor is equipped with LCD. The patient parameters, waveforms, alarm messages, bed number, time, monitor status and other data can be reflected from the screen.

The screen is divided into three areas:

1 Information area ① ④

2 Parameter area ②

3 Waveform / Trend table / Alarm list area ③
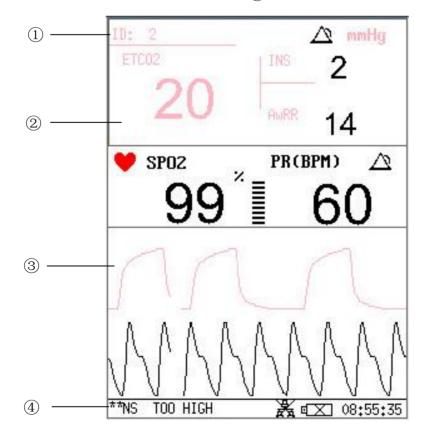
Figure 1-2 Main display with waveform
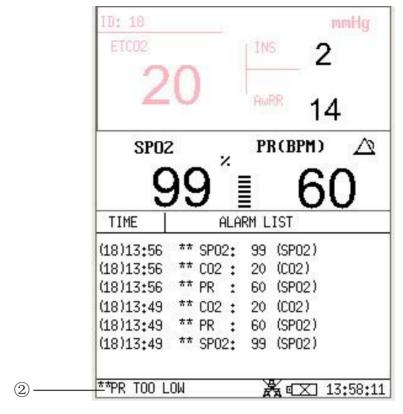
Figure 1-3 Main display with data

The icons on the interface and their meanings are as follows:

▭▰▰▰	Battery status indicator
⊣⊏	Connected to mains power supply
몸몸	Network connection indicator
윻	Network connection off
△	Medium/Low alarm icon
△	High alarm icon
⚲	Audio system off icon
⚲	Audio alarm paused icon
⚠	Parameter alarm off
🯅	Patient type: ADU

	Patient type: PED
	Patient type: NEO
	Heart beat
ID	Current patient ID
08：55：35	Current time

Information Area (① ④)

The Information area is at the bottom and right part of the screen, displaying operating state of the monitor and status of the patient.
The information area contains following data:

— Patient type and ID;
— Signs indicating the net connection status;
— Signs indicating the battery or mains power supply status;
— Current time;
— Signs indicating the sensor off or alarm off.

Parameter Area (②)

Parameter area is on the right of Waveform area, and parameters are displayed:

SpO_2:
— SpO_2 (Unit: %)
— PR (Pulse Rate, unit: BPM)

CO_2:
— $EtCO_2$ (unit: mmHg or kPa)
— INS (unit: mmHg or kPa)
— AwRR (Unit: times/minute)

Waveform Area / Trend Tab / Alarm List (③)

It can display SpO_2 and CO_2 waveform, Trend tab or Alarm list. You can select it in the SELECTION of SYSTEM MENU.

Alarm Indicator and Alarm Status

Under normal status, the alarm indicator does not light.
When alarming, the alarm indicator lights or flashes. The color of light represents the alarm level.
Refer to Chapter **Alarm** for details.

Refer to relative content of parameter for Alarm information and prompt.

Charge Indicator and Charge Status

To indicate the status of charging: When the battery is charging, the light turns to yellow; after the charge is finished, the light will be off.

1.3 Button Functions
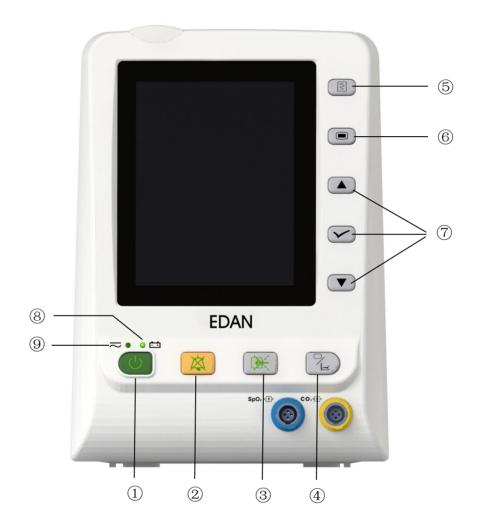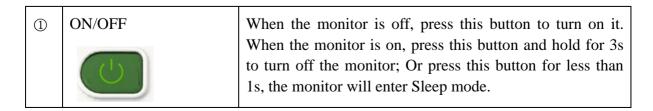
Figure1-4 Buttons

All the operations to the monitor can be finished by several buttons.

①	ON/OFF	When the monitor is off, press this button to turn on it. When the monitor is on, press this button and hold for 3s to turn off the monitor; Or press this button for less than 1s, the monitor will enter Sleep mode.

②	SILENCE	Press this button for less than 2s to pause audio alarm for 2min, then the icon displays. When repress it or the pause time is over, the audio alarm can resume to the normal monitoring status. Press this button for more than 2s can turn off the audio system, including audio alarm, key volume and pulse tone. The icon displays in Information area. Press the button again can resume the audio system.
③	CO_2 START/STOP	Press to start the CO_2 measuring. During the measuring process, press the button to stop measuring.
④	TREND/WAVEFORM	Press this button to change the display screen for data list.
⑤	RECORD	Press to print out current displayed trend list or alarm list.
⑥	MENU	Press to call up the SYSTEM MENU. Refer to Chapter SYSTEM MENU for details in User manual.
⑦	UP OK DOWN	Select the items in menu, or decrease or increase the items. Confirm the selection by OK button.

Above the ON/OFF button are the charge indicator ⑧ and power indicator ⑨.

1.4 Interfaces

For the convenience of operator, interfaces of different function are in different sites of the

monitor.

Left Side of the Monitor

At the left side of the monitor, there is the recorder's paper inlet cover (①).

Figure1-5 Left Panel

Sensor port on the front panel

Connectors for cables and sensors are as shown in Figure 1-5.

1. SpO_2 sensor connector ②

2. CO_2 sensor connector ③

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

Rear Panel

⚠

This symbol means "BE CAREFUL". Refer to the manual.

This symbol indicates that the instrument is IEC/EN60601-1 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, and is suitable for use during defibrillation.
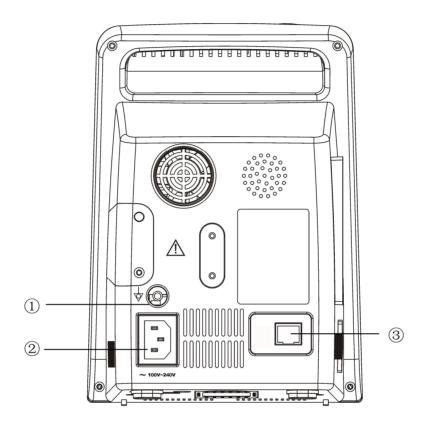
Figure1-6 Rear Panel of M3

Sockets on the rear panel are shown in Figure1-6,

① Equipotential grounding terminal for connection with the hospital's grounding system.

② Power supply socket: AC100 ~ 240 V, 50/60 Hz.

③ Network Interface (reserved): Standard RJ45 Socket, for connecting to MFM-CMS of EDAN.

Bottom panel

There are battery compartment and fuse box at the bottom panel.
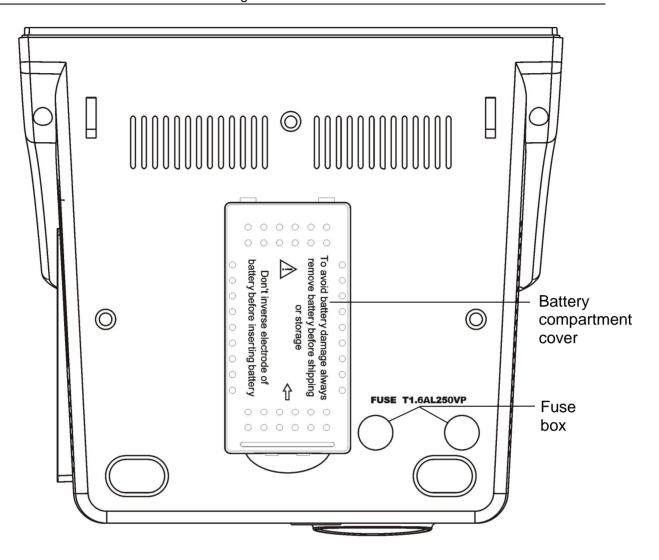
Figure1-7 Bottom panel

1.5 Built-in Rechargeable Battery

The monitor is equipped with a built-in rechargeable lithium-ion battery (hereinafter called battery). When switch on AC power supply, the battery will be recharged automatically until full electric energy. There is a sign " ⊏⊢ " or " ▣▰▰▰ " in the lower right corner of screen.

— when the monitor is working with AC mains power, and it has no battery or the battery has full electric quantity, it displays ⊏⊢;

— when the monitor is working with AC mains power, and the battery is recharging, it displays ▣▰▰▰;

— when the monitor is working with battery, it displays ▰▰▰. If the battery is empty, it displays ▣✕.

If the monitor is off, you can see recharging status from the charger indicator. Battery status light is yellow when recharging, off when full.

For recharging, the battery is 90% to 100% charged after 5 hours of recharging.

Replace Battery

During monitoring state or communication state, when the electric energy of battery is low or empty, the battery state icon will display and flash.

When the lifespan of battery is over, or foul odor and leakage has been detected, please contact with manufacturer or local distributor for replacement of battery.

⚠ **WARNING** ⚠

Do not take off the battery when monitoring.

The unexpected power supply off can not impact the monitor normal working, for it has battery for standby.

⚠ **WARNING** ⚠

Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, recharge, or storage. Keep it away from the monitor.

⚠ **WARNING** ⚠

Make sure the monitor is used in the appointed range of voltage, the effect of power supply can be not noticeable.

⚠ **WARNING** ⚠

Before using the rechargeable battery, be sure to read the user manual and safety precautions thoroughly.

⚠ **WARNING** ⚠

Do not place battery in the monitor with the (+) and (-) in the wrong way around.

⚠ **WARNING** ⚠

Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal object, which can result in short circuit.

⚠ **WARNING** ⚠

Do not heat or throw battery into a fire.

Do not use, leave battery close to fire or other places where temperature may be above 60℃.

⚠ **WARNING** ⚠

Do not immerse, throw, and wet battery in water/seawater.

⚠ **WARNING** ⚠

Do not destroy the battery: Do not pierce battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not

disassemble or modify the battery.

⚠ **WARNING** ⚠

Before transporting, the battery should be taken off from monitor.

⚠ **WARNING** ⚠

Please take out the battery before storing the monitor for more than 1 month.

2 Principle

2.1   General Parts

The monitor has been designed to measure physiological parameters including SpO_2 and CO_2.

There are five parts in monitor, see figure 2-1.

- Parameter measuring part
- Main control part
- Interface part
- Power supply part
- Other auxiliary parts
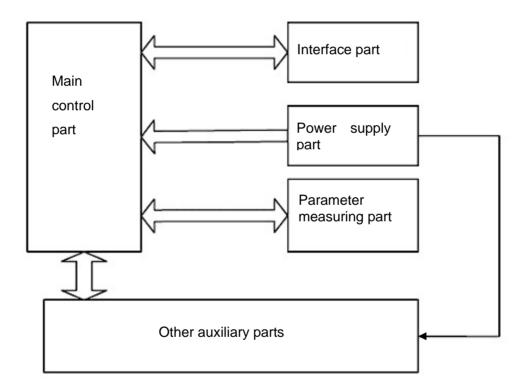

Figure2-1 Monitor Structure

2.1.1 Parameter Measuring Part

The monitor acquires the physiological signals of Oxygen saturation of the blood (SpO_2) and CO_2. The Parameter measuring part can transform physiological signals to electrical signals, process and transfer the values, waveforms and alarm information to Main control part, and then display them by Interface part.

2.1.2 Main Control Part

Main control board consists of Core board and Interface board. It has CPU/memory, display circuit, network circuit and I/O interface. Main control board of the integrated board is used to drive man-machine interface, manage parameter measurement and provide other specific functions to the user such as configuration storage, waveform and data review, etc.

2.1.3 Interface Part

The man-machine interfaces are LCD display, recorder, speaker, indicator, keys and encoder.
The LCD display is the most primary output interface, displaying real-time or history data and waveforms, various patient information and alarm prompts on the screen for the user's observation.
Recorder is an auxiliary device to the display, which could print out various user-selected data for use and preservation.
Speaker gives heart beat tone and audio alarm.
Indicator provides additional information about power supply, battery and alarm.
Keys and encoder are user-input interfaces of the monitor, user could input information and instructions into the monitor by using them.

2.1.4 Power Supply Part

Power supply is an important part of the system, consisting of power board, power switch board, battery and fan.
The main power board converts the AC mains supply into 5V and 12V DC to energize other parts of the system. The power switch board can supply special power supply to LCD display. The battery could maintain the formal function of the system for a short period when AC mains supply is disconnected. A small fan requiring DC input is used to realize superior ventilation.

2.1.5 Other Auxiliary Parts

RJ45 on-line upgrade port is available on the monitor, which allows the service engineer to upgrade the system software without necessarily opening the enclosure of the monitor. This port is NET function.

2.2 Hardware Functional Principle

The following figure shows the hardware structure of the whole monitor as well as the connection relationships between different parts. The board in the center of the figure is the core part of the monitor, i.e., integrated board for main control and parameter measurement, which, though being a single board, could realize the measurements of all the parameters; accordingly uniform A/D conversion and digital processing system is used.
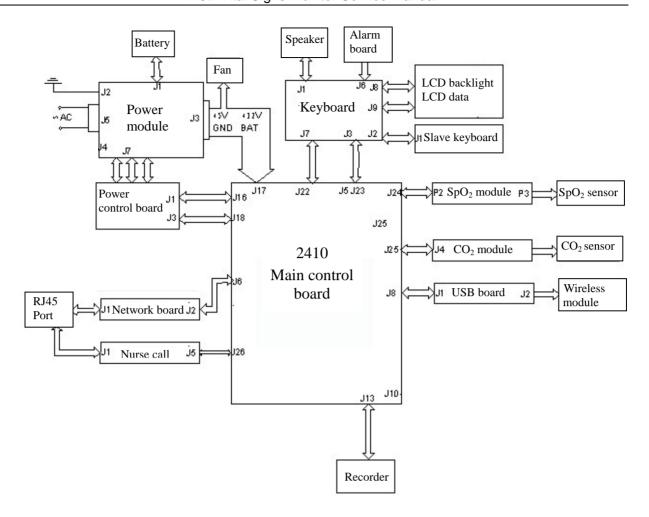
Figure2-2 Structure and Part Relationship

NOTE:

The Nurse call board and the Network board are optional configuration, they can not be installed at the same time. If you want to use the Nurse call function, you should install the Nurse call board, otherwise you should install the Network board.

2.2.1 Power Module

This module provides DC supplies to other board.

Schematic Diagram
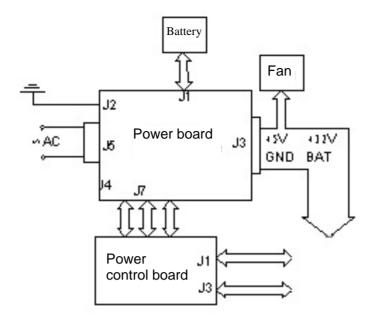
Figure2-3 Schematic Diagram of Power Board

Principle Introduction

This module converts 220V AC mains power supply or battery power into 5V, 12V and -12V DC supplies to power other boards. If AC mains and battery coexist, the former take the priority to power the system and charge the latter at the same time.

AC/DC

Converts high-voltage AC supply into low-voltage DC supply to power subsequent circuits and charge the battery.

Battery Control Circuit

If AC supply and battery coexist, this circuit controls the output from AC/DC part to charge the battery. If AC supply is disconnected, this circuit controls the battery to power the subsequent circuits.

5V DC/DC

Convert the DC supply from the previous circuit into stable 5V DC supply to power other boards.

12V/-12V DC/DC

Convert the DC supply from the previous circuit into stable 12V/-12V DC supply to power other boards.

Power Switch Circuit

Control the working status of 5V DC/DC and 12V DC/DC in order to control ON/OFF action of the monitor.

Voltage Detection Circuit

Detects the output voltage of every part in detection circuit, converts analogue signals to digital signals and then send them to Main control board for processing.

2.2.2 Main Control Board

Main control board which is consisted of Interface board and Core board, is the heart of monitor, it can do system control, system adapter, system management, data processing, file management, display processing, recorder management, data storage, system diagnosis, fault alarm, etc.

Main control board schematic diagram
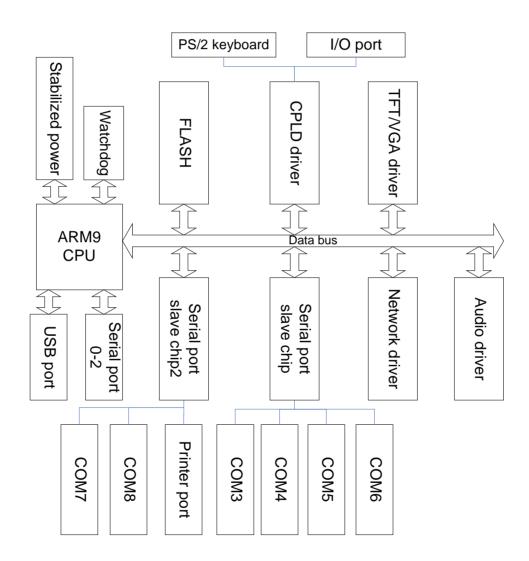
Figure2-4 Schematic Diagram of Main Control Board

CPU System

CPU is the kernel of ARM9, it is the core part of the Main control board. CPU connects with other periphery modules by bus and I/O cable, it can realize data communication, data processing, logical control and other functions.

RTC

RTC can offer second, minute, hour, day, month, year and other calendar information. CPU can gain such calendar information from RTC, it also can rewrite the data in RTC.

Ethernet Controller

Ethernet controller supports IEEE 802.3/IEEE 802.3u Ethernet standard, supports 10Mbpsdata transmission rate. CPU exchanges data with Ethernet via Ethernet controller.

LCD Controller

LCD controller can control LCD display.

2.2.3 Keyboard

This module acts as the man-machine interface.

Schematic Diagram
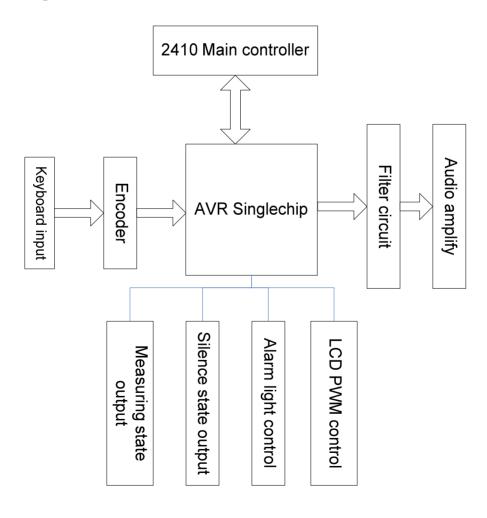
Figure2-5 Schematic Diagram of Keyboard

Principle Introduction

This module detects key and encoder input signals, converts them into codes and sends to Main control board. Main control board sends command to the keyboard and the latter accordingly control indicator and audio process circuit to realize audio and visual alarm.

CPU

Detect key and encoder input signals;

Control LED status;

Regularly zero Watchdog Timer;

Communicate with Main control board.

Audio Process Circuit

Advance audio signals to drive the speaker to give sound.

Watchdog

After power-on, supply Reset signal to CPU;

Provide functions of Waterdog Timer Output and voltage detection.

2.2.4 Recorder Module

This module is designed to drive line thermal recorder.

Schematic Diagram
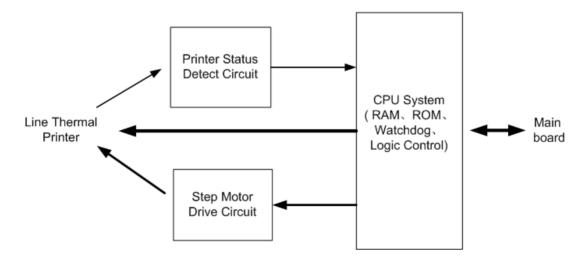
Figure2-6 Schematic Diagram of Recorder Module

Principle Introduction

This module receives printing data from Main control board. At the same time of converting the

data into dot matrix data and sending them to the thermal recorder, it also drives the recorder to start printing action.

Step Motor Drive Circuit

A step motor is used in the recorder to feed paper. This circuit is designed to drive the step motor.

Recorder Status Detect Circuit

Detect the status of the recorder and send the information to CPU System, including the position of paper platen, whether there is paper, temperature of thermal head.

CPU System

Process printing data;
Control recorder and step motor;
Collect recorder status information and realize corresponding control;
Communicate with Main control board.

2.3   Software Function Principle

2.3.1 System Software
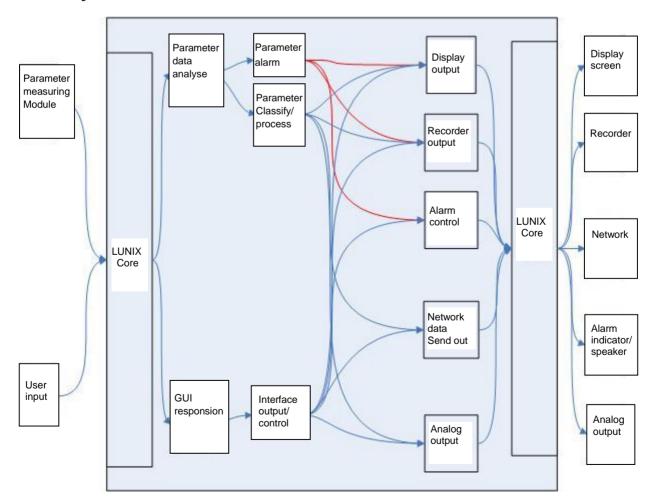
Figure 2-7 System Function General Diagram

It indicates software system inner the frame above, on the left of frame is software system input, and on right is software system output; parameter measuring module exchanges data with software system by serial ports, while user communicates with system by keyboard; among the output devices, recorder and alarm devices receive data via serial ports, the analogue output apparatus is MBUS, screen and network controller are controlled directly by CPU.

2.3.2 System Software Function

No.	Task name	Task function	Perform cycle
1	System initialization	System initialization task	Once after POST
2	Parameter data process	Parameter data analysis and processing, result storage task	Real-time data processing
		Parameter waveform data analysis	
3	Timing information display	Accomplish timing display fresh function	Once per second
4	Module and interface transform task	Waveform and parameter interface transform task	Interface change task
5	User commend and interface processing	Processing user key information and displaying user interface	With key task
6	System monitor	System monitor, voltage monitor, battery management task	Once per second
7	Recorder task	Accomplish output all the records	Have record task
8	Parameter processing task	Accomplish every commend and response processing of relative parameters	Real-time processing
9	Watchdog task	Accomplish system watchdog management task	Once per second

Table2-1 System Task Table

2.4   System Parameters

2.4.1 General

Parameter module is the basic unit to acquire signals for monitoring parameters in monitor. The results are transmitted to Main control board by keyset to finally accomplish processing and displaying of data and waveforms. Main control board commends and module status messages can also be transmitted via keyset. The keyset can also realize power switching and conversion. The whole system structure is show in the figure below:
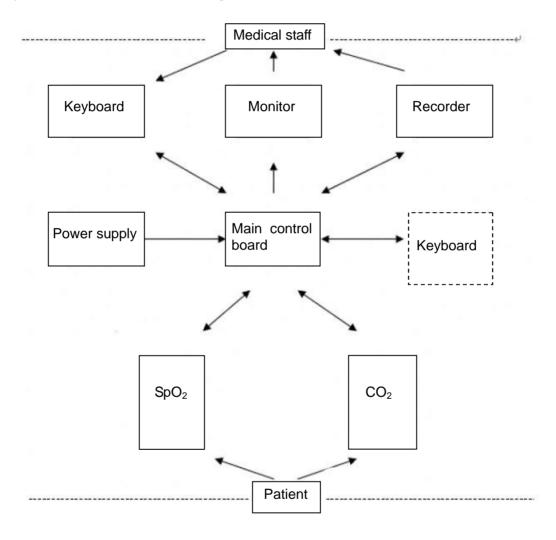
Figure2-8 System structure

As shown in the above figure, the two parameter modules execute real-time monitoring of SpO_2 and CO_2 respectively through using cuff and measuring cables, the results can send to Main control board for processing and displaying, and they can also be sent to recorder for output and printing. Hereinafter the function details of parameter monitor will be explained.

2.4.2 SpO$_2$

SpO$_2$ is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO$_2$ measuring unit. The light-electronic transducer in finger sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The PLETH curve and numeral value of SpO$_2$ will be obtained.

By tracing the pulse waveform in the fingertip, using specified arithmetic and consulting the clinical data table, we can obtain the SpO$_2$ value. The SpO$_2$ sensor consists of two LED and a photodetector. The two LED are respectively red diode and infrared diode, which are lighted on according to certain time sequence. When the capillary vessel of the fingertip congests repeatedly, the light of the LED is absorbed by blood vessels and organs and then projected onto the photodetector. The photodetector can detect the light intensity varying with pulse changes and display the changing light intensity in the form of changing electronic signals. The ratio between the DC and AC of the two types of signals for light is the proportion of oxygen in the blood. Then we can calculate correct SpO$_2$ value by using specified arithmetic and also calculate pulse rate according to the SpO$_2$ waveform.

The SpO$_2$ module mainly consists of following four parts: sensor, signal processing, control unit of LED driving sequence, singlechip.

2.4.3 CO$_2$

The measure of CO$_2$ is based on infrared absorption characteristic of CO$_2$ module. CO$_2$ molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO$_2$ concentration of patient sample, the CO$_2$ concentration will compute from the detecting CO$_2$ absorption intensity of patient sample. The relation between partial pressure and percentage of CO$_2$ concentration is given below:

$$P \text{ (mmHg)} = \text{Percentage (\%)} \times \text{Pamp (ambient pressure)}$$

There are Mainstream and Sidestream modules according to different connecting way of infrared sensor.
SideStream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO$_2$ sensor. MainStream measurement uses a CO$_2$ sensor attached to an airway adapter directly inserted into the patient's breathing system. This method is available using the monitor's built-in CO$_2$ measurement.

This module can be applied in operation room, monitor units etc, it can measure the CO$_2$ partial pressure or concentration of patient Air Way, obtain End tidal CO$_2$ (EtCO$_2$), Inspired minimum CO$_2$ (InsCO$_2$), Air Way Respiration Rate (AwRR), and display CO$_2$ concentration waveforms.

3 Installation of Monitor

3.1 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.

n   Check for any mechanical damage.

n   Check all the cables, modules and accessories.

If there is any problem, contact the manufacturer or local representative immediately.

3.2 Connect the Power Cables

Connection procedure of the AC power line:

n   Make sure the AC power supply complies with following specification: 100~240VAC, 50/60Hz.

n   Apply the power line provided with the monitor. Plug the power line to input interface of the monitor. Connect the other end of the power line to a grounded 3-phase power output.

n   Connect to the ground line if necessary. Refer to Chapter Safety Guidance in User manual for details.

NOTE:
When the battery configuration is provided, after the monitor is transported or stored, the battery must be charged. Powering on without connecting AC power supply may cause the monitor out of work. Switch on AC power supply can charge the battery no matter if the monitor is powered on.

3.3 Power on the Monitor

Power on, LOGO information will be displayed on the screen.

NOTE:
Check all the functions that may be used to monitor and make sure that the monitor is in good status.

NOTE:
If chargeable batteries are provided, charge them after using the monitor every time to ensure the electric power is enough.

3.4 Connect Sensor to Patient

Connect all the necessary patient sensors between the monitor and the patient.

NOTE:
For information on correct connection, refer to related chapters in User manual.

3.5 Check the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if paper is properly installed in the slot. If no paper present, refer to User manual for details.

3.6 Other Notes

l   When the monitor is used with other electrical medical equipment, it should comply with the relative regulations to protect against burns to the patient and medical staff.

l   EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

4 Test and Calculation

4.1 Check the Monitor

For the conventional testing contents of monitor, please refer to the User Manual. The information in this chapter is only a brief introduction.

First check the device appearance and installation, and be sure that:

1) The shell of the device is clean and has no scratches. The installation is stable. When shaking the device, these is no inside leftovers.

2) Buttons are smooth and free for operation.

3) Labels are complete and sufficient and correct in delivering information.

4) Standard configuration is complete, the sockets are installed safely. All the outer cables, inserted modules and accessories are in good condition.

5) There is any mechanical damage.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital or our company service personnel immediately.

Connect all the cables well, then turn on the monitor，the POST (Power-On-Self-Test) is performed automatically. After successfully POST, the EDAN logo will display, then enter the main interface.

Check if all the monitoring functions of the monitor can work normally so as to make sure that the monitor is in good condition.

Routine Check

The overall check of the monitor, including the functional safety check, must be performed by qualified personnel once every 6 to 12 month or each time after fixing up. All checks that need to open the monitor enclosure must be performed by qualified service personnel.

⚠ WARNING ⚠
If the hospital or agency does not follow a satisfactory maintenance schedule when using monitor, the monitor may become invalid, and the human health may be endangered.

4.2 CO$_2$ Calibration

The MainStream C5 CO$_2$ module and SideStream LoFlo CO$_2$ module are optional configuration

for CO_2 monitoring function. Before you using the CO_2 module, you can do zero calibration by ZERO CAL in CO_2 SETUP.

Zero Calibration:

Enter SYSTEM MENU → CO2 SETUP, the menu displays:

```
┌─────────────────────────────────┐
│           CO2 SETUP             │
│- - - - - - - - - - - - - - - - -│
│  WAVE SCALE    LOW              │
│                ┌───────┐        │
│  WAVEFORM      │FILLED │        │
│                └───────┘        │
│  WORK MODE     STANDBY          │
│  BARO PRESS    760mmHg          │
│  O2 COMPENS     16%             │
│  ANE AGENT     0.0%             │
│  BALAN GAS     ROOM AIR         │
│  APNEA ALM     20S              │
│  ZERO CAL                       │
│- - - - - - - - - - - - - - - - -│
│              EXIT               │
└─────────────────────────────────┘
```
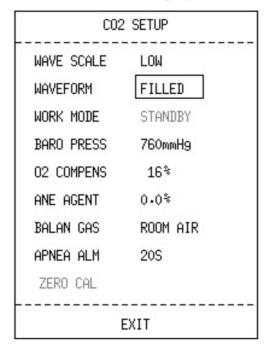
Figure4-3 CO_2 Gain Calibration

ZERO CAL: used to perform zero calibration for CO_2 module.

When a dramatic change in CO_2 measurement or the accuracy of reading is suspected by the clinician, please select "ZERO CAL" item, then the system will automatically inhale clean room air to the air inlet of CO_2 module beside the monitor, and start zero calibration.

When the zero calibration is started, there will be prompts:

Zeroing

Zero successfully

Zero required

Zero started

Zero not ready

Breath detected
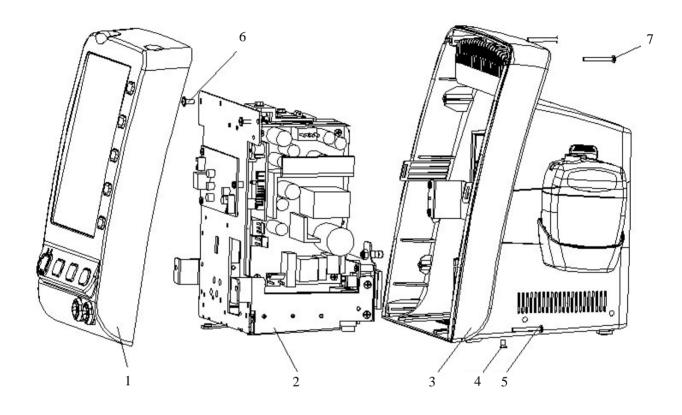
If the breath is detected during the zero calibration, it will prompt "Breath detected". After the zero calibration is finished successfully, it will prompt "Zero successfully".

The Zero calibration is intended to decrease the effect caused by baseline drifting. When doing calibration, the item ZERO CAL in CO_2 SETUP menu is unavailable. After the Zero calibration is finished successfully, the item is reactive.

5 Disassembly Graph

This chapter introduces the inner structure and parts of the monitor, including disassembly graph, front shuck assembly, rear shuck assembly and main bracket assembly.
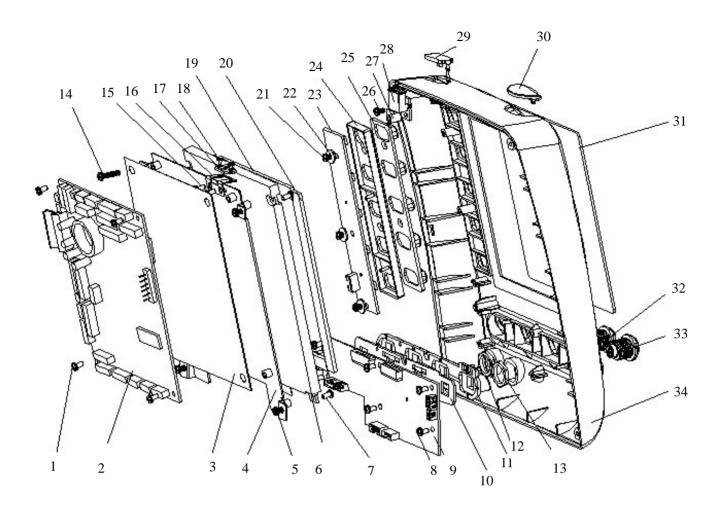
5.1   Disassembly Graph

1: M3 Front shuck assembly; 2: Main bracket assembly; 3: M3 rear shuck assembly; 4: Cross recessed countersunk head screw M3×6; 5, 7: Cross recessed round head screw M3×25; 6: Cross recessed pan head coil spring screw.

Figure5-1 Monitor disassembly, exploded
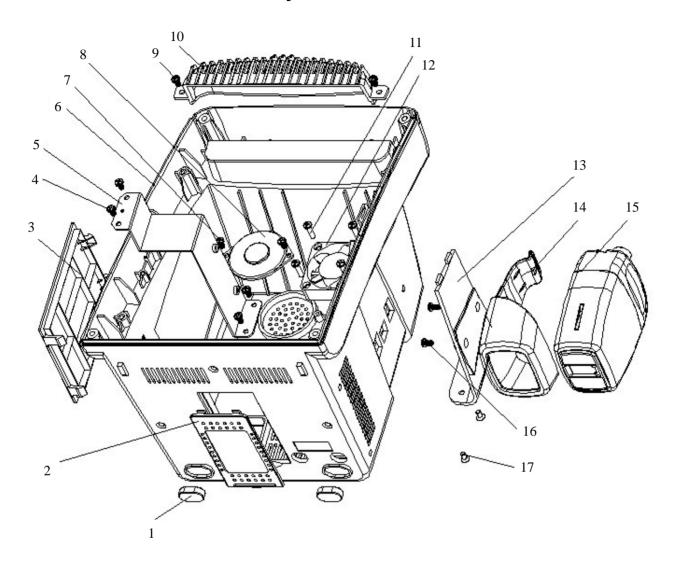
5.2   Front Shuck Assembly

1, 7: Cross recessed pan head screw M3×6; 2: Main control board; 3: M3 Main control board Insulated gasket; 4: M3 Screen bracket; 5, 8, 21, 26: Cross recessed pan head self-tapping screw ST3×8; 6: 5.7 inches LCD; 9: Main control keyboard; 10: M3 Main control keyboard pressure plate; 11: M3 Main control keyboard silica gel button; 12, 13: M14 hexagon head nut; 14: Cross recessed pan head self-tapping screw ST3×15 plain; 15: Cross recessed pan head screw M3×4 (iron); 16: M3 alarm light fixed board; 17: Alarm light board; 18: Cross recessed pan head screw M2×3; 19: M3 short sponge bar 91.6×9×2.5; 20: M3 long sponge bar 136×9×2.5; 22: Insulated plain washer Φ10.3MM (red); 23: Slave keyboard; 24: M3 slave keyboard pressure plate; 25: M3 slave keyboard silica gel button; 27: M3 copper grounding sets; 28: USB board; 29: M3 USB silica gel seal cover; 30: M3 alarm lampshade; 31:5.7 inches LCD screen protection/Homochromy; 32: CO_2 connector; 33: SpO_2 connector; 34: M3 front shuck and seal Φ2.0×160MM.

Figure5-2 Front shuck assembly
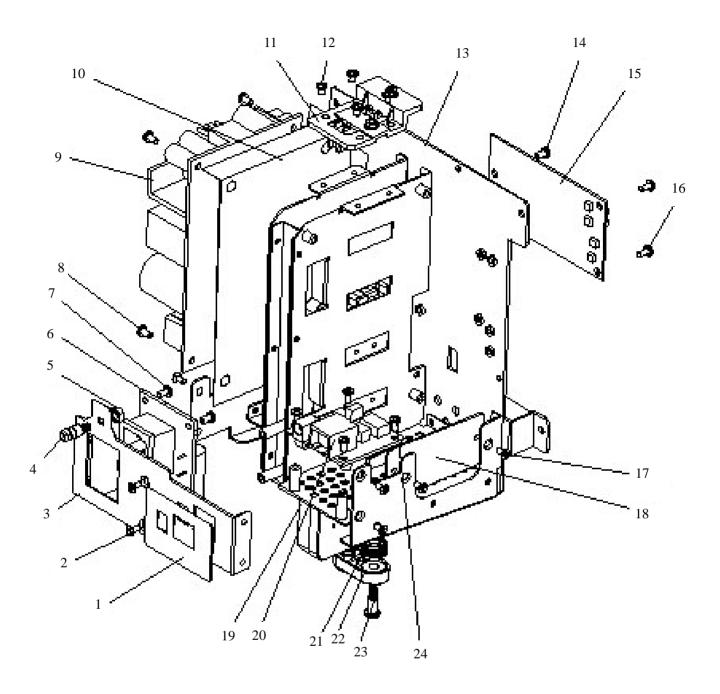
5.3 Rear Shuck Assembly

1: M3 rear shuck rubber feet; 2: M3 battery compartment cover; 3: M3 recorder slot cover; 4, 9: Cross recessed pan head self-tapping screw ST3×8; 5: M3 recorder bracket; 6: M3 Rear shuck; 7: Cross recessed pan head self-tapping screw ST2.6×6; 8: Speaker; 10: M3 pull hand; 11: Cross recessed pan head screw M3×12 stainless steel; 12: Fan; 13: CO_2 bracket link board; 14: SideStream CO_2 bracket; 15: SideStream CO_2 module; 16: Cross recessed pan head self-tapping screw ST3×6 plain; 17: Cross recessed countersunk head screw M3×6.

Figure5-3 Rear shuck assembly

5.4 Bracket Assembly

1: Label on M3 rear board; 2: Cross recessed countersunk head screw M3×6; 3: M3 rear board; 4: M3 grounding wire pole; 5, 17: Nut M4; 6: AC power supply interface board; 7, 8, 12, 14, 16, 24: Cross recessed pan head screw M3×6; 9: Power board; 10: M3 power module insulated gasket; 11: Lithium battery box connector components; 13: M3 main bracket; 15: SpO$_2$ module; 18: M3 baffle; 20: Lithium battery; 19: Lithium battery; 20: Network interface board; 21: M3 battery baffle; 22: M3 battery baffle torsion spring; 23: M3 battery baffle fixed nut.

Figure5-4 Support assembly

6 Troubleshooting

In transportation, storage and use of monitor, various factors such as unstable network voltage, changing environmental temperature, falling-down or impact, component aging may all result in monitor failures and therefore affect normal application of the device. In failure conditions, professional personnel with the experience of repairing electronic medical devices should perform component-level upkeep for the failure classification listed in the table below. Component-level upkeep means based on analyzing, replacing or trial-operating the component, we can pinpoint the failure on a certain component of the device, such as power board, Main control board, LCD assembly, measuring cable or parameter module, etc. Repair of only some components means component-level repair. The repair operation must be conducted by a service engineer with abundant experience and with the assistance of special equipment and in specific environment and conditions.

6.1   Device Failures

Failure	Possible cause	Solution
No display after power-on, power indicator light is not on or fan does not run.	① Fuse damage (If has fuse on)	① Replace fuse
	② Power damage	② Replace power board
	③ Component short-circuit	③ Anchor the short-circuit component
No display after power-on or black screen during operation, however, power indicator lights on and fan runs normally.	① Main control board failure or display failure.	① Refer to the information about confirming display failure.
Characters are displayed normally, however waveforms are displayed intermittently.	① Data communication error between Main control board and parameter module	① Based on error prompt, replace Main control board, keyset or parameter module so as to confirm the failure.
An operation or measurement function is disabled.	①Main control board or corresponding component damage	① Examine Main control board and corresponding components
Device is occasionally stoned.	① Moment intensive interference of network	① Check power supply and grounding system
	② Poor performance of power board	② Replace power board

	③ Poor performance of Main control board	③ Replace Main control board
	④ Bad connection of power supply or Main control board	④ Replace or repair connectors

6.2 Display Failures

Failure	Possible cause	Solution
When powering on the device, power supply is in normal operation, however, there is no display or screen goes black during normal operation.	①Power switch board damage	① Replace Power switch board
	② Bad connecting wire of display	② Repair or replace connecting wire
	③ Damage of Main control board	③ Replace Main control board
	④ Keyboard display driver failure	④ Replace keyboard main control board

6.3 Operation, Recording, Network Linking Failures

Failures	Possible cause	Solution
Keys are disabled.	① Keyboard is damaged.	① Replace keyboard.
	② Connecting wire of keyboard is damaged.	② Replace or repair connecting wire of keyboard
Sound is raucous or there is no sound.	① Keyboard failure	① Replace keyboard
	② Speaker or connecting wire failure	② Replace speaker or connecting wire
Recorder can not execute printing operation.	① Recorder has no paper or paper bail is not pressed down.	① Install paper and press down the paper bail
	② Recorder failure	② Replace the recorder
	③ Driving power of the recorder has failure	③ Replace the power supply
	④ Connecting wire of the recorder is damaged.	④ Replace or repair the connecting wire of the recorder

Record paper goes out skewwhiffly.	① Bad recorder installing or positioning.	① Adjust the installation of recorder.
Can not be linked into network	① Network linking wire is damaged.	① Check and repair network linking wire or HUB.
	② Network bed No. conflicts	② Change bed No.
	③ Main control board failure	③ Replace Main control board

6.4 Power Board Failures

Failure	Possible cause	Solution
Fuse is burned upon power-on	① Short-circuit occurs in power supply or other part.	① Check after power on
Fuse is burned although all loads are disconnected.	① Power failure	① Replace power supply
Fuse is burned after connecting a part.	① This part occurs short-circuit.	① Replace this part
Power indicator lights on, however, the fan does not run and the indicator of keyset does not light.	① +12V DC power supply has failure.	① Replace the power
Power indicator does not light on, however, the fan runs normally and the indicator of keyset lights on.	① +5V DC power supply has failure.	① Replace the power

6.5 Parameter Failures

Failure	Possible cause	Solution
No SpO_2 waveform	① Sensor or SpO_2 module is damaged	① Replace the sensor and confirm the failure
SpO_2 waveform has strong interference.	① Patient is moving	① Keep the patient quiet
	② Environment light is very intensive	② Weaken the light intensity in the environment
SpO_2 value is inaccurate	① Coloring agent has been injected into patient body	① Remove the coloring agent before perform measurement

No CO_2 waveform	① Poor connection of the CO_2 module	① Turn off the monitor and reconnect the CO_2 module
	② The CO_2 module is damaged	② Replace the CO_2 module
The CO_2 waveform is a beeline	① The CO_2 module is at STANDBY mode	① Change the STANDBY mode to MEASURE mode
	② The sample line is blocked or disconnected	② Draw off the sample line, clear it or replace it to another one.
The CO_2 waveform is abnormal, values are incorrect.	① Long time no zero calibration, the measured values are incorrect	① Enter the CO_2 SETUP, do CO_2 calibration by ZERO CAL
The measured CO_2 values are displayed as "---"	① The CO_2 module is at STANDBY mode	① Change the STANDBY mode to MEASURE mode
Prompts for CO_2 catheter is blocked on screen	① The CO_2 sample line is blocked	① Draw off the CO_2 sample line, clear it or replace it to another one.
The CO_2 measured value has error	① Long time no zero calibration, the measured value is incorrect	① Enter the CO_2 SETUP, do CO_2 calibration by ZERO CAL
	② The compensatory gas and barometric is set incorrectly	② Enter the CO_2 SETUP, set BARO PRESS or O2 COMPENS items in menu for compensatory gas or barometric correctly.

7 Maintenance and Cleaning

7.1   General Cleaning

⚠ **WARNING** ⚠

Turn off the power and disconnect the line power before cleaning the monitor or the sensor/probe.

⚠ **CAUTION** ⚠

Pay special attention to avoid damaging the monitor:

1) Avoid using ammonia-based or acetone-based cleaners such as acetone.
2) Most cleaning agents must be diluted before use. Dilute the cleaning agent as the manufacturer's direction.
3) Do not use the grinding material, such as steel wool, etc.
4) Do not let the cleaning agent enter the monitor. Do not immerse any part of the system into liquid.
5) Do not leave the cleaning agents at any part of the equipment.

⚠ **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 off any agent remained on the monitor.

⚠ **CAUTION** ⚠

Do not use EtO gas or formaldehyde to disinfect the monitor.

The monitor must be kept dust-free.
It is recommended that you should clean the outside surface of the monitor enclosure and the display screen regularly. Only use non-caustic detergents such as soap and water to clean the monitor enclosure.

Care and Cleaning

■   Cleaning:
Use fine-hair cloth moistened in mild soap liquid or cleaning agent containing 70% ethanol to clean the equipment.
Use any of the solutions listed below as the cleaning agent.

       a.   Diluted Sodium Hyoichlo (Bleaching agent)

       b.   Diluted Formaldehyde 35% ~ 37%

      c.   Hydrogen Peroxide 3%

      d.   Alcohol

      e.   Isopropanol

■   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. Recommended sterilization material:

     1   Ethylate: 70% alcohol, 70% isopropanol

     2   Acetaldehyde

■   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.

7.1.1 SpO$_2$ Sensor Maintenance and Cleaning

⚠ WARNING ⚠

Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.

⚠ WARNING ⚠

Do not subject the sensor to autoclaving.
Do not immerse the sensor into any liquid.
Do not use any sensor or cable that may be damaged or deteriorated.

For cleaning:

n   Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the sensor, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit.

n   The cable can be cleaned with 3% hydrogen dioxide, 7% isopropanol, or other active reagent. However, connector of the sensor shall not be subjected to such solution.

7.1.2 CO$_2$ Maintenance and Cleaning

NOTE:

Before cleaning the module, it should be disconnected from the monitor.

NOTE:

Do not immerse the module into liquid, or the module will be damaged.

For cleaning C5 CO$_2$ module or LoFlo CO$_2$ module:

1. Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), disinfectant spray cleaner such as mild soap.
2. Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

7.2 Maintenance Menu

Select "MAINTAIN" item in "SYSTEM MENU" to call up "ENTER MAINTAIN PASSWORD" dialog box as shown below, in which you can enter password and then customize maintenance settings. Factory maintenance function is only available for the service engineers of EDAN or representative authorized by EDAN.

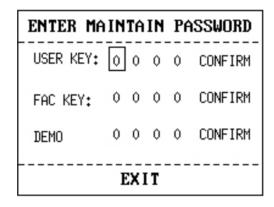Figure7-2 Enter Maintain Password

User Maintain

Input the password **9 9 8 1** in the USER KEY box and press OK button, the USER MAINTAIN menu will pop up, in which you can set up following items.
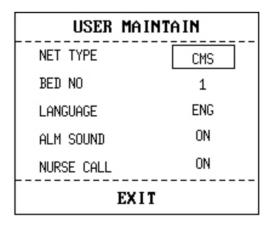

Figure7-3 User Maintain

n NET TYPE: set the net type as CMS.

n BED NO: you can set the bedside number as 1~16.

n LANGUAGE: You can set interface languages to ENG (ENGLISH), CHN (CHINESE),

ITALIAN, GERMAN, RUSSIAN, POLISH, FRENCH or SPANISH.

NOTE:
Please restart the monitor after changing the language.

n ALM SOUND: You can set alarm sound to ON or OFF. For more details refer to Chapter Alarm.

n NURSE CALL: turn on or off the nurse call. When the parameter alarm occurs, the monitor gives 3s nurse call alarm prompt; if the audio alarm or the audio system is off, the monitor can also give the nurse call alarm in abnormal condition.

n EXIT: exit the menu.

Factory Maintain

Factory maintenance function is only available for the service engineers of EDAN or representative authorized by EDAN.

Enter factory maintain through password **9 9 8 0.**

```
┌─────────────────────────────────┐
│       FACTORY MAINTAIN          │
│ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ │
│  SPO2 DEV      MEC9006           │
│                                  │
│  CO2 DEV         C5              │
│                                  │
│  POWER TYPE    ┌───────┐         │
│                │  900B │         │
│                └───────┘         │
│ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ ─ │
│           EXIT                   │
└─────────────────────────────────┘
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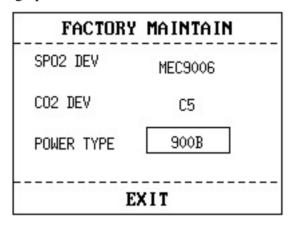
Figure7-4 Factory Maintain

Set SpO_2 and CO_2 module by SPO2 DEV (SpO_2 device) and CO_2 DEV (CO_2 device).

POWER TYPE: can set this item to 900B or 900F.

8 Accessories and Ordering Information

⚠**WARNING**⚠

The specification of accessories recommended is listed below. Using other accessories may damage the monitor.

The following accessories are recommended when using this monitor.

Part No.	Accessories
MS3-109069	EDAN SH1 Adult Reusable SpO_2 Sensor (Only compatible with EDAN SpO_2 module)
M15-40099	ENVITE Child Reusable SpO_2 Sensor (Only compatible with EDAN SpO_2 module)
M15-40125	ENVITE Neonate Disposable SpO_2 Sensor (Only compatible with ENVITE SpO_2 Extension cable)
M13-36091	ENVITE SpO_2 Extension cable (Only compatible with ENVITE Neonate Disposable SpO_2 Sensor and EDAN SpO_2 module)
MS2-30043	Nellcor Reusable Adult SpO_2 Sensor (DS-100A OxiMax) (Only compatible with Nellcor SpO_2 Extension cable)
M15-40096	Nellcor Reusable Adult/Neonate SpO_2 Sensor (OXI-A/N OxiMax) (Only compatible with Nellcor SpO_2 Extension cable)
M15-40107	Silica gel SpO_2 Sensor/ Adult CRY036-260LB ENVITEC
M15-40108	Silica gel SpO_2 Sensor/ Pediatric CRYS-3212-260LB
MS1-30131	Nellcor SpO_2 Extension cable (Compatible with Nellcor Nell-3 OXI-Max SpO_2 module and Nellcor sersor)
M50-078137	SideStream CO_2 module/SideStream 1022054
M50-078139	CO_2 Nasal Cannula, Adult/SideStream 3468ADU
M50-078140	CO_2 Nasal Cannula, Pediatric/SideStream 3468PED
M50-078141	CO_2 Nasal Cannula, Infant/SideStream 3468INF
M50-078154	Cannula, with screw locks, dehumidification/Intubation baby. SideStream 3475
M50-078166	SideStream CO_2 bracket/1027730
M15-040143	MainStream CO_2 sensor/ MainStream 1015928

M50-078155	Adult Airway Adapter/MainStream 6063
M50-078156	Infant Airway Adapter/MainStream 6312
M50R-78035	Printing Paper
MS3-30493	Mounting system (Simple)
MS3-30164	Mounting system
M21R-064115	Rechargeable Lithium-Ion Battery/HYLB-1049 (14.8V, 4.4Ah)
MS3-109480	Rolling Stand

9 Warranty and Service

Standard Service

The warranty period begins on the date the products are shipped to customers. If customer promptly notifies EDAN of customer's warranty claim hereunder, EDAN will either repair, adjust or replace (with new or exchange replacement parts) the EDAN's product. EDAN warrants that any service it provides to customers will be performed by trained individuals in a workmanlike manner.

Limitation of Warranty

Direct, indirect or final damage and delay caused by the following situations for which EDAN are not responsible may void the warranty:

- Groupware is dismounted, stretched or redebugged.
- Unauthorized modification or misuse.
- Damage caused by operating beyond the environmental specifications for the medical product.
- Change or remove original serial number label or Manufacturer symbol.
- Improper use.

Service Procedure

(1) Fill in **Service Claim Form (SCF)**.

Fill in the SCF with detailed information including: **Model Name**, **Serial Number (SN)** and **Problem Phenomena**.

EDAN should not have any obligation to take over the case without this information. The form can be downloaded at: http://www.edan.com.cn or obtained from EDAN's Service Department.

(2) Send EDAN the SCF and Select a Solution.

Once service department receives the fully filled SCF, EDAN's engineer will offer a solution in three working days. EDAN will follow out the case based on below two conditions:

Within Warranty:

There are two options:

i) After receiving the **Return Material Authorization (RAM)** form from EDAN service department, customer sends EDAN the defective parts and informs the shipment tracking number. Then we will dispatch new part(s) to your confirmed address with confirmed shipping invoice.

ii) Customer signs the **Declaration Form** and sends it back by email or fax. This form is legally certificated to make sure the customer or end-user will return the defective parts to

EDAN on time. We will, at this option, dispatch the replace one(s) with confirmed shipping invoice.

NOTE:

(1) Both Return Material Authorization Form and Declaration Form are offered by EDAN service department once the SCF is confirmed by service engineer.

(2) Customer is responsible for freight & insurance charges when the equipment is shipped to EDAN for service including custom charges. EDAN is responsible for the freight, insurance & custom charges from EDAN to customer.

Out of Warranty:

After receiving the RMA from service department, customer sends defective parts to EDAN in advance. We will analyze the problems and discuss with customer about either repairing or replacing the part(s). Once the maintenance fee is invoiced and paid, we will make sure to dispatch good part(s) to confirmed address.

NOTE: Customer is responsible for any freight & insurance charge for the returned product.

(3) Obtain RMA Form.

Before the shipment of the materials, customer must obtain a RMA form from our service department, in which the RMA number, description of returning parts and shipping instruction are included. The RMA number should be indicated on the outside of the shipping container.

NOTE: EDAN should not have any obligation to end-user or customer who returns the goods without the notification by EDAN's service department. The sender takes the whole responsibility of accounted fee.

---

(4) Send the Parts to EDAN.

Follow these recommended instructions:

- Disassemble the parts with anti-static facility. Do not touch the parts with naked hand.
- Pack the parts safely before returning.
- Put the RMA number on the parcel.
- Describe the returned parts. The total value on the invoice should be less than USD100, and note on the invoice as "sample, no commercial value".
- Confirm the invoice with EDAN before shipment.
- Send back the parts after EDAN's confirmation.

Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, do not hesitate to contact us.

EDAN Instruments, Inc.

TEL: +86-755-26898321, 26899221

FAX: +86-755-26882223, 26898330

E-mail: support@edan.com.cn

Appendix Ⅰ Product Specification

A1.1 Classification

Anti-electroshock type	Class Ⅰ equipment and internal powered equipment
EMC type	Class A
Anti-electroshock degree	SpO_2, CO_2 BF Defibrillation type
Ingress Protection	IPX1
Working system	Continuous running equipment (less than 7 days)

A1.2 Specifications

A1.2.1 Size and Weight

Size	173.5 (L) × 241 (H) × 189 (D) mm
Weight	3kg

A1.2.2 Environment

Temperature	
Working	5 ~ 40 °C
Transport and Storage	-20 ~ 55 °C
Humidity	
Working	25% ~ 80%（no coagulate）
Transport and Storage	25% ~ 93%（no coagulate）
Atmospheric pressure	
Working	860 hPa ~ 1060 hPa
Transport and Storage	700 hPa ~ 1060 hPa
Power Supply	100 ~ 240 VAC, 50/60Hz,
	Pmax= 45VA FUSE T 1.6AL

A1.2.3 Display

Device
5.7 inch, Monochrome LCD,
Resolution 320×240, LED backlight
Messages

　　　　　　　　1 Power Indicator LED (Green)

1 Power On Indicator LED (Green)

1 Alarm Indicator LED (Orange/ Red)

1 Charge Indicator LED (Yellow)

1 Alarm Sound Indicator LED (Backlight)

1 CO_2 Working Status Indicator LED (Backlight)

3 Sound Modes correspond to Alarm Mode

A1.2.4 Battery

Quantity	1
Type	Li battery
Power-off delay	5 ~ 15min
Voltage	14.8 VDC
Capacitance	4, 400 mAh
Working period	>290min(at 25℃,continuous SpO_2 measuring mode)
Rechargeable period	< 5 hours

A1.2.5 Recorder

Record Width	48 mm
Paper Speed	25mm/s
Recording types	

Current displayed parameter list recording

Current displayed alarm list recording

A1.2.6 Review

Trend List	72 hrs, 1 min. Resolution
Alarm List	800 groups

A1.2.7 SpO₂

Measuring Range	0 ~ 100 %
Alarm Range	0 ~ 100 %
Resolution	1 %
Accuracy	
Adult (including Pediatric)	±2 digits（70%~100% SpO_2）
	Undefined（0~70% SpO_2）
Neonate	±3 digits（70%~100% SpO_2）
	Undefined（0~70% SpO_2）
Pulse Rate	

Measuring and Alarm Range	15 ~ 254 bpm
Resolution	1 bpm
Accuracy	± 3bpm
	Under Motion Condition, ±5 bpm
Anti-low-perfusion	Strong Anti-low-perfusion, 0.075 ~ 0.1%
Anti-motion Interference	Strong Anti-motion Interference, Anti-electrotome

Nellcor module (optional)

Measuring Range	1 ~ 100 %
Alarm Range	1 ~ 100 %
Resolution	1 %
Accuracy	
Adult and Low-perfusion	±2 digits（70%~100% SpO_2）
	Undefined（0~70% SpO_2）
Neonate	±3 digits（70%~100% SpO_2）
	Undefined（0~70% SpO_2）
Pulse Rate	
Measuring and Alarm Range	20~250bpm
Resolution	1bpm
Accuracy	±3 bpm
Low Perfusion	0.03 % ~ 20%

A1.2.8 CO_2

Method	Infra-red Absorption Technique
Measuring mode	Sidestream, Mainstream
Measuring range	
CO_2	0 ~ 99 mmHg
$InsCO_2$	0 ~ 99mmHg
AwRR	0 ~ 150 rpm
Unit	mmHg, %, Kpa
Resolution	
CO_2	1 mmHg
$InsCO_2$	1mmHg
AwRR	1 rpm
Accuracy	
CO_2	± 2 mmHg, 0 ~ 40 mmHg
	Reading ± 8%, 41 ~ 76 mmHg

	Reading ±10%, 77 ~ 99 mmHg	
AwRR	±2 rpm	
Alarm range		
CO_2	ADU	15 ~ 50 mmHg
	PED	20 ~ 50 mmHg
	NEO	30 ~ 45 mmHg
$InsCO_2$	ALM HI	4 mmHg
AwRR	ADU	8 ~ 30 rpm
	PED	8 ~ 30 rpm
	NEO	30 ~ 100 rpm

Suffocation Alarm Delay	
AwRR	10 ~ 40 seconds
Response time	<3 seconds, includes transport time, risetime
Calculation Method	BTPS (Body Temperature Pressure Saturated)

Stability	
Short Term Drift	<0.8 mmHg (drift for 4 hours)
Long Term Drift	Accuracy maintains over 120 hours

O_2 Compensation	
Range	0 to 100%
Resolution	1%
Default	16%

N_2O Compensation	
Range	0 (off) or 1 (on)
Default	Off

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