EDAN INSTRUMENTS, INC.

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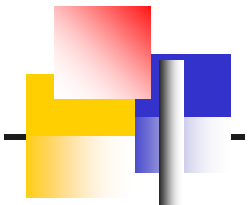

Patient Monitor

Service Manual

Manual Ver: V1.3

Release Date: Feb. 2009

Part Number: MS1R-100381-V1.3

P/N：MS1R-100381-V1.3

Copyright

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) can not be held liable.

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EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

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.

It is important for the hospital or organization that employs this equipment to carry out a

reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

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

Using This Label Guide

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

⚠WARNING⚠

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

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

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

Revision History

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

Date	ECO	Version	Revision history
1st, Feb. 2008	ECO-MPM-8003	V1.0	1st edition
8th, Apr. 2008	ECO-MPM-8005	V1.1	Add M8B model; add 3-channel recording; delete VGA output.
20th, Aug. 2008	ECO-MPM-8013	V1.2	Update menus and disassembly graphics.
2nd, Feb 2009		V1.3	Add data storage, ECG smart lead and NIBP pulse rate. Delete software update information.

Table of Contents

1 Introduction

1.1 General Information

Patient Monitor (hereinafter called monitor) monitors parameters such as ECG, RESP, SpO_2, NIBP, dual-TEMP, dual-IBP, CO (Cardiac output), CO_2 and GAS (Anesthetic gas), and is suitable for adult, pediatric, and neonatal patients in a hospital environment and during patient transport both inside and outside hospitals. The user can select different parameter configurations according to different requirements.

It integrates the functions of parameter measurement module, display, record and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the high-resolution display screen, 7 waveforms and all the monitoring parameters can be displayed clearly.

The POWER switch is on the left of the front panel (Figure 1-1, 1-2 ①). The POWER indicator lights when the monitor is powered on (Figure 1-1, 1-2 ②). The CHARGE indicator shows the charging status (Figure 1-1, 1-2 ③). The ALARM indicator flashes when the alarm is triggered (Figure 1-1, 1-2 ④). The sockets of various sensors are on the left panel. Other sockets and power plug-ins are on the rear panel. The recorder is on the right panel.

The monitor is a user-friendly device with operations conducted by a few buttons and the rotary knob on the front panel (Figure 1-1, 1-2 ⑤⑥). Refer to **Button Functions.**

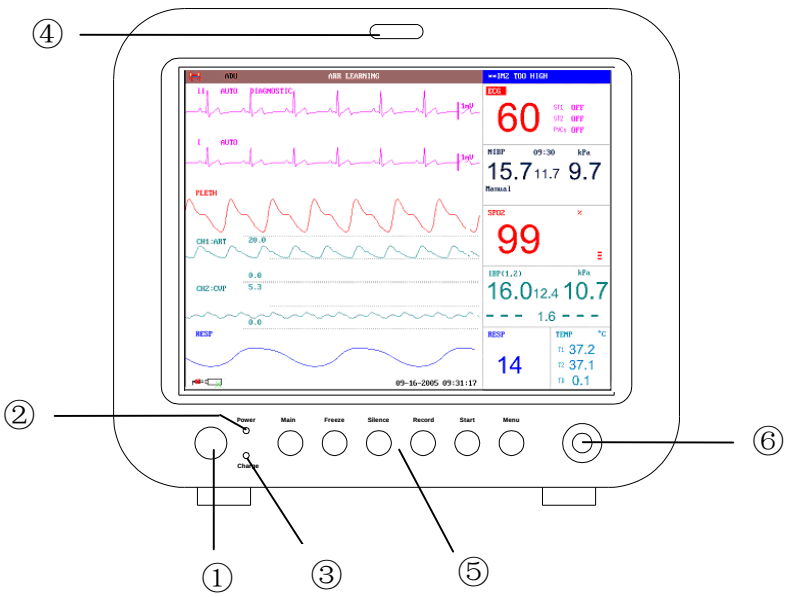


Figure 1-1 M9 Patient Monitor

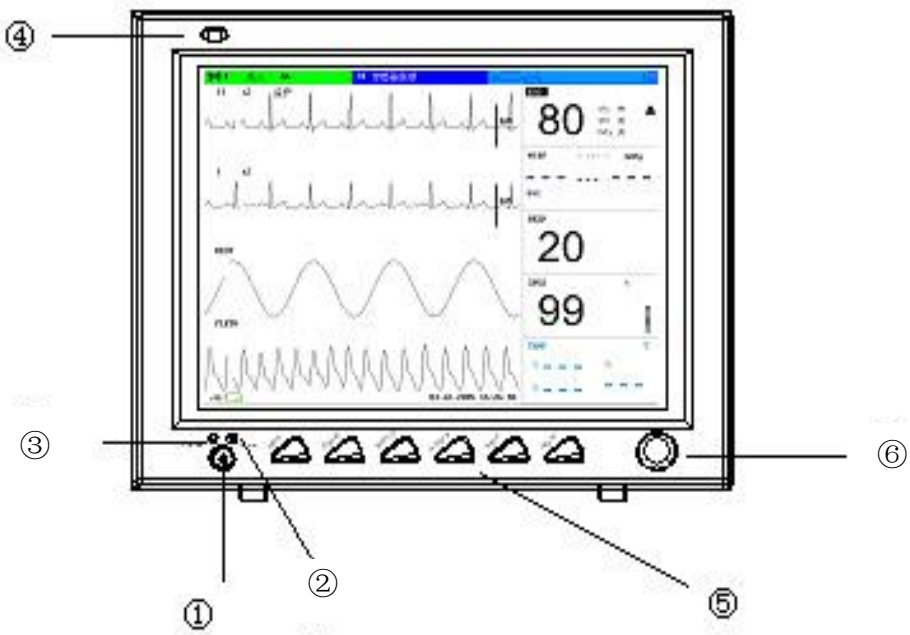


Figure 1-2 M8 Patient Monitor

The monitor has six product models: M9, M9A, M9B, M8, M8A and M8B.

Product Models	Size（L×W×H）	Shell Figure/ Screen Size	Functions
M9	Host: 322mm×150mm×285mm	Round / 12 inches	ECG/RESP, SpO_2, NIBP, TEMP, IBP, CO, CO_2, GAS
M9A	Host: 322mm×150mm×285mm	Round / 10 inches	ECG/RESP, SpO_2, NIBP, TEMP, IBP, CO, CO_2, GAS
M9B	Host: 320mm×150mm×265mm	Square / 10 inches	ECG/RESP, SpO_2, NIBP, TEMP, IBP, CO_2
M8	Host:	Square /	ECG/RESP,

	320mm×150mm×265mm	12 inches	SpO_2, NIBP,TEMP, IBP, CO_2
M8A	Host: 320mm×150mm×265mm	Square / 10 inches	ECG/RESP, SpO_2, NIBP, TEMP, IBP, CO_2
M8B	Host: 320mm×150mm×265mm	Square / 10 inches Wide_screen	ECG/RESP, SpO_2, NIBP, TEMP, IBP

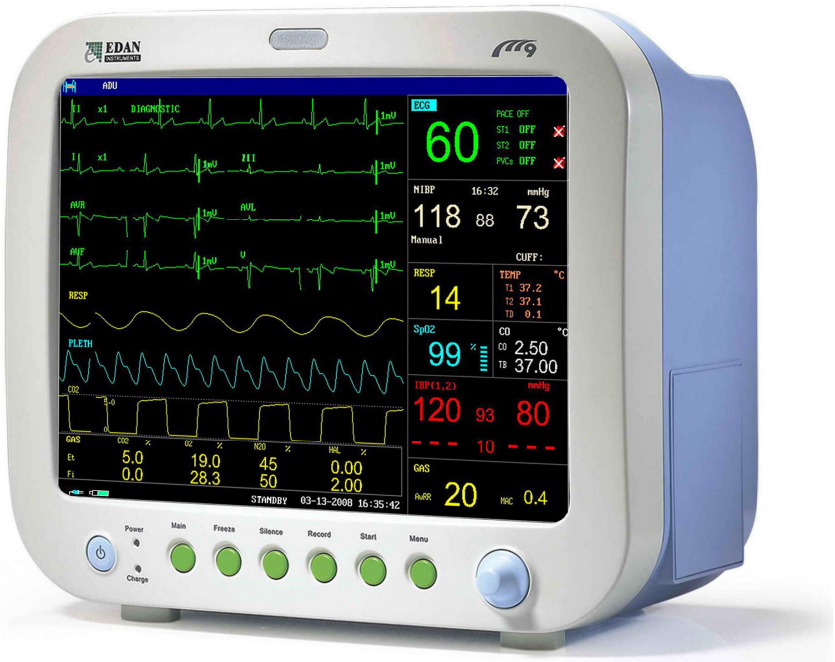


Figure 1-3 M9 Patient Monitor

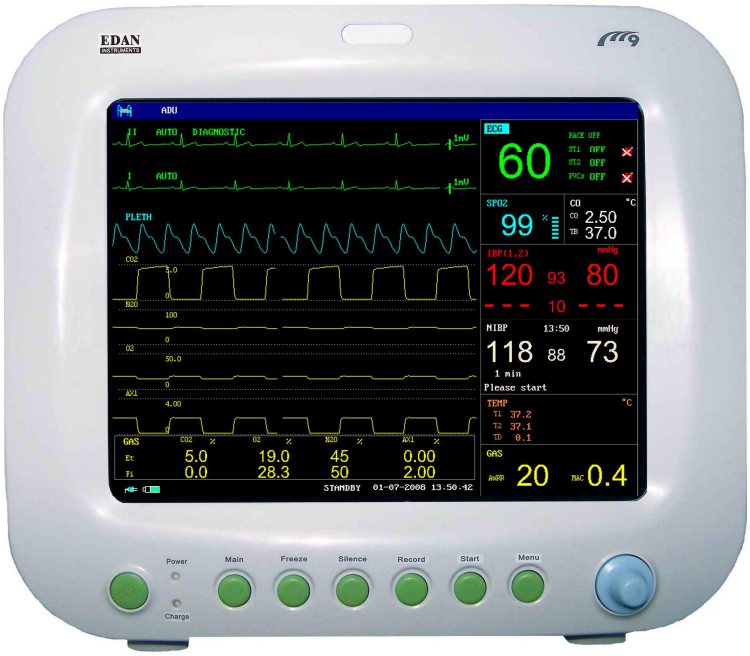


Figure 1-4 M9A Patient Monitor

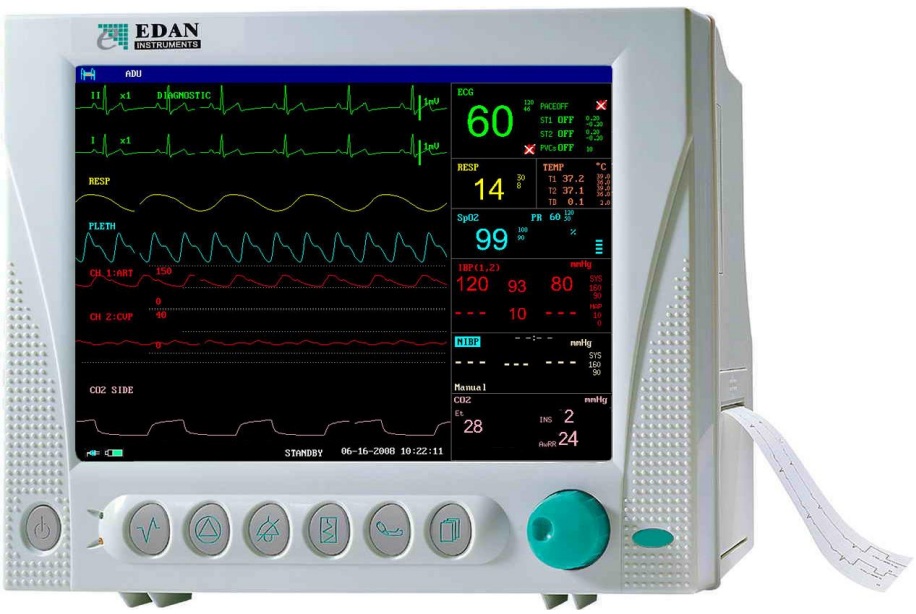


Figure 1-5 M9B Patient Monitor

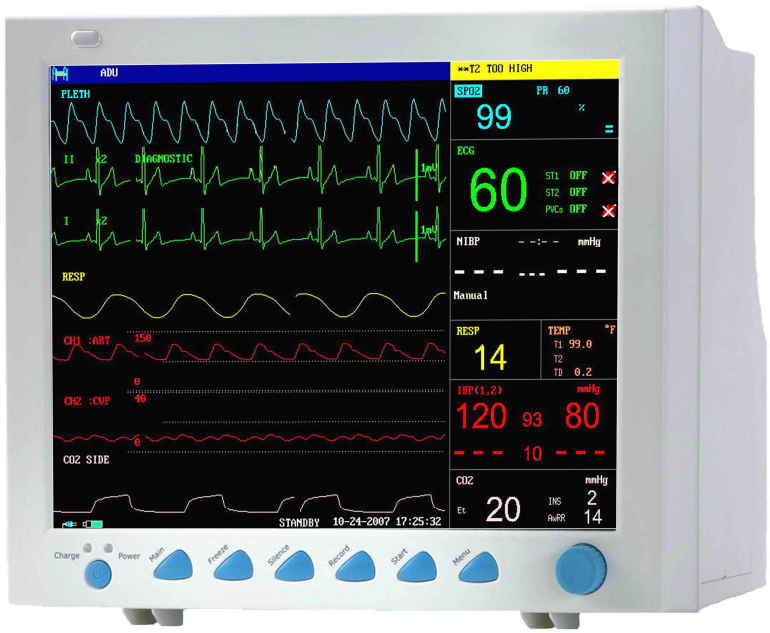


Figure 1-6 M8 Patient Monitor

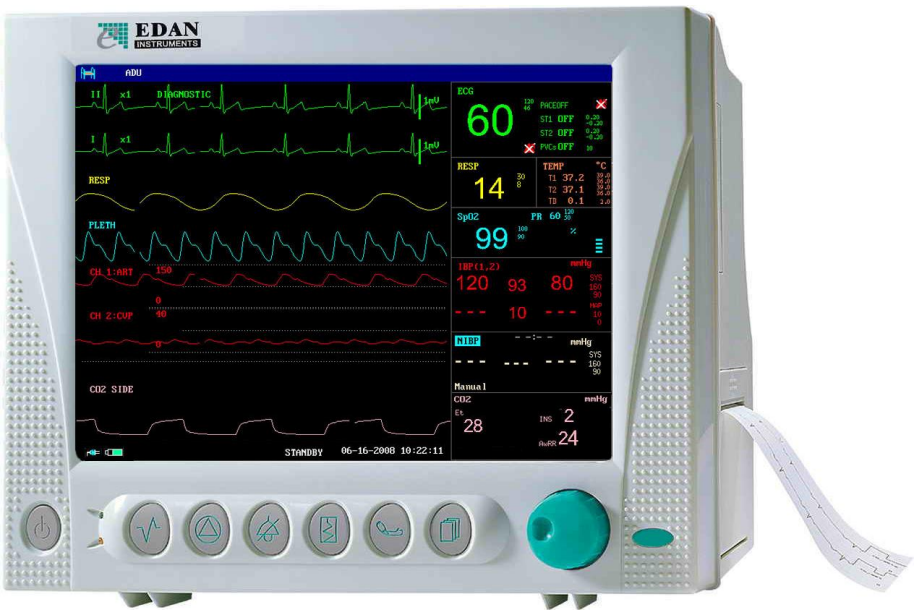


Figure 1-7 M8A Patient Monitor

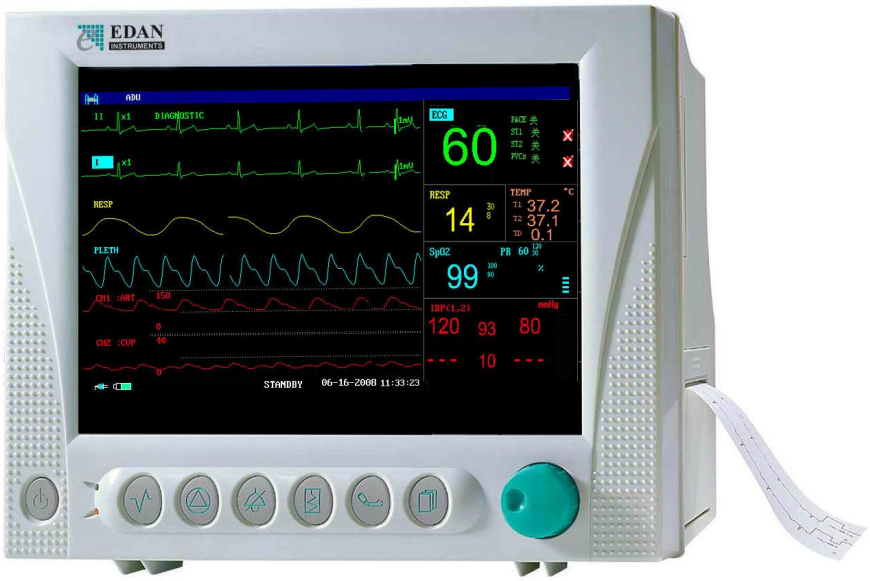


Figure 1-8 M8B Patient Monitor

The monitor can monitor the following parameters and waveforms:

ECG: Heart Rate (HR)
Maximum 7-channel ECG waveform
Arrhythmia and ST-segment analysis (optional)

RESP: Respiration Rate (RR)
Respiration Waveform

SpO_2: Oxygen Saturation (SpO_2), Pulse Rate (PR)
SpO_2 Plethysmogram

NIBP: Systolic Pressure (SYS), Diastolic Pressure (DIA), Mean Pressure (MAP)

TEMP: Channel-1 Temperature (T1), Channel-2 Temperature (T2),
Temperature Difference between two channels (TD)

IBP: Channel-1 SYS, DIA, MAP
Channel-2 SYS, DIA, MAP
Dual-IBP waveforms

CO_2: End Tidal CO_2 ($EtCO_2$)
Inspired Minimum CO_2 ($InsCO_2$)
Air Way Respiration Rate (AwRR)
CO_2 waveform

CO: Blood Temperature (TB)
Cardiac Output (CO)

GAS: Inspired or expired CO_2 ($FICO_2$, $ETCO_2$)

Inspired or expired N_2O (FIN_2O, ETN_2O)

Inspired or expired O_2 (FIO_2, ETO_2)

Inspired or expired Anesthetic Agent (FIAA, ETAA):

HAL (Halothame)

ISO (Isoflurane)

ENF (Enflurane)

SEV (Sevoflurane)

DES (Esflurane)

Airway respiration rate (respiring time per minute, rPM), AwRR

Minimal Alveolar Concentration (MAC)

4 anesthetic gas waveforms (CO_2, N_2O, O_2, AA)

The monitor provides extensive functions such as visual and audible alarms, trend data storage, NIBP measurements, alarm events, and drug dose calculation and so on.

1.2 Screen Display

The monitor is equipped with a high-resolution multicolor TFT LCD screen. 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 Waveform Area ②;

3 Parameter Area ③.

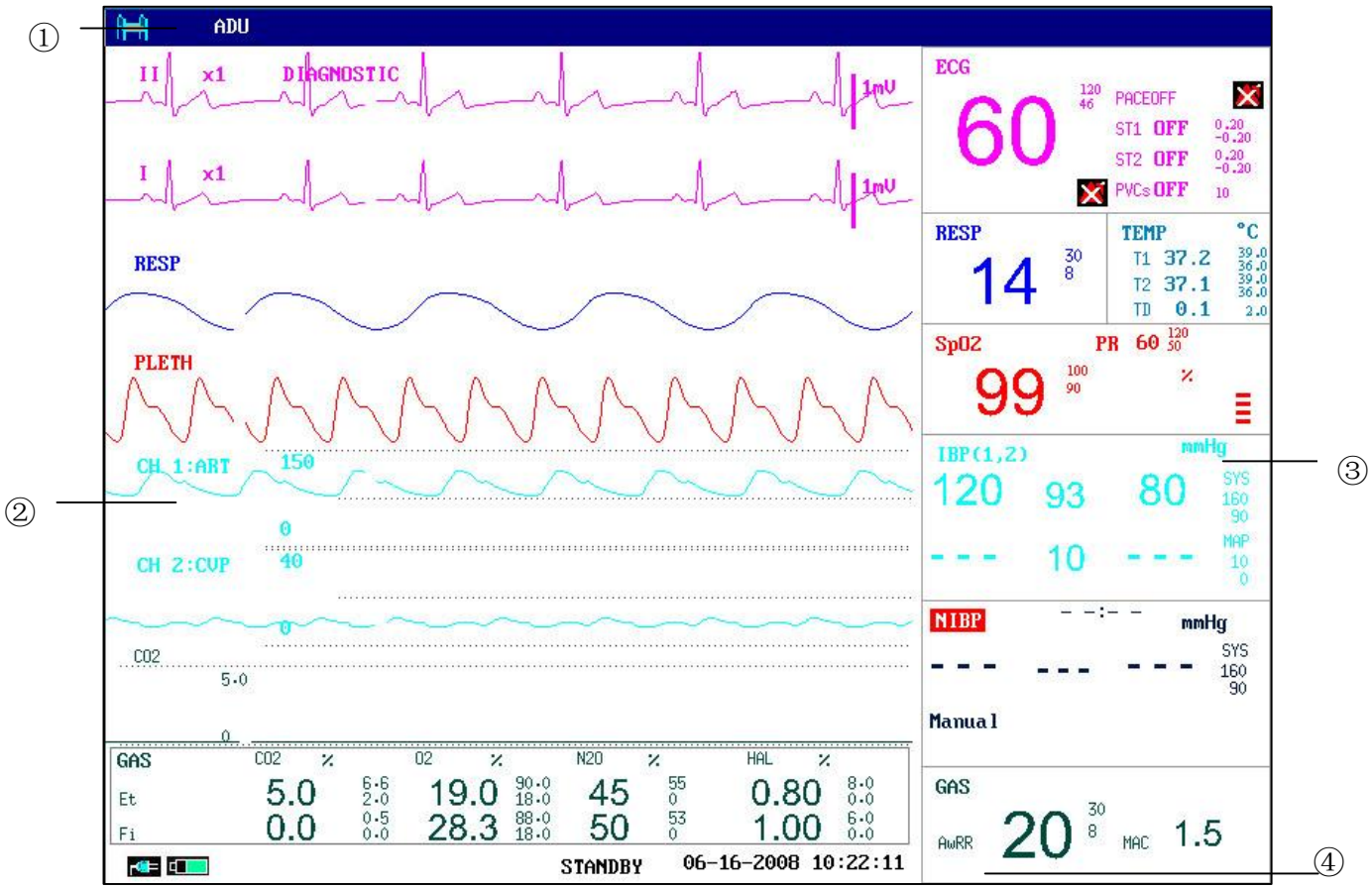


Figure 1-9 Main Display

Information Area(① ④)

The Information Area is at the top and bottom of the screen, displaying operation state of the monitor and status of the patient.

The information area contains the following data:

Bed number of the monitored patient

ADU Type of patient. Three options: Adult, Pediatric, Neonatal

Name Name of the monitored patient, when the user inputs the patient name, this name will be displayed on the right side of the patient type. If the user doesn't input the patient name, this position will be vacant.

06-16-2008 Current date

10: 22: 11 Current time

Indicates the status of mains power supply

 means the main power supply is turned on,

 means the main power supply is turned off.

Indicates the battery is equipped in the monitor and its capacity;

 Gives information about the remaining battery charge, estimated

operation time and maintenance requirements;

 means there is no battery equipped in the monitor.

 Indicates the audio alarm is turned off.

 Indicates the audio alarm pauses.

 Displays beside parameter to indicate the alarm is turned off.

STANDBY Choose this item to enter Standby mode, the dialog pops up:

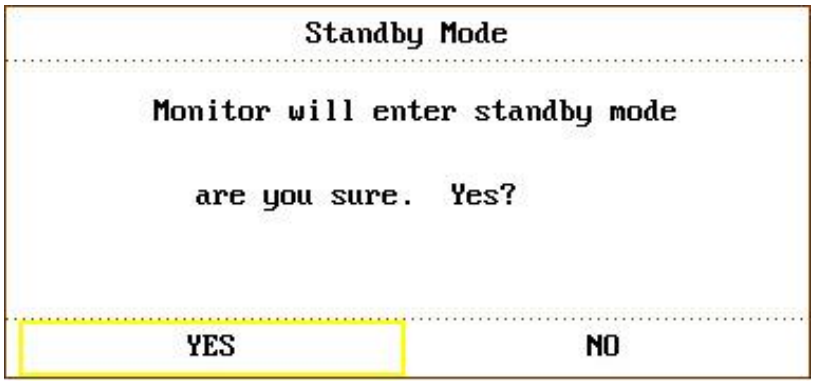


Figure1-10 Standby Mode

Select **YES** to enter the **standby mode** and display the current time; select **NO**, the monitor will return to the main interface.

Other information of the Information Area comes up only with respective monitoring status. They are:

- Signs indicating the operation status of the monitor and the sensors are displayed at the right side of the patient name.
- Alarm message is displayed at the right most area.
- "**FREEZE**" appears when the waveforms are frozen.

Waveform Area (②)

Seven waveforms can be displayed at a time. The sequence of waveforms can be adjusted. Under the maximum configuration, the system can display two ECG waveforms, one SpO_2 waveform, one Respiration waveform (can be from ECG module), two IBP waveforms and one CO_2 waveform.

In the **TRACE SETUP** menu, all the waveforms are listed. The user can select the waveform to be displayed, and adjust the display position. Refer to Chapter 3.8 for details.

The waveform name is displayed on the upper left part of the waveform. The name of ECG is user-selectable. Gain and filter way of this channel are displayed as well. A 1mv scale is marked on the right of ECG waveform. The IBP waveform scale can also be selected according to the actual requirement. Its range is described in the part: IBP Monitoring. In the IBP waveform area,

the waveform scale is displayed. The three dotted lines for each IBP waveform from top to down represent respectively the upper limit scale, reference scale and lower limit scale. The values of these three scales can be set. The specific method is given in the part: IBP Monitoring.

When a certain menu is displayed, some waveforms become invisible. Main display is restored when you exit from the menu.

The user may set up the rate to refresh the waveform. The method to adjust the refreshing rate of each waveform is discussed in the setup description of each parameter.

Parameter Area(③)

Parameter area is on the right of the Waveform area, and parameters are displayed corresponding to waveforms basically. They are:

ECG:

- Heart Rate (Unit: beats per minute, bpm)
- ST-segment analysis of Channel 1 & 2–ST1, ST2 (Unit: mV)
- PVCs (Premature Ventricular Contraction) events (Unit: event/min)

SpO_2:

- Oxygen Saturation SpO_2 (Unit: %)

NIBP:

- (From left to right) Systolic pressure, Mean pressure, Diastolic pressure (Unit: mmHg or kPa)

TEMP:

- Temperature of channel1, channel2 and their temperature difference: T1, T2, TD (Unit:°C or °F)

RESP:

- Respiration Rate (Unit: breath/min)

IBP:

- The blood pressure of channel 1 and 2. From left to right, there are Systolic pressure, Mean pressure and Diastolic pressure（Unit: mmHg or kPa)

CO_2:

- $EtCO_2$ (Unit: %, mmHg or kPa)
- INS CO_2 (Unit: %, mmHg or kPa)
- AwRR (Unit: times/minute)

CO:

- CO (Unit: liter/minute)
- TB (Unit: °C or °F)

GAS:

- Airway Respiring Rate (Respiring per minute)
- Minimal Alveolar Concentration.

Alarm Indicator and Alarm Status

In normal status, the alarm indicator does not light.
When alarming, the alarm indicator lights or flashes. The color of the 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 charged, the light color turns into orange.

1.3 Button Functions

All operations to the monitor can be finished by several buttons and a knob. They are:

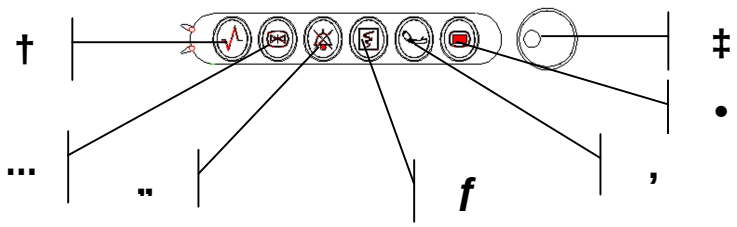


Figure 1-11 Buttons

① Menu	Press it to call up the SİSTEM MENÜ. Refer to Chapter **SYSTEM MENU** and Chapter **Trend and Event** for details.
② Start	Press it to fill air into cuff and start blood-measurement. During the measurement process, press the button to stop measurement.
③ Record	Press it to start real-time recording. The recording time is set in RT REC TIME of RECORD submenu.
④ Silence	When the SYSTEM MENU→ MAINTAIN → USER MAINTAIN → ALARM SETUP is set to **ON**， Press this button to silence the alarm. All the alarm audio will be turned off. At the same time, "Alarm Pause ×× s" and  will be displayed in the Information area. When you re-press it or the pause time is over, the system will resume the normal monitoring status. And "Alarm Pause ×× s" and icon will vanish. Pressing and holding this button for more than 3 seconds can turn off the audio alarm.  is shown in the Information area. Pressing or holding the button again can resume the alarm.

	NOTE: Whether alarms will be reset depends on the status of the alarm cause. But pressing SILENCE button (suspend alarm) can permanently shut off audio of the Lead Off or Sensor Off alarms. So the user can exit from the Alarm Silence Status by Technical Alarm.
⑤ Freeze	In normal mode, press this button to freeze all the waveforms on the screen. When in FREEZE mode, press it to restore the waveform refreshment.
⑥ Main	Press it to return to the main interface.
⑦ Rotary Knob	The user can use the rotary knob to select the menu item and modify the setup. It can be rotated clockwise or anticlockwise and pressed. The user can use the knob to realize the operations on the screen, in the SYSTEM MENU and parameter menu.

Method of Using the Knob to Operate on the Screen:

The rectangular mark on the screen that moves with the rotation of the knob is called “cursor”. Operation can be performed at any position where the cursor stays.
When the cursor is in the waveform area, the user may immediately modify the current setup. When the cursor is in the parameter area, the user may open the setup menu of the corresponding parameter module so as to set up the menu items of the module.

Operation method:

- Move the cursor to the item where the operation is required.
- Press the knob.
- One of the following four situations may appear:
  1. The cursor with background color may become a frame without background color, which implies that the content in the frame can change with the rotation of the knob.
  2. Menu or measurement window may appear on the screen, or the original menu is replaced by the new menu.
  3. A check mark “√” appears at the position, indicating that the item is confirmed.
  4. The system immediately executes a certain function.

1.4 Interfaces

For the convenience of the operator, interfaces of different functions are located in different sites of the monitor.

Right Side of the Monitor

At the right side of the monitor, there are the bracket of water trap for CO_2 module and the Anesthetic gas module water slot (①), and the recorder's paper inlet cover (②).

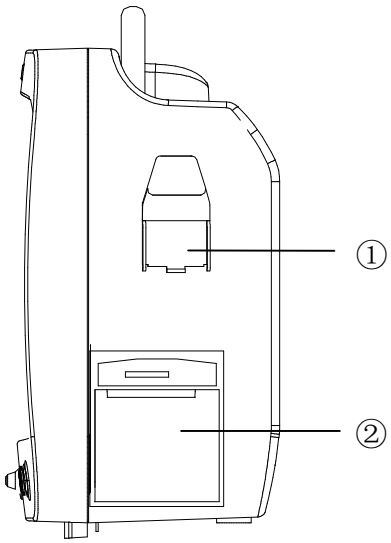


Figure1-12 Right Panel of M9, M9A

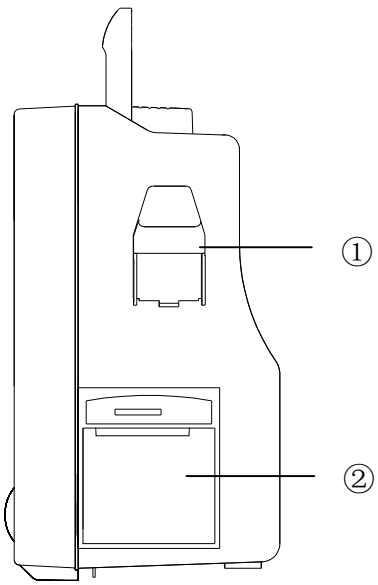


Figure1-13 Right Panel of M9B, M8, M8A and M8B

Left Side of the Monitor

Connectors for cables and sensors are as shown in the following figure.

1. Air inlet
2. CO_2 sensor connector
3. IBP1 transducer connector
4. ECG cable connector

5. NIBP cuff connector
6. Air outlet
7. TEMP1 probe connector
8. TEMP2 probe connector
9. IBP2 transducer connector
10. CO sensor connector
11. SpO_2 sensor connector

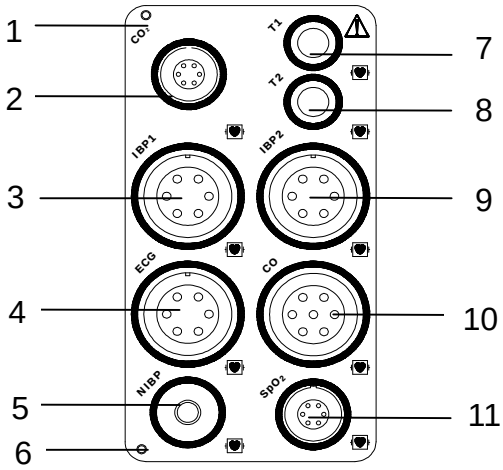


Figure 1-14 Left Panel

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

This symbol indicates that the instrument is IEC/EN60601-1 Type BF equipment, of defibrillation type.

This symbol indicates that the instrument is IEC/EN60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during the defibrillation.

Rear Panel

Figure 1-15 Rear Panel of M9 and M9A

Figure 1-16 Rear Panel of M9B, M8, M8A and M8B

Sockets on the rear panel are shown in Figure 1-15, 1-16.

① Network Interface (reserved): Standard RJ45 Socket, for connecting to MFM-CMS of EDAN.

② Equipotential grounding terminal for connection with the hospital's grounding system.

③ Fuse box, used to put fuse.

④ Power supply socket: AC100-240 V, 50/60 Hz.

⑤ Probe Holder (optional), used to place various types of probes.

1.5 Built-in Rechargeable Battery

The monitor is equipped with a built-in chargeable battery. When switching on AC power supply, the battery will be charged automatically until the electric energy becomes full. There is a sign "  " in the lower left corner of screen to show the charging status, and the green part is the electric energy of battery. When the monitor is not equipped with battery, the battery status will be showed as the sign "  ", which means no battery.

One battery can power the monitor. Under the cable connectors is the cover of battery compartment. See Battery compartment in the following figure.

The charging time for battery resuming to 90% of electric energy is about 150min for 2Ah, and 360min for 4Ah.

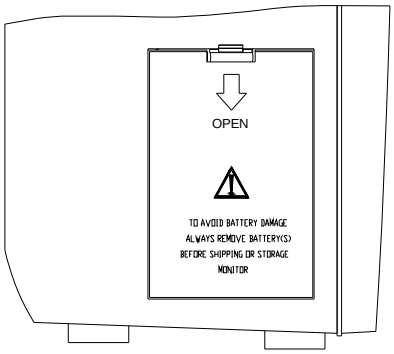


Figure 1-17 Battery Compartment

Replacing Battery

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

⚠ **WARNING** ⚠

Do not unplug the battery during monitoring. When the AC power supply is switched off unexpectedly, the device will not be affected, if it has a standby battery.

⚠ **WARNING** ⚠

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

⚠ **WARNING** ⚠

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

2 Principle

2.1 General Parts

The monitor has been designed to measure physiological parameters including ECG, RESP, TEMP, NIBP, SpO_2, IBP, CO_2, CO and GAS.

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

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

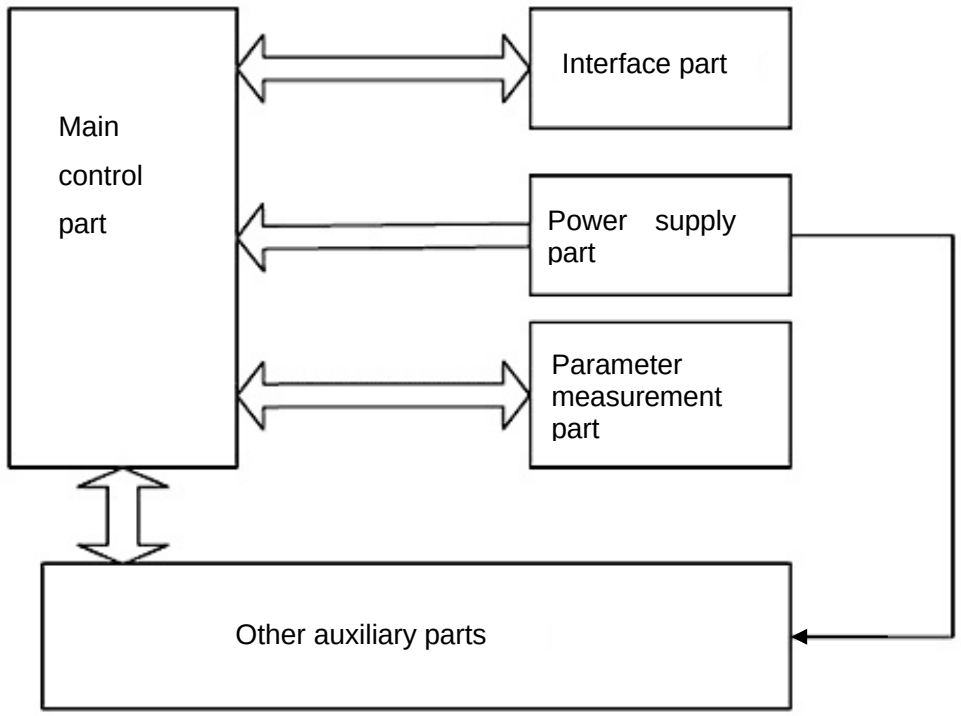


Figure 2-1 Monitor Structure

2.1.1 Parameter Measurement Part

The Patient Monitor acquires the physiological signals of ECG, respiration, non-invasive blood pressure (NIBP), oxygen saturation of the blood (SpO_2), temperature (TEMP), invasive blood pressure (IBP), cardiac output (CO), CO_2 and Anesthetic gas (GAS). The Parameter Measurement Part can transform the physiological signals to the electrical signals, and process signals and transfer the values, waveforms and alarm information to the Main Board, and display

them on the Interface Board.

2.1.2 Main Control Part

The main board consists of Interface board and Core board. It has CPU/memory, display circuit, network circuit and I/O interface. Main 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 recall and so on.

2.1.3 Interface Part

The man-machine interface consists of the TFT display, a recorder, a speaker, an indicator, keys and knob.
The high-resolution TFT 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.
The recorder is an auxiliary device compared with the interface, which could print out various user-selected data for usage and preservation.
The speaker gives heart beat tones and audio alarms.
The indicator provides additional information about power supply, battery and alarm.
The keys and knob are user input interface of the system and the user could input information and instructions into the monitor through 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 input into 5V and 12V DC to energize other parts of the system. Similarly TFT display requires particular supply, for this reason a power switch board is supplied. 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 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 five parameters mentioned.

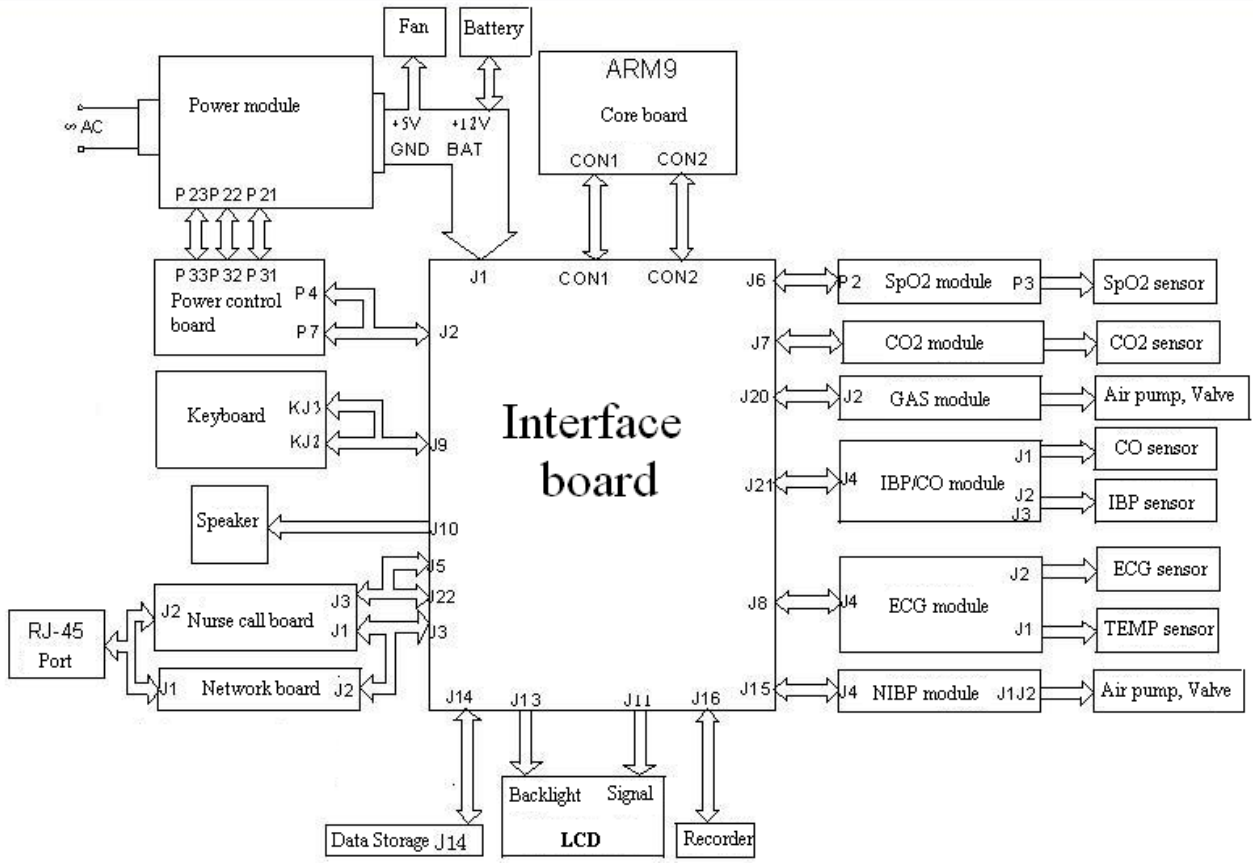


Figure 2-2 M9/M9A Structure and Part Relationship

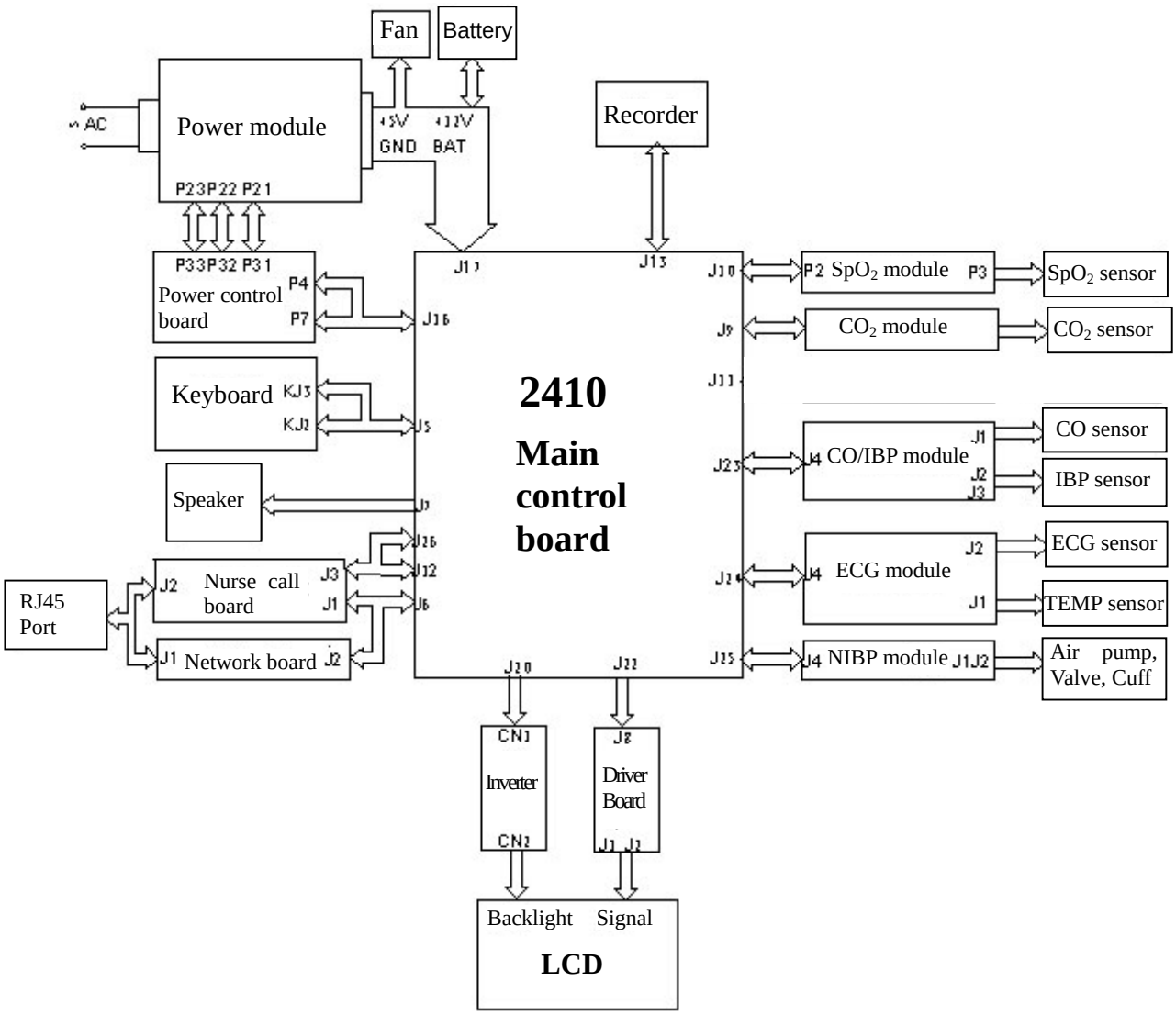


Figure 2-3 M9B/M8/M8A/M8B Structure and Part Relationship

NOTE:

The Nurse call board and the Network board are optional configuration, they can not be installed at one 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 boards.

Schematic Diagram

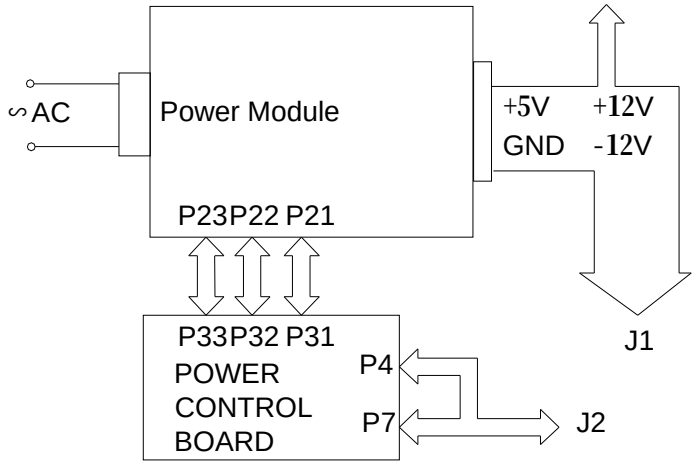


Figure 2-4 Schematic Diagram of the Power Board

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

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

Power Switch Circuit

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

Voltage Detection Circuit

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

2.2.2 Main Board

Main board is the heart of the monitor and it can do system control, system adaption, system management, data processing, file management, display processing, printer management, data storage, system diagnosis, fault alarm, etc.

Main board schematic diagram

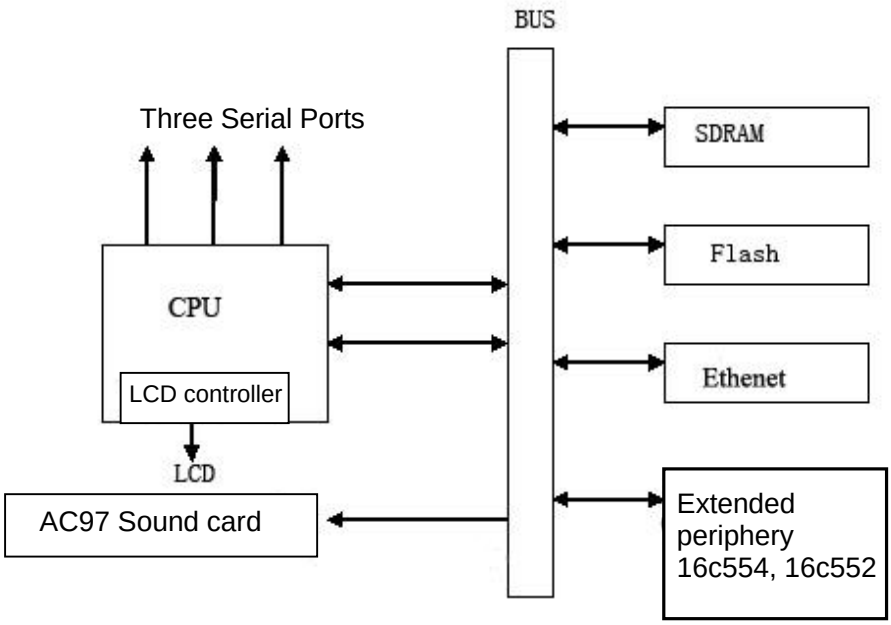


Figure 2-5 Schematic Diagram of Main Board

CPU System

CPU is the kernel of ARM9 and it is the core part of the Main board. CPU connects with other periphery modules via buses and I/O cables. 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 and can also rewrite the data in RTC.

Ethernet Controller

Ethernet controller supports IEEE 802.3/IEEE 802.3u Ethernet standard, supports 10Mbps and 100Mbps data 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 a man-machine interface.

Schematic Diagram

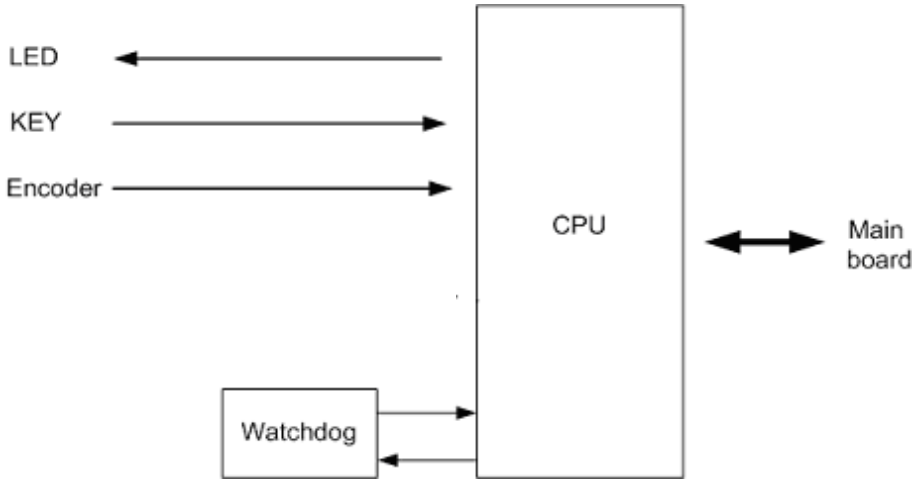


Figure 2-6 Schematic Diagram of Keyboard

Introduction to Principle

This module detects key and encoder input signals, converts them into codes and sends to Main board. Main board sends commands to the keyboard and the latter accordingly controls the alarm indicator state.

CPU

Detect key and encoder input signals;

Control LED status;

Regularly zero Watchdog Timer;

Communicate with Main board.

Audio Process Circuit

Advance audio signals to drive the speaker to give sound.

Watchdog

Upon power-up, 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 the line thermal printer.

Schematic Diagram

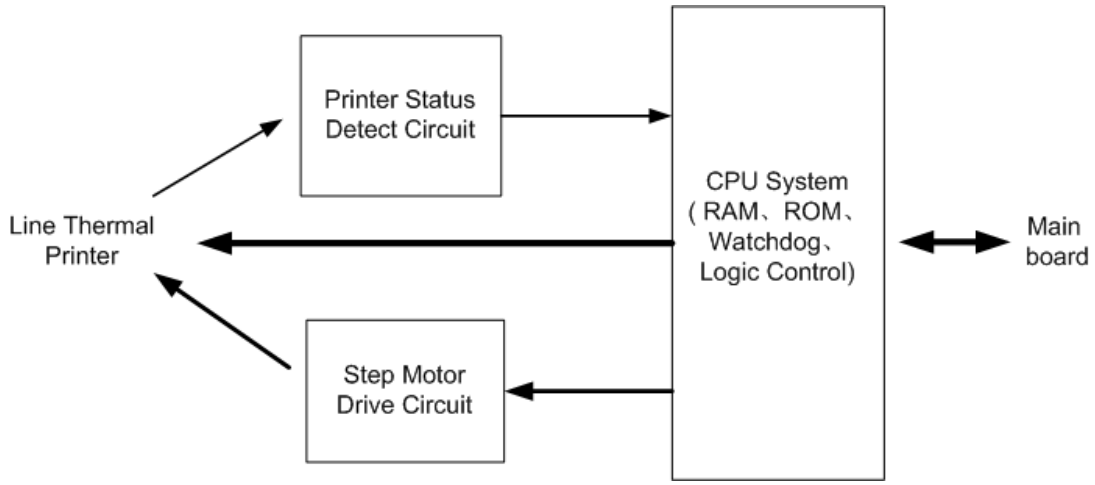


Figure 2-7 Schematic Diagram of Recorder Module

Introduction to Principle

This module receives printing data from Main board and converts the data into dot matrix data and sends them to the thermal printer. It can also drive the printer to perform printing action.

Step Motor Drive Circuit

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

Printer Status Detect Circuit

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

CPU System

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

2.3 Software Function Principle

2.3.1 System Software

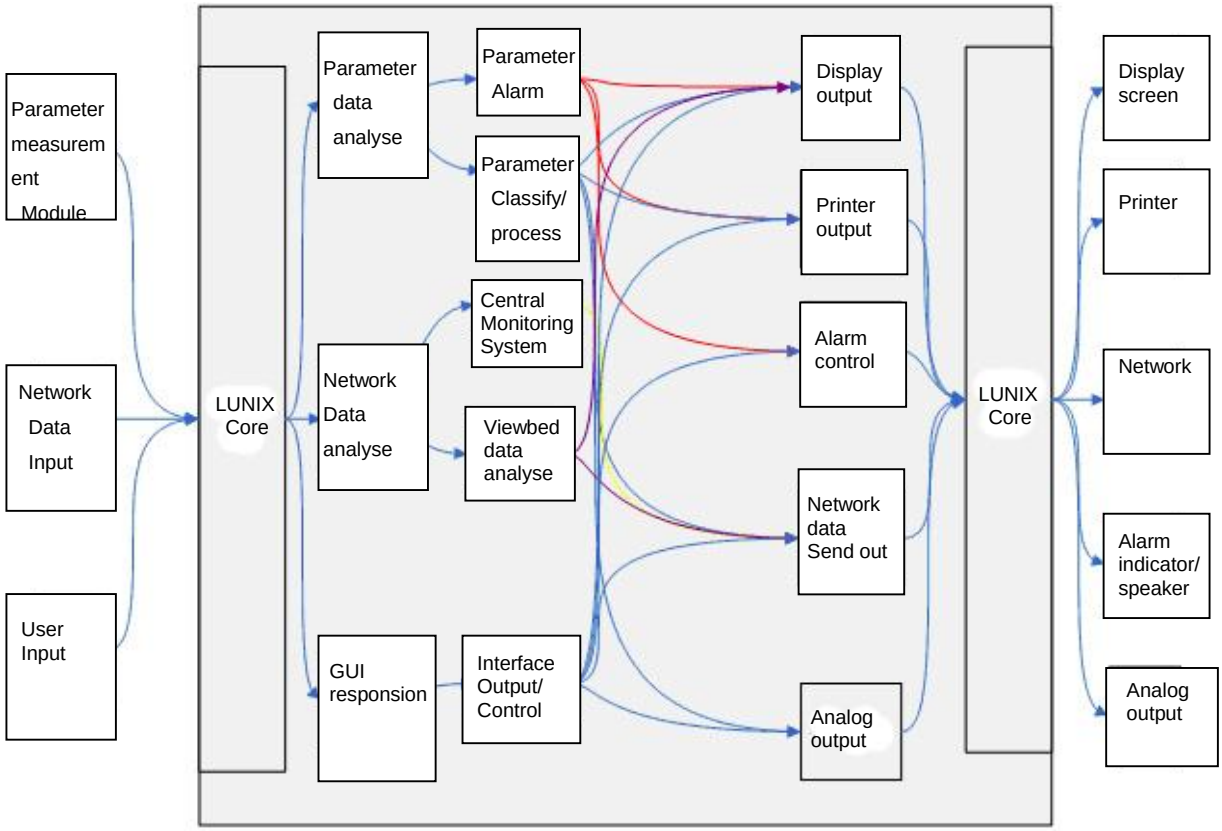


Figure 2-8 System Function General Diagram

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

2.3.2 System Software Function

No.	Task Name	Task Function	Performance 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

		Parameter waveform data analysis	processing
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 command 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	Central Monitoring System network connection	Central Monitoring System network connecting task	Once per 5 seconds
8	Network data processing	Send and receive task of Central Monitoring System network data	Once per second
		Send and receive task of Viewbed network data	
9	Cardioelectric analysis task	Accomplish cardioelectric signals analysis, calculate all the cardioeletric parameters: heart rate, arrhythmia, ST segment, and store analysis results.	Once per second
10	Printer task	Accomplish output all the records	Have record task
11	Parameter processing task	Accomplish every command and response processing of relative parameters	Real-time processing
12	Watchdog task	Accomplish system watchdog management task	Once per second

Table 2-1 System Task Table

2.4 System Parameters

2.4.1 General

Parameter module is the basic unit to acquire signals for monitoring parameters in the monitor. The results are transmitted to main board via keyset to accomplish processing and displaying of data and waveforms. Main board commands 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:

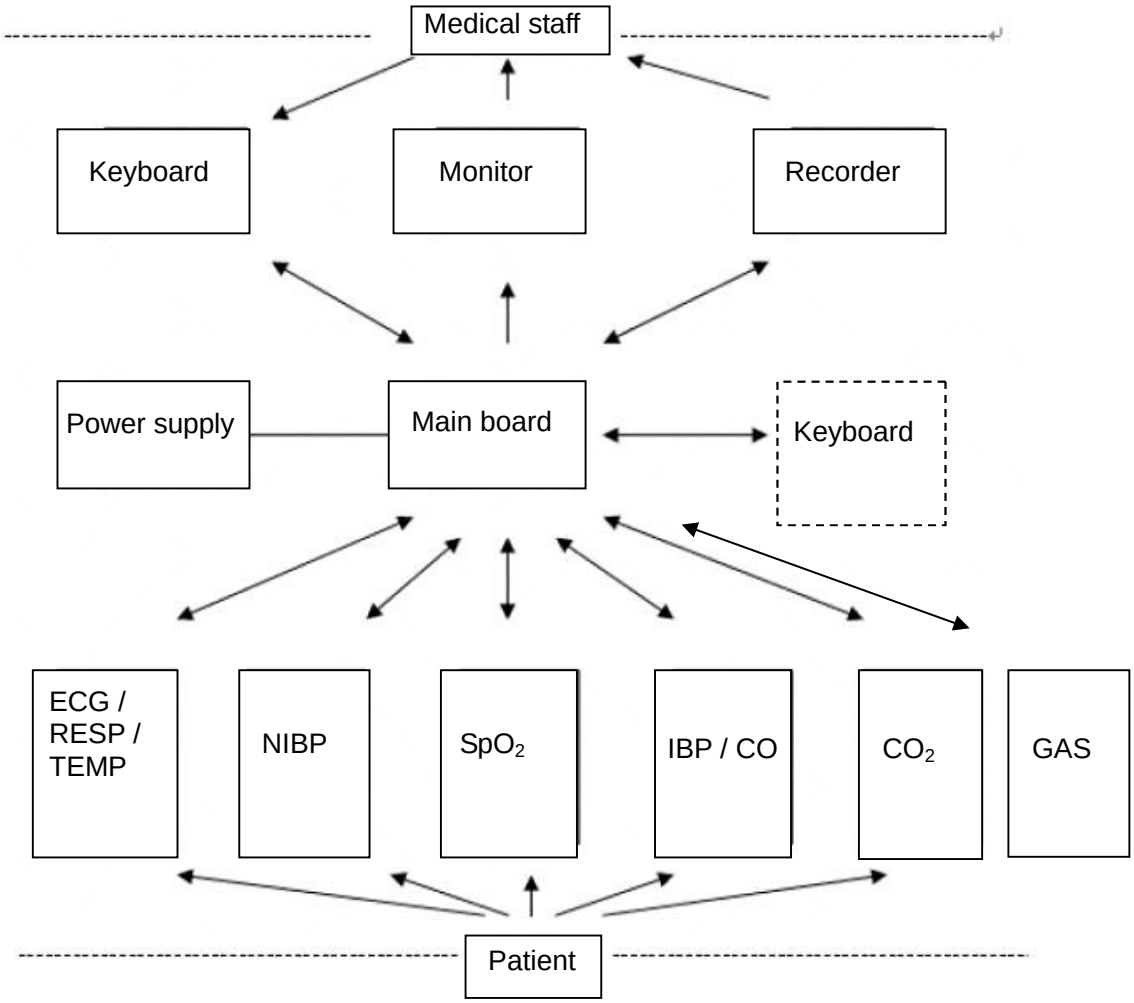


Figure 2-9 System Structure

As shown in the above figure, the eight parameter modules execute real-time monitoring to Non-invasive blood pressure, SpO_2, ECG / Respiration / Temperature, Invasive blood pressure / Cardiac Output, CO_2 and GAS respectively through cuff and measurement cables. The results can be sent to Main board to process and display, and they can also be sent to recorder for output and printing. The function details of Parameter monitor will be explained in the following sections.

2.4.2 ECG/RESP

1. ECG

ECG module detects low voltages of about 1 mV that appear on the skin as a result of cardiac activity. Three or five electrodes arranged in standard configurations are called leads and placed on the skin to sense these voltages. Two electrodes are required for one ECG lead at least and the third electrode is used as a reference to reduce electrical interference. Each lead can present ECG waveform whose P waves, QRS complex, and T waves vary in amplitude and polarity. The signals from the different leads provide the cardiologist with a complete representation of the electrical

activity of the heart, including the HR, which is interpreted as the R-to-R Interval. The timing and wave shape of ECG provide information on whether the patient's HR is characterized by arrhythmia or other altered functions requiring treatment. The ECG is also used to monitor the effects of infusing antiarrhythmia or cardiotonic agents. Blood pressure, the force exerted by the blood against the blood vessel walls, is more reliable than an ECG signal in assessing effective pumping blood of the heart and the flexibility of blood vessel.

The main functions concerning ECG of Patient Monitor:

a. Lead: 3-lead, 5-lead;
b. Lead method: I, II, III, AVR, AVL, AVF, V
c. Float input
d. Right-leg drive
e. Lead-off detection
f. Dual-channel ECG amplification, simultaneously processing ECG signals of any two leads.

The ECG circuit is responsible for processing the ECG signals from human body and consists of the following parts:

a. Input circuit: the ECG electrodes are connected into the circuit through the cables. This circuit is mainly used to protect ECG input phase and filter the signals to remove the outside interference.
b. Buffer amplifying circuit: it is used to convert the impedance of ECG signals in order to ensure that the ECG has very high input impedance but very low output impedance.
c. Right-foot drive circuit: the middle output point of the buffer amplifying circuit is reversely amplified and then fed to the RL of the 5-lead ECG to maintain the human body in a equipotential state. This method can reduce the interference and raise the common-mode rejection ratio of the circuit.
d. Lead-off detection: based on the theory that the lead-off may cause the output potential of the buffer amplifying circuit to change, we can use the comparator to accurately determine if the lead has fallen off. In this way, the level can also be converted into TTL level for the singlechip to test.
e. Lead connection circuit: under the control of singlechip and as per requirement, we can connect different lead electrodes into the main amplifying circuit for amplification.
f. Main amplifying circuit: a measurement amplifier constructed by three standard operation amplifiers.
g. Next phase processing circuit: is mainly used to couple ECG signals, program-control the magnitude of the gain, filter the waveform and move the level, amplify the signal and send it to the Analog-to-Digital converter.

2 ECG Smart Lead

The main functions concerning ECG smart lead are shown as follows:

a. Interface: smart lead off switch; Other setting in ECG parameter setup has the setting switch to turn on/off this function;
b. Function: The monitor can display a measurable ECG waveform when the selected waveform for channel 1 and channel 2 can't be measured.
c. It can switch to other leads except the currently-displayed lead when the smart lead

is working

d. This function is active in 5-lead mode only.

3. RESP

When a person is respiring, his chest goes up and down. This action equals the impedance changes between electrodes RA and LA. The monitor converts the high-frequency signals passing through RA and LA into amplitude-modulated high-frequency signals, which are demodulated and amplified into electric signals varying with the respiration changes and transmitted to Analog-Digital Converter. RESP module is made up of a respiration circuit board and a coupling transformer. The circuit includes those parts such as oscillation, coupling, demodulation, preliminary amplification, and high-gain amplification, etc.

2.4.3 NIBP

Blood pressure monitors commonly measure arterial pressure, which is produced by the contractions of the heart and constantly changes over the course of cardiac cycle. Three blood pressure values, expressed in millimeters of mercury above atmospheric pressure, are typical obtained. The systolic pressure is the maximum cycle pressure; which occurs during ventricular contraction. The diastolic pressure is the minimum cycle pressure, occurring during the ventricle's filling stage between contractions. The means arterial pressure (MAP) is the mean value of the blood pressure over the cardiac cycle.

The monitor measures non-invasive blood pressure using the oscillometric method. Following are detailed measurement procedures. Inflate the cuff encircling the upper arm until the pressure in the cuff blocks the blood flow in the artery of the upper arm. Then deflate the cuff gradually according to the requirement of certain arithmetic. With the decreasing of the pressure in the cuff, the artery blood will palpitate with the pulse, which results in palpitation in the cuff. Through the pressure sensor connected with the inflating pipe of the cuff, a palpitation signal palpitating with the pulse will be generated. After being filtered by a high-pass filter (about 1Hz), this signal becomes pulsating signal and is amplified. Then the amplified signal is converted into digital signal by A/D. After using the single chip to process this digital signal, we may obtain systolic pressure, diastolic pressure and mean pressure. Be careful to choose appropriate cuffs for neonatal, pediatric and adult patients so as to avoid generating measurement error. NIBP module also has protection circuit to prevent the cuff from being inflated to a very high pressure. The following are the main operating modes of NIBP.

a. Adult/pediatric/neonate: select it based on the patient weight and age.
b. Manual measurement, auto measurement, continuous measurement: Manual measurement is also called single measurement. It means the monitor only performs one measurement for each time. Auto measurement means to perform one measurement within selected cycle. Time interval can be set to 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240 and 480 minutes. Continuous measurement means after being activated, the monitor will perform quick measurement continuously within 5 minutes. Continuous measurement is effective in monitoring changes in blood pressure.

The main functions concerning NIBP pulse rate are shown as below:

a. Interface: NIBP pulse rate switch. The PR setup switch on the NIBP parameter setup

interface can turn on/off the function.

b. Add function: Measured pulse rate value is displayed on the lower right corner of the screen when the PR is turned on. If there is no measurement or an invalid pulse rate value, PR is displayed "---"in the PR column. If the valid value is obtained after the measurement, the measured pulse rate value will be displayed and added to the NIBP measurement recall. The NIBP interface won't display any PR information if the PR is turned off. And the PR column displays "---" in NIBP measurement recall to indicate that the pulse rate function is turned off by the user. The follow-up added functions are included in the alarm recall based on the requirement. The NIBP pulse rate value at alarm time displays "PR(NIBP): xx" when the NIBP pulse rate is turned on. And it isn't displayed in the alarm recall when the NIBP pulse rate is turned off. The NIBP pulse rate set for alarm recording is the same as that set for the real-time recording.

l In real-time recording, the NIBP pulse rate value is recorded in real time when the PR is turned on and isn't recorded when the PR is turned off. The NIBP measurement recall recording should include the PR item. The recording result is consistent with the PR in NIBP recall.

2.4.4 SpO2

SpO_2 measurement employs the principle that the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO_2 measurement 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 on 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 LEDs and a photodetector. The two LEDs 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 % 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 the sensor, the signal processing, the control unit of LED driving sequence and the singlechip.

2.4.5 TEMP

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is layed on the oxter.

The temperature of human body is first converted into electronic signals, which are then amplified by amplifier and processed. In this way we can obtain the TEMP value. The circuit includes proportional amplifier constructed by operational amplifiers. The temperature passes the thermal sensor, producing pressure signals, which are amplified and transmitted to A/D converter

for further processing. Sensor detection circuit includes voltage comparator constructed by operational amplifiers. When disconnecting the sensor, the input voltage is lower than the comparative pressure, therefore the voltage comparator outputs low level. When connecting the sensor, the input voltage is higher than the comparative pressure, therefore the voltage comparator outputs high level.

2.4.6 IBP

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display. IBP monitors arterial blood pressure, central venous pressure and pulmonary arterial pressure and other parameters.

Measurement method:
Stab and implant the catheter into blood vessel of part to be measured, catheter's port outside body connects directly with pressure transducer. Inject saline into catheter. Because the liquid can transfer pressure, so the blood pressure inside blood vessel can be transferred to exterior pressure transducer via inner catheter liquid. So real-time dynamic waveforms for changing pressure inside blood vessel can be acquired, through specified calculation method, we can gain systolic, diastolic, mean arterial pressure.

2.4.7 CO

Thermal dilution is the method widely used to measure CO. Insert the floating catheter into the pulmonary artery by passing the right atrium. Then use this catheter to injectate normal saline into the right atrium. A temperature sensor is installed at the front end of the catheter. When the cold liquid of normal saline mixes up with the blood, temperature will change. Therefore, when blood after mix-up enters the pulmonary artery, the temperature sensor can detect the change. According to the time of infusing normal saline and temperature changes after mixing up, the monitor can calculate CO and cardiac index, stroke index of both left and right ventricles, and resistance in pulmonary blood vessels, etc.

2.4.8 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:

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

There are Mainstream and Sidestream modules according to different connecting way of infrared sensor. Sidestream module consists of circuit board, built-in sidestream infrared sensor, air pump and control unit. When using Sidestream, the user should also use exterior water trap, dry tube

and sampling tube; Mainstream consists of circuit board and external mainstream infrared sensor. IR sensor requires preheating; in Sidestream mode, the pumping rate can be set as 100, 150 or 200 ml/min according to patient situation, and the user can set up compensation in anesthetic monitoring, such as water vapor, oxygen, temperature, Des, etc. when not performing CO_2, it is recommended to close Sidestream air pump, Mainstream module sensor and IR source, for extending the lifespan of module and reducing power consumption. In Mainstream mode, IR preheating time is relative long, and the module has no air way like that of Sidestream.

2.4.9 GAS

Concentration of GAS (Anesthetic gas) is measured for its characteristic of absorbing infrared ray. All the anesthetic gases measured in "AG module" have this characteristic, and each gas has its own absorption characteristic. First the gas to be measured is driven into a sample cell. Then optic infrared filter selects the infrared ray with special wavelength to penetrate this gas. For a given volume, the higher gas concentration is, the more infrared rays are absorbed. It means the higher the concentration of the absorbed infrared is, the fewer infrared rays penetrated the gas. First measure the quantity of infrared rays that have penetrated the gas and then calculate the gas concentration via specialized formula. For multiple gases measuring, it need install various infrared filters in "AG module".

For measuring O_2, we apply Galvanic oxygen sensor. Through the oxidation and deoxidation reaction the sensor can produce current, so we can measure the current to calculate the O_2.

2.4.10 Data Storage Function

- Storing Data

It can fulfill power-off storage function automatically. The single data file can save up to 96 hours and one minute of trend data, one hour and one second of trend data, 60 groups of ecological parameter alarm data, 60 groups of ARR data, 120 seconds of waveform data and patient information.

The data file will be stored into the folder of patient-data/patient ID in the USB storage. If the patient ID has not been set, the data will be stored into the default folder "patient" in USB storage.

Data can't be saved when there is no enough space and a prompt is displayed in the lower left corner of screen: No enough space in the USB storage device.

- Browsing data

You can browse the trend graphs/tables, NIBP recall list, ecological parameter alarm data, ARR data, hologram waveform data, patient information on the monitor which are saved by the patients. A data storage button is displayed on the main menu interface. Press this button to call up the data storage interface. And press [**data query**], all patient bed number in the USB storage device will be displayed. Press [**patient ID button**], all data about this patient will be displayed on the interface. Press the **UP/DOWN** button to see the remaining data if one page can't display all data. Select the data to be queried and the data will be imported to the memory from the USB storage device. And then you can browse trend table/graph, NIBP recall list, waveform recall, alarm data and so on. The monitor can only display the saved trend data.

- Deleting Data

It is used to delete all patients' data and one patient's data. Two Deletion buttons are displayed on

both patient ID interface and patient data interface. They are used to delete all data and patient ID data respectively. [**Delete all data**] can delete all patients' data including data from network package data. [**Delete Patient ID data**] can delete the data about this patient ID (including network package data). A prompt is displayed when the data is deleted. A prompt of "It is successful to delete the data " is displayed after the data is successfully deleted. The patient ID saving data can't be deleted.

- Removing USB storage device

It is used to remove USB. Press this button before unplugging the USB storage device. If the data is being saved when you press the button, a prompt of "Data is transmitting, please waiting" will display. If data is successfully deleted, a prompt of "It is successful to delete" will display. Unplug the USB storage device after successful deletion.

Note: The USB storage device may be damaged or patient monitoring data may be lost if you don't follow those steps and unplug the USB storage device directly.

3 Installation of Monitor

- Open the package and check
- Install wall mount for patient monitor
- Connect the power cables
- Power on the monitor
- Connect patient sensors
- Check the recorder

NOTE:
To ensure that the monitor works properly, please read user manual and service manual carefully, and follow the steps before using the monitor.

3.1 Opening the Package and Checking

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. Please note that:

1. If the user buys optional parts or other accessories, he should also verify if they are placed in the package.

2. If the goods in the package are not consistent with those on the packing list, please contact the supplier.
3. If the device or any part is damaged during transportation, please save all packing material and goods for future inspection and immediately contact the supplier.

3.2 Connecting the Power Cables

Connection procedure of the AC power line:

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

NOTE:
Connect the power line to the jack special for hospital usage.

- Connect to the ground line if necessary.

NOTE:
When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Switching on AC power supply can charge the battery no matter if the monitor is powered on.

3.3 Powering on the Monitor

Once the monitor is powered on, the LOGO information will be displayed on the screen.

NOTE:
Check all the functions the monitor may use and make sure that the monitor is in good status. Only qualified service personnel should perform a full function check procedure.

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

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

NOTE:
The interval between double pressing of POWER should be longer than one minute.

3.4 Connecting Sensors

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

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

3.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if the paper is properly installed in the slot. Refer to Chapter 7 in User manual for more details.

3.6 Installing Wall Mount for the Monitor (Optional)

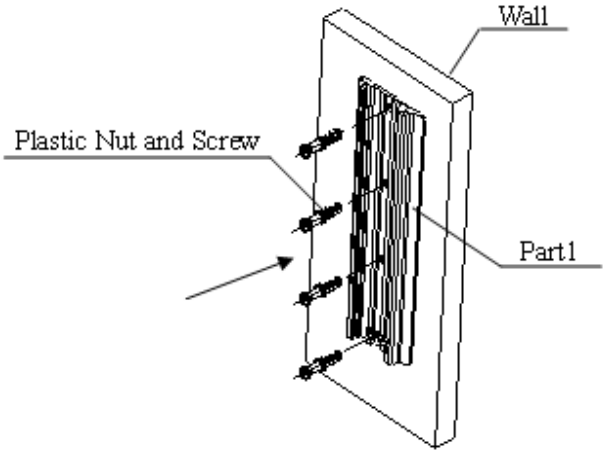


Figure 3-1

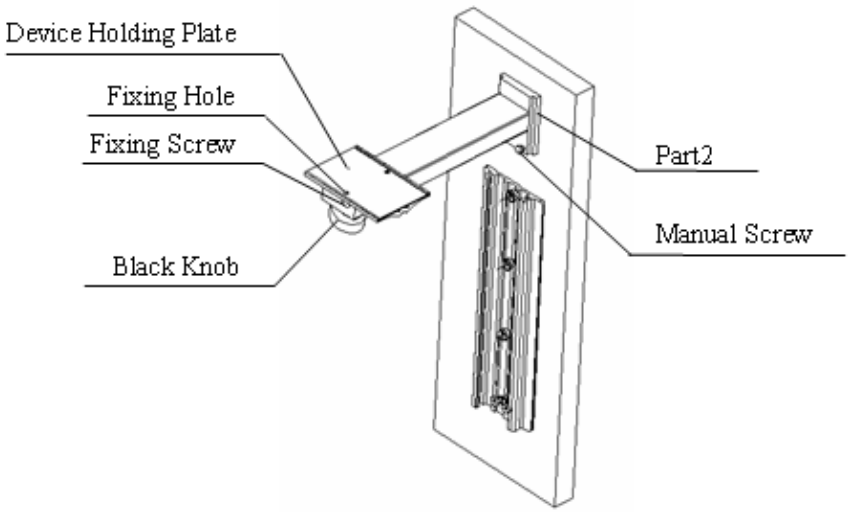


Figure 3-2

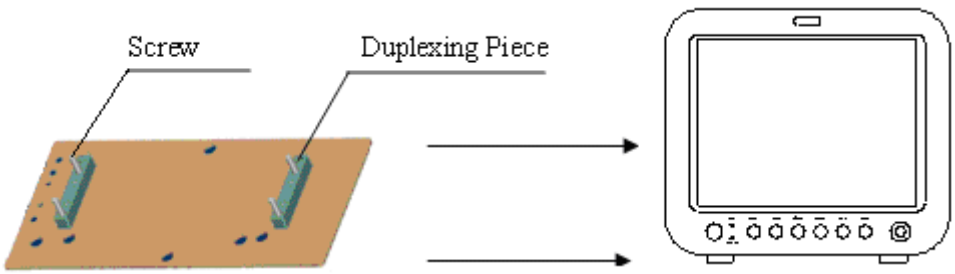


Figure 3-3

Installation Steps:

1. Use part 1 to draw lines on the wall at the desired location.
2. Drill four holes of 6mm in diameter in the wall, and then knock the plastic nuts into the

holes completely.

3. Knock four screws in the plastic nuts, when tightened; secure the channel (part1) at the desired location of the wall (as shown in Figure 3-1).
4. Slide the arm (part2) into channel (part1) as Figure 3-2 shows to the desired location.
5. Tighten the manual screw and secure the arm (part2) at the desired position within the channel (part1).
6. Face the side with duplexing piece of the device holding plate to the underside of the patient monitor, fix it with M4×25mm screw (as shown in Figure 3-3).
7. Pull out the fixing screw from the fixing hole.
8. At the same time, put the arm (part2) into the patient monitor with the device holding plate, and secure the fixing screw totally through the fixing hole.
9. The patient monitor can be adjusted by a maximum 15 degrees by rotating the black knob.

NOTE:

1. When using the monitor and other medical devices at the same time, requirements regarding power distribution of medical equipment must be abided by for fear that the leakage currents of devices overlap and consequently injury the patient or the medical personnel.
2. Do not use the monitor in the presence of flammable anesthetics to avoid the hazard of explosion.

4 Test and Calculation

4.1 Checking the Monitor

The information in this chapter is only a brief introduction.

First check appearance and installation of the device, and make sure that:

1) The shell of the device is clean and has no scratches. The installation components are stable. When you shake the device, there are no loose or fallen parts inside the monitor. But it is recommended not to shake the device often in order to avoid damaging the device.
2) Buttons are smooth and new.
3) All labeling is present and legible.
4) Standard configuration accessories are complete and the sockets are installed safely. All the outer cables and accessories are in good condition.
5) There is no mechanical damage.

If you find any damage on the monitor, stop using the monitor on patient, and contact the biomedical engineer of the hospital, the manufacturer or local representative immediately.

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

Routine Check

The overall check of the monitor, including the functional safety check, must be performed by qualified personnel every 6 to 12 months or each time after repair of the monitor. 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 NIBP Calibration

It is recommended that the user should calibrate the patient monitor at least every two years, in case the measurement results are inaccurate. The calibration should be executed by professional personnel authorized by EDAN.

NOTE:

The calibration of NIBP is just a method for checking the measurement results, it will not change the measurement standard.

NIBP Calibration needs T-connector, hose and Thermometer.
Calibration procedure:

1. Enter NIBP menu;
2. Connect air way as indicated in figure 4-2;
3. Press **CALIBRATE** in **NIBP** menu, as shown in the following figure:

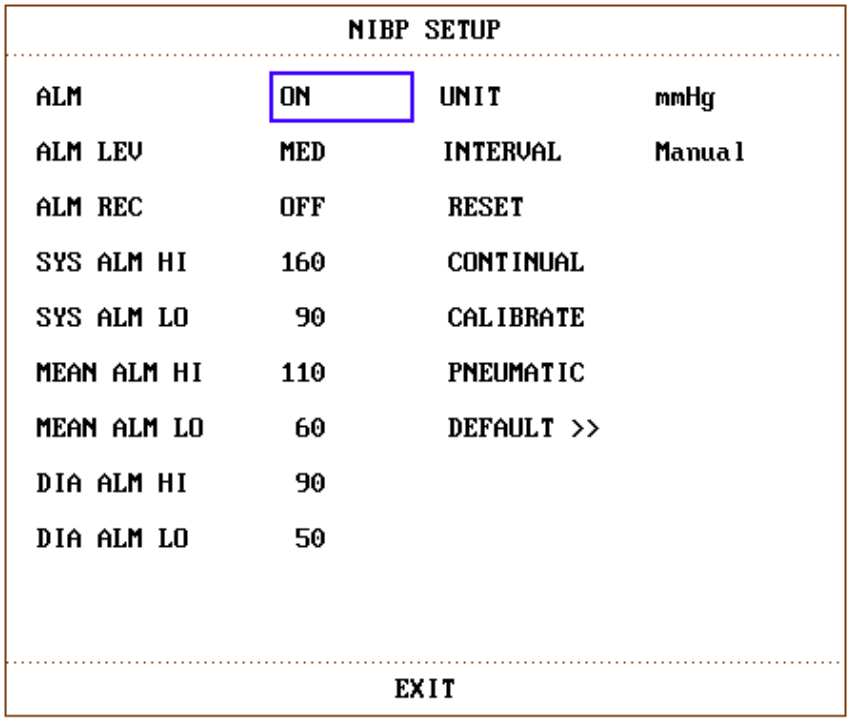


Figure 4-1 NIBP Calibration

4. Make sure the air way is sealed well, the pneumatic value is less than 3mmHg/min. Fill the system with gas, observe real-time pressure value and displayed pressure value in Thermometer.

If the two values are equal, we can consider the NIBP measurement of the monitor has no failure.

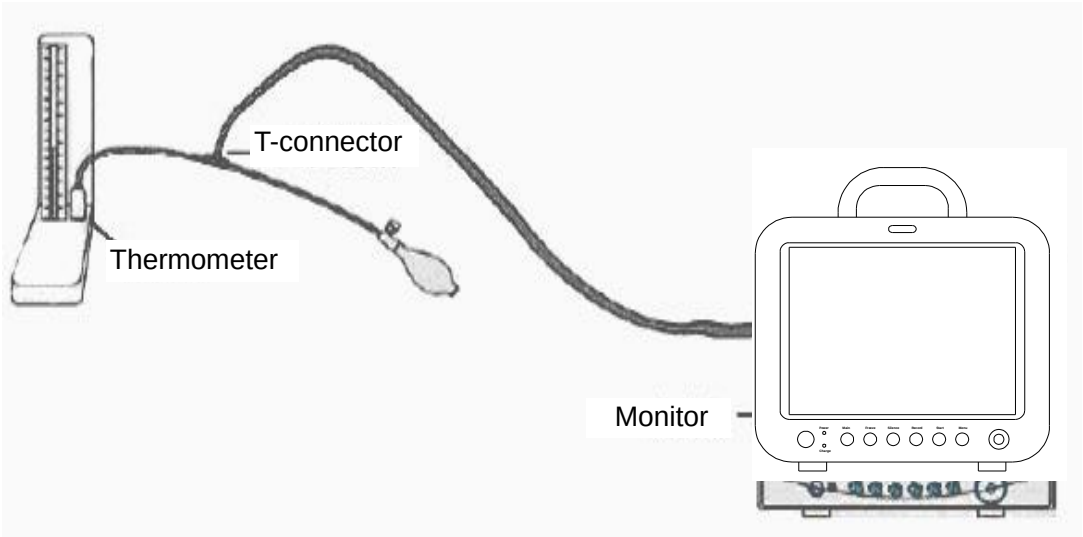


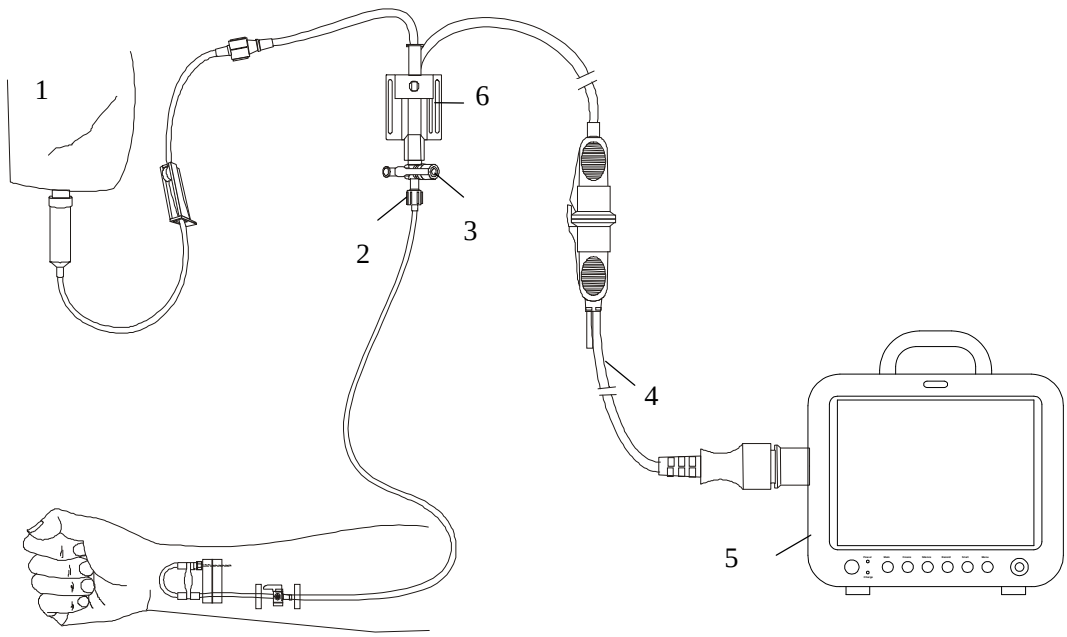
Figure 4-2 NIBP Calibration

4.3 IBP Calibration

You should do zero calibration every time before IBP measurement and do calibration when the sensor is replaced (or according to the regulations of the hospital); before calibration, you should do zero calibration.

The zero calibration procedure is shown as follows:

Turn the 3-way stopcock to the **OFF** position before calibration, then the air can pass through the pressure sensor. Then select **CALIBRATE** in menu. After successful calibration, it prompts in menu.



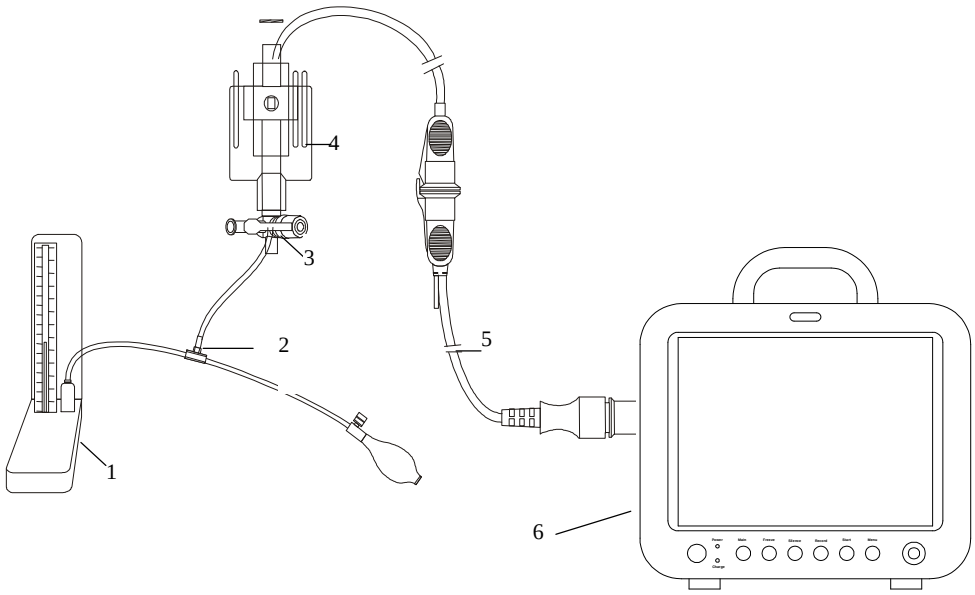
1: Normal Saline with Heparin; 2: Distal end to patient; 3: 3-way stopcok; 4: Pressure transducer interface cable; 5: Monitor; 6: Pressure transducer.

Figure 4-3 IBP Monitoring

Calibration procedure is shown as follows :

Connect the airway as shown in figure 4-4. Inflate to the Hydrargyrum pressure meter, let its displayed value equal the set IBP pressure value in menu. Then select **CALIBRATE** in menu. After you calibrate successfully, there will be a prompt in the menu.

It is recommended that the calibration pressure is 160mmHg or 200mmHg.



1: Hydrargyrum pressure meter; 2: 3-way connector; 3: 3-way stopcock; 4: Pressure transducer; 5: Pressure transducer interface cable; 6: Monitor.

Figure 4-4 IBP Calibration

4.4 CO_2 Calibration

The CPT CO_2 module, C5 CO_2 module and LoFlo CO_2 module are optional configuration for CO_2 monitoring function. If you use CPT CO_2 module, you can calibrate by "CO_2 CHECK>>" in USER MAINTAIN and do zero calibration by "ZERO CAL" in CO_2 setup; if you use C5 CO_2 module or LoFlo CO_2 module, you can also do zero calibration by "ZERO CAL" in CO_2 setup, but the "CO_2 CHECK >>" is unavailable.

Calibration:

If you want to use the CPT CO_2 module, connect as the following figure shows:

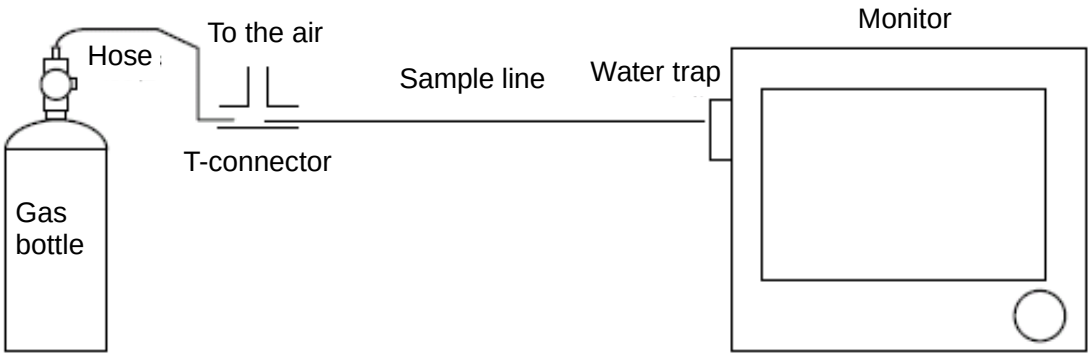


Figure 4-5 Connecting Way for Calibration

Enter **SYSTEM MENU → MAINTAIN → USER MAINTAIN** by password, select CO_2

CHECK >> to show the following interface:

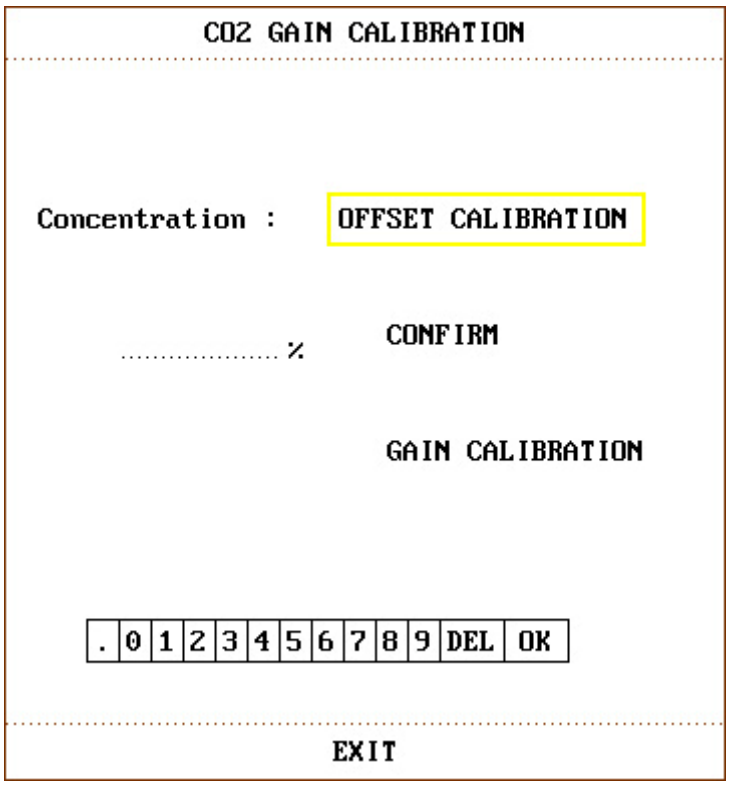


Figure 4-6 CO2 Gain Calibration

Fill the CO_2 concentration in the item "Concentration" (unit: %), then perform the calibration.

NOTE:

If you use C5 CO_2 module and LoFlo CO_2 module, the "CO_2 check>>" item is unavailable.

Zero Calibration

The Zero calibration is intended to decrease the effect caused by baseline drifting. When you perform calibration, the item ZERO CAL in CO_2 setup menu is unavailable. After the Zero calibration is finished successfully, the item is reactive. It is recommended that user should do the Zero Calibration before Calibration.

NOTE:

CPT CO_2 module, C5 CO_2 module and LoFlo CO_2 module need to perform Zero Calibration.

Pick the hot key **CO_2** on the screen to access the **CO_2 SETUP** menu, select **OTHER SETUP**. Then the following menu will pop-up:

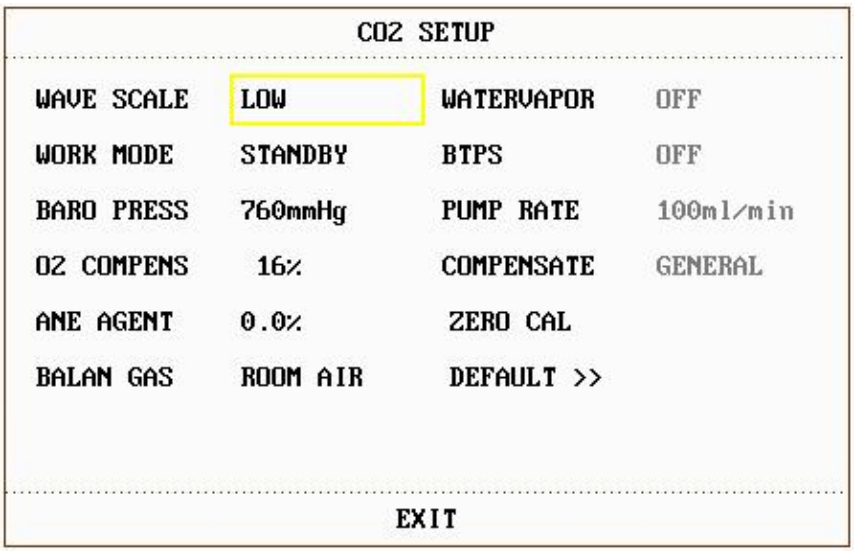


Figure 4-7 CO2 SETUP

ZERO CAL: used to perform zero calibration for CO_2 module.
When dramatic change in CO_2 measurement occurs or the accuracy of reading is suspected by the clinician, please select "**ZERO CAL**" item. Then the system will automatically inhale clean CO_2-free 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".

4.5 GAS Calibration

Enter **SYSTEM MENU > MAINTAIN > USER MAINTAIN > OTHER SETUP > GAS SPAN CALIBRATION** for AG calibration. This calibration is operated by the user.

The calibrated anesthetic gas concentration must be higher than 1.5%, CO_2 is higher than 1.5%, N_2O is higher than 40%, O_2 is higher than 40%. The main screen is shown as follows:

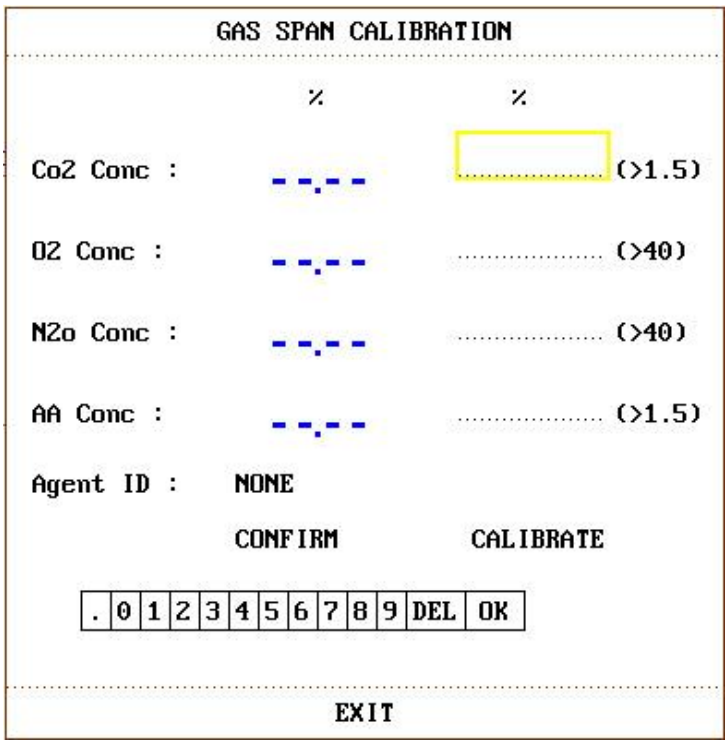


Figure 4-8 Gas Span Calibration

Fill the concentration of calibrating gas in the right blank, compare it with the measured concentration. If the two values have discrepancy, select **CALIBRATION** to calibrate.
If the two values are equal, select **CONFIRM** to exit the menu.

NOTE:

1. Make sure the discrepancy of calibrating gas is less than ±1;
2. The gas flux should be set in the range of 10～50ml/min;
3. The calibrating anesthetic gas concentration should be higher than 1.5%, CO_2 is higher than 1.5%, N_2O is higher than 40%, O_2 is higher than 40%;
4. Set up menu according to the 02 module or 03 module;
5. The discrepancy between calibrated value and measured value is less than 15%.

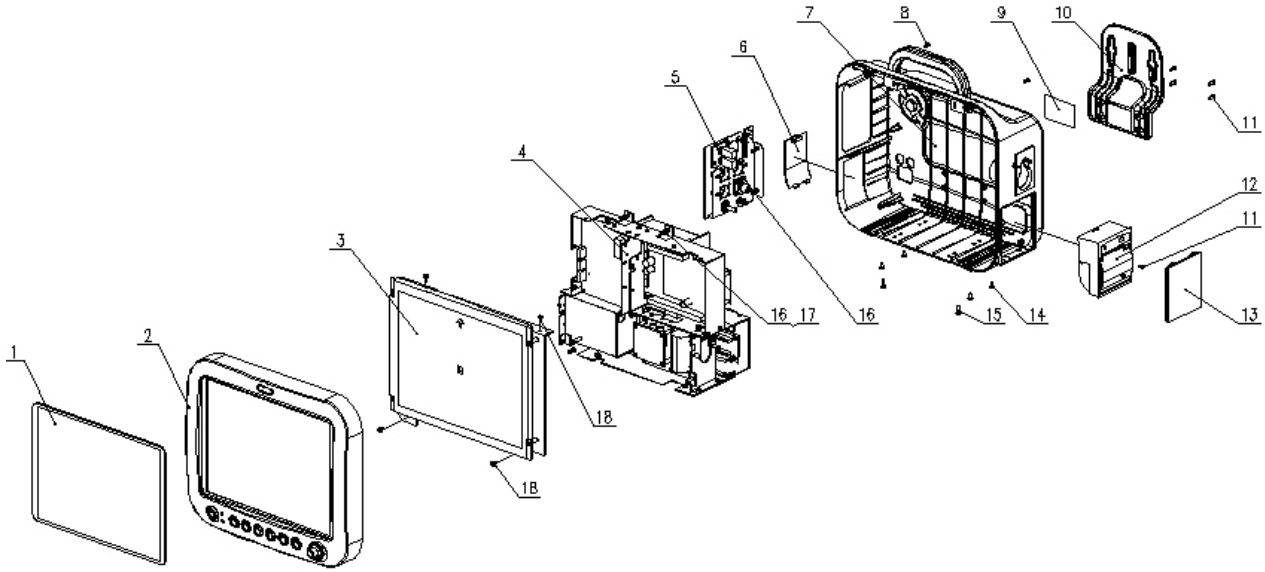
NOTE:

The calibration should be done before high concentration O_2 measurement.

5 Structure and Part List

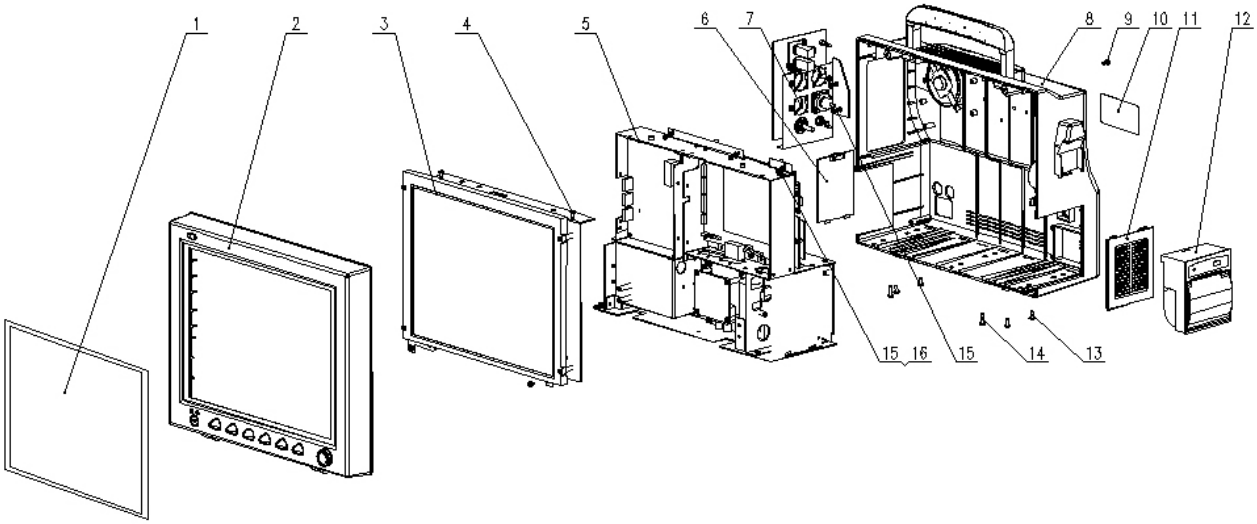
This chapter introduces the inner structure of the monitor.
There are monitors with round shell (M9, M9A), and monitors with square shell (M9B, M8, M8A and M8B).

5.1 Disassembly Graphics



1: 12.1 M9 LCD; 2: M9 front shuck assembly; 3: LCD assembly; 4: Main bracket assembly; 5: Sensor module assembly; 6: M9 battery compartment cover; 7: Rear shuck assembly; 8: Cross recessed pan head self-tapping screw ST3×12; 9: M9 label; 10: M9 cuff bracket; 11: Cross recessed pan head screw M3×8; 12: Recorder; 13: M9 recorder slot cover; 14: Cross recessed pan head coil spring screw M4×10; 15: Cross recessed pan head coil spring screw M3×10; 16: Cross recessed pan head self-tapping screw ST3×8; 17: Plain washer 3.5; 18: Cross recessed pan head coil spring screw M3×6.

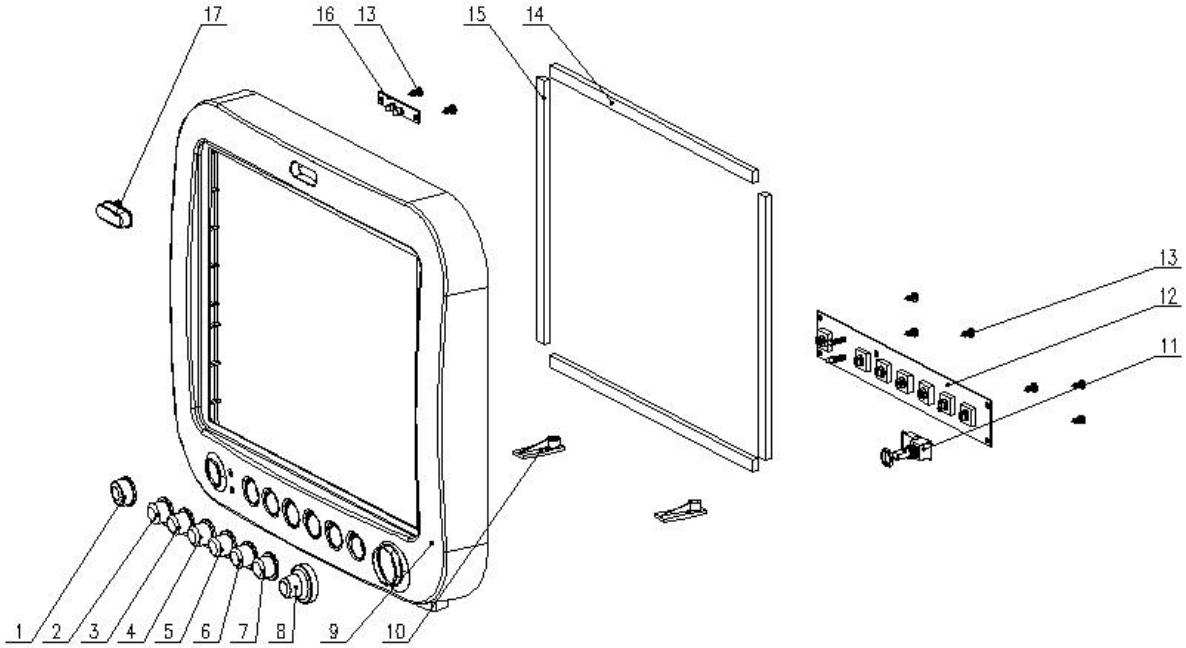
Figure 5-1 M9 Series Disassembly Graphics



1: M9B 10.4 LCD; 2: M9B 12.1 front shuck assembly; 3: M8 12.1 front shuck assembly; 4: Cross recessed pan head coil spring screw M3×6; 5: M8 series main bracket assembly; 6: M9B battery compartment cover; 7: Sensor module assembly; 8: Rear shuck assembly; 9: Cross recessed pan head self-tapping screw ST3×12; 10: M9B general label; 11: M9B recorder slot cover; 12: Recorder; 13: Cross recessed pan head coil spring screw M4×10; 14: Cross recessed pan head coil spring screw M3×10; 15: Cross recessed pan head self-tapping screw ST3×8; 16: Plain washer 3.5.

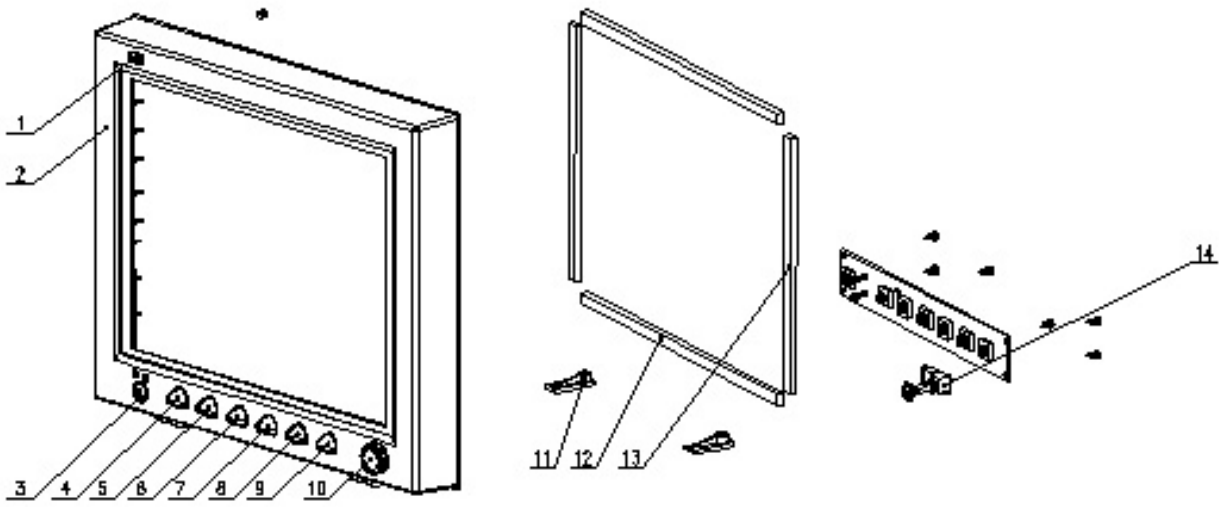
Figure 5-2 M8 Series Disassembly Graphics

5.2 Front Shuck Assembly



1-8: Function button; 9: Front shuck; 10: Connector for front shuck and rear shuck; 11: M9 shuttle PCBA; 12: M9 keyboard PCBA; 13: Cross recessed pan head self-tapping screw; 14: Sponge pad, Breadthwise; 15: Sponge pad, lengthways; 16: M9 alarm light board PCBA; 17: M9 alarm lampshade.

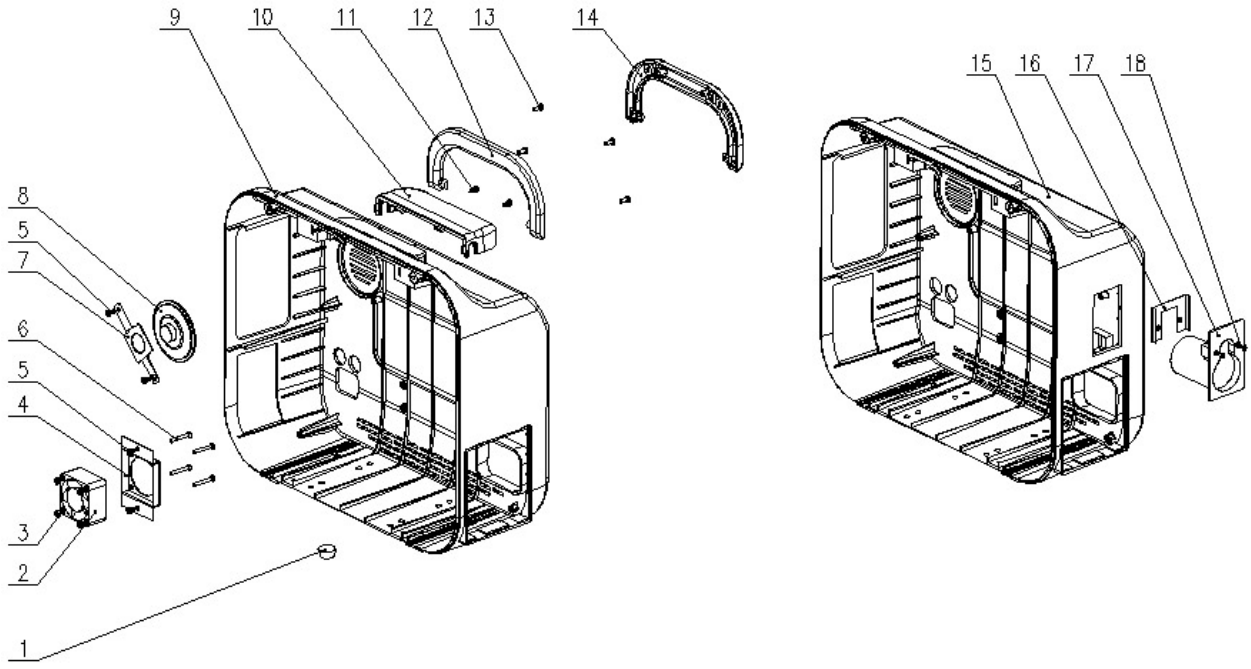
Figure 5-3 M9 Series Monitor Front Shuck Assembly



1: 12.1 inches screen lampshade; 2: Front shuck; 3: Power supply switch; 4-10: Function button; 11: Connector for front shuck and rear shuck; 12: Sponge pad, breadthwise; 13: Sponge pad, lengthways; 14: Narrow keyboard PCBA.

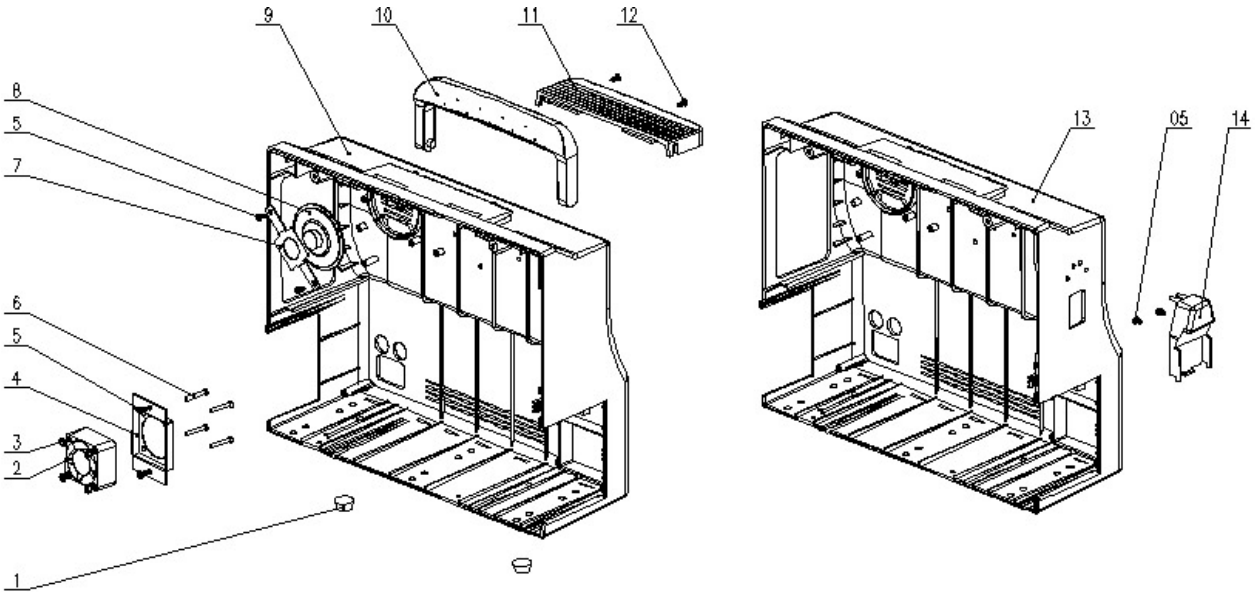
Figure 5-4 M8 Series Monitor Front Shuck Assembly

5.3 Rear Shuck Assembly



1: SONATINA Rubber feet; 2: Fan; 3: Nut M3； 4: SONATINA Fan bracket; 5: Cross recessed pan head self-tapping screw ST3×8; 6: Cross recessed countersunk head screw M3×23; 7: M9D Speaker bracket; 8: Moving speaker; 9: M9 Rear shuck; 10: M9 handle cover; 11: Cross recessed pan head self-tapping screw ST3×12; 12: M9 handle top cover; 13: Cross recessed pan head screw M3×8; 14: M9 handle bottom cover; 15: M9 rear shuck/add GAS seat slot; 16: GAS seat fixed sheet; 17: GAS seat; 18: Cross recessed pan head screw M3×8.

Figure 5-5 M9 Series Monitor Rear Shuck Assembly



1: SONATINA Rubber feet; 2: Fan; 3: Nut M3； 4: SONATINA Fan bracket; 5: Cross recessed pan head self-tapping screw ST3×8; 6: Cross recessed countersunk head screw M3×23; 7: M9D Speaker bracket; 8: Moving speaker; 9: M9B Rear shuck; 10: SONATINA handle; 11: SONATINA top cover; 12: Cross recessed pan head self-tapping screw ST3×12; 13: CO_2 functional rear shuck (with recorder); 14: CO_2 water trap.

Figure 5-6 M8 Series Monitor Rear Shuck Assembly

5.4 Main Bracket Assembly

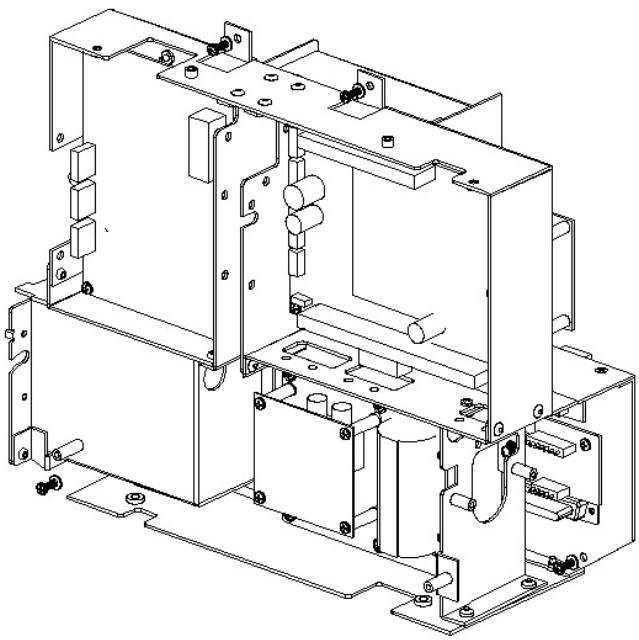


Figure 5-7 Main Bracket of M9 Series Monitor

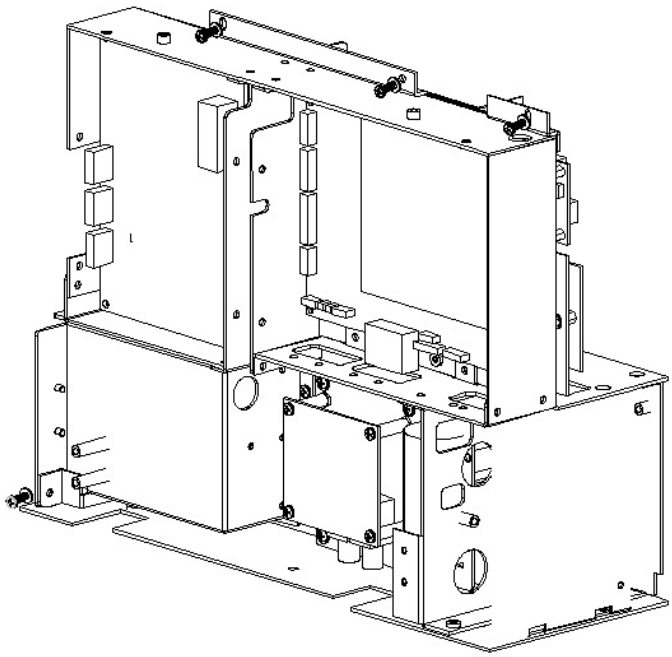
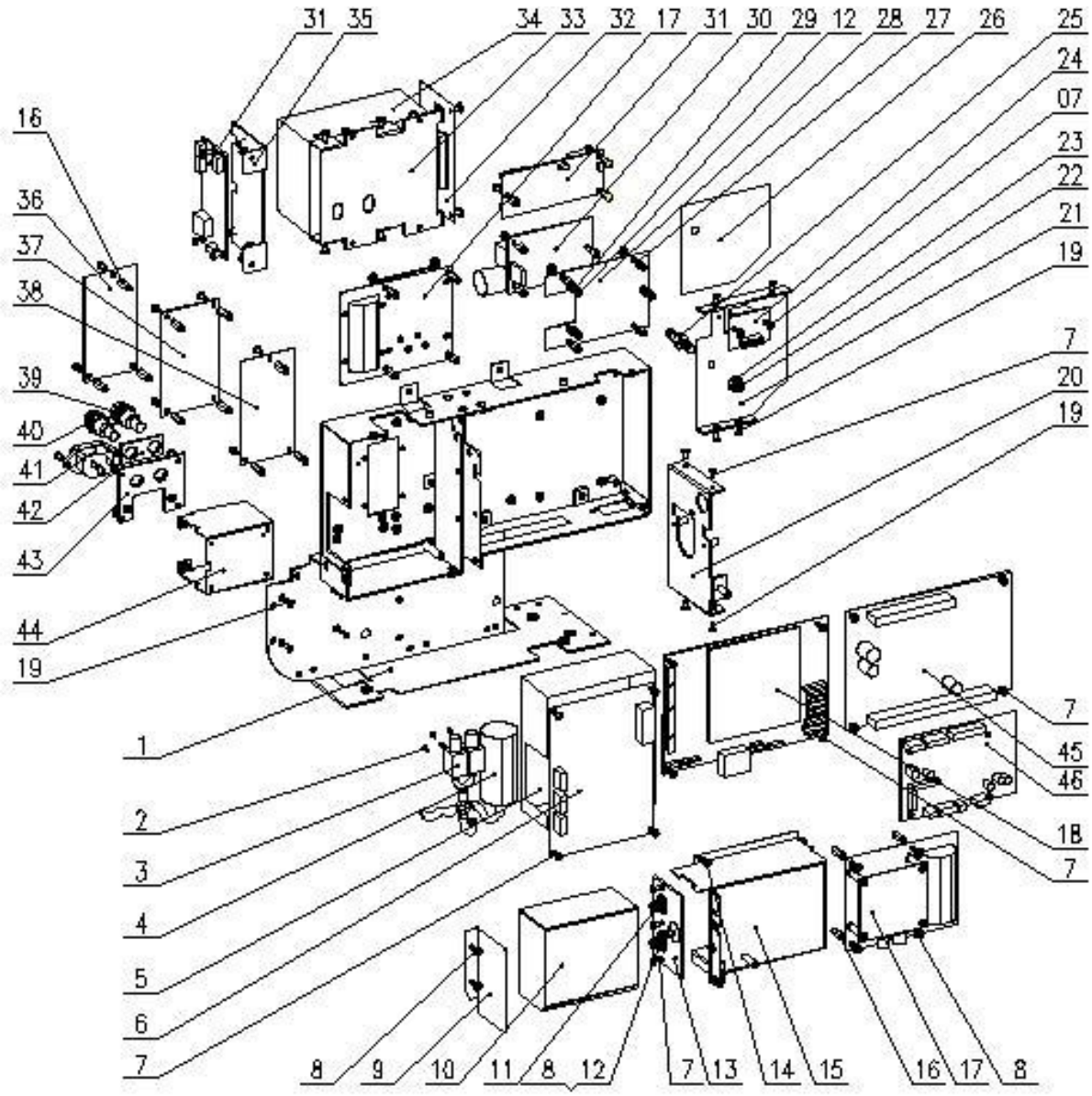
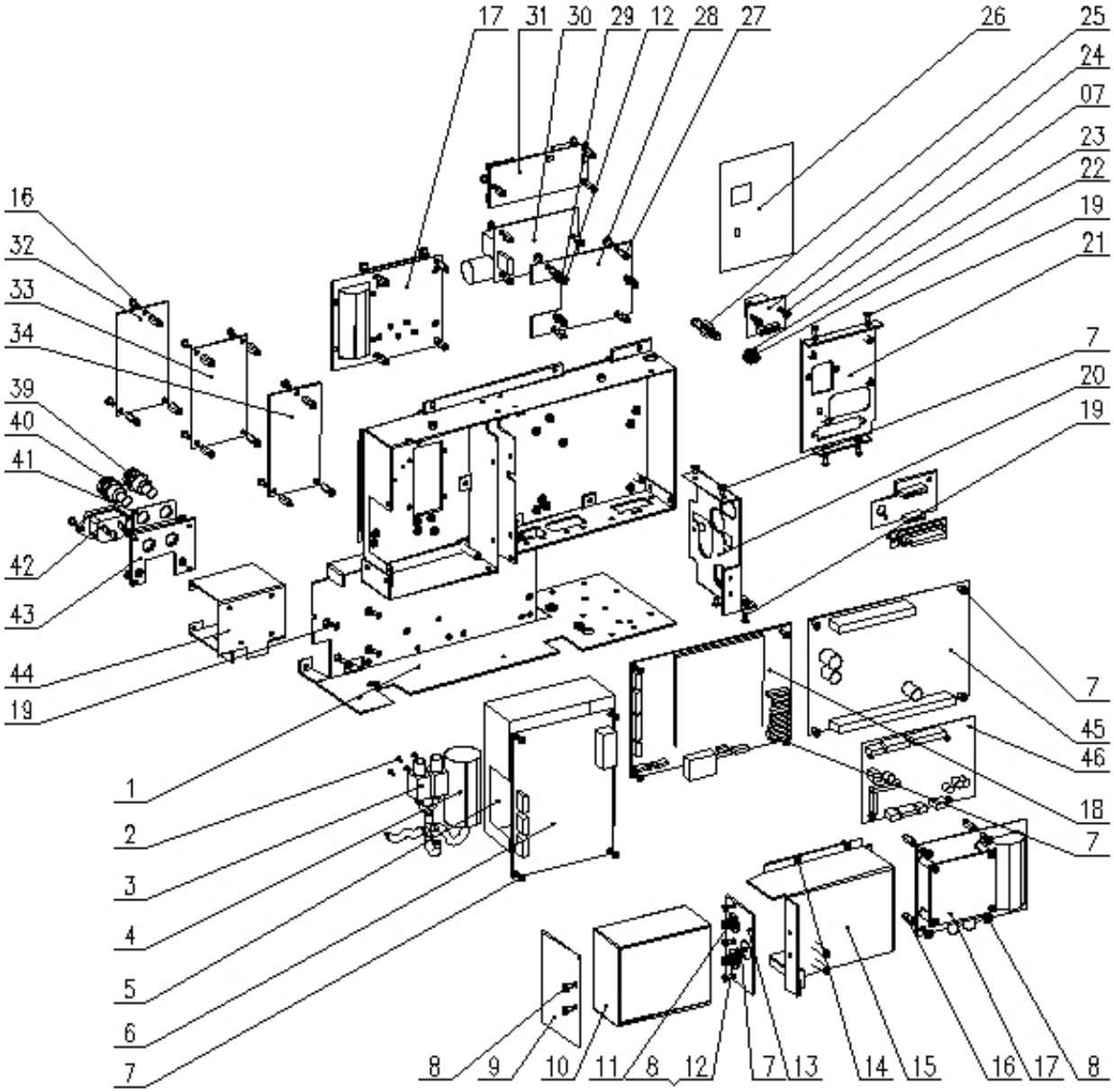


Figure 5-8 Main Bracket of M8 Series Monitor



1: M9 series main bracket; 2: Cross recessed pan head screw M2.5×6; 3: SONATINA(B) Valve; 4: SONATINA(B) air pump; 5: BM100 insulated gasket; 6: BM100 monitor module/with CE; 7: Cross recessed pan head screw M3×6; 8: Cross recessed pan head coil spring screw M3×6; 9: M9 battery baffle; 10: Ni-H battery; 11: SONATINA(B) battery spring; 12: Nut M3; 13: SONATINA(B) battery board PCBA; 14: Cross recessed pan head coil spring screw M3×5; 15: M9 battery compartment; 16: Copper stud H4.75*13+3 (M3); 17: V6 module; 18: 2410 main board; 19: Cross recessed countersunk head screw M3×6; 20: M9 build-in recorder bracket; 21: M9 rear board; 22: Hexagon nut M6; 23: Plain washer 6; 24: M9B network board PCBA; 25: Grounding wire pole; 26: M9 label on rear board; 27: Copper stud H4.75*8+3 (M3); 28: CO_2 module setting board; 29: Plain washer Φ3.5; 30: CO_2 module; 31: CO/IBP module; 32: Artema GAS module interface PCBA; 33: GAS module fixed board; 34: GAS module; 35: COIBP side fixed bracket; 36: SpO_2 module A6; 37: SpO_2 module MP506; 38: SpO_2 module MR9006; 39: CADENCE fuse seat connecting line component/blue; 40: CADENCE fuse seat connecting line component/brown; 41: Power supply socket; 42: M9B Fuse seat gasket; 43: M9 power supply rear board; 44: Power supply bracket; 45: Industrial control main board(with sound card)/EW-AM 3902B0 version; 46: M9 rear shuck interface PCBA/without 485 network, with LVDS.

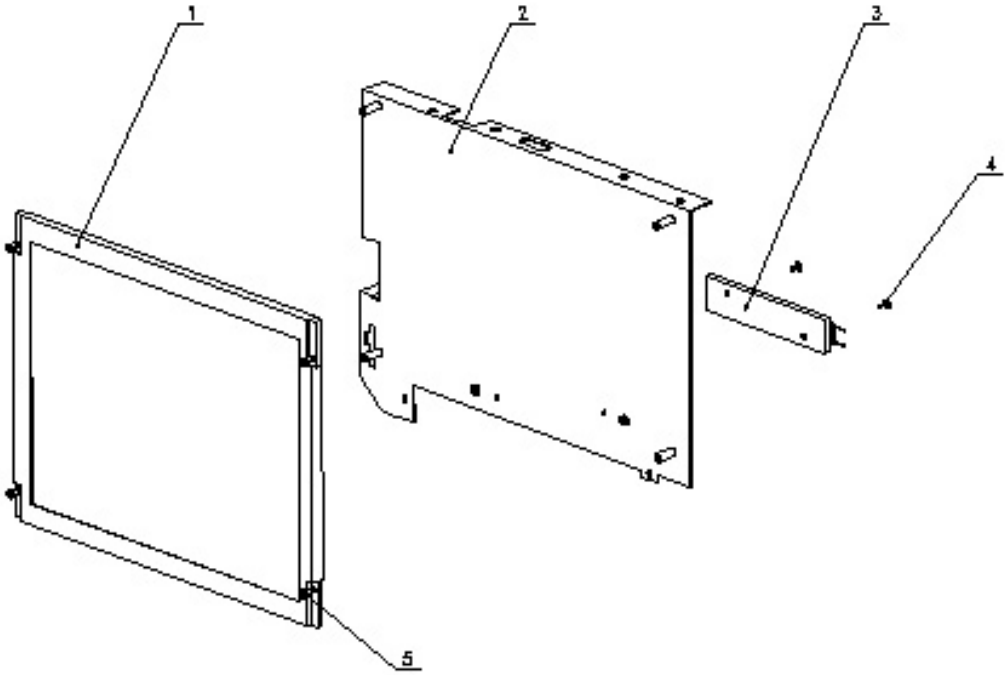
Figure 5-9 M9 Series Monitor Main Bracket Disassembly, Exploded



1: M8 series main bracket; 2: Cross recessed pan head screw M2.5×6; 3: SONATINA(B) Valve; 4: SONATINA(B) air pump; 5: BM100 insulated gasket; 6: BM100 monitor module/with CE; 7: Cross recessed pan head screw M3×6; 8: Cross recessed pan head coil spring screw M3×6; 9: SONATINA(B) battery fastener; 10: Ni-H battery; 11: SONATINA(B) battery spring; 12: Nut M3; 13: SONATINA(B) battery board PCBA; 14: Cross recessed pan head coil spring screw M3×5; 15: M9B battery compartment (12.1 LCD); 16: Copper stud H4.75*13+3 (M3); 17: V6 module; 18: 2410 main board; 19: Cross recessed countersunk head screw M3×6; 20: M9 build-in recorder bracket; 21: M9 rear board; 22: Hexagon nut M6; 23: Plain washer 6; 24: M9B network board PCBA; 25: Grounding wire pole; 26: M9 label on rear board; 27: Copper stud H4.75*8+3 (M3); 28: CO_2 module setting board; 29: Plain washer Φ3.5; 30: CO_2 module; 31: CO/IBP module; 32: SpO_2 module A6; 33: SpO_2 module MP506; 34: SpO_2 module MR9006; 39: CADENCE fuse seat connecting line component/blue; 40: CADENCE fuse seat connecting line component/brown; 41: Power supply socket; 42: M9D Fuse seat gasket; 43: M9 power supply rear board; 44: Power supply bracket; 45: Industrial control main board(with sound card)/EW-AM 3902B0 version; 46: M9 round rear shuck interface PCBA/without 485 network, with LVDS.

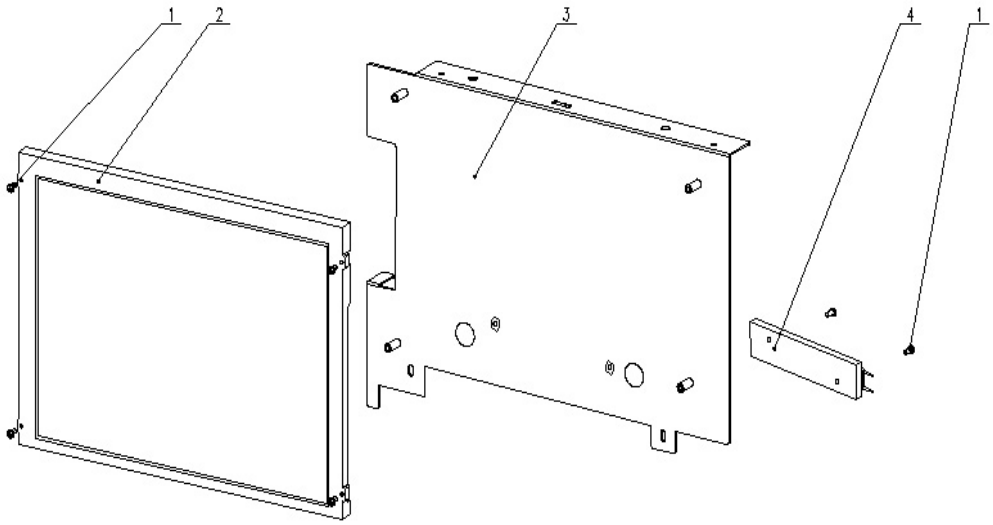
Figure 5-10 M8 Series Monitor Main Bracket Disassembly Graphics, Exploded

5.5 TFT Assembly



1: 12.1 inches LCD screen; 2: M9 screen bracket; 3: SONATINA(B) LCD screen power switch board; 4: Cross recessed pan head screw M3×6; 5: Cross recessed pan head coil spring screw M3×6.

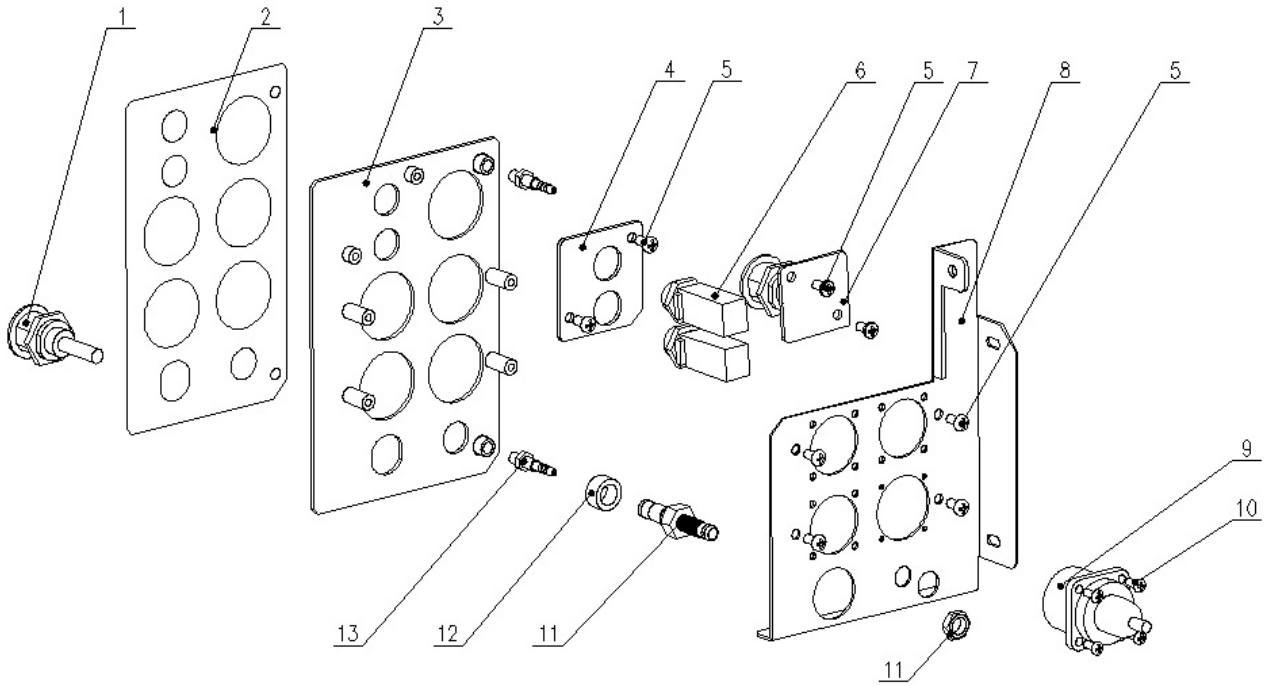
Figure 5-11 M9 Series Monitor TFT Assembly



1: Cross recessed pan head screw M3×6; 2: 12.1 inches TFT LCD screen G121SN01; 3: M8 12.1 LCD bracket; 4: Power switch board 0426-K.

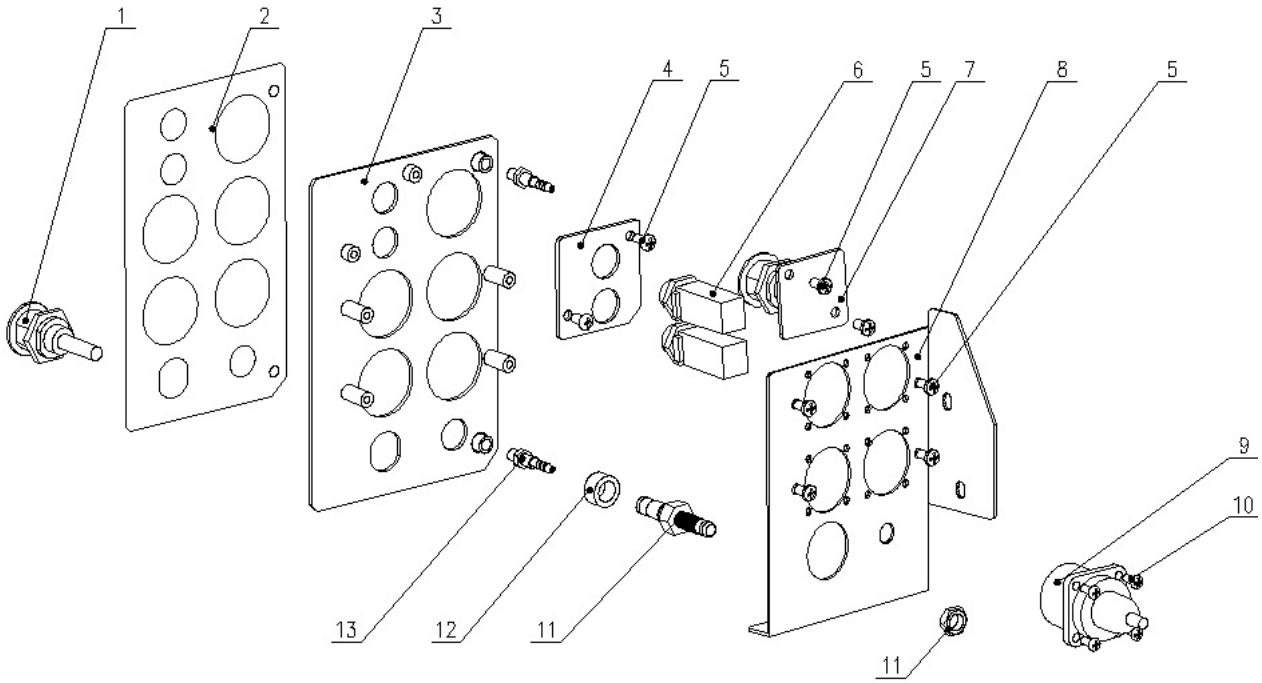
Figure 5-12 M8 Series Monitor TFT Assembly

5.6 Sensor Module Assembly



1: Digital SpO_2 sensor socket connecting wire; 2: M9 sensor label; 3: M9 sensor outer board; 4: M9 TEMP seat gasket; 5: Cross recessed pan head screw M3×6; 6: BM100 monitor module TEMP socket connecting wire; 7: CO_2 link board; 8: M9 sensor inner board; 9: BM100 monitor module ECG socket connecting wire; 10: Cross recessed pan head screw M2.5×6; 11: SONATINA NIBP socket; 12: M9B NIBP sensor gasket; 13: CO_2 cannula air outlet.

Figure 5-13 M9 Series Monitor Sensor Bracket Assembly



1: Digital SpO_2 sensor socket connecting wire; 2: M9 sensor label; 3: M9 sensor outer board; 4: M9 TEMP seat gasket; 5: Cross recessed pan head screw M3×6; 6: BM100 monitor module TEMP socket connecting wire; 7: CO_2 link board; 8: M9 sensor inner board; 9: BM100 monitor module ECG socket connecting wire; 10: Cross recessed pan head screw M2.5×6; 11: SONATINA NIBP socket; 12: M9B NIBP sensor gasket; 13: CO_2 cannula air outlet.

Figure 5-14 M8 Series Monitor Sensor Bracket Assembly

6 Troubleshooting

In transportation, storage and usage of patient monitor, various factors such as unstable network voltage, changing environmental temperature, falling-down or impact, component aging may all result in patient 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 as per 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 board, TFT assembly, measuring cable or parameter module, etc. Repair of only some components means component-level repair. The repair must be conducted by a service engineer with abundant experience and with the assistance of special equipment and in specific environments and conditions.

6.1 Device Failures

Failure	Possible cause	Solution
No display after power-on, power indicator is not on or fan does not run.	① Fuse damage (If it 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 and the fan runs normally.	① Main 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 board and parameter module	①Replace the main board, keyset or parameter module based on the error prompt.
Operation or measurement function is disabled.	① Main board or corresponding component damage	① Examine the main board and the corresponding components
Device is occasionally	① Moment intensive	① Check power supply and

stoned.	interference of network	grounding system
	② Poor performance of power board	② Replace power board
	③ Poor performance of Main board	③ Replace Main board
	④ Bad connection of power supply or main 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 the screen goes black during normal operation.	① Power switch board damage	① Replace power switch board
	② Bad connecting wire of display	② Repair or replace connecting wire
	③ Damage of main board	③ Replace main board

6.3 Operation, Recording, Network Linking Failures

Failure	Possible cause	Solution
Keys or the rotary encoder is disabled.	① The keyboard or rotary encoder is damaged.	① Replace keyboard or rotary encoder.
	② Connection wire of keyboard is damaged.	② Replace or repair connection wire of keyboard
Sound is raucous or there is no sound.	① Keyboard failure	① Replace keyboard
	② Speaker or connection 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 a failure.	③ Replace the power supply
	④ Connection wire of the recorder is damaged.	④ Replace or repair the connection wire of the recorder
Record paper goes out on the skew.	①Recorder is installed or positioned badly .	① Adjust the installation of recorder.
The monitor cannot be linked to the network	① Network linking wire is damaged.	① Check and repair network linking wire.
	② Network bed No. conflicts	② Change bed No.
	③ Main board failure	③ Replace Main 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 parts.	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 Short-circuit occurs in this part	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 a 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 a failure.	① Replace the power

6.5 Parameter Failures

Failure	Possible cause	Solution

No ECG waveform	① Poor connection of ECG electrode films	① Use new electrode films to ensure good contact
	② ECG wave is closed	② Open wave in System menu
	③ No square waveform exists during CAL self-test	③ Replace ECG/RESP module
	④ RL electrode is suspended	④ Connect RL electrode
	⑤ ECG/RESP module is damaged	⑤ Replace ECG/RESP module
ECG waveform is abnormal or has interference	① Electrodes are connected incorrectly	① Correctly connect electrode films
	② There is suspending electrode film	② Remove electrode films that are not used
	③ AC power has no grounding wire	③ Use 3-wire power
	④ ECG filter way is incorrect	④ Select appropriate filter way
	⑤ ECG/RESP module is damaged	⑤ Replace ECG/RESP module
No RESP waveform or RESP waveform is abnormal	① Electrodes are connected incorrectly	① Use RL-LL electrode, connect to the correct positions
	② Patient is moving constantly	② Keep patient quiet
	③ RESP waveform is closed	③ Open waveform in System menu
	④ RESP wave amplitude is weak	④ Adjust wave amplitude in RESP menu
	⑤ ECG/RESP module is damaged	⑤ Replace ECG/RESP module
TEMP value is incorrect	① Measuring sensor is poorly connected	① Connect TEMP sensor stably
HR value is inaccurate, Arr. and ST analysis are incorrect.	① ECG waveform is not good	① Adjust the connection to make the ECG waveform normal
NIBP cuff can not be inflated.	① Air way is folded or has leakage	① Adjust or repair the air way

Blood pressure can not be measured occasionally.	① Cuff becomes loose or patient is moving	① Keep the patient quiet, bind the cuff correctly and safely
Error of blood pressure measurement is too great.	① Cuff size does not fit the patient	① Use the cuff of appropriate size
	② NIBP module has bad performance	② Replace NIBP module
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 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 in 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 in 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 CO2 SETUP, do CO_2 calibration by ZERO CAL

	② The compensatory gas and barometric is set incorrectly	② Enter the CO2 SETUP, set BAROPRESS and COMPENSATE items in menu for compensatory gas and barometric correctly.
No GAS waveform	① Poor connection of the GAS module	① Turn off the monitor and reconnect the GAS module
	② The GAS module is damaged	② Replace the GAS module
The GAS waveform is a beeline	① The GAS module is in STANDBY mode	① Change the STANDBY mode to MEASURE mode
	② The catheter is blocked or disconnected	② Turn off the monitor and clear or replace the catheter
	③ Caused by automatic zero calibration of module	③ The beeline caused by automatic zero calibration is abnormal
GAS measured value is incorrect	① Long time no zero calibration, the measured value is incorrect	① Do zero calibration for GAS module.
	② When using AION 02 module, The AGENT in GAS SETUP has not been set	② For using AION 02 module, set the AGENT in GAS SETUP
	③ The GAS measurement is not in Full accuracy mode.	③ After the 10-minute warm up, the GAS measurement enters Full accuracy mode.

7 Maintenance and Cleaning

7.1 General Cleaning

⚠ **WARNING** ⚠

Turn off the power and disconnect the power line 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 per 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 away from 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.

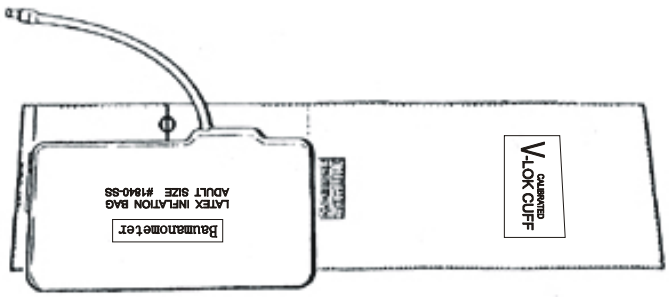
7.1.1 Cuff Maintenance and Cleaning

⚠ **WARNING** ⚠

- Do not squeeze the rubber tube on the cuff.
- Do not allow liquid to enter the connector socket at the front of the monitor.
- Do not wipe the inner part of the connector socket when cleaning the monitor.
- When the reusable cuff is not connected to the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.
The cuff can also be machine-washed or hand-washed, the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing. Then reinsert the rubber bag.



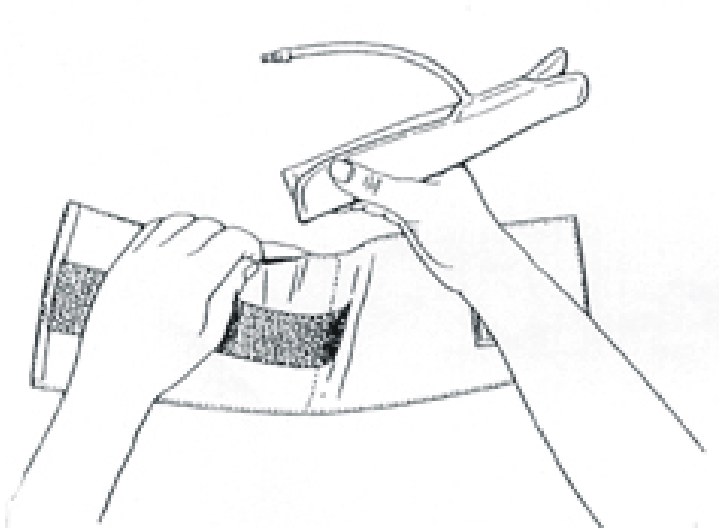


Figure 7-1 Replace Rubber Bag in Cuff

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

Disposable Blood Pressure Cuffs

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.

NOTE:
For protecting the environment, the disposable blood pressure cuffs must be recycled or disposed of properly.

7.1.2 IBP Sensor Maintenance and Cleaning

⚠ **WARNING** ⚠
Before cleaning the monitor or the transducer, make sure that the equipment is switched off and disconnected from the power line.

Cleaning of IBP Transducer (Reusable)

After the IBP monitoring operation is completed, remove the tubing and the dome from the transducer and wipe the transducer diaphragm with water. Soaking and/or wiping with soap can clean the transducer and cable and water or cleaning agents such as those listed below:

Cetylcide
Wavicide-01

Wescodyne
Cidex
Lysol
Vesphene

Do not immerse the connector in any liquid. After cleaning, dry the transducer thoroughly before storing. Slight discoloration or temporary increase of surface stickiness of the cable should not be considered abnormal if adhesive tape residue must be removed from the transducer cable. Double seal tape remover is effective and will cause a minimum of damage to the cable if used sparingly. Acetone, Alcohol, Ammonia and Chloroform, or other strong solvents are not recommended because over time the vinyl cabling will be damaged by these agents.

NOTE:

The disposable transducers or domes must not be re-sterilized or re-used.

NOTE:

For protecting environment, the disposable transducers or domes must be recycled or disposed of properly.

Sterilization

- Liquid Chemical Sterilization

  Remove obvious contamination by using the cleaning procedure described previously. Select a sterilant that your hospital or institution has found to be effective for liquid chemical sterilization of operating room equipment. Buffered gluteraldehyed (e.g. Cidex or Hospisept) has been found to be effective. Do not use quaternary cationic detergents such as zephiran chloride. If the whole unit is to be sterilized, immerse the transducer but not the electrical connector into the sterilant for the recommended sterilizing period. Be sure that the dome is removed. Then rinse all transducer parts except the electrical connector with sterilized water or saline. The transducer must be thoroughly dried before storing.

- Gas Sterilization

  For more complete asepsis, use gas sterilization.

  Remove obvious contamination by using the cleaning procedure described previously. To inhibit the formation of ethylene glycol when ethylene oxide gas is used as the disinfectant, the transducer should be completely dry.

  Follow the operating instructions provided by the manufacturer of the gas disinfectant.

⚠ **WARNING** ⚠

The sterilization temperature must not exceed 70°C (158°F). Plastics in the pressure transducer may deform or melt above this temperature.

7.1.3 TEMP Sensor Care and Cleaning

⚠ **WARNING** ⚠

Before cleaning the monitor or the probe, make sure that the equipment is switched off

and disconnected from the power line.

Reusable TEMP Probes

1 The TEMP probe should not be heated above 100°C (212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100°C (212℉).
2 The probe must not be sterilized in steam.
3 Only detergents containing no alcohol can be used for disinfection.
4 The rectal probes should be used, if possible, in conjunction with a protective rubber cover.
5 To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

NOTE:
Wash the probe with clean water after disinfecting and sterilizing to remove any remaining solution. The probe can only be reused after being dried thoroughly.

NOTE:
Do not disinfect the probe by means of water boiled.

NOTE:
The product has not been disinfected at the factory.

NOTE:
Any residue should be removed from the probe before being disinfected and sterilized, and avoid contacting corrosive solvent. Dipping the cable into alcohol or alkalescent solvent for a long time, may reduce the flexibility of the scarfskin of the cable. Also, the connector should not be dipped.

NOTE:
After monitoring, disinfect the probe according to the instruction described in the service manual and user manual.

NOTE:
Disposable TEMP probe must not be re-sterilized or reused.

NOTE:
Cavity temperature probe is only suggested to be used inside the recta. We recommend that you use the disposable cannula to prevent cross infection.

NOTE:
For protecting environment, the disposable TEMP probe must be recycled or disposed of properly.

NOTE:
Do not force the cavity temperature probe against resistance when inserted into human body. Also it is not recommended to use it in bleeding part and cankerous part of human

body.

7.1.4 SpO_2 Sensor Maintenance and Cleaning

Care 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:

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

7.1.5 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.

For cleaning CPT CO_2 module:

1. Sample line is for disposable use. Do not sterilize or clean for reuse on another patient.
2. When occlusion happens to the sample system, first check kinks for sampling line. If no kinks are found, then check water trap after disconnecting sample line from the water trap. If the occlusion message on the screen disappears, the sampling line must be replaced. If the occlusion message on the screen remains, the water trap must be replaced.

3. No routine calibration is required in CO_2 module.

7.1.6 CO Maintenance and Cleaning

CO cables cleaning:

1. If adhesive tape residue must be removed from the transducer cable, double seal tape remover is effective and will cause a minimum of damage to the cable if used sparingly. Acetone, Alcohol, Ammonia, Chloroform, or other strong solvents are not recommended because they will eventually damage the vinyl cabling.
2. Sponge the cable with warm water and soap, or another suitable cleaning solution, and dry. Do not immerse them in water.
3. Check each cable for corrosion, cracks and deterioration.
4. Gas Sterilization

   For more complete asepsis, use gas sterilization.

   - Remove obvious contamination by using the cleaning procedure described previously. To inhibit the formation of ethylene glycol when ethylene oxide gas is used as the disinfectant, the transducer should be completely dry.
   - Follow the operating instructions provided by the manufacturer of the gas disinfectant.

⚠ **WARNING** ⚠

Do not autoclave the cable or heat it above 75℃ (167℉). The cable should be stored in an environmental temperature between -20℃ and 75℃ (-68℉ to 167℉). It should be hung up or laid flat to prevent damage to the cable.

7.1.7 GAS Maintenance and Cleaning

n GAS module

For detailed cleaning information about "AG Module", refer to the chapter of "Maintenance/Cleaning" in User manual.

n Bacteria filter

The bacteria filter is one-off type, i.e., one bacteria filter can only be used on one patient.

n Sample line

The sample line is one-off type.

n Gas exhaust outlet

The gas exhaust outlet is reusable. You need to replace it only when it is damaged or becomes loosely connected. This tube can be cleaned and disinfected.

Cleaning: use cloth moistened with warm soap water to clean the tube. Do not immerse the tube into the liquid.

Disinfection: use cloth moistened with cool chemical disinfector (ramification mainly containing aldehyde, ethanol or ramification mainly containing ethanol) to clean the tube. Do

not immerse the tube into the liquid. After cleaning, use wet cloth to wipe off the disinfector and then use dry cloth to wipe the tube.

n Occlusion handling

If the GAS module passage is occluded, the screen will display the message AG OCCLUSION. The following are a few examples of occlusion, which you may remove one by one until this message disappears.

Entrance Occlusion

If the part at the entrance such as filter, sample line or airway connector is occluded by condensed water, the screen will display the message telling that the airway is occluded.

The optimal method to remove clogs of this kind is:

Check for clogs in entrance parts:

a. Replace the bacteria filter at the entrance.

b. Check the sample pipe for clogs and/or entangle. If necessary, replace it.

c. Check the airway connector for water. If necessary, drain off the water and install the connector again.

Internal Occlusion

If the interior of the GAS Module is contaminated by condensed water, the screen will also display the message telling that the airway is occluded.

The optional method to remove clogs of this kind is:

Step 1: as usual, check the entrance or the exit for clogs and remove them.

Step 2: if occlusion still persist after step 1, you should consider the existence of interior occlusion. In this situation, contact the manufacturer.

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

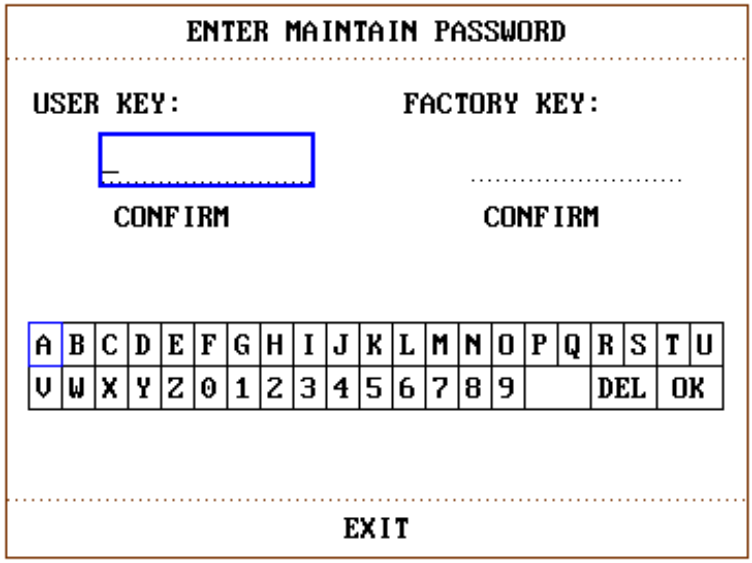


Figure 7-2 Enter Maintain Password

User Maintainance

Input the password into the "**ENTER MAINTAIN PASSWORD**" box and press "**CONFIRM**", the "**USER MAINTAIN**" menu will pop up, in which you can set up following items.

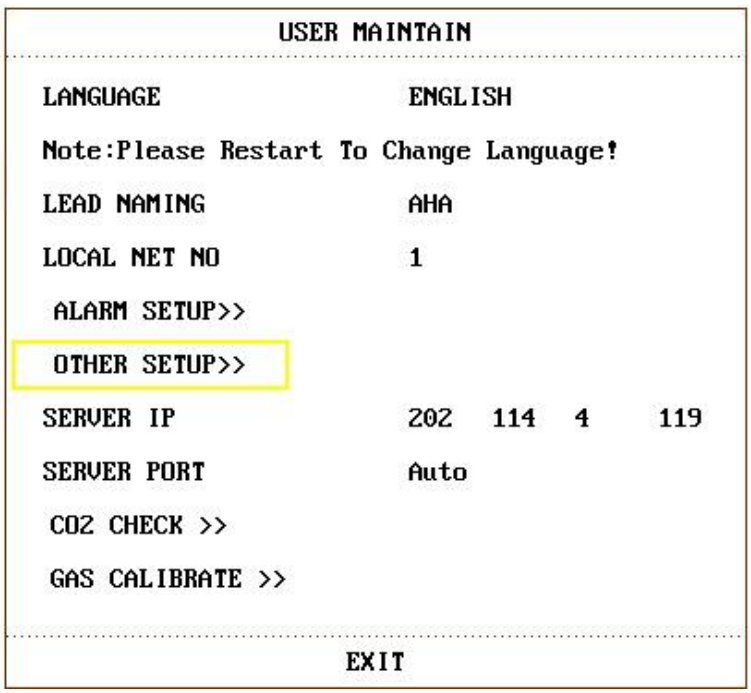


Figure 7-3 User Maintain

Factory Maintain

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

1. Enter factory maintain through password.

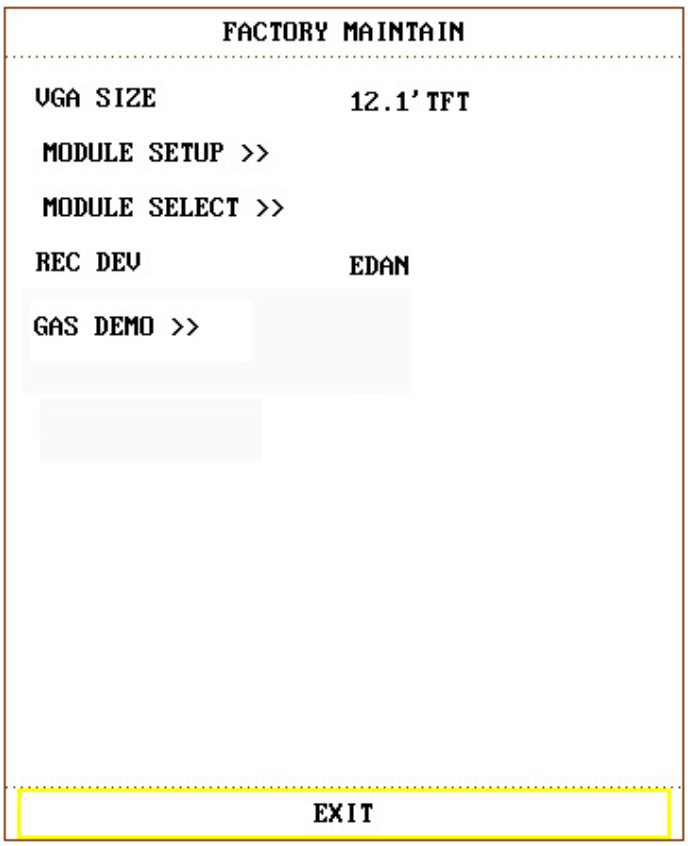


Figure 7-4 Factory Maintain

- SELECT MODULE >>:

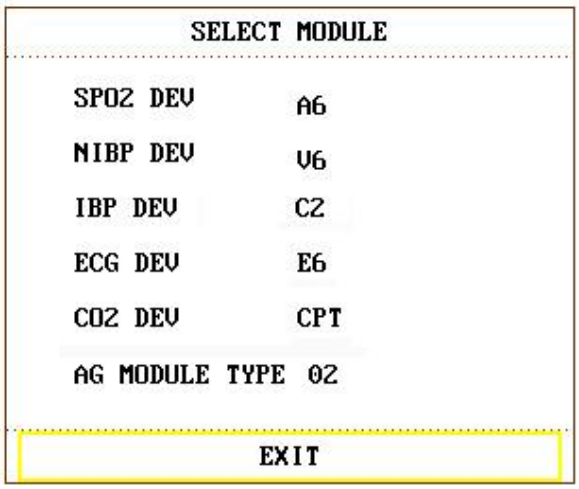


Figure 7-5 Select Module

2. Enter representative maintain through password.

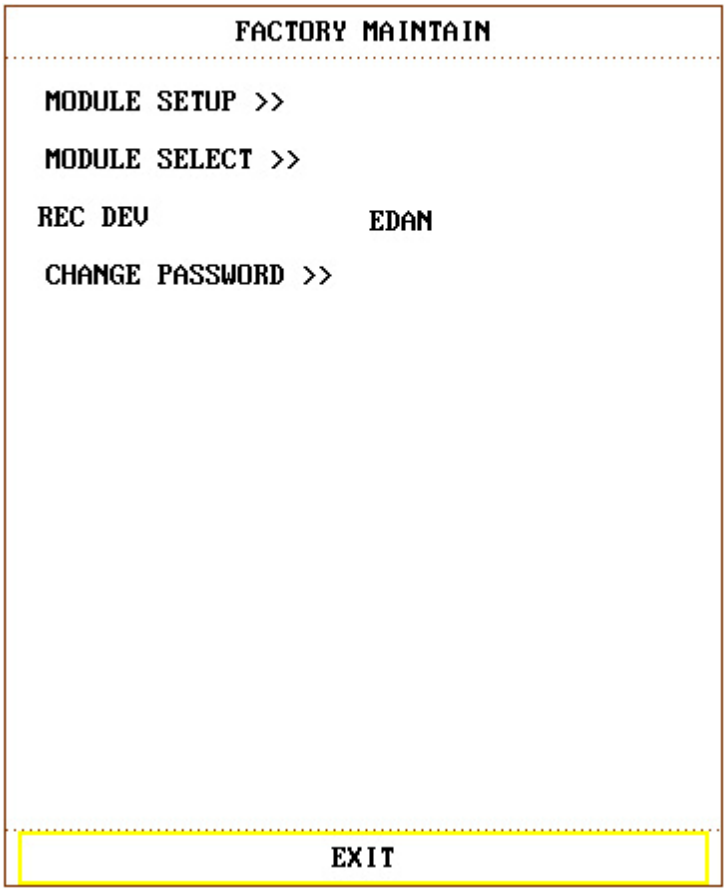


Figure 7-6 Representative Maintain

For changing password:

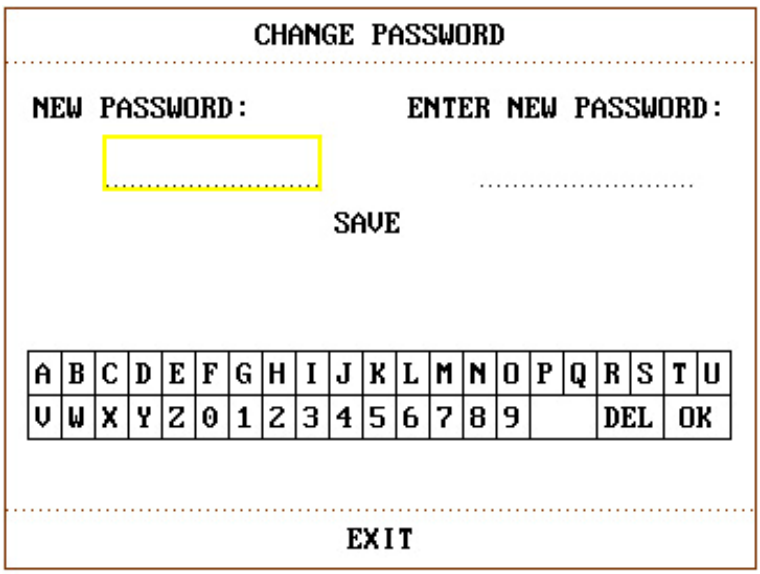


Figure 7-7 Change Password Interface

8 Accessories and Ordering Information

⚠ **WARNING** ⚠

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

NOTE:

For using neonatal disposable cuff, one NIBP Tube, one connecting tube and one neonatal disposable cuff are necessary.

The following accessories are recommended when using this monitor.

Parts No.	Accessories
M15-40000	ECG Cable With 5-lead Wires（EUR Standard）
M15-40010	ECG Cable With 5-lead Wires（USA Standard）
M15-40060	ECG Cable With 5-Lead Wires（Defibrillation）(EUR Standard)
M15-40094	ECG Cable With 5-Lead Wires（Defibrillation）(USA Standard)
M15-40046	ECG Cable With 3-lead Wires（EUR Standard)
M15-40028	ECG Cable With 3-lead Wires（USA Standard）
M15-40090	ECG Electrodes (1pc)
M15-40024	Pediatric electrodes (1pc)
M15-040155	ECG Cable with 5-Lead Wires (clamp) （USA Standard）
M15-40109	Neonatal electrodes (3pcs/pack) match clamp
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)
M15-40029	Adult Cuff (25cm-35cm)
M15-40074	Large Adult Cuff (33-47cm)
M15-40043	Adult Thigh Cuff (46-66cm)
M15-40018	Child Cuff (18-26cm)
M15-40020	Infant Cuff (10-19cm)
M15-40097	Neonatal Disposable Cuff 5102 (About 6-9cm)
M15-40098	Neonatal Disposable Cuff 5104 (About 9-14cm)
M13-36036	NIBP Tube (3m)
MS1-30437	Connecting Tube for Neonatal Cuff
M15-40007	Skin Temperature Probe
MS0-18927	Rectal / Oral Temperature Probe
M13-36087	Pressure transducer interface cable
M15-40121	Disposable pressure transducer kit (BD DT-4812)
MS1-100174	Cardiac output cable
M15-40119	In-line Injection temperature probe (BD 684056-SP4042)
M15-40120	In-line Injection temperature probe housing (BD 680006-SP5045)
MS1-100175	Control Syringe (Medex MA387)
M50-78085	CO_2 Tube for CPT $EtCO_2$
M50-78084	CO_2 T Adapter for CPT $EtCO_2$
M50-78083	CO_2 Water Trap for CPT $EtCO_2$
MS1-100214	DRYLINE™ Water Trap, Adult (Artema 60-13100-00)

MS1-100216	DRYLINE™ Water Trap, Neonate (Artema 60-13200-00)
MS1-100217	DRYLINE™ Sampling Line, Adult (2.5m) (Artema 60-15200-00)
MS1-100218	DRYLINE™ Sampling Line, Neonate (2.5m) (Artema 60-15300-00)
M12-031446	DRYLINE™ Airway Adapter, Straight (Artema 60-14100-00)
M12-031447	DRYLINE™ Airway Adapter, Elbow (Artema 60-14200-00)
M15-040138	OXIMA™ Galvanic Oxygen Sensor (Artema 60-10351-00)
M50R-78035	Printing Paper
MS3-30493	Mounting system (Simple)
MS3-30164	Mounting system
M21-064089	Rechargeable Lithium-Ion Battery (14.8V, 2Ah)
M21-64044	Rechargeable Lithium-Ion Battery (14.8V, 4Ah)
MS9-100403	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.

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Appendix Ⅰ Product Specification

A1.1 Classification

Anti-electroshock type	Class Ⅰ equipment and internal powered equipment	
EMC type	Class A	
Anti-electroshock degree	ECG (RESP), TEMP, IBP, CO	CF
	SpO_2, NIBP, CO_2, GAS	BF
Ingress Protection	IPX1	
Disinfection/sterilizing method	Refer to Chapter 12~Chapter 19 for details.	
Working system	Continuous running equipment	

A1.2 Specifications

A1.2.1 Size and Weight

Weight	5 kg

A1.2.2 Environment

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

A1.2.3 Display

Display screen	
	10.4/12.1 inch, Multicolour TFT LCD, Resolution 800×600, 1 LED

Messages	
	11 Waveforms Maximum
	1 Power LED (Green)
	1 Alarm LED (Yellow/Red)
	1 Charge LED (Yellow)
	3 Sound Mode corresponding Alarm Mode

A1.2.4 Battery

Quantity	1
Type	Li battery
Power-off delay	5 ~ 15min
Voltage	14.8 VDC
Capacitance	2 Ah, 4Ah (optional)
Working period	2Ah 80min
	4Ah 180min
	(At 25℃, continuous SpO_2 measuring mode and NIBP automatic measuring mode)
Rechargeable period	2Ah 150min
	4Ah 360min
	(Monitor is turned on or in Standby mode.)

A1.2.5 Recorder (Optional)

Record Width	48 mm
Paper Speed	25mm/S, 50mm/S
Trace	3
Recording types	
	Continuous real-time recording
	8 second real-time recording
	Auto 8 second recording
	Parameter alarm recording
	Drug Calculation and titration table recording

A1.2.6 Recall

Trend Recall	
Short	1 hrs, 1 Second Resolution
Long	96 hrs, 1 min. Resolution
NIBP Measurement Recall	500 NIBP measurement data

A1.2.7 ECG

Lead Mode	3 Leads (R, L, F or RA, LA, LL), 5 Leads (R, L, F, N, C or RA, LA, LL, RL, V)
Lead selection	3 Leads: I, II, III, drive leads change accordingly 5 Leads: 2of I, II, III, AVR, AVL, AVF, V, drive lead is RL
Waveform	3 Leads: 1 channel 5 Leads: 2 channel 7 waveforms display on screen
Analog channel setup	12 bits, 500Hz,
4 selectable plus:	×0.25, ×0.5, ×1, ×2 cm/mV
Pacing rate higher limit	>320 mV/s (RTI)
Pacing rejection (HR report has no error)	
Impulse amplitude	±2 ~ ±700 mV
Impulse width	0.1 ~ 2.0 ms
Ascending time	10μs ~ 100μs（less than 10％ of pulse width）
PACE detection	
Detection leads	7 selectable leads: I, II, III, AVR, AVL, AVF, V
Can detect impulse as follows:	
Pulse amplitude	±2 ~ ±700mV
Pulse width	0.1 ~ 2.0 ms
Ascending time	10μs ~ 100μs（less than 10％ of pulse width）
Defibrillation energy distributary	
Over-voltage	<5000V
Energy	<360J
Resume time	<5s
Energy absorption	<10%
Release charge	< 100 μC
Anti-electrotome signal resume time	<10s
Least detection signal	
Rate×2	Display accuracy 0.5mV/10mm Least detection signal 10μV
Rate×1	Display accuracy 1mV/10mm Least detection signal 20μV
Rate×0.5	Display accuracy 2mV/10mm Least detection signal 40μV

Rate×0.25	Display accuracy 4mV/10mm
	Least detection signal 80μV
Input voltage range	±8mV, polarized voltage: ±500mV
CMRR	
Diagnosis	>100 dB (no 50Hz/60Hz software wave trap)
Monitor	>110 dB (has 50Hz/60Hz software wave trap)
Surgery	>100dB (50Hz/60Hz software wave trap)
Frequency response	
Diagnosis	0.05Hz ~ 120Hz (-3dB)
Monitor	0.5Hz ~ 40Hz (-3dB), 50Hz/60Hz wave trap
Surgery	1Hz ~ 20Hz (-3dB), 50Hz/60Hz wave trap
System noise	<30μV p-p (RTI)
HR Measuring and Alarm Range	
Adu/Ped	15 bpm ~ 300bpm
Neo	15 bpm ~ 350bpm
Accuracy	±1% or ±1bpm, which great
Resolution	1 bpm
Sensitivity	> 200 μV P-P
Differential Input Impedance	≥ 5 MΩ
Electrode offset potential	±300mVd.c. ➙ ± 600mVd.c.
Patient leakage current	< 10 uA
Working Mode	Monitor
	Surgery
	Diagnosis
ST Segment Monitoring Range	
Measure and Alarm	-2.0 ~ +2.0 mV

A1.2.8 RESP

Method	Impedance between R-F (RA-LL), R-L (RA-LA)
Base line Impedance Range	200 ~ 2500Ω (no leads cables resistance)
	2200Ω ~ 4500Ω (leads cables 1KΩ resistance)
Measuring Sensitivity	0.3Ω (baseline impedance is 1KΩ)
Noise	< 0.1Ω
Max. dynamic range	500Ω resistance, 3Ω variable resistance, no clipping
Waveform bandwidth	0.2Hz ~ 2.5Hz（-3dB）
Clampe time	<0.5s (software clamp after baseline changed,)
Resume time	<1s (RESP resume time after baseline changed)

RR Measuring and Alarm Range:	
Adult	0 rpm ~120rpm
Neo/Ped	0 rpm ~150rpm
Resolution	1 rpm
Accuracy	±2 rpm
Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Resp. data sampling	500Hz, 12 bits (sample RESP signal per 2ms)

A1.2.9 NIBP

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode	
	1/2/3/4/5/10/15/30/60/90/120/240/480 Min
Continuous	5min, interval is 5s
Measuring Type	Systolic Pressure, Diastolic Pressure, Mean Pressure
Measuring Rang	
Adult Mode	
SYS	40~270mmHg
DIA	10~215mmHg
MAP	20~235mmHg
Pediatric Mode	
SYS	40~200mmHg
DIA	10~150mmHg
MAP	20~165mmHg
Neonatal Mode	
SYS	40~135mmHg
DIA	10~100mmHg
MAP	20~110mmHg
Cuff Pressure measurement range	0~290mmHg
Pressure Resolution	1mmHg
Mean error	5mmHg
Maximum Standard deviation	8mmHg
Auto cuff inflation	Adult/Pediatric 120s
	Neonate 90s
Typical Measurement Period	30~45s (depend on HR/motion disturbance)
Overvoltage protection	Dual Overvoltage protection
Adult	297±3mmHg
Pediatric	240±3mmHg

Neonatal	145±3mmHg
PR	
Measurement range	40~240bpm
Resolution	1 bpm
Accuracy	±3bpm or 3.5% (the larger)

A1.2.10 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	30 ~ 254 bpm
Resolution	1 bpm
Accuracy	± 3bpm
	Under Motion Condition, ±5 bpm

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 %

A1.2.11 TEMP

Channel	2
Measuring Range	0 ~ 50 °C
Sensor type	YSI (B series) and CF-FI
Resolution	0.1°C
Accuracy	±0.1°C (25 ~ 45 °C)
	±0.2°C (0 ~ 25°C，45～50°C)
Refresh Time	Every 1 ~ 2 seconds
Selftest	Every about 5 ~ 10 minutes
Data sample	50Hz, 12 bits

A1.2.12 IBP

Channel	2
Label	ART, PA, CVP, RAP, LAP, ICP, P1, P2
Pressure Sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300 ~ 10, 000 (Ohm)
Static Pressure Measuring Range	-50 ~ +300 mmHg（up to 350 mmHg）
Static Pressure Accuracy	±2 % or 1mmHg which bigger
Dynamical Pressure Measuring Range	-50 ~ +300 mmHg
Dynamical Pressure Accuracy	±2 % or 1mmHg which bigger
Frequency Response	d.c. ~ 15 Hz, d.c. ~ 40 Hz
Measuring and Alarm Range	
ART	0 ~ 300 (mmHg)
PA	6 ~ 120 (mmHg)
CVP/RAP/LAP/ICP	-10 ~ 40 (mmHg)
P1/P2	-50 ~ 300 (mmHg)
Resolution	1 (mmHg)
Zero range	±200 mmHg

A1.2.13 CO2

Method	Infra-red Absorption Technique
Measuring mode	Sidestream, Mainstream
Measuring range	
CO_2	0 ~ 150 mmHg
AwRR	2 ~ 150 rpm

Resolution	
CO_2	1 mmHg
$InsCO_2$	1mmHg
AwRR	1 rpm
Accuracy	
CO_2	± 2 mmHg, 0 ~ 40 mmHg
	Reading ± 5%, 41 ~ 70 mmHg
	Reading ± 8%, 71 ~ 100 mmHg
	Reading ±10%, 101 ~ 150 mmHg
AwRR	± 1 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	Drift over four hours < 0.8 mmHg
Long Term Drift	120 hour period
O_2 Compensation	
Range	0 to 100%
Resolution	1%
Default	16%

A1.2.14 CO

Method	Thermodilution Technique
Measuring range	
CO	0.1 ~ 20L/min
TB	23 ~ 43°C
TI	-1 ~ 27°C
Resolution	
CO	0.1L/min
TB, TI	0.1°C
Accuracy	
CO	±5% or ± 0.2 L/min
TB	±0.1°C
TI	±0.1°C
Output parameters	
	CO
	Hemodynamic Calculation

Alarm range	23 ~ 43°C

A1.2.15 GAS

Technology	Infra-red absorption characteristic
Measuring range	
CO_2	0 ~ 10%
O_2	0 ~ 100%
N_2O	0 ~ 100%
AwRR	2 ~ 100 rmp
Halothame	0 ~ 5%
Isoflurane	0 ~ 5%
Enflurane	0 ~ 5%
Sevoflurane	0 ~ 8%
Desflurane	0 ~ 18%

Gas	Concentration[%REL]	Inaccuracy [%ABS]
CO_2	0-1	±0.1
	1-5	±0.2
	5-7	±0.3
	7-10	±0.5
	>10	Unspecified
N_2O	0-20	±2
	20-100	±3
O_2	0-25	±1
	25-80	±2
	80-100	±3
HAL, ENF, ISO	0-1	±0.15
	1-5	±0.2

	>5	Unspecified
SEV	0-1	±0.15
	1-5	±0.2
	5-8	±0.4
	>8	Unspecified
DES	0-1	±0.15
	1-5	±0.2
	5-10	±0.4
	10-15	±0.6
	15-18	±1
	>18	Unspecified

Updating frequency	Once per second
Calibrate	Once per year
GAS calibrate stability	After continuously using for 12months, error is <1%.
Descending time	240ms (10% ~ 90%)
Delay time	<4s

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