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Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior consuma notice.

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Preface

Manual Purpose

This manual provides detailed information about the assembling, disassembling, testing and troubleshooting of the equipment to support effective troubleshooting and repair. It is not intended to be a comprehensive, in-depth explanation of the product architecture or technical implementation. Observance of the manual is a prerequisite for proper equipment maintenance and prevents equipment damage and personnel injury.

This manual is based on the maximum configuration, Therefore, some contents may not apply to your monitor. If you have any question, please contact our Customer Service Department.

Intended Audience

This manual is for biomedical engineers, authorized technicians or service representatives responsible for troubleshooting, repairing and maintaining the patient monitors JM 0

Passwords

A password may be required to access different modes within the monitor. The passwords are listed below:

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Demo mode: 5188

5188

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User maintenance:

Factory maintenance:

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Chapter 1 Safety

1.1 Safety Information

1.1.1 Danger

There are no dangers that refer to the product in general. Specific "Danger" statements maybe given in the respective sections of this manual.

1.1.2 Warning

Warning

- This monitor is used for monitoring the clinical patients, so only the doctors and nurses who are qualified through training can use this monitor.
- Before use, the user shall check whether this instrument and its accessories can work normally and safely.
- The alarm volume and upper and lower limits for alarm shall be set for different patients. When a patient is monitored, the audible alarm system cannot be merely depended on. Alarm volume too low or totally off will result in invalid alarm and endanger patient safety.. The most reliable patient monitoring method shall be to closely monitor the actual clinical situation of the patient.
- This instrument can only be connected to a power socket with protective grounding. If the power socket is not connected to grounding conductor, do not use it, but use the rechargeable batteries for power supply.
- Do not open the enclosure of this instrument to avoid the possible electric shock hazard. The maintenance and upgrading of this monitor must be conducted by the service personnel trained and authorized by *COMEN*
- The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.
- Do not use this instrument at the place where there are flammable articles such as anesthetic to prevent explosion or fire from happening.
- Please carefully install the power lines and the cables for various accessories to avoid the

patient from being constricted or suffocated or the cables from getting entangled and keep the patient free from electrical interference.

- Do not use mobile phone near the monitor, because the mobile phone will generate a very strong radiation field and disturb the functions of the monitor.
- For the patient with pacemaker, cardio tachometer might measure the heart rate by the pulse of pacemaker when cardiac arrest or arrhythmia. Do not completely rely on the alarm of cardio tachometer. The patient with pacemaker shall be closely monitored. For the inhibiting capacity of relevant equipment on the pacemaker, refer to the Instruction Manual.
- The operators shall not touch the patients, tables and instruments during the defibrillation period.
- Before reusing these cables, check whether the function is normal.
- The equipment connected with the monitor shall form an equipotential body (the protective grounding wire is effectively connected).

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- When the monitor is used in conjunction with the electro surgery unit, the user (doctor or nurse) shall ensure the patients safety.
- The physiological waveforms, physiological parameters and alarm information, etc. displayed by this monitor shall be for the doctors' reference only and cannot be directly used as the clinical treatment basis.
- The electromagnetic field will affect the performance of this instrument, so the use of the other equipment near this instrument must meet corresponding EMC requirements. For example: Mobile phone or X-ray equipment may be an interference source, because they will transmit high-strength electromagnetic radiation,

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- This monitor cannot be used in MRI room.
- This is not a treatment device.

1.1.3 Cautions

Caution

- To avoid damage to this instrument and guarantee patient safety, please use the accessories designated in this instruction manual.
- Please properly install or move this instrument and prevent the instrument from being damaged due to fall, collision, strong vibration or other external mechanical forces.
- Before the instrument is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated specified on the nameplate label or in the instruction manual of this instrument.

When this instrument and its accessories are about to exceed the service life, they must be disposed of according to local relevant laws and regulations or the rules and regulations of the hospital.

1.1.4 **Notes**

∕∐Notes Please install the equipment in a place that is convenient for observation, operation and maintenance. This instruction manual introduces the product according to the most complete C configurations. The product you have purchased may not possess some configurations or functions. 0

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- Please place this instruction manual near the instrument for easy and timely reference. This instrument cannot be used at home. This instrument can be used for one patient only at the same time. •

1.2 **Equipment Symbols**

1. **Instrument Symbols**

	Attention! please see the accompanying documents	e dive	AC indicator lamp
4 () +	The application part of Type CF has the defibrillator-proof function		Production Date Mark
	The application part of Type CF	SN	Serial number mark
★	The application part of Type BF	\bigtriangledown	Equipotential symbol
Ċ	Start/Stop Key		Network connection symbol
	Battery working state indicator lamp	• • • •	Multifunctional socket

(+/←	Battery charging indicator lamp	Nurse Call	Nurse calling socket
\ominus	DVI interface	Δ	SD card interface
ECG Defib	Synchronous interface for defibrillation		Main menu (reserved)
●	USB interface	⇒0←	Offset calibration (reserved)
2. Packaging Sy	ymbols		



Chapter 2 Warranty and Service

2.1 Warranty Terms

COMEN provides warranty for the device (main unit) and the accessories. The warranty period begins on the date products are shipped to customer. If a customer promptly notifies us of customer's warranty claim hereunder, we will either repair, adjust or replace (with new or exchange replacement parts) our products. COMEN warrants that any service it provides to customers will be performed by trained individuals in a e abile workmanlike manner.

2.2 What is excluded

COLOU The warranty does not cover for the situations caused by the following condition:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service ٠ people. 0
- Malfunction or damage caused by use of parts or accessories not approved by COMEN
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.



2.3 Service Procedure



2.3.1 Fill in the Service Claim Form (SCF)

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

COMEN should not have any obligation to take over the case without this information. The form can be gotten from our company's Service Department.

2.3.2 Send COMEN the SCF and Select a Solution

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

Within Warranty •Ì

There are two options:

- After receiving the Return Material Authorization (RMA) form from our service department, customer 1. sends us the defective parts and informs about the shipment tracking number. Then we will dispatch new part(s) to your confirmed address with confirmed shipping invoice.
- The customer signs the Declaration Form and sends it back by email or fax. This form is legally 2. certificated to make sure the customer or end-user will return the defective parts to us on time. We will, at this option, dispatch the replacement(s) with confirmed shipping invoice.

MNOTE

- Both Return Material Authorization Form and Declaration Form are offered by *COMEN* service department once the SCF is confirmed by service engineer.
- The customer is responsible for freight& insurance charges when the equipment is shipped to *COMEN* for service, including custom charges. We are responsible for the freight, insurance & custom charges from *COMEN to* the customer.

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• Out of Warranty

After receiving the RMA form from the service department, the customer sends defective parts to COMEN in advance. We will analyze the problems and discuss with the 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 the confirmed address.

MNOTE

• The customer is responsible for any freight & insurance charge for the returned product.

2.3.3 Obtain the RMA Form

Before the shipment of the materials, the customer must obtain an RMA form from our service department, in which the RMA number, description of returning parts and shipping instructions are included. The RMA number should be indicated on the packaging box.

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NOTE

• *COMEN* should not have any obligation to the end-user or customer who returns the goods without the notification by our service department. The sender takes full responsibility for the accounted fee.

2.3.4 Send the Parts to COMEN

Follow these suggested instructions:

• Please disassemble the parts with anti-static facility.

- Please pack the parts safely before return.
- Please put the RMA number on the parcel.
- Please describe the returned parts as 'sample of *****' and put the total value on the invoice, and note on the invoice as 'sample, no commercial value'.
- Please confirm the information (such as price in invoice, address and other necessary issues) with us ٠ before shipment.
- Please send back the parts after our company's confirmation. ٠

Contact Information 2.3.5

si consumabili If you have any question about maintenance, technical specifications or malfunctions of devices,

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do not hesitate to contact us.

- COMEN International After-Sale Dept. •
- Monday to Friday 09:00-18:00 (UTC +08:00) •

Chapter 3 Principle Introduction



3.1 Star8000 System Principle Block Diagram

The main board is the heart of the patient monitor. It implements a series of tasks including input& output control, data storage and processing, display processing, system control communication management, printing management and alarming, etc.

The main board comprises the core board and bottom board. The core board is an essential CPU system containing the CPU, FLASH, memory, realtime clock, EEPROM, etc. It interfaces to the bottom board only. The bottom board is in charge of connections and communications with other internal modules

PIN ID	Description	Working Voltage S
P1	LCD signal socket(LVDS)	12V,5V
J29	LCD signal socket(TTL)	12V,5V,3.3V
J33	FPC socket(to DC board)	19V,18V,12V,5V,1.8V
J1	Key1 socket	019 V,12V,5V
J4	Key2 socket	19 V,12 V,5 V
J32	Printer socket	18V,5 V
P7	WIFI socket	3.3V
J7	Alarm socket	5V
16	Touch screen socket	/
J8	LCD bright socket	12V,5V
J15	Touch screen socket	/
	2	

The 7 parameter ECG board is a parameter measurement components, it provides the following functions:

- 1. 3 or 5 leads ECG and RESP measurement;
- 2. 2-channel TEMP measurement;
- 3. Data exchange with the 7 parameter NIBP module.

PIN ID	J2	J3
Description	To NIBP board	To ECG interface panel
Working voltage	6.6V,5V,3.3V	5V Z
Module Function	Measure ECG parameter	, IN
.3 7 Parameter NIB	P Module	consu

3.2.3 7 Parameter NIBP Module

The 7 parameter NIBP board is a parameter measurement components, it provides the following functions:

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- 1. NIBP measurement;
- 2. SpO2 installation place;
- IBP installation place; 3.
- Data exchange with the main board through the serial ports. 4.



	NIBP	NIBP	То	IBP	IBP	То	7Paramete	То	CAS
D	pump	valves	SpO2	socket	socket	IBP	r	ECG	NIBP
on	socket	socket	interfa			interfac	communic	board	socket
OII			ce			e panel	ation		
			panel				socket		
Working	12V	12V	3.3V	12 V ,5	5V	5V	12V,5V	6.6V,	12V
voltage				V				5V,3.	
voltage								3V	
Module	Measure NIBP, SpO2, IBP, parameter								
Function									

3.2.4 Power Supply Module

The power module is located at the back of the patient monitor. The main part of the power module is the power board, which contains charging & power management, distributed different DC power to main board ,7-parameter board, USB port, speaker and battery charging.

The AC power module transforms the input power into DC and then forwards them to each component of the patient monitor. The input power comes from AC source. The patient monitor will run power from the AC source whenever an AC source is available. If the AC source becomes unavailable, the patient monitor will automatically switch to the battery power. This does not affect the monitor's operating status.



	CN1(A	CN2	2(A	J1	J4	J5	J7	J10	J25
PIN ID	C)	C	-(
	AC	То	DC	To AC	То	Loud	Co2	То	Battery
	input	boar	ď	board	mainbo	speaker	socket	USB/NET	socket
Description	socket	sock	et	socket	ard	socket		board	
					socket			socket	
Working	100-250	15V		15V	15 V,12	/	5V	5V,1.8v	16.8V
working	V(AC)				V,5V,1.				
voltage					8V				
Module	Provide p	ower 1	to ma	in board					
Function									$\langle \rangle$
									v i
.2.5 Butt	on Board			4					n.

3.2.5 **Button Board**

The button board, located at the lower part of the monitor's front panel, button board including knob that can be pressed, knob can also be rotated both clockwise and counter-clockwise, signals are sent to main board CPU by the single chip processor on button board. It also controls display of power indicator, AC indicator S and charge indicator.



There are 3 types of SpO2 modules: Digital SpO2, Masimo SpO2 and Nellcor SpO2 module.

The SpO2 board implements SpO2 signals collection amplified simulation, relative digital/analog conversion and signal processing.

The pulse extent of optical signal changes during monitoring. SpO2 parameter, pulse rate signal and pleth waveform will be acquired after calculation. These data will be transmitted to the main board with special communication protocol.

3.2.7 Analog SpO2 Module

	RISZGIB. 180661 DGITAL_SPO2_B DGITAL_SPO2_B DGITAL_SPO2_B	
PIN ID	J1	J2 0
Description	SPO2 Power Socket	SPO2 Power Socket
Working voltage	5V	5V 6
Module Function	Measure SPO2 parameter	n

3.2.8 MASIMO SpO2 Module



	· · · · · · · · · · · · · · · · · · ·	
PIN ID	J1	J2
Description	SPO2 Power Socket	SPO2 Power Socket
Working voltage	5V	5V
Module Function	Measure SPO2 parameter	

3.2.9 NELLCOR SpO₂Module



PIN ID	J4	J5
Description	SpO ₂ Power Socket	SpO ₂ Power Socket
Working voltage	5V	5V
Module Function	Measure SpO ₂ parameter	3
e chipan	ente medical	

Chapter 4 Troubleshooting

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4.1 Introduction

In this chapter, patient monitor problems are listed along with possible causes and recommended corrective actions. Refer to the tables to check the patient monitor, identify and eliminate the troubles. The troubles we list here are frequently arisen difficulties and the actions we recommend can correct most problems, but not all of them. For more information on troubleshooting, contact our International After-sale Dept.

4.2 Part Replacement

Printed circuit boards (PCBs), major parts and components in the patient monitor are replaceable. Once you isolate a PCB you suspect defective, follow the instructions in Chapter **7** *Disassembly Procedure* to replace the PCB with a known good one and check that the trouble disappears or the patient monitor passes all performance tests. If the trouble remains, exchange the replacement PCB with the original suspicious PCB and continue troubleshooting as directed in this chapter. Defective PCB can be sent to us for repair. To obtain information on replacement parts or order them, refer to *Parts* **6**.

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4.3 Patient Monitor Status Check

Some troubleshooting tasks may require you to identify the hardware version and status of your patient monitor.

monitor.

Software Version Check

Some troubleshooting tasks may require you to identify the configuration and software version of your patient monitor

• To view information on the system configuration and system software version, Select[Main Menu]

→[Maintain] →Password"5188"→Monitor Info

4.5 Technical Alarm Check

Before troubleshooting the patient monitor, check for technical alarm message. If an alarm message is presented, eliminate the technical alarm first. For detailed information on technical alarm message, possible cause and corrective action, refer to the patient monitor's User Manual.

4.6 Troubleshooting Guide

Symptoms	Possible Cause	Corrective Action	
	AC power cable not connected	Check that AC power is properly connected	
	and the battery capacity is too	and check that the battery capacity is	
	low	sufficient.	
		Use a Multi-meter to check it out, if you	
	Fuse(s) is (are) broken	don't know how to use, please refer to our	
The patient monitor fails		International Service Dept.	
to start (AC LED or		1. Check that cables from button board to	
battery LED does not light)	Cables defective or poorly	power module properly connected.	
	connected	Check that cables and connectors are not	
	e d	damaged.	
	KEY board is defective	Replace the KEY board	
	Power module is defective	Replace the power module	
	The cable between power		
The patient Monitor fails	supply board to keyboard	Check this cable to see if it's connected well	
to start. (AC indicator or	defective		
battery indicator are	Key board is Defective	Replace the key board	
lighting)	Power module is defective	Reconnected the power module	
	Motherboard is Defective	Replace the Motherboard	

4.6.1 Power On/Off Failures

4.6.2 Display Failures

Symptoms Possible Cause Corrective Action		Symptoms	Possible Cause	Corrective Action
---	--	----------	----------------	-------------------

Integrated display is blank but the patient monitor still	Cables connected Motherboard with screen defective or connected poorly	 Check that cables from the screen to the Motherboard and from the screen adapter board to the button board display are correctly connected. Check that the cables and connectors are not damaged. 	
works	Adapter board or its cables	Replace the adapter or reconnected the	
	defective	cables	
	Screen is defective	Replace the Screen.	
	Motherboard is defective	Replace the Motherboard	
	Power module is defective	Replace the power module.	
Integrated display is blank	Cables defective or poor connected.	Check the cable from power supply board to main board, replace it if it's defected	
does not work	The power board is defective	Replace the power board	
	Motherboard is defective	Replace the Motherboard	
Screen displays splash or	Cables defective or are poorly connected.	Check that the cable between the display and the Motherboard(or inverter board) is correctly connected.	
flashing specks	The screen inverter board is defective	Replace the Screen inverter board	
	The screen is defective	Replace the screen	
	The Motherboard is defective	Replace the Motherboard	
4.6.3 Battery Failures			

Symptoms	Possible Cause	Corrective Action
		Recharge the battery for about 4 hours, check out
		how long it can operate and check out its voltage
	Battery is defective	with a multi-meter. Please refer to our international
Battery can' t be recharge	e	after sales Dept about the exact values
	Cable defective or	Check that cable between battery and power module
	poorly connected	is correctly connected.
	Power board failures	Replace power board
	The Mother board is defective	Replace the mother board

4.6.4 ECG Failures

Symptoms	Possible Cause	Corrective Action
The ECG Parameter or waveform signals cannot be detected or incorrect	The settings of ECG is incorrect	Check the ECG channel or Lead Type settings
	ECG cable is defective or is not connected well	Replace the ECG detector or reconnect the electrodes
	The skin of patient is dry	Clean the skin and paint certain electrode cream
	Cable from Mother board and ECG module does not connect well with the Motherboard	Check the cable from Motherboard to ECG module
	The cable from the ECG module to side plate socket is not connected well	Check the cable from ECG module to side plate socket and reconnect them
	ECG module is defective	Replace the ECG module
	Motherboard is defective	Replace the Motherboard S
	Internal wire is loose or	Check from Motherboard to ECG board and replace with
ECG No	damage	a new one and have a try
baseline	ECG module defective	Replace the ECG module
	Motherboard defective	Replace the Motherboard
	ECG setting is incorrect	Reset the ECG settings on ECG setup menu
	The monitor does not connect to grounding	Connect the grounding cable to the right place
ECG	ECG cable is not connected well with the Motherboard	Check the cable from Motherboard to ECG module
waveform has	The cable from the ECG module to side plate socket is not connect well	Check the cable from ECG module to side plate socket and reconnect them
	Disturbed by some electronic machine	Remove some electronic machine from the monitor
	ECG module defective	Replace the ECG module
HR value is	External ECG cable is	Replace the ECG accessories or change the HR source

incorrect	damage or the HR channel is	
	The electrodes are connected poorly	Reconnect the electrode
	The wire between ECG module and main board poorly connected	Reconnect the cable or replace it
	ECG module defective	Replace the ECG module
	Motherboard defective	Replace the Mother board
4.6.5 SpO ₂	Failures	

4.6.5 SpO₂ Failures

Symptoms	Possible Cause	Corrective Action
	The SPO2 probe is defective	Replace the SPO2 probe
The SpO ₂ no waveform and value	The cable from the SPO2 module to side plate socket is not connect well	Check the cable from SPO2 module to side plate socket and reconnect them
	Cables from Motherboard to SPO2 module are defective or poorly connected.	 Check that the cable between the Motherboard to the SPO2 module is correctly connected. Check that the cables and connectors are not damaged
	SPO2 module is defective	Replace the SPO2 module
	Motherboard is defective	Replace the Motherboard
	The probe type of the patient is wrong	Change a right probe type of patient
SpO ₂ value is incorrect	Long period of NIBP measurement on the same limb or some other condition such as shock or low temp	Start the SPO2 measurement in a normal state
	SPO2 module is defective	Replace the SPO2 module
/	Motherboard is defective	Replace the Motherboard

NIBP Failures 4.6.6

Symptoms Possible Cause Corrective Action

Can't start air inflation	Cables from mother board to NIBP module are defective or poorly connected.	First, check that the cable between the motherboard to the NIBP module is correctly connected. Then, check that the cables and connectors are not damage.
	The keyboard defective	Replace the Keyboard
	The wire from the NIBP module	Check the wire from NIBP module to air pump,
	to air pump is not connected well	replace it if it's broken
	NIBP module is defective	Replace the NIBP module
	Mother board is defective	Replace the mother board
Inflate sin	The NIBP settings are wrong	Check out the type of the patient in the patient management
Inflate air repeatedly (NO NIBP values)	The accessories have air leakage	Check out the cuff ,the cuff pipe ,or the interface socket
	The NIBP pump has air leakage	Inflatable with numerical display, but the value is not stable, it can be seen that the numeric declines
	2in 1 functions board	Replace the 2 in 1 functions board
	The type of the patient is wrong	Check out the type of the patient in the patient management
The NIBP values are incorrect	A continue NIBP measurement for a Long time	The measurement should start every 5 minutes at least
	The NIBP accessories have	1. The cuff is tied up too tight or too loose
	leakage	 The cuff has leakage or is defective The NIBP tubing has leakage
	The NIBP module is defective	Replace the NIBP module
	The Mother board is defective	Replace the Mother board

4.6.7 RESP Failures			
Symptoms	Possible Cause	Corrective Action	
NO RESP data	The RESP is disabled	Enable the RESP on setup menu	
	ECG cable or electrode is	Paplage the ECC apple	
	defected	Replace the ECG cable	
	Cables from Motherboard to	1. Check that the cable between the Motherboard to the	
	ECG module defective or poorly	ECG module is correctly connected.	
	connected.	2. Check that the cables and connectors are not damage	
	The cable from the ECG module	Check the cable from ECG module to side plate socket	

	to side plate socket is not	and reconnect them
	connected well	
	ECG module is defective	Replace the ECG module
	Motherboard is defective	Replace the Motherboard
	The signal of patient is so weak	Check out the patient condition
RESP wave and reading are incorrect	The electrode is defective	Replace the ECG probe
	ECG module is defective	Replace the ECG module
	Motherboard is defective	Replace the Motherboard
4.6.8 IBP Module Defective		, e

4.6.8 IBP Module Defective

Symptoms	Possible Cause	Corrective Action
	The monitor is not equipped	Check out whether there is a IBB module in the monitor
	with IBP module	Check out whether there is a TBP module in the monitor
	IBP module is disabled	Please enable the IBP module, For more details, you can refer to the user manual.
The IBP has	Cables from Motherboard to	1. Check that the cable between the Motherboard to the
no readings	IBP module are defective or	IBP module is correctly connected.
and no	poorly connected	2. Check that the cables and connectors are not damage.
waveforms	The cable from the IBP module to side plate socket is not connect well	Check the cable from IBP module to side plate socket and reconnect them
	IBP module is defective	Replace the IBP module
	Motherboard is defective	Replace the Motherboard
	0	1. Zeroing must be done before use
	2	2. Disposable IBP sensor must be change after single
	The IBP settings are incorrect	use
IBP readings	N.	3. Ensure the channel you set is the channel you are
are incorrect	00	using
	The IBP extension cable or	Deploce the extension cohis on concer
	sensor is defected	Replace the extension cable or sensor
	The IBP module is defective	Replace the IBP module

4.6.9 TEMP Module Defective

Symptoms	Possible Cause	Corrective Action
	The temperature is lower than the monitor can measure range	Check out the TEMP is in the normal range
	The TEMP probe is defective	Change another TEMP probe
NO TEMP values	Cables from Motherboard to ECG module are defective or poorly connected	 Check that the cable between the Motherboard to the ECG module is correctly connected. Check that the cables and probe are not damage
	The cable from the ECG module to side plate socket is not connected well	Check the cable from ECG module to side plate socket and reconnect them
	TEMP module is defective Motherboard is defective	Replace the TEMP module Generation Replace the Motherboard
	The type of temp sensor is incorrect	it can supports CF and YSI, change the setting you need
incorrect	TEMP probe is incorrect	Replace the TEMP probe
	ECG module is defective	Replace the ECG module
	The TEMP socket defective	Change a TEMP probe
TEMP Value unstable	The ECG module is defective	Replace the ECG module
	The Mother board is defective	Replace the Mother board

4.6.10 EtCO₂ Failures

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Symptoms	Possible Cause	Corrective Action
NO EtCO2	Accessories (sampling line	Replace sampling line or airway adapter.
readings and wave	or adapter) is defective	

	1	
	Cables from Motherboard to	1. Check that the cable between the Motherboard to
	side plate connector poorly	the side plate connector is correctly connected.
	connected	2. Check that the cables and connectors are not
		damage
	The cable from the	Check the cable from EtCO ₂ module to side plate
	EtCO ₂ module to side plate	socket and reconnect them
	socket is not connected well	
	EtCO ₂ module is defective	Replace the EtCO ₂ module
	Motherboard is defective	Replace the Motherboard
EtCO ₂ readings or	EtCO ₂ sampling line or air	Replace the EtCO ₂ probe
wave are incorrect	adapter is defective	
	EtCO ₂ module is defective	Replace the EtCO ₂ module
	Motherboard is defective	Replace the Motherboard
4.6.11 Button and Knob Failures		
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4.6.11 Button and Knob Failures

Symptoms	Possible Cause	Corrective Action
	Cable defective or poorly connected	Check that cable between button board
Buttons do not work		and Motherboard is properly connected.
	Button board failure	Replace button board.
		1. Check that cables from knob to button
	Cable defective or	board, and button board to Motherboard
Knob does not work Knob Knob Knob Knob Knob Knob Knob Knob		are properly connected
		2. Check that connecting cables and
	×.	connectors are undamaged.
	Knob failures	Replace the knob
	Button board failure or knob board is	Button board malfunctions. Replace the
	defective	button board

4.6.12 Recorder Failures

Symptoms	Possible Cause	Corrective Action
	Paper reversed	Re-install the paper roll.
No printout	The record door does not close	Check out door and indicator light
	well	(green is the working status)

	The type of paper is wrong	Install the right paper
	Cable defective or poorly connected	 Check that cable between recorder and Motherboard is properly connected.
		2. Check that connecting cables and connectors are not damaged.
	Recorder power supply failure	Check if the power module outputs 5 V DC and 12V DC correctly, if no, reconnect the cable or change the main
	Recorder failure	board Replace the recorder.
Poor print quality	Paper roll not properly installed	Stop the recorder and re-install the paper roll.
	Print head dirty	 Check the thermal print head Clean the thermal print head with an appropriate cleaning solution.
	Print head failure Recorder failure	Replace the print head. Replace recorder.
Paper jam	paper feeding not improperly Recorder defected	Reloading the paper Replace the paper

4.6.13 Network Related Problems			
Symptoms	Possible Cause	Corrective Action	
Can't communicate with CMS,	Inner network cable defective	1. Reconnect the network cable	
indicator of RJ45 port is not	or poor connection	2. Replace the network cable	
illuminated or flashing	JR45 Connector problem	Replace the connector	
ő	AP adapter/router is defected	Replace the AP adapter or router	
Can't communicate with CMS,	Settings problem	Reset the IP address and monitor	
but connection is ok		configuration according the user manual	
	Computer system compatible	Install the right version of windows	
	problem	system	

Monitor software problem	Ensure the monitor's software support
	the CMS

4.6.14 Software Upgrade Problems

Symptoms	Possible Cause	Corrective Action
	Upgrade software is damaged	Get new software from manufacturer
System upgrade failure "system tips"	Software name incorrect	Check the software name to make sure there is not error, specially the capital words
	Main board is defective	Chang the main board
	Software is incorrect	Use the incorrect software for patient monitor
	USB-stick defective or can't be detected by patient monitor	Chang the usb-stick for testing
	Software is damaged or incorrect name	Check the software name or change the software
Fail to upgrade "not system tips"	USB socket is damaged or internal cable defected	Check the software on another patient monitor to confirm if the usb-stick and software no problem, then check the patient monitor usb socket and internal
<u> </u>	Main board is defected	cable Replace the main board
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4.6.15 Technical Alarm Messages

Please refer to the User manual.

Chapter 5 Software Upgrade

The system software is able to be upgraded with the USB disk through USB interface on monitor.

5.1 Tools

The following tools are required during the software upgrade:

• USB-stick 2GB/4GB(recommend)

5.2 Preparation before Upgrade System Software

- Before software upgrade, please check software version and record it to make sure you are able to revert back in case the failure of software upgrade.
- Take a USB-Stick, the size of the USB Stick should be 2GB/4GB(recommend), format it to "FAT" format before software upgrade;
- 3. Unzip the package file that got from us and copy the folder * to the root directory in USB-Stick, do not change the folder name or the file name(s) in the folder unless you are informed by us to have the necessary change.

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4. The folder name should be "SOFTUPDATE" in capital.

5.3 System Software Upgrade

Connect the USB-Stick to patient monitor;

- 2. Power on the patient monitor(you would see the software upgrade progress on screen);
- 3. When the software upgrade is done, Remove the USB-Stick and Power off the patient monitor;
- 4. Restart the monitor and check the software version.

NOTE

- Make sure you have confirmed with *COMEN* Customer Service Department the software package is fit for the software upgrade for the monitor you are currently operating on.
- Disconnect the patient monitor from patient before software upgrade;
- Make sure the battery capacity is enough or plug on AC power while doing the software upgrade process, it takes around 2-10 minutes during the whole upgrade;
- Program upgrade should be performed by qualified service personnel only.
- Do not unplug the USB-Stick during the software upgrade process.

Chapter 6 Performance Verification

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6.1 **IBP** Test

6.1.1 **BP**\Performance Test

Tool required: MX960 (medex)

Follow this procedure to perform the test.

- 1. Connect the patient simulator to IBP1 socket..
- Click the IBP baseline on the screen, select "CH press set up", set "ART" as CH1(arterial 2. pressure).Enter "SURVEY set up" menu, select IBP (1,2) setup select "IBP PRESSURE ZERO", select consu "CH1 ZERO". Follow up the next step after screen display "IBP CH1 zero success"
- 3. Press MX960 keypad continuously.
- 4. The IBP value show 100±1mmHg
- Repeat the steps above for all the IBP channels. 5.

6.1.2 **IBP** Pressure Calibration

- Connect the patient simulator to IBP1 socket. 1.
- Click the IBP baseline on the screen, select "CH press set up", set "ART" as CH1(arterial pressure). 2.

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- Enter "SURVEY set up" menu, select IBP(1, 2)setup, select "IBP PRESSURE ZERO", select "CH1 3. ZERO", and set the CH1 pressure value as 100.
- Press MX960 keypad straightly then click Channel 1Calibration. 4.
- The IBP value on the display will be "100" means the IBP calibration success, otherwise repeat below 5. ${\cal O}$ operation.
- Repeat the steps above for all the IBP channels. 6.

6.2 **NIBP** Test

6.2.1 **NIBP Leakage Test**

Tools required:

- NIBP cuff for adult patient
- Appropriate tubing
- Cylinder

Follow this procedure to perform the test:

- 1. Set [Patient type] to [Adult].
- 2. Connect the NIBP cuff with the NIBP socket on the monitor.
- 3. Apply the cuff to the cylinder as shown below.



- Select [Main menu]→ [MAINTAIN]→Password "5188" →[Leakage Test]. The message[Leakage Testing...] is displayed in the NIBP parameter area.
- 5. The cuff automatically deflates after 20s, which means NIBP leakage test is completed. If no message is displayed in the NIBP parameter area, it indicates that the system has no leakage. If the message [NIBP Pneumatic Leak] is displayed, it indicates that the system may have a leakage. In this case, check if all connections are good and the cuff and tubing have no leakage. Perform the test again after making sure all connections are good and the cuff and tubing have no leakage.

You can either perform a manual leakage test:

- 1. Raise the pressure in the rigid vessel to 250 mmHg with the balloon pump. Then, wait for 5 seconds to let the measured values becoming stable.
- 2. Record the current pressure value and meanwhile use a time counter to count time. Then, record the pressure value after counting to 60s.
- 3. Compare the two values and make sure the difference should not be greater than 5 mmHg.

6.2.2 NIBP Calibration

Tools required:

- T-shape connector
- Appropriate tubing
- Balloon pump
- Metal Vessel with volume 500 ± 25 ml

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Reference manometer (calibrated with accuracy equal to or greater than 1 mmHg)

Follow this procedure to perform a NIBP calibration:

1. Connect the equipment as shown below.



- 2. Before inflation, the reading of the manometer should be 0. If not, open the balloon pump to let the whole airway open to the atmosphere. Close the balloon pump after the reading is 0.
- 3. Check the manometer values and the monitor values. Both should be 0mmHg.
- Set [NIBP Pressure] to 150 mmHg in the [NIBP Measurement Circuit]. Raise the pump pressure to 150 mmHg. After the pressure value is stabilized, select the [Calibrate] button to start a calibration.

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- 5. Set patient type to [Adult/Pediatric] in the [Overpressure Protection Circuit], and raise the pressure to 350 mmHg. After the pressure value is stabilized, select [Calibrate] to start a calibration.
- 6. Set the patient type to [Neonate] in the [Overpressure Protection Circuit], and raise the pressure to 165 mmHg. After the pressure value is stabilized, select [Calibrate] to start a calibration.

All calibration results are displayed in the [Calibrate NIBP] menu. If the calibration fails, check the test system for leakage and perform another calibration.

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6.3.1 Accuracy Test

Tools required:

- A steel gas cylinder with 6±0.05% CO2 and balance gas N2
- T-shape connector
- Tubing

Follow this procedure to perform the test:

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1. Plug the module into the module rack.

- 2. Wait until the CO2 module warmup is finished, and check the airway for leakage and perform a leakage test as well to make sure the airway has no leakage.
- 3. In the [CO2] menu—->CO2setup \rightarrow select [Zero].
- Connect the test system as follows: 4.



Open the relief valve to vent standard CO2 and make sure that there is an excess gas flow through 5. theT-shape connector to air.

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Check the realtime CO2 value is within $6\pm0.05\%$ in the [zero CO2] menu. 6.

ECG Test 6.4

ECG Performance Test 6.4.1

Tool required:

Fluke Medsim 300B, MPS450 or other patient simulator recommended δ

Follow this procedure to perform the test:

- Connect the patient simulator with the ECG module using an ECG cable. 1.
- Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitudes 1mV. 2.
- Check the ECG waves are displayed correctly without noise and the displayed HR values within 80 ± 1 3. bpm. О
- Disconnect each of the leads in turn and observe the corresponding lead off message displayed on the 4. screen.
- Set that the simulator outputs paced signals and set [PACE] to [ON] on the monitor's patient manage 5. interface. Check the pace pulse marks on the monitor screen.

6.4.2 **ECG** Calibration

Tool required:

Vernier caliper

Follow this procedure to perform a calibration:

- 1. Select the 1st channel ECG waveform area \rightarrow [**FILTER**] \rightarrow [**DIA**].
- 2. Select [MAIN MENU] \rightarrow [MAINTAIN] \rightarrow PASSWORD "5188" \rightarrow [ECG Calibrate].
- 3. Select [ECG CAL]. A square wave appears on the screen and the message [CAL, can't monitor] is displayed.
- 4. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
- 5. After completing the calibration, select [STOP ECG CAL].

If necessary, you can print out the square wave and wave scale through the recorder and then measure the difference.

6.5 **RESP Performance Test**

Tool required:

Fluke Medsim 300B, MPS450 or other patient simulator recommended

Follow this procedure to perform the test:

- 1. Connect the patient simulator to the module using a non ESU-proof cable and set lead IIas the respiration lead.
- 2. Configure the simulator as follows: lead II as the respiration lead, base impedance line as 1500Ω ; delta impedance as 0.5Ω , respiration rate as 40 rpm.

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3. Check the RESP wave is displayed without any distortion and the displayed RESP value is within 40 ± 1 rpm.6.1 Spo2 Test

Tool Required: None.

Follow this procedure to perform the test:

- 1. Connect SpO2 sensor to the SpO2 connector of the monitor. Set [Patient type.] to [Adu]on the monitor and set [PR Source] to SpO2 on the monitor.
- 2. Measure SpO2 on your finger. (Assume that you stay healthy)
- 3. Check the PLETH wave and PR reading on the screen and make sure that the reading of SpO2 is within 95%-100%.
- 4. Remove the SpO2 sensor from your finger and make sure that an alarm of SpO2 Sensor Off is triggered.

TEMP Test 6.6

Tool required:

Resistance box (with accuracy above 0.1Ω)

Follow this procedure to perform the test:

Connect the two pins of any Temp connector of a module to the two ends of the resistance box using 2 a) wires.

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- Set the resistance box to 1354.9Ω (corresponding temperature is 37° C). b)
- Verify each Temp channel of the monitor and make sure that the displayed value is within 37 c) 0.1°C. You can also use a patient simulator to perform the Temp test.

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Chapter 7 Disassemble Procedure

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The following section describes the disassembly and reassembly procedures for the monitor and its components

7.1 **Who Should Perform Repairs**

Only qualified service personnel (biomedical engineers or technicians) should open the monitor housing, remove and replace components or make adjustments. If your medical facility does not have qualified ~``\ ~`` service personnel, contact COMEN or your local COMEN representative.

ACaution

High-Voltage - Voltages dangerous to life are present in the instrument when it is connected to the mains power supply. Do not perform any disassembly procedures (other than server removal) with power applied to the instrument. Failure to adhere to this warning could cause serious injury or death. echipamente medicale

Tools required

- Screwdrivers
- Small flat head screwdriver
- Needle Nose Pliers •
- ESD mat and wrist strap
 - Cleaning agent
 - Tweezer

Removing the Battery 7.2

- 1. Open the battery compartment by removing the 4 screws on the back of monitor.
- 2. Disconnect the battery cable and then take out the battery as below shows.



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Separating the Front and Rear Housing 7.3

- 1. Remove the Battery as described above;
- 2. Remove the 5 screws on the rim of rear panel;
- S Lay down the monitor and remove the 2 screws on the bottom of monitor; 3.
- Disconnect the cable between the power module and the main board; 4.





7.4 **Removing the Recorder**

- Remove the Battery as described above; 1.
- 2. Separate the front and rear housing as described above;
- 3. Unplug the cable which connects to the printer inside the monitor:
- onsum Unscrew the two PWM 3.0×8mm screws inside the recorder and pull out the recorder: 4.



7.5 Removing the Button Board

- Remove the Battery as described above; 1.
- 2. Separate the front and rear housing as described above;
- Disconnect the cables that connect the Button Board, unscrew the five PB3×5mm screws to dismantle 3. the Button Board



Removing the Knob Encoder 7.6

- Remove the Battery as described above; 1.
- 2. Separate the front and rear housing as described above;
- 3. Disconnect the cable on Knob Encoder;
- onsumabile Unplug the cap of knob (tip: stick some 3M double-side tape on cap, then unplug it by hand) 4.

Remove cap

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5. Unscrew the screw nut on the Knob Encoder:



Disconnect inner wire

Remove nut e 0, 0 0

Removing the LCD Screen 7.7

Caution:

- Do not touch the LCD panel
- Disassemble the LCD in an environment as dust-free as possible
- Screen panel is fragile, be careful in installation or disassemble
- Remove the Battery as described above; 1.
- 2. Separate the front and rear housing as described above;
- 3. Disconnect the cables on keyboard, alarm lamp board, LCD cable;



- 4. Unscrew the 7 screws to separate the LCD carefully from the front panel of the monitor show as above;
- 5. Unscrew the 4 screws on top and bottom of LCD frame to separate the LCD carefully from the LCD frame, as show below;



Remove the Battery as described above;

1.

- 2. Separate the front and rear housing as described above;
- 3. Disconnect the cable that connects to the Alarm LED Board, and then unscrew the two PA3×8mm screws to remove the Alarm LED Board;



7.9 **Removing the 7 Parameter NIBP Board**

- 1. Remove the Battery as described above;
- 2. Separate the front and rear housing as described above;
- Unplug the cables that connect to the 7 Parameter NIBP Board; 3.
- 4. Unscrew four PM3×6mm screws to remove the 7 Parameter NIBP Board.



Removing Main Board 7.10

1.

- Remove the Battery as described above;
- Separate the front and rear housing as described above; 2.
- Unplug the cables that connect to the Main Board; 3.
- Unscrew the four PM3×6mm screws on main board to remove the Main Board. echile 4.

7.11 Removing the SpO₂ Module Assembly

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- 1. Remove the Battery as described above;
- 2. Separate the front and rear housing as described above;
- 3. Remove the 7 Parameter NIBP module as described above;
- 4. Remove the SpO2 module shield case, unscrews 2 screws on the back of the 7 parameter NIBP module, you can take out the SpO2 module;

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Removing the Power Supply Module 7.12

- 1. Remove the Battery as described above;
- 2. Separate the front and rear housing as described above;
- UM 3 Unplug the cables that connect to the Power Supply Module, and then unscrew the $6 \text{ PM3} \times 6 \text{mm}$ and 3. ം on the Power Supply Module;

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4. After removed the DC power module, unscrew 4 screws on the AC power module, then you can remove 5 the AC power module;



7.13 Removing the Speaker and Side Panel

- 1. Remove the Battery as described above;
- 2. Separate the front and rear housing as described above;
- 3. Unscrew the 5 screws, you can take out the 7 parameter chassis and the side panel, unscrew the 2 screws, then you can separate the side panel and the 7 parameter chassis.

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4. Unscrew the 2screws on speaker holder to remove the speaker.



