PMS8210A (IRIS)

VITAL SIGNS PATIENT MONITOR

Service Manual

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Announcement

- **3F reserves the right of final explanation about this service manual.**
- **3F reserves the right that update this manual without advanced notice.**
- **3F reserves the right to change the monitor's specifications change without advanced notice.**
- **3F doesn't guarantee this manual in any form.**

3F is responsible for the effects of safety, reliability, and performance only if:

- **Assembly operations, extensions, readjustments, modifications, or repairing is carried out 3F technical personnel or 3F's authorized agent.**
- **The electrical installation complies with the requirements of the appropriate government regulations.**
- **The instrument must be connected to the ground correctly.**
- **The monitor is used in accordance with the operation manual.**

3F is not responsible for the effects of safety, reliability, and performance when:

- **Spare Parts have been removed, debugged or readjusted.**
- **The monitor isn't used in accordance with the operation manual.**

Guarantee

The range of free service:

The instrument, which is listed in the range of maintenance item can have the free service.

The range of charged service:

- **The monitor which is not on the above free service list, and needs the maintenance, 3F will charge according to the service.**
- **If the maintained monitor is man-made damaged, voltage out of the required range, or force majuere by natural calamities, even it is within warranty period, 3F will charge for the service.**

3F is not responsible for the direct, indirect, completely damaging or delay in such condition:

- **Using instrument improperly.**
- **Tearing down, maintaining, debugging the instrument, replacing components or changing electrical wires by the technician without 3F's agreement or commission.**

Essential Guides for the Users

Warning: All Users must read following warnings and guide before operating the Monitors. Any abnormalities or malfunction of the monitor or body harms caused by the violations of the operational guides will not be responsible by our company, nor any warranties will be made by us.

- **The instrument is not therapeutic instrument.**
- **The instrument must be operated under the direction of the professional medical staff.**
- **All of the monitoring parameters are used as a reference and should not be used as the clinical diagnosis. For abnormalities occurred, clinical methods should be used to check out the reasons.**
- **The instrument should not be operated in the circumstance with flammable gas or corrosive gas.**
- **Prevent the liquid or electrical conductive substance entering into the instrument.**
- **The instrument must be grounded correctly, and the power supply must be in accordance with the specified requirement.**
- **Delete all the previous data when monitoring a new patient. Only one patient once.**
- **If monitor connects to the other instrument, the leakage circuit must be tested by qualified biological technician before use, and must accord to IEC 60601-1.**
- **It can be used on many parts of this monitor together, and the security meets the demand of IEC 60601-1.**
- **Make sure the connection is not dangerous to the patient or circumstance before the monitor connects to the other instrument.**
- **Must use the defibrillation ECG cable supplied by 3F, or the monitor can't be use together with defibrillator.**
- **Checkout the alarm system periodically.**
- **Do not touch the patient in defibrillation. Otherwise, it may lead to serious injury or death.**

- **All cables must be away from patient's throat to avoid asphyxia.**
- **When using together with pacemaker or other electric equipment, all other parts can't be connected with patients, except the defibrillation ECG cable supplied by pacemaker of 3F.**
- **The high frequency electrical bistoury can't be touched the electrode when use it together with the monitor, in order to avoid of burning the patients.**
- **Forbidden to place the electrode onto the injured or edematous site to prevent infection.**
- **Blood pressure measurement mode are forbidden to use in the blood pressure monitoring or test for neonates to prevent injuries.**
- **Do not measure the blood pressure on the limbs with catheter or infusion. Do not put on the cuff at or near the wounded position.**
- **Local bleeding may be caused when using the blood pressure monitoring in the patients with severe bleeding tendency. Be careful to use on the patients with sickle cell disease.**
- **Forbidden to place the blood oxygen sensor onto the injured skin, edematous or fragile tissues.**
- **Discomfort or pain may be caused by the continuous use of the clip type of blood oxygen sensor especially in patients with micro-circulation disorder. Better not to place the sensor over 2 hours at the same place.**
- **Non-disposable accessories should be sterilized before it is used on next patient to prevent cross infection.**
- **Opening the apparatus by the unauthorized personnel of our company is forbidden.**
- **Don't need to note the user when the types of the accessories are changed.**
- **To the disposal of package waste, please deal with by the local waste law.**

⚠ Note especially for neonate

1、ECG Measurement

Warning: Away from the throats of the neonate to avoid asphyxiation.

The electro-cardio cables and the electrode must be used correctly because neonate's body is shorter and tender. Avoid the injury of the electrode. And check on time and change with the finger.

2、Blood Pressure Measurement

Warning: The pattern of blood pressure measurement for neonate must be selected before the neonate measures, otherwise accidents will be caused.

The cuff that fits neonate must be used to take the measurement of neonate. Set correctly the parameters of the air pressure of the cuff and alarm when neonate takes the blood pressure. Please select the default. Especially, note these parameters that neonate fit if you have to adjust parameters.

3、Blood Oxygen Measurement

Caution: Blood oxygen value (SpO2) may be not obtained precisely because the neonate moves. To measure precisely, please keep neonate at rest.

Use correctly the blood oxygen probe to neonate. Do not place the blood oxygen probe on the fingers with skin injury, edema or fragile. Do not place the probe on the same finger over 2 hours to prevent discomfort of the finger. Check on time and change with the finger.

4、Temperature Measurement

Use the inside temperature probe when taking neonate's temperature.

Terms for safety and symbols

■ Terms for safety

In this manual, warning, caution, and notice are used to describe the level of danger. Please be familiar with their definition and meaning.

Warning: Instructions to avoid potential danger and incorrect operation. Obey the instructions, otherwise death and serious injury may be caused.

Caution: Instructions to avoid potential danger and incorrect operation. Obey the instructions, otherwise injury and product loss may be caused.

Note: Operational instructions or other useful information to use the instrument fully.

■ Symbols

The list of the symbols used in this instrument is as follows:

Symbol for “caution, consult accompanying documents”

CE mark, when a device has been past CE test, we must put the CE mark on the device. And the CE number can be after the symbol.

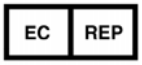
a. This symbol shall be accompanied by the manufacturer’s serial number. The serial number shall be after or below the symbol, adjacent to it;

b. The relative size of the symbol and the serial number are not specified;

c. So far our product serial number is made of seven digits, two digits for the year and two digits for the month and three digits for sequence number. So the serial number could be show the date of made.

a. The symbol shall be accompanied by the name and the address of the manufacturer, adjacent to the symbol. The address is not required with the symbol on an immediate container as specified in EN375 AND EN376, except when the immediate container is also the outer container.

b. The relative size of the symbol and the name and address is not specified.



a. The symbol shall be accompanied by the name and the address of the authorized representative in the European Community, adjacent to the symbol. The address is not required with the symbol on an immediate container as

specified in EN375 AND EN376, except when the immediate container is also the outer container.

b. The relative size of the symbol and the name and address is not specified.

Smbol for “do not reuse”, “single use”, “use only once”

Symbol for “temperature limitation”

Symbol for “consult instructions for use”, “consult operating instructions”

Symbol for “biological risks”

Defibrillation-proof type CF applied part , on medical equipment to identify a defibrillation-proof type CF applied part.

Equipotentiality, to identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential. Not necessarily being the earth (ground) potential. e.g. for local bonding.

The symbol indicating separate collection for electrical and electronic equipment consists of the crossed-out wheeled bin. The symbol must be printed visibly, legibly and indelibly.

The interface of networking

CONTENT

Chapter 1 Complete Appliance Introduction

1.1 Overview

IRIS Vital Sign Patient monitor is one of the PMS8 monitor series products of the 3F Medical Company, and is born on the base of the 3F PMS series multi-parameter monitor. Fully considered the increasing need of clinical applications, 3F develops IRIS with the latest technology, making it as a new generated medical electronic product.

IRIS monitor can monitor the patient's vital physiology signals, including: ECG, RESP, NIBP, SPO2 and TEMP. It can be used for adults, pediatric and neonatal.

IRIS uses 50HZ, 100V or 220V main power supply, displaying real-time data and waveform with 3.2 inches high definition color LCD and LED. It can display one waveform or two and all monitor parameters, can be connected to the central network monitoring system. It equips with a 50mm thermal-sensitive recorder, and optional with a 8V built-in replaceable & rechargeable lithium battery. It has many advantages: full parameters, compact size, clear observation, convenient usage, and can be used for emergency monitoring.

1.2 Model

MODEL	TRADE NAME	SPECIFICATION	CONFIGURATION
PMS8210A	IRIS	I-B	NIBP, TEMP, Nellcor SpO_2,
		I-A	NIBP, TEMP, 3F SpO_2,
		II-B	NIBP, TEMP, Nellcor SpO_2, ECG,RESP
		II-A	NIBP, TEMP, 3F SpO_2, ECG, RESP

1.3 Tag Structure

PMS8210A I/II

I/II — Product configuration code: I: Without ECG
II: With ECG＋RESP rate

PMS8210A — Product type code: Vital Signs Patient Monitor: LCD+LED

IRIS — PMS8210A’s trade name

1.4 Parameters

1.4.1 ECG

Lead	3 lead(RA,LA,LL) / 5lead(RA,RL,LA,LL,V))
Lead option	monitor lead / standard lead
Gain	5mm/mv, 10mm/mv
Sweep speed	12.5mm/s, 25mm/s, 50mm/s
Wave gain	5 %
Range of heart rate monitoring	0, 20～350 bpm
Resolution	1 bpm
Precision	5%
Alarm setting	the limit of alarm (setup range：20～350 bpm), and leads-off alarm display.
Aalarm mode	audible and visual alarm, and record the data during alarm for the retrospection
Input resistance	≧5 MΩ
CMRR	≧89 dB
S-T detecting range	-1.00～1.00mv
Heart disorder analysis	NO
Anti-polarized voltage	±500 mV
Baseline renewing time	<5 s after the defibrillation
ECG mode	mode 1, mode 2, mode 3, mode 4
Frequency characteristic	0.5Hz-40Hz
Safeguard	4000V high voltage isolation，anti-defibrillation，anti-high frequency electrical bistoury

1.4.2 Blood Pressure (NIBP)

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in auto mode	0~480(min.)
Data unit	mmHg / kPa optional
Data storage/review	4000 blood pressure value at most
Alarm setup	SYS、DIA、MAP(the range is the same as parameter measurement range)
Alarm method	sound light alarm，and record the alarm status for review

Measuring range

Adult Mode

SYS	40~255 (mmHg)
DIA	10~195 (mmHg)
MAP	20~215 (mmHg)

Child Mode

SYS	40~200 (mmHg)
DIA	10~150 (mmHg)
MAP	20~165 (mmHg)

Neonate Mode

SYS	40~135(mmHg)
DIA	10~110(mmHg)
MAP	20~125(mmHg)

Resolution	1 mmHg
Precision	the average error ≤±5mmHg
	the standard error ≤±8mmHg
Overpressure Protection	software and hardware double protection
Adult Mode	290(mmHg)
Child Mode	220(mmHg)
Neonate Mode	150(mmHg)

1.4.3 Blood Oxygen (3F)

SpO_2

Measuring method	double length infrared wave
Measuring range	0~100%
Alarm setup range	70~100%
Resolution	1 %
Precision	±2% (70~100% adult/child)
	±3% (70~100% neonate)
	±4% (40~69%)

Pulse rate

Measuring range	25~250bpm
Alarm setup range	20~250bpm

Resolution	1 bpm
Precision	±3 bpm(Geostationary)or±5 bpm(Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SpO2 overruns、pulse rate overruns
Alarm method	sound light alarm，and record the alarm status for review

1.4.4 Blood Oxygen (Nellcor)

SpO_2

Measuring method	double length infrared wave
Measuring Range	0~100%
Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/child) ±3% (70~100% neonate) Unspecified (0~69%)

Pulse rate

Measuring Range	20~250bpm
Alarm setup range	20~250bpm
Precision	±3 bpm(Geostationary)or±5 bpm(Campaign)
Sweep speed	12.5mm/s, 25mm/s
Alarm setup	SpO2 overruns、pulse rate overruns
Alarm method	sound light alarm，and record the alarm status for review

1.4.5 Respiration

Measuring method	the thorax impedance method (used with ECG lead)
Measuring range	0, 10～120rpm
Resolution	1 rpm
Precision	the bigger one between ±2 rpm or ±2 %
Alarm setup	Resp rate overruns, asphyxiation
Alarm method	sound light alarm，and record the alarm status for review

1.4.6 Temp

Channel	1
Measuring mode	Thermal
Measuring and Alarm Range	0～50°C (32～122°F)
Resolution	0.1 °C
Precision	± 0.1 °C (25~45°C)
	± 0.2 °C (Others)
Actualization interval	1 (Sec.)
Average Time Constant	< 10 (Sec.)
Data unit	°C/ °F

1.4.7 Others

Power supply	100～240VAC(± 10%), 50/60Hz(±3Hz),40VA
Ambulance power supply	9V~15V
Internal battery input	6.4V~8.4V
Power consumption	≤40VA
Display	LED+3.2" colorful TFT/ LCD (320×240)
Input	NIBP, ECG, Temperature, SpO_2
Output	Printer and internet

CLASS:

- According to the type of protection against electric shock: Class I internal power supply.
- According to the degree of protection against electric shock: Anti-defibrillation CF type
- According to the degree of protection against ingress of water as detailed in the current edition of IEC 529: Ordinary equipment(sealed equipment without liquid proof)
- According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE: not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTUREWITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- According to the mode of operation: Continuous.

1.5 Appearance

1.5.1 Front View of IRIS

Picture 1-1 IRIS Vital Sign Monitor

① Switch: Power on/off;

② Print Switch: Start/Stop the printer;

③ Measure Blood Pressure: Start/Stop measuring the Blood Pressure;

④ Real-Time Waveform Recording: Freeze/unfreeze the current ECG Waveform;

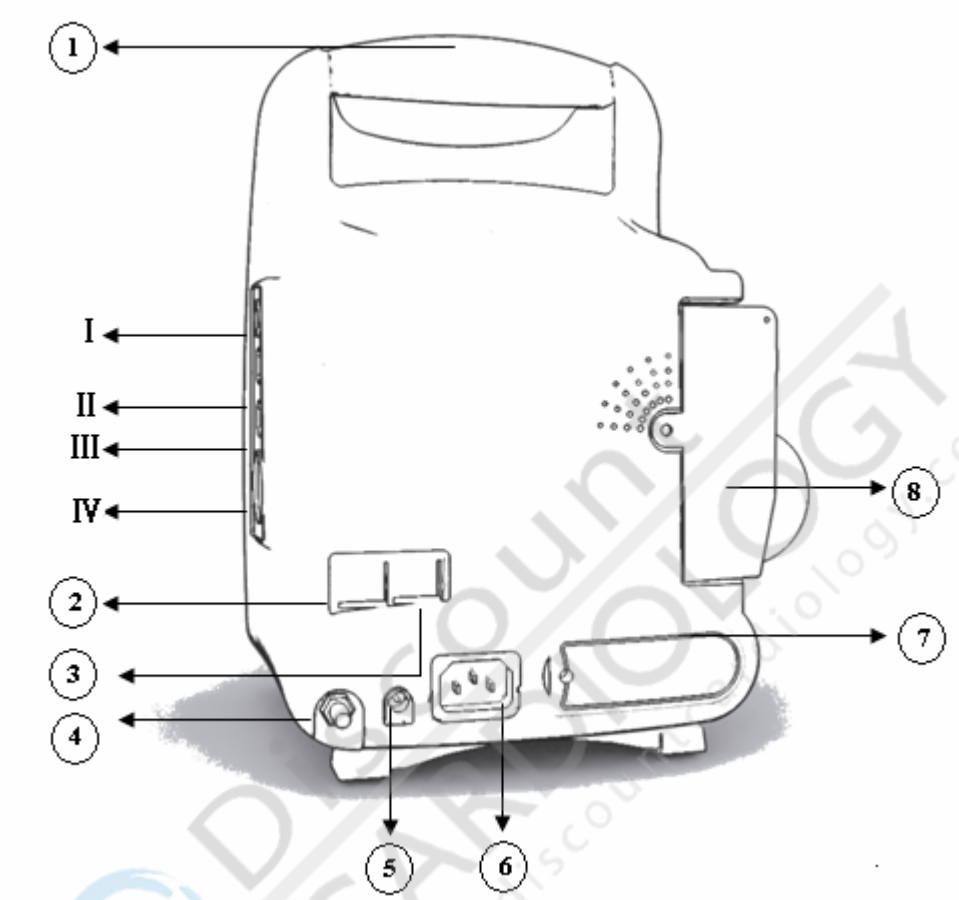
⑤ Mute switch: Turn Off/On the sound effects;

⑥ Multi-function Key: SD Card storage, and the input of patient data;

⑦ Functional Indicator: Display the status of each function

⑧ Menu Key: Adjusting the system parameters, and the patient data retrospection.

1.5.2 Back View of IRIS



①Indicator light: Alarm Indicator;

②Communication port: Nurse Call;

③Network interface: Standard RJ45 input net connection with 3F Center Station.

④Ground Cable interface: Interface for connecting the ground wire;

⑤Car DC input port: 9V~15V;

⑥Power: 100～240VAC(10%),50/60Hz(±3Hz);

⑦Lithium battery cabin: 6.4V~8.4V;

⑧Printer: Out-built printer;

I, Channels of temperature sensor;

II, Channels of NIBP Cuff;

III, SPO2 sensor;

IV, ECG Cable interface.

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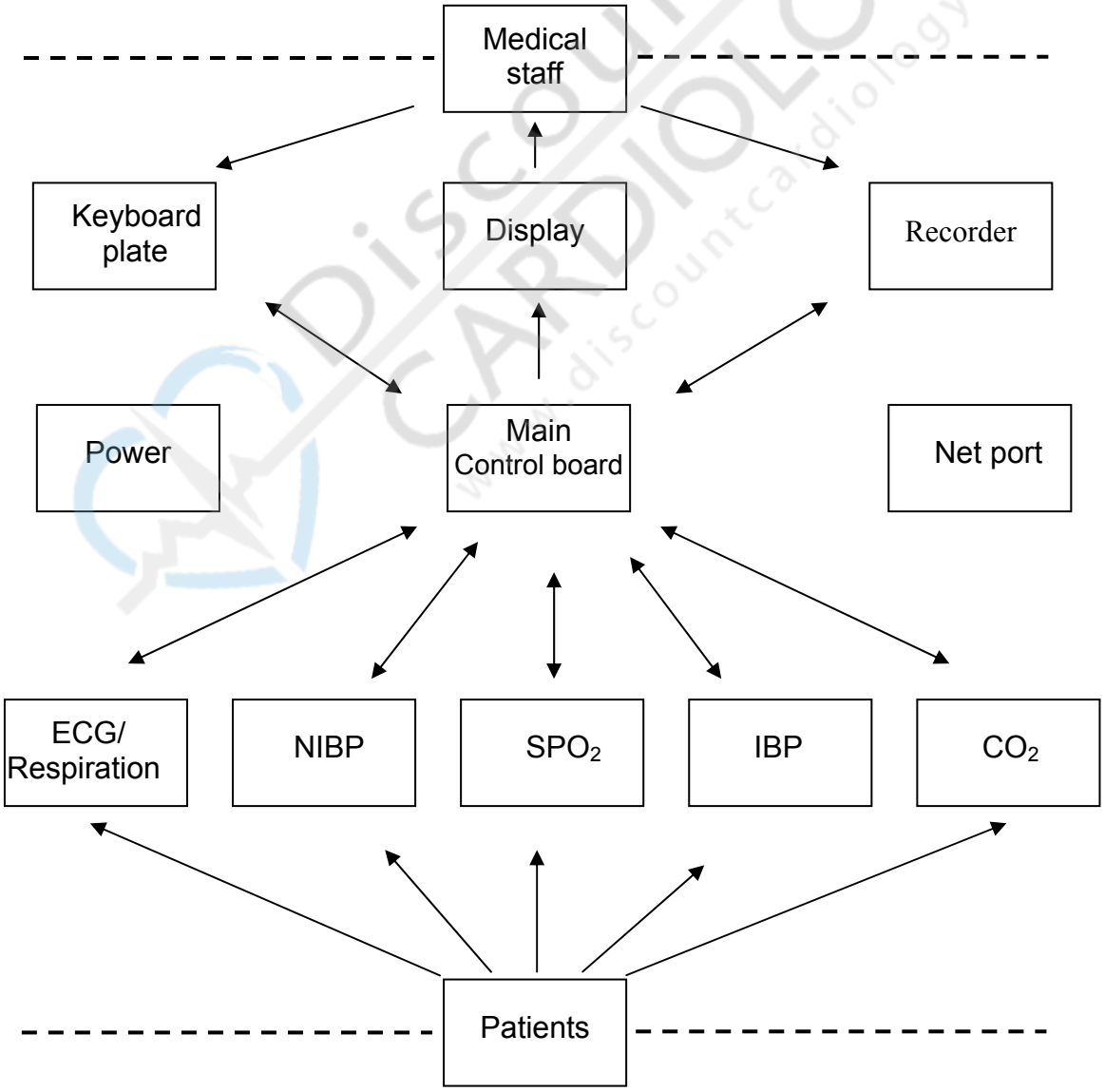
Chapter 2 Patient Monitor parameters and theory

2.1 Summary

IRIS adopts parameter signal on the base of parameter modules, and transmits the result to the main control panel through the switch board, and display the data and waveform on the screen. The commands of main control panel and module's information are also transmitted through the switch board. The switch board can also transfer the power.

The framework of system is demonstrated as below:



2.2 Parameters and theory

The five parameter modules do the real time monitoring on non-invasive blood pressure, SpO2, ECG/respiration, (body) temperature through the cuff and cables. The results are transmitted to the main control panel for processing and displaying, and input to print by the thermal recorder.

2.2.1 ECG

2.2.1.1 The IRIS main function of ECG:

a) Lead: 3-Lead, 5-Lead
b) Lead measurement: I, II, III, avR, avL, avF, V, CAL
c) Drive by right foot
d) Anti- defibrillation
e) Detection of lead off
f) Magnify dual channel ECG, while process the ECG signal by any two lead measurement.

2.2.1.2 The processing of ECG signals is achieved by circuit of ECG parameter, and the circuit is constructed by several parts:

a) Input electric circuit: ECG electrode is connected to the input circuit with the ECG cable. The main function of the circuit is to protect the input port of ECG, and signal filter out interference from the outside.
b) Buffer amplifier circuit: complete the ECG signal's impedance transformation to ensure that ECG has a high input impedance and a low output resistance.
c) Right foot drive circuit: The mid-point of the output buffer amplifier circuit to the RL of the five lead ECG by reversed amplifying to ensure the human body in an equipotential state, thereby reducing interference and improve the circuit's common mode rejection ratio.
d) Lead off Detection: According to lead off caused by a buffer amplifier output level change, adjust the lead off via comparing device and converted into TTL-level for single-chip detection.
e) Lead connecting to the circuit: In the single-chip control, enlarge the main release according to the requirements of connecting different lead electrode access to the main circuit.
f) Main output circuit: By a standard consisting of three op amp instrumentation amplifier.

g) Post-processing circuit: The main function is to complete the coupling of ECG signals, the size of programmable gain, filtering and level shifting, and the signals amplification to a certain extent into the mode - the digital converters.

2.2.1.3 Respiratory (RESP) parameters

IRIS vital sign monitor RESP measurement method is based on the principle of impedance. The body chest is up and down when breathe, which is equivalent to impedance changes between RL and LL, and through the ECG electrode RL and LL's high-frequency signal into a high-frequency signal. The signal is amplified to electric-signal output, with changes in respiration, and sent to mode-digital converters. Respiratory parameters is combined by the respiration electric board and coupling transformer. Circuit is included by: oscillometry, coupling, detection, early release, high-gain amplification and so on.

2.2.2 Noninvasive blood pressure (NIBP) parameters

NIBP adopts the theory of pulse oscillometry. Puff the cuff around the upper arm until the pressure which generated by the cuff interdict the flow of the brachial artery, and then deflated gradually according to a certain algorithm requirements. As the pressure reduced, with the beat in the pulse, the arterial blood will generate a pulse signal. Filter out the pulse signal and enlarge it with a high-pass filter (about 1HZ), and convert it into digital signal by the A / D. The systolic, diastolic and the mean blood pressure can measure after the treatment by the single-chip microcomputer.

For neonate, pediatric and adult, we must choose the correct size of the cuff in order to avoid the measurement error.

NIBP prevents the excessive pressure with the protection electric circuit.

Main work mode to NIBP:

1. Adult/Pediatric/Neonate mode: choose according to the body figure, weight and age.
2. Manual/Auto/Series: Manual measurement also means a single measurement. Only measured once after choosing the Manual. Auto can measure once in the selected time intervals, period can be 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 200 or 280 minutes. Series measurement starts the fast consecutive measurements in five minutes, and can be effectively measure the blood pressure changes.

2.2.3 SPO2 parameter

SPO2 is obtained through describing the pulse wave of fingertip, which passing through the specific algorithm and looking up the clinical data table.

The SO2 probe is the surveying sensor, built of two light emitter diodes and an electro-optical battery part. Two light emitter diodes conclude a red diode and an infrared diode. They light alternately according to certain succession. When fingertip's blood capillary hyperemia repeatedly along with heart's pump blood, the blood vessel and the organization absorb the light of the emitter diode, and project on to the solar battery, the solar battery may sense luminous intensity along with the pulse blood change, and be formed of changed electrical signal. The ratio of current and alternating current component is according to the content of oxygen in blood. The correct value of oxygen saturation degree is obtained though the specific algorithm; simultaneously the arteries rate may be calculated according to the blood oxygen pulse profile.

The circuit module of SPO2 mainly includes four parts:

1. Probe parts: Luminescence tubes launch infrared and red radiant to measured position alternately; phototubes will receive the light into electrical signals.
2. Signal processing parts: The electric signal is amplified by the measuring amplifier, and after high-pass filter and program-controlled amplification by A/D conversion to digit. It is through D/A switch to control signal baseline, and amplify to the communication signal, to get an appropriate pulse wave. A/D conversion for the digital quantity is processed by SCM.
3. Light emitting diode drivers control parts: led transferring and light degree is controlled by the sequential circuits and DAC. SCM control the size of the electric current according to algorithm requirements.
4. SCM parts: conclude by CPU, RAM, ROM and interface circuit.

2.2.4 Temperature (TEMP) parameters

Temperature measurement is to convert the temperature to the electrical signal by a sensor, enlarge it by the amplifier, and process into data. The circuit is made of proportional amplifier which is constituted by operational amplifier. Turned into voltage signal by the thermistor probe, the temperature is magnified and sent to the A/D converter.

Probe examination electric circuit is constituted to voltage comparator by operational amplifier. When probe off, the input voltage is lower than the comparison voltage, and the voltage comparator outputs the low level; when insert the probe, the input voltage is higher , the voltage comparator outputs the high level.

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Chapter 3 Installation and Inspection

3.1 Instrument installation

Please refer to the “PMS8210A operation manual” for the usual measurement of IRIS. So here we will not describe in detail. The following steps are to indicate the main point of the measurement as well as some parts which is not carefully described.

3.1.1 The checking for appearance and assembling

Take out the instrument from the package carefully. Check the aspect first. If there are some occurrences due to transportation as that the aspect of monitor is damaged, the LCD panel is broken, or there is abnormal sound when shaking the instrument mainly caused by fall-off of some components, please don’t plug into the power socket or try to open the instrument to examine or repair. Instead, contact with the local dealer or the customer service department of 3F as soon as possible.

If the instrument looks well and buttons operate well, put in on the flat desk or fix it on the bracket. Please put the electro cardio lead plug, blood pressure plug and blood oxygen probe plug in the corresponding socket on the right panel. If one of the parameters is not wanted, the probe or cable could be taken off from the side panel.
Connect one side of the power wire to the power socket on the back side of the instrument and the other side to the output of 220V AC power supply.

Complete marks, with correct content. And standard configuration and fixed socket is ok. Now the instrument can be used.

If there is battery supply, the instrument can work relying on the internal power when it isn’t connected to the 220V AC. When the AC220V is connected, the instrument uses the AC power supply and the internal battery is charged by the AC power.

⚠ **Warning:**

1) **Can’t be put under direct sunlight, to avoid damages by the high temperature in the machine box.**
2) **Don’t use the instrument in the environment with poisonous, flammable or caustic gas.**
3) **Pay attention to the unsteady of the local voltage, if the voltage is over the permitted range, we advise to add voltage stabilizing device.**

4) **Don’t use keyboard in order to avoid damage to internal information and procedures.**

3.1.2 Power on

Before power on, you should check:

1. The power voltage meets the requirement of the instrument.
2. The three-wire power cable is necessary, and the power inlet must match three-wire. Do not use the two-wire AC power supply.
3. When IRIS is used together with other medical devices, the protective ground should be reliably connected to other device.
4. Do not put monitor below the perfusion bag or some other places with the liquids leakage to avoid the liquids enter into the monitor.

When the power is on, check whether the patient monitor can function properly, the screen display is OK, and no error message; the two waveforms can show correctly the parameters are refreshed every second, the tracking time is precise too.

3.1.3 Configuration

Users can setup related function in “MENU”, including the switch of the recorder, ECG, type of the lead，network bed number setting and the switch of arrhythmia.

3.1.4 Running Normally

1. When operate any key, the patient monitor can run according to the operation manual's guidelines.
2. When rotate or press the knob, the patient monitor can run according to the operation manual's guidelines.
3. Operate the patient monitor as the user’s manual, and check sound and audio alarm normal or not, alarm-mute and turn off-alarm is working or not.
4. Check the machine to make sure that the memory function is OK.

3.1.5 Network function

1. Start Central Station and the bedside monitor, make sure the net is connected, and the bed number shows correctly.
2. The transfer of data between IRIS and central station normally.
3. Central Station receives waveform parameters, alarm level, alarm limits, and the

patient information correctly.

4. Waveform parameters, alarm level, alarm limits, and the patient information correctly turned to the central station.
5. IRIS portable shutdown correctly after the Central Station response time required, see the relevant technical indicators.
6. Make the network connection from a certain aspect disconnect the central station can direct the machine to resume after the networking to connect and work normally, the time required, see the relevant technical indicators.

3.1.6 Clock

Instructions correctly, walking evenly, not mutation, non-stop.

3.1.7 ECG waveform output

Connect IRIS to ECG lead and simulator, and connect D / A output (chassis behind) to the oscilloscope (Universal oscilloscope), select the 5V or 1V respectively and compare oscilloscope waveform with the output waveform of IRIS.

3.1.8 Long time run

After long time run, observe the monitor state whether ok.

3.1.9 Factory settings

The initial values set by software, except for the "factory settings" menu.

3.1.10 Safety testing

1 The test of the protective earthing impedance: the impedance must not exceed 0.2Ω between the protective earth terminal in MAINS plug and any accessible MAINS part. Please refer to the standard of the clause 18 f) of IEC 60601-1+A1+A2.

2 Earth leakage current: when the MAINS is 250V, the current must not exceed 0.5mA; under single fault conditions, the current must not exceed 1.0mA. Please refer to the standard of the clause 19 of IEC 60601-1+A1+A2.

3 The patient leakage current: when the MAINS is 250V, the current must not exceed 10uA.Please refer to the standard of the clause 19 of IEC 60601-1+A1+A2.

3.2 The parameters of testing and calibration

At least once a year, the following parameters are tested and calibrated in order to guarantee the accuracy of IRIS. After repair, the various parameters shall re-calibration.

3.2.1 ECG and respiratory parameters testing

3.2.1.1 Tools

Simulator of human body physiology parameter

3.2.1.2 Test steps

A Connect IRIS to ECG simulator.

B Confirm the number of ECG waveforms on the screen, and accord with the selection of EC menu.

C Configure the default values of ECG1 I and ECG2 (when ECG2 exist).

D Ensure the waveform of ECG and RESP to be ok.

E Set parameter values of simulator are as follows:

HR = 30 (gain * 4)

RR = 15

F Check to the waveform or values of ECG, RESP, HR and RR, are correct.

G To change the simulator's configuration:

HR = 240

RR = 120

H Check the ECG, RESP, HR, RR values set with the simulator parameter values consistent.

I If ECG leads is off, IRIS should be reported immediately.

3.2.2 Non-invasive blood pressure parameter test

3.2.2.1 Inspection Tools

Non-invasive blood pressure simulator

3.2.2.2 Test steps

Calibration function with the use of non-invasive blood pressure simulator, in accordance with the "user manual" give the calibration method and calibrated to determine the accuracy of measurement of blood pressure pump. If the calibration

passes, the following tests are performed:

A Simulator and monitor all set adult model.

B In the non-invasive blood pressure simulator select a group of blood pressure measurement within the scope of value, such as:

NS = 90

NM = 70

ND = 60

C Inspection IRIS portable measuring whether the outcome of the actual simulator set with consistent value.

D change the simulator set pressure value, re-measurement

3.2.3 SPO2 parameters test

3.2.3.1 Inspection Tools

SPO_2 Simulator

3.2.3.2 Inspection steps

A Connect SPO2 Simulator with IRIS.

B Set SPO2 simulator parameter values are as follows:

SPO2 = 98

PR = 70

C Inspection IRIS portable SPO2 and PR display value is consistent with the simulator. (Note: To observe PR value must be in the ECG heart rate menu will be selected as the source of PETH.)

D Change in SPO2 Simulator SPO2 and RP settings.

E Check IRIS display value consistent with the settings.

F If SPO2 probe is off, IRIS shall immediately report.

3.2.4 Temperature Parameters Test

3.2.4.1 Inspection Tools

Physiological signal simulator

3.2.4.2 Inspection steps

A Temperature sensor will take a simulator, then an IRIS portable TEMP mouth. Through the simulator settings: TEMP = 34 ℃.

B Inspection IRIS portable screen shows the value of the TEMP for 34 ℃;

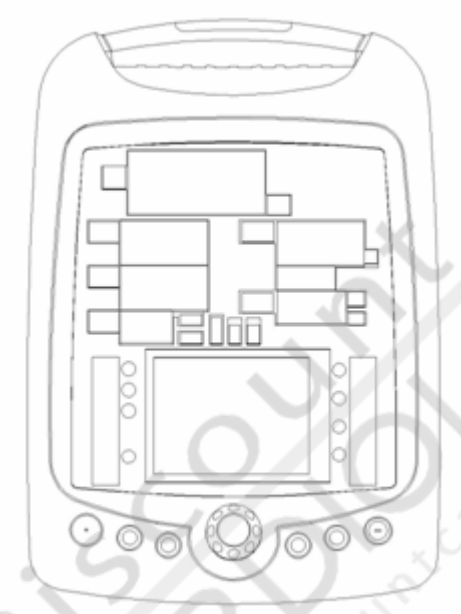
C Change the simulator settings: TEMP = 40 ℃.

D Inspection IRIS portable screen shows the value of the TEMP for 40 ℃.

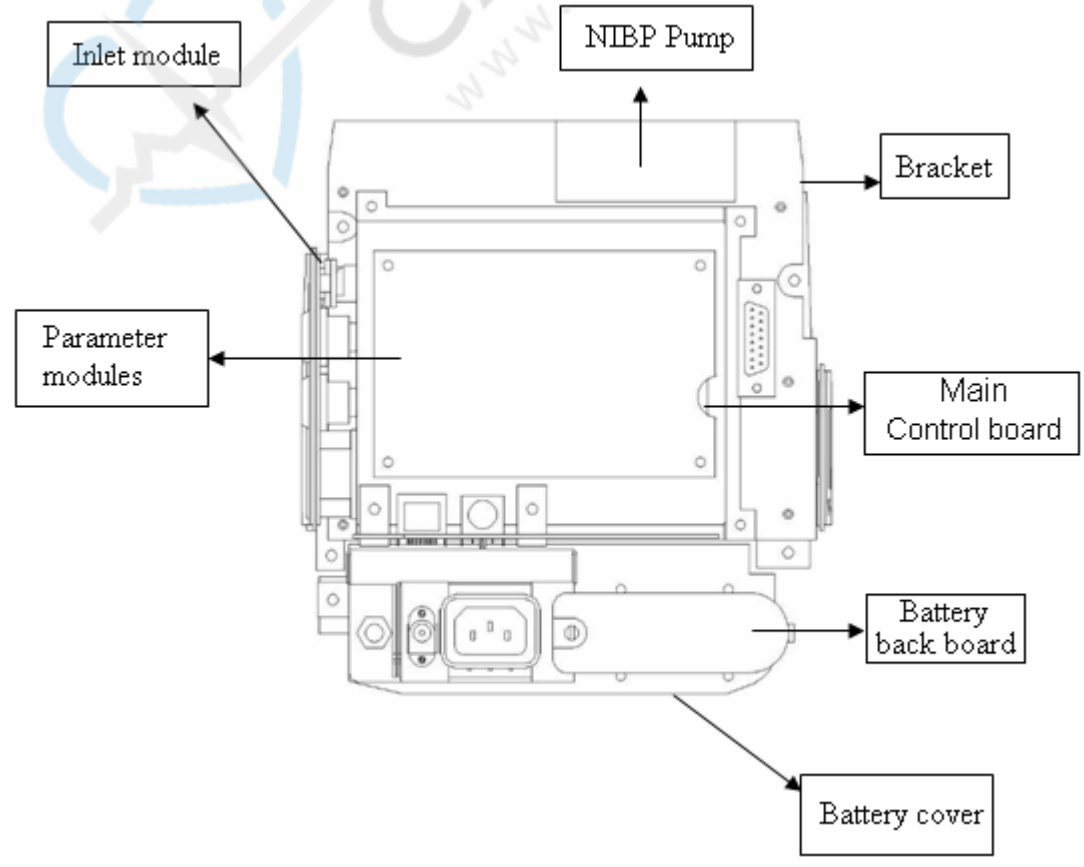
Chapter 4 Maintenance

4.1 The assembly parts drawing

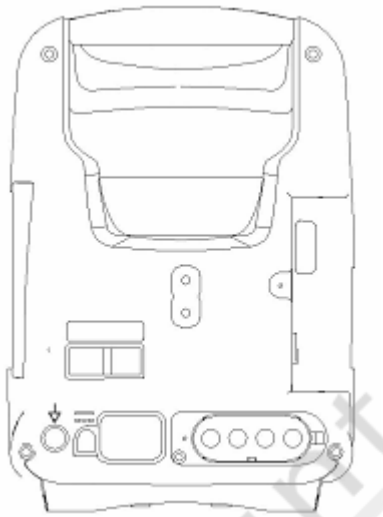
4.1.1 The front assembly view



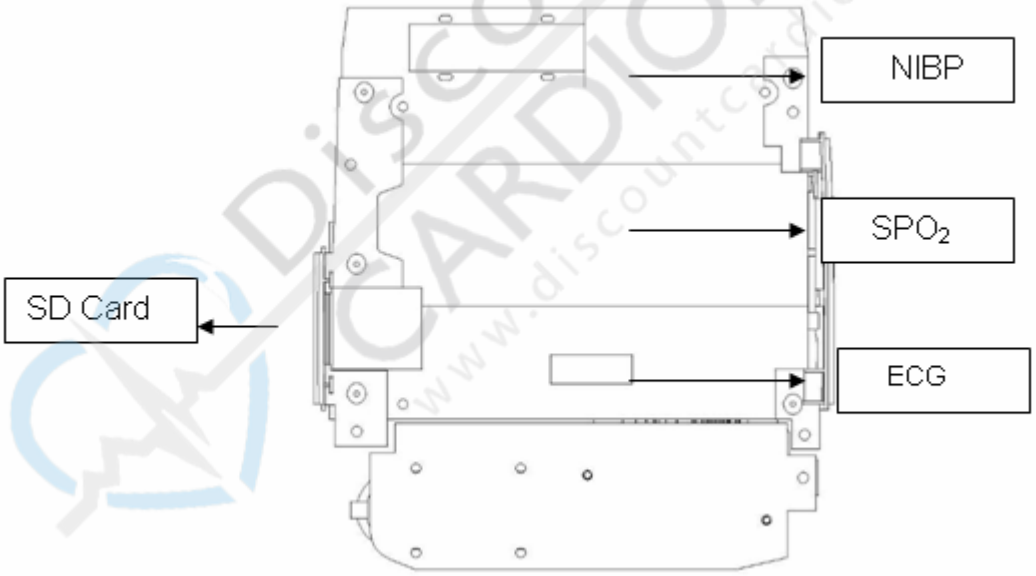
4.1.2 The front frame view



4.1.3 The back assembly view



4.1.4 The back frame view



4.2 Malfunction guide

On the process of transport, storage and usage, IRIS may produce some malfunctions. If the instrument has malfunctions in use, the problems can be disposed as shown in the table below. If the malfunction is not debugged, please contact with our dealer or service department.

4.2.1 Simple and apparent malfunction checking

When you check the malfunctions of the monitor, two problems must be checked first.

1) Whether the battery is full (if the monitor own the re-changeable battery)
2) If it is supplied by the AC, check if the monitor is plugged in and if the power line is connected to the monitor.

   If there is no problem with power supply, observe the three power indictor lights on

the front panel to judge where the malfunction exits.

1) "~" blue indicator light for AC

   If AC power is supplied, press the "start/stop" button for about 2~3 seconds when the instrument is off, the instruments will be started, and the blue indicator light is on (the blue DC indicator light is off). If the light is not on, there may be possibilities as follows: the power line is not plug in well, the fuse is broken, the power module is broken or the indicator light is bad.

2) "⎓" : blue DC indicator light(suitable for the instrument power supplied by the battery)

   The instrument is not plugged in but if there is battery installed in it, press the "start/stop" button for about 2~3 seconds when the instrument is off, the instruments will be started, and the blue indicator light is on(the blue DC indicator light is off), and it shows that the instrument can work through battery supply. If the indicator light isn't on, there may be some possibilities as follows: the "start/stop" button is loose contact, some malfunctions in the charging control board, DC indicator light is bad, the capacity of the battery is not enough or the battery is damaged.

3) " " : blue indicator light(suitable for the instrument with battery installed supplied by the AC power)

   When AC is supplied, the instrument will charge up automatically. If the blue light is on, it shows that the battery is charged up. If the capacity of the battery is full, the blue light will be off. Generally, the battery needs 4~8 hours to be charged up with full capacity. If the time for charging up is above 24 hours and the blue light is on yet, there may be the possibilities as follows: the charging control board has malfunction or the battery is damaged.

4.2.2 Instrument malfunctions

Malfunction phenomena	Possible causes	Means to dispose
The screen is black and power is not on	1. the fuse is damaged 2. the power is damaged 3. Other components are short.	1. Replace the fuse. 2. Replace power. 3. Confirm the component and replace.
The screen is black when power on	1. LCD or mainboard is damaged. 2. The lines of LCD is loose contact or damaged	1. Replace the LCD or mainboard. 2. Re-plug or replace the lines
The word is ok but the waveform is not continuous	Mainboard or parameters module is loose contact or damaged.	Base on the error display, replace the module.
The operation or measurement is fault	Mainboard or parameters module is damaged.	Base on the error display, replace the module.
Halt on sometime	1. The MAINS fluctuates. 2. The performance of power board or main board is not well. 3. The connector of power board or main board is not well.	1. Check the MAINS and GROUND 2. Replace the power board or main board. 3. Replace or repair the connector.

4.2.3 Error code displayed on the Screen

The error code is only used in blood pressure measurement in this monitor.

Malfunction phenomena	Possible cause	Means to dispose
The value of blood pressure cannot be read or the value is incorrect.	Cuff tied incorrectly	Tie the cuff again according to 2.3
	The patient's arm with cuff is moving	Keep the patient quiet when taking the blood pressure
	Cuff is tied outside the clothes	Tie the cuff after taking off the clothe
	Air leakage for the cuff	Change the new cuff
	The connection between the cuff tube and the plug is not tight	Connect again and ensure its tightness
	Rubber tube of the cuff twisting	Release the tube to keep the airway smooth
	Patients belongs to the one who is not allowed to measure blood pressure	Take the value repeatedly

Blood pressure measurement error code contrast table

Error Code	Description
00	No error
06	Wrong cuff (Cuff not connected or not tied)
07	Air leakage
08	Air pressure wrong(unstable pressure)
09	Signal weak
10	Upper measurement
11	Too much motion
12	Over pressure tested
13	Signal saturated
19	Over time testing

4.2.4 Operation, record, displayed and network malfunction

Malfunction phenomena	Possible cause	Means to dispose
Initialization	1. Malfunction of parameter modules 2. The communicational signal line or connect board is loose or damaged.	1. Replace the module. 2. Re-plug or replace communicational signal lines or module
Lead off	The parameters probe or electrode is damaged, or the electrode is invalidation.	Replace the probe, electrode or electrode.
The speaker is hoarse or invalid.	1. The key board is damaged. 2. Speaker or the line is damaged.	Replace the key board or speaker.
The printer does not print.	1. Printer electric line off or bad connection 2. Printer failure 3. Printer not set. 4. Print paper not set.	1. Reconnect or replace the printer electric line 2. Replace the printer 3. Add the paper.
The print record is tilted.	The installation of printer is not well.	Adjust the printer.
The buttons or the knob is invalid.	1. the keyboard signal lines is loose contact or damaged 2. malfunction of keyboard PCB	1. re-plug the signal line 2. replace the keyboard

Not connect to the center station	1. “offline” is set in the menu 2. the net wires are loose contact or damaged 3. the connect board is damaged	1. set “online” in the menu 2. rep-plug or replace the net wires 3. replace the connect board

4.2.5 Power board malfunction

Malfunction phenomena	Possible cause	Means to dispose
The fuse burn when power is on.	The power or other parts is short.	Open the instrument to check.
Cut the load but The fuse burn still	The power is damaged.	Replace the power board.
The fuse burn when the part connects.	The part is short.	Replace the part.
The LED of power and main board is light, but the fan is not work or the LED of trans-board is not light.	The +12VDC power is damaged.	Replace the power.
The fan is work and the LED of trans-board is light but the LED of power and main board is not light,	The +5VDC power is damaged.	Replace the power.

4.2.6 Parameters malfunction

Malfunction phenomena	Possible cause	Means to dispose
No ECG waveform	1. Electrode patch is bad contact. 2. CAL self-check does not detect square wave. 3. RL electrode hangs in the air. 4. ECG/RESP module is damaged.	1. Stock the good electrode patch. 2. Replace the ECG/RESP module. 3. Re-plug RL electrode.
ECG waveform is abnormality or interfered.	1. The electrode connects error. 2. The AC does not connect the ground. 3. The electrode may hang. 4. Filter mode of ECG is error. 5. ECG/RESP module is damaged.	1. Connect the electrode right. 2. Adopt the three-wire power line. 3. Move the free electrode patch. 4. Select the right filter mode. 5. Replace ECG/RESP module.
No RESP waveform or abnormity.	1. The electrode connects error. 2. The patient move frequent. 3. ECG/RESP module is damaged.	1. Connect the electrode right. 2. Keep patient still. 3. Replace ECG/RESP module.
HR or ST is not correct.	The measurement bad connect.	Adjust the ECG electrode.
The value of TEMP is error	1. The probe connects badly. 2. The performance of probe is bad.	1. Re-fix the probe. 2. Replace the probe.
NIBP is not puff.	Air windpipe may be twisted.	Adjust the windpipe.
Sometimes, NIBP can be not measured.	The cuff is loose or the patient moves.	Keep patient still and adjust the cuff
The measurement error is large.	1. The size of cuff is not fit. 2. NIBP module is bad.	1. Select the correct size. 2. Replace the NIBP module.
No SPO_2 waveform	The probe or module of SPO_2 is damaged.	Replace the probe or module.

The SPO_2 wave is interfered.	1. The patient move. 2. The ray of ambience is too strong.	1. Keep patient still. 2. Weaken the ray of ambience.
Measurement of SPO_2 is not correct.	The patient may be injected staining material.	Before measuring, exclude the factor of the staining material

4.3 Periodic Check

1) The using life of the instrument is designed at 5 years.
2) Clean the instrument and accessories often.
3) Check the instrument once a year in its using life.
4) Calibrate all kind of parameters once a year in its using life.
5) Check the accessories once half a year in its using life.
6) If the instrument with battery hasn't been used for a long time, then it needs to be charged up once half a year at least. Otherwise, the battery performance will be affected or invalid. The means to charge up is that plug into the power socket for about 4~8 hours at least

Chapter 5 Basic instruction

5.1 Basic instruction

5.1.1 Functional Button

There are such below buttons from left to the right, when viewing from IRIS front panel:

(1)  (**START/STOP)** Power on/off button;

(2)  (**RECORDER)** Start/stop printing;

(3)  (**NIBP)** Start/stop the NIBP measurement;

(4)  (**MENU)** enter the system menu, the main set-up button for the system function

(5)  (**FREEZE)** Freeze/unfreeze the current waveform;

(6)  (**MUTE)** Mute/turn on/suspended the alarm sound

5.1.2 Screen Displaying

There are three parts on the screen: indication, waveform, and parameters field.

- Indication field

It is on the top side of the screen, can display the bed number, system time/date, indication information, and alarm information.

- Waveform field

This field can show 2 waveforms at most. On each waveform's top left, there is a name. When select these names by the knob, users can control the name, gain, and monitoring type. (All these control is limited to ECG waveform.)

- Parameter field

It is on the upper half of the front panel. Users can select the parameters by the knob, and enter into related menu, and operate each item on the menu to reach the demand.

5.2 Monitor Usage

Users should take the steps as below when take measurement:

1. Read carefully the user's Operation Manual
2. Check carefully the possible damages caused by transportation, and bad connection of power cable, ECG cable, NIBP cuff, SpO2 probe, slots, sockets, and ports.
3. Press the power on button, wait about 10 minutes, the screen will show: "Initializing the system, please wait..." And pls. Wait another 12 minutes, the monitoring picture and waveform will appear. If the power if off during the working process, the power indicator will extinguish, and the monitor stops working.
4. Check out all the function, and confirm the monitor is working normally, then put the cable/probe to the related body place of the patient. The IRIS will start the real-time monitoring.

Chapter 6 Cleaning

Warning:
But can not dip the liquid into the monitor.
Be forbidden the caustic chemical materials that will make erosion.

6.1 Clean

Wipe the instrument and the cables by a clean wet cloth, if wanted, usual cleanser or alcohol is available.

6.2 Sterilize

After cleaning, the ECG leads, SPO_2 probe, NIBP cuff and TEMP probe can be sterilized sometimes.

The material of sterilization can use alcohol (70%), formaldehyde (35%~37%) or javelle water (the concentration of chloros is 500ppm-5000ppm) .

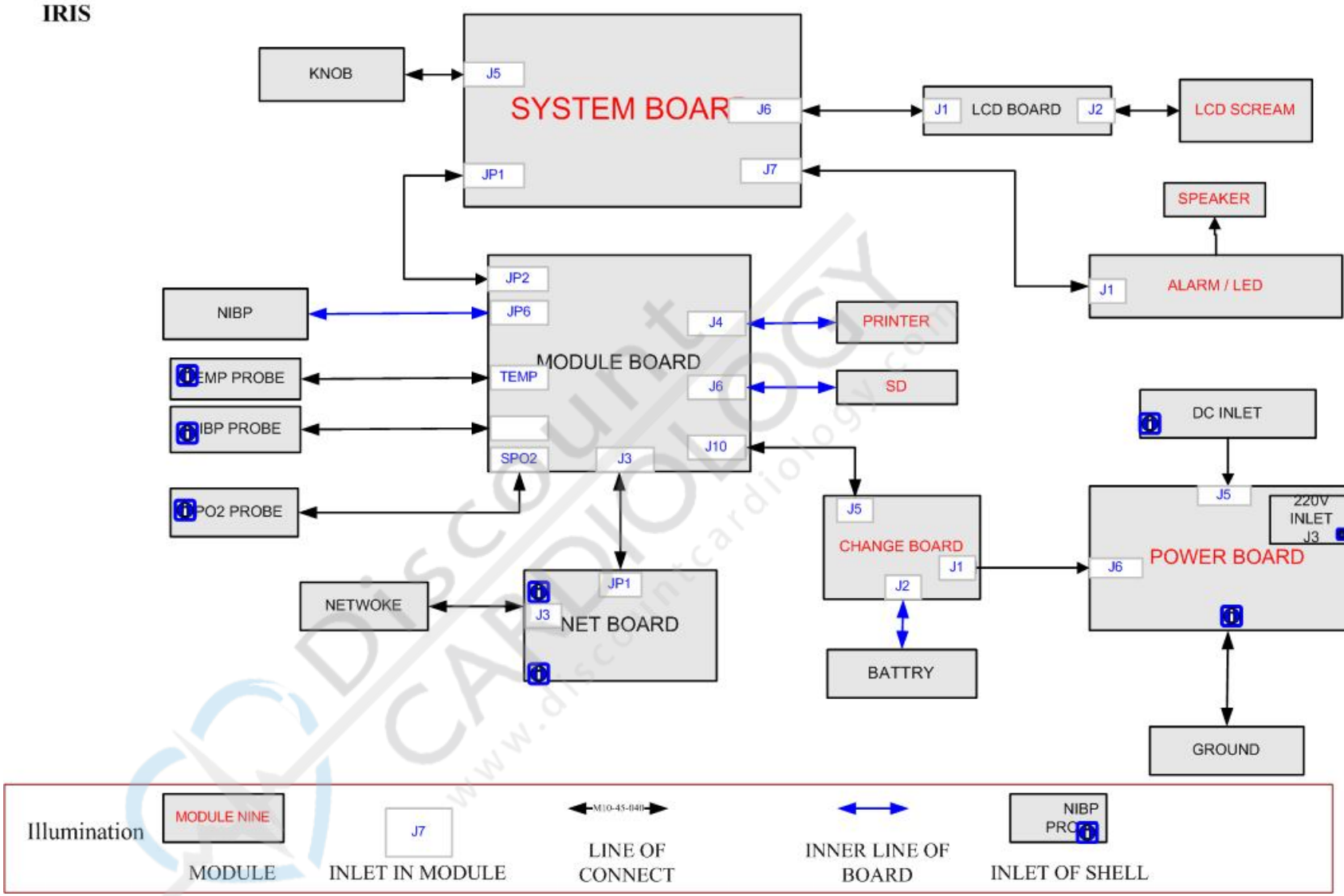
- The ECG leads can be sterilized by formaldehyde (35%~37%).
- The SPO_2 probe and NIBP cuff can be sterilized by alcohol (70%) or formaldehyde (35%~37%).
- The TEMP probe can be sterilized by javelle water (the concentration of chloros is 500ppm-5000ppm)

6.3 Disinfection

After cleaning, the disinfection can be done sometimes. But the process must be according to the hospital order.

Annex A Electric connect diagram

IRIS



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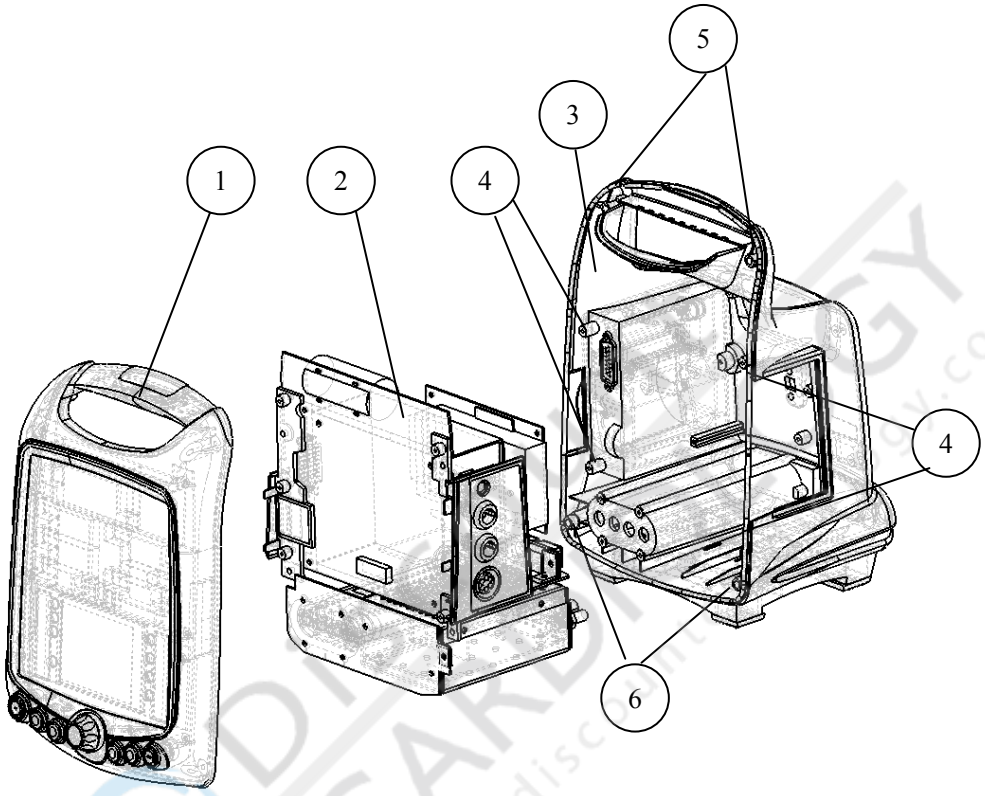
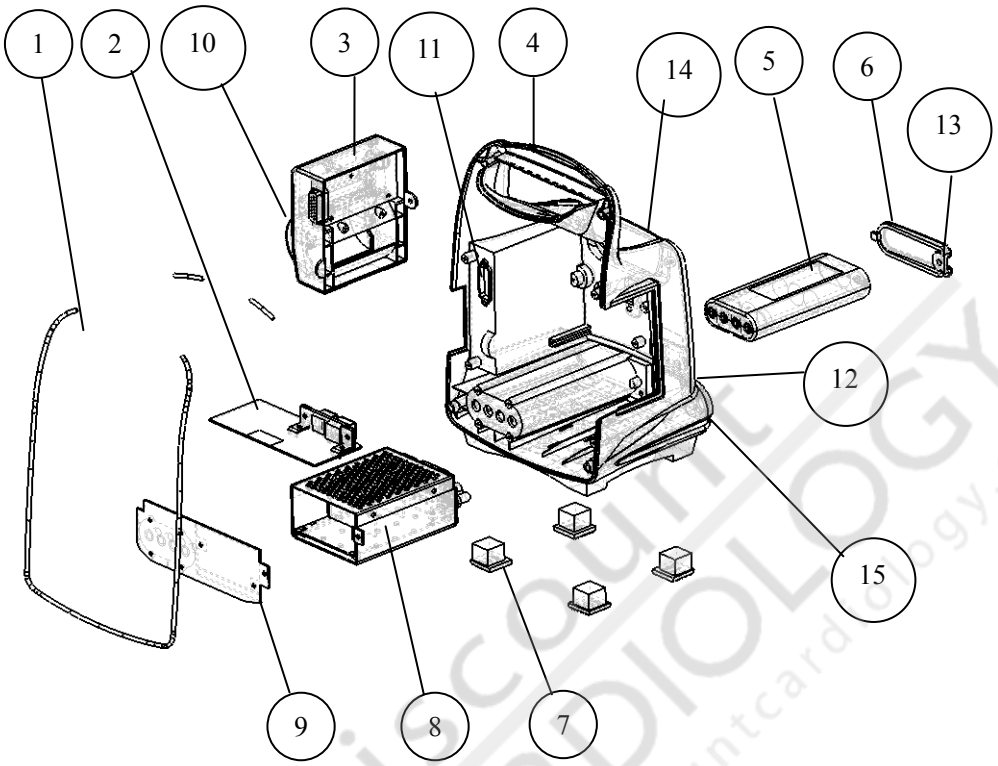
Annex B Electric diagram of modules

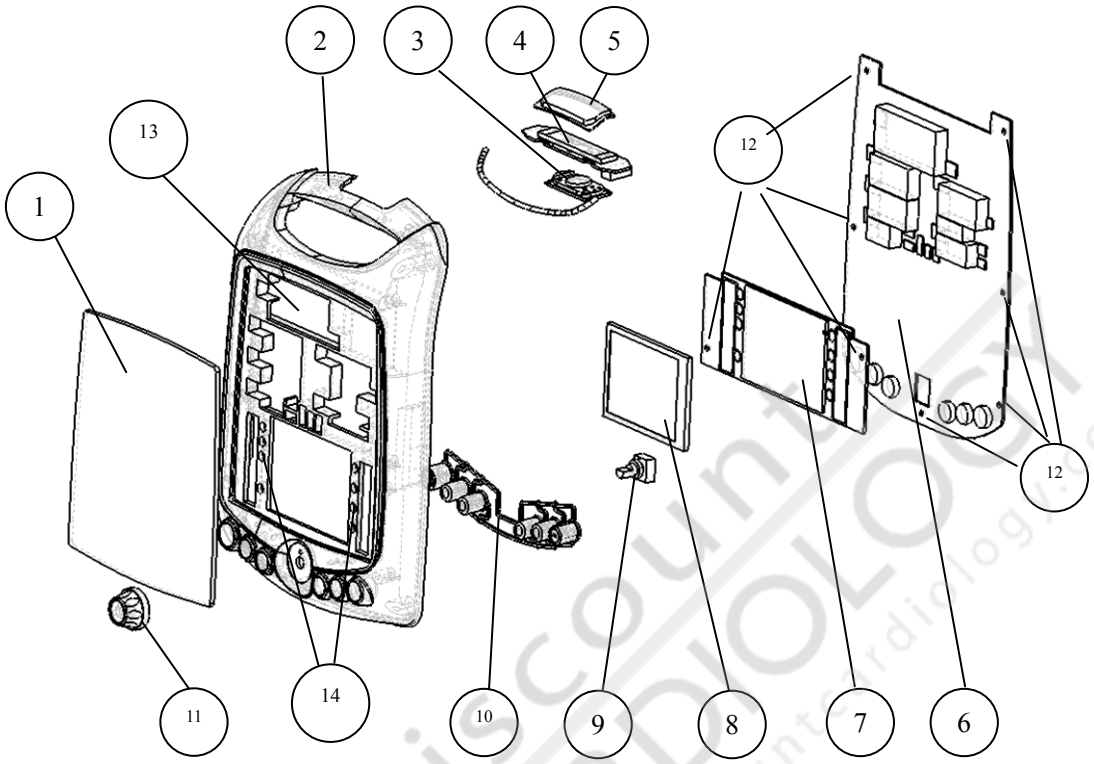
1、Host Assembly



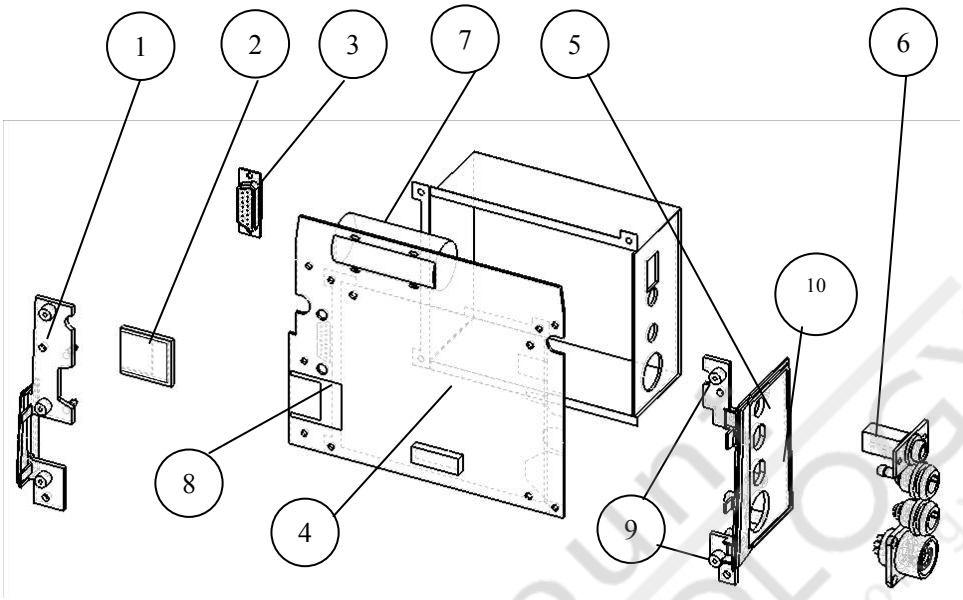
No	Std.Code	Name & Spec.	Qty.
1	M10-70-010	Front Housing Component	1
2	M10-07-000	Main Housing Component	1
3	M10-70-040	Rear Housing Component	1
4	GB/T 818-2000	Pan Head M3X6 Screws	4
5	GB819-M4*8	Pan Head M4X8 Screws	2
6	GB/T 823-1988	Pan Head M4X14 Screws	2



No	Std.Code	Name & Spec.	Qty.
1	M10-70-011	Front Housing Panel	1
2	M10-06-010	Network Interface Board	1
3	M10-55-000	Printer	1
4	M10-71-020	Rear Housing Cover	1
5	M10-92-020	Li-ion Battery	1
6	M10-70-062 M10-70-063	Li-ion Battery Shell	1
7	M71-01-020	Foot Pad	4
8	M10-05-010	Power Module	1
9	M10-03-010	Li-ion Battery Interface Board	1
10	M10-55-001	Print Paper	1
11	M10-92-050	Printer Slot	1
12	M10-71-032 M10-45-020	AC, DC Input	1+1
13	GB/T 845-1985	Self Tapping M3X8 Screws	1
14	M10-92-040	Name Plate	1
15	UL-F002	Functional Ground Port	1



No	Std.Code	Name & Spec.	Qty.
1	M10-70-011	Front Housing Facing	1
2	M10-70-010	Front Housing Cover	1
3	M10-04-010-1	Alarm and Optic-sense Eye Board	1
4	M10-04-010-2	Speaker Board	1
5	M10-70-050	Alarm Window	1
6	M10-01-010	Display and Key Board	1
7	M10-02-010	LCD Driver Board	1
8	G240320LTSW	LCD	1
9	M10-70-030	Knob	1
10	M10-70-020	Key	1
11	M10-45-010	Knob Head	1
12	GB41-M3	Screws & Nuts	9
13	7SEG3/0.8, 3*8	LED Digital Tube	7
14	SMDLED	LED Indicator Light	8



No	Std.Code	Name & Spec.	Qty.
1	M10-71-010	SD Card Interface Panel	1
2	SD-1GDB	SD Card	1
3	M10-55-001	Printer Interface	1
4	M10-07-010	Signals Process Board	1
5	M10-71-020	Signals Interface Panel	1
6	M10-92-013	ECG/SpO2/NIBP/TEMP interface	1
7	M00-06-020	Pump	1
8	M00-06-050	SD Card Slots	1
9	GB/T9074.5-2004	Screws	2
10	M10-92-010	Right Name Plate	1