NESO Patient Monitor

(PMSH-100, PMSH-200, PMSH-300)

OPERATION MANUAL

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General Warnings for Users

Caution:

Federal law restricts this device to sale by or on the order of a physician.

Warning:

All Users must read following warnings, cautions and guide before operating the Monitors. Our company will not be held responsible nor any warranties will be made by us for any abnormalities or malfunction of the monitor or body injury caused by the violations of the operational guides.

General Warnings

- The instrument is not a therapeutic instrument.
- This instrument must be operated under the direction of professional medical staff.
- All of the monitoring parameters are used as a reference and should not be used as the clinical diagnosis. For abnormalities, 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 ingress of liquid or electrical conductive substance into the instrument.
- Delete all the previous data when monitoring a new patient. Only one patient should be monitored at once.
- Please make sure all sensors clean and dry before attached to a patient.
- If monitor connects to the other instrument, the leakage current must be tested by qualified technician before use, and must comply with EN 60601-1.
- Many components may be attached to this monitor, but the entire unit, with accessories must comply with EN 60601-1.
- The connection must be proved no danger to the patient by the qualified technician before use. Tests and operations is required to be comply with IEC60601-1 and under the direction of the operation manual issued by the manufacturer.
- 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 kept away from patient’s throat to avoid asphyxia.
- In order to avoid of burning the patients, high frequency electrical bistouries cannot touch the electrode when used with the monitor.
- Local bleeding may be caused when using the blood pressure monitoring in patients with severe bleeding tendency. Be careful when using on patients with sickle cell disease.

- Do not place the SPO2 sensor onto the injured skin, edematous or fragile tissues.
- Discomfort or pain may be caused by the continuous use of the clip type SPO2 sensor especially in patients with microcirculation disorder. Do not place the sensor over 2 hours at the same place.
- EtCO2 cannot be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition.
- Non-disposable accessories should be sterilized before used on next patient to prevent cross infection.
- The instrument can only be opened or repaired by authorized personnel by manufacturer.
- Users may not be notified for changes of accessories.
- Use the battery provided by the manufacturer only. The manufacturer will not responsible for the possible consequences caused by the using of battery from other channels.
- Please deal with the package waste according to the local regulations.

⚠ Warnings and Notes Especially for Neonates

1、SPO2 Measurement

- **Caution:** SPO2 may be not obtained precisely because the neonate moves. To measure precisely, please keep the neonate at rest.
- **Caution:** Use the proper probe to neonate. Do not place the SPO2 probe on the fingers that have skin injury, edema or fragile. Do not place the probe on the same finger over 2 hours to prevent discomfort of the finger. Check timely and change the fingers when necessary.

2、EtCO2 Measurement

- **Warning:** Avoid direct contact between the EtCO2 probe and the infant's body, or an insulation material must be placed between the probe and the body.

About This Operation Manual

This manual is only for NESO series patient monitor manufactured by Better Life Medical Technology Co., Ltd. (here after referred to as BLMed).

This manual provides guidance to clinical staff on how to correctly operate the device.

The contents of this manual can be changed without notice.

The manufacturer reserves the right to change specifications or to cease the supply of any products without notice and without any obligation, and will not bear the consequences because of improper use the manual.

If necessary, please contact our customer service department, we will provide you with better service.

About Safety

BLMed is responsible for the safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by the manufacturer or authorized agent.
- The electrical installation of the relevant room complies with the requirements of the appropriate government regulations.
- The instrument is used in accordance with the instructions for use.

About Service

- Contact servicing to the manufacturer or the authorized service personnel only.
- The manufacturer or the authorized agents will provide telephone, email and other communication services.
- In addition to components expanse, payment for service may be required for some kind of services.
- Any unauthorized attempt to repair the instrument under warranty voids that warranty.
- Product’s serial number must be provided to the manufacturer for services.
- Under warranty, damages due to inartificial factors do not need to take any service expense and components expense.
- Under warranty, damages due to artificialness only need to take components expense and need not take any service expense.
- Outside warranty, damages due to artificialness need to take service expense and components expense.
- All boards and components that come from repair belong to the manufacture.
- Care should be taken in shipping the defective equipment to the manufacturer or the agent to prevent any damage due to shipment.

Terms for safety and symbols

Terms for safety

In this manual, **Warning, Caution, and Note** 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, equipment failure or data loss may be caused.

Note: Operational instructions or other useful information to help the users to operate the instrument correctly.

Symbols

The followings list of symbols may be used in this instrument.

CE	CE mark. It may be accompanied by the identification number of the notified body.
EC REP	Followed by the name of the authorized representative in the European Community.
	Symbol for “caution”.
	Symbol for “Follow instructions for use”.
SN	Followed by the serial number of the instrument.
	Followed by the manufacturer’s name and adress.
	Followed by the manufacture date of the instrument
	Symbol for “temperature limitation”.
	Symbol for “humidity limitation”.
	Symbol for “air pressure limitation”.
	Symbol for “do not reuse”, “single use”, “use only once”.
	Defibrillation-proof type BF applied part, on medical equipment to identify a defibrillation-proof type BF 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 exit of exhaust gas
	The symbol indicating separate collection for electrical and electronic equipment.

CONTENT

1 GENERAL DESCRIPTION

Note:

This manual contains information about the NESO(PMSH series) Handheld Patient Monitor.

All operators must read and understand this manual before using the monitor.

All information in this manual, including the illustrations, is based on a monitor with all optional configurations. If your monitor lacks any of these options, some information in this manual may not apply.

Caution:

Federal law restricts this device to sale by or on the order of a physician.

1.1 Scope

PMSH series handheld patient monitor applies to all clinical situations including ICU, CCU, EMS, Neonates and so forth with the continuous monitoring of Oxygen Saturation (SPO2) , Pulse Rate (PR), End-Tidal CO2 (EtCO2, FICO2) and Airway Respiration Rate (AwRR).

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1.2 Models and Configurations

The NESO (PMSH series) handheld patient monitor can be configured with the following physiological parameter monitoring modules: SPO2 and ETCO2. To meet with different application needs, some different combinations of these modules can be selected. The following table shows the selectable model configurations:

1.2.1 Product Name

The product name for the handheld patient monitor is **NESO.**

1.2.2 Models and Configuration

Brand Name	Model	Configuration Code	Standard Function Module
NESO	PMSH-100	H100(s)	SPO2
	PMSH-200	H200(e)	EtCO2
	PMSH-300	H300(se)	SPO2+EtCO2

The lowercase of the Configuration code indicates the optional function modules as below:

Code	Function	Description
s	SPO2	B / S / R = BLMed / Masimo-Set / Masimo-Rainbow
e	etCO2	MM / MS = Masimo Mainstream(IRMA) / Masimo Sidestream(ISA) AM / AS = AccuFlow Mainstream(SME) / AccuFlow Sidestream(SSI)

1.3 Product Features

Applied Patients: Adult, Pediatric, Neonatal
Structure: Handheld
Display: 3.5" color LCD with high luminance
Touch Screen: Resistive touch screen
Brightness: Brightness adjustment of 10 levels
User Interface: Auto switch of portrait and landscape mode. Display modes of different parameter combination.
SpO2: BLMed, Masimo Rainbow, Masimo Set optional
EtCO2: Mainstream and sidestream optional
Parameters Displayed: SPO2 Module：SPO2、PR
EtCO2 Module：EtCO2、FiCO2、AwRR
Waveforms Displayed: PLE, CO2
Trend Table Displayed: 15min、1H、4H、24 H、120H、720H
SIQ Displayed: Dynamic strip chart and waveform for SIQ
Data Storage and Review: at least 100 patients with tend data of 720 hours for each
Data communication: Can be connected to the bedside patient monitor or central station by Wifi (optional).
Indicator: Power light, charging light, alarm light
Sound: Heart beat/pulse frequency (fixed /adjustable), Alarm (3 levels)
Alarm Modes: Light, sound, message, flashing parameter
Alarm Record/Reviews: More than 3000 group of alarm events can be record and reviewed
Internal Battery: Removable lithium battery (3.7V, 2550mAh), over 6 hours of standby time
Power Interface: Adaptor: AC input (2-pins connector), DC output (connect to the desktop charger)
Desktop Charger: DC input (connect to the adaptor), charging output (connect to the main unit)
Main unit: charging input (connect to the desktop charger)
Signal interface: SpO2, EtCO2
Data interface: Micro-SD card (software upgrading and data import/export support)
Communication interface: optional internal Wifi
Fixation and protection: optional bumper, carrying bag, bracket for ambulance, bedrail bracket
IPX: IPX45, applied to the field application
Shockproof: Proved durable and reliable by the drop test from the height of 1.5m
Classification: IIb
Protection against electric shock: Internal power supplies of type I, BF
Standard complied: EN 60601-1
EN 60601-1-2
EN 60601-1-6
EN 60601-1-8
EN 60601-2-49
EN ISO 80601-2-61
EN 80601-2-55
EN ISO10993-1
EN 62304:2006
EN 62366
EN ISO 15223-1
EN 1041

1.4 Technical Specifications

1.4.1 Physiological parameters

PMSH Series Handheld Patient Monitor (NESO) can be configured with several function modules which supports the monitoring of the following physiological parameters:

Physiological Parameters	
SPO2	Saturation of Pulse Oxygen, Golden standard module supported. BLMed or Masimo SPO2 module is selectable.
EtCO2	End-Tidal CO2, Micro stream method.

Some of the function modules have several options to meet the special requirements of user.

For detailed parameters, please refer to appendix A.

1.4.2 Power and Interface specifications

Power and Interface specifications	
AC Supply (Charger input)	100~240VAC(±10%), 50/60Hz(±3Hz), 10VA
DC Supply (Charger output)	DC5V(±10%), 10VA
Internal Supply	Rechargeable lithium battery, DC 3.7 V (±0.5V), 2550 mAh, 9.4 Wh
Display	3.5” TFT LCD(320x480)
Input interface	SPO2, EtCO2

For detailed parameters, please refer to appendix A.

1.4.3 Environment Requirements

Parameters	Specification
Runtime Environment Requirements	
Temperature	0 ~ 50°C
Relative humidity	≤95% (non-condensing)
Air pressure	70kPa ~ 106kPa
Other	Drafty and without corrosive gas
Transportation and Storage Environment Requirement	
Temperature	-40°C ~ +70°C
Relative humidity	≤95%
Air pressure	16.5kPa ~ 106kPa
Other	Drafty and without corrosive gas

1.4.4 Size and Weight

Instrument	Size	78mm × 151mm × 24mm
	Weight	0.9 Kg / 240 g (main unit only)
Package	Size	285mm ×145mm × 98mm
	Weight	1.3 kg

1.4.5 Related instrument

PMSH series handheld patient monitor can be connected and used with the BLMed Central Monitoring Software. For further introduction and operation instruction, please refer to the operation manual of the related products.

1.5 Conformance Information

1.5.1 EMC

The equipment complies with all applicable and required standards for electromagnetic interference.

The safety and efficacy had been certified by the sold monitors. Though standards that the monitors accords with may not accord to the monitors had sold, the safety and efficacy do not be weakened.

For more detailed information about EMC, please refer to appendix B of this operation manual.

1.5.2 Harmonized Standards

This patient monitor complies with the following harmonized standards:

EN 60601-1
EN 60601-1-2
EN 60601-1-6
EN 60601-1-8
EN 60601-2-49
EN ISO 80601-2-61
EN 80601-2-55
EN ISO10993-1
EN 62304:2006
EN 62366
EN ISO 15223-1
EN 1041

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For more information, please contact BLMed or BLMed’s authorized agent.

2 INSTALLATION

WARNING:

- The instrument must be used under the direction of a professional medical person.
- The instrument can't be used in the environment with flammable or caustic gas.
- Avoid liquid or electric conducting material entering the instrument.
- The charger of the instrument use AC110V~240V, user must confirm the power before plugging into the power socket.
- The instrument must be connected to ground correctly and reliably.
- All the non disposable accessories must be sterilized before it is used for the next patient to prevent cross infection.

2.1 Instrument Installation

2.1.1 Unpacking and Checking

Take out the instrument and the accessories from the package carefully. Check the appearance first. If there are damages due to transportation such as the LCD panel is broken and the abnormal sound found when shaking the instrument, please do not plug into the power socket or try to open the instrument to examine or repair. Instead, contact the local dealer or the service department of BLMed immediately for help.

Caution:

Please take care of the instrument package. If the return factory repair is needed, the instrument should be well packed in the original package to avoid possible damages during transportation.

Check the accessories item by item with the reference of the packing list. If anything is found missing, please contact the local dealer or the service department of BLMed immediately for help.

Caution:

The instrument might be contaminated by microorganisms during the storage and transportation. Please make sure all the package of the accessories is intact. If any damage is found, please contact the local dealer and the service department of BLMed to confirm the availability of the item.

Do not use the disposable accessories with the broken package.

2.1.2 Installation of bracket

After the check of the instrument and accessories, the device can be placed on the flat table or fixed to the brackets.

There are various kinds of brackets provided by BLMed to fix the instrument to locations like ground, wall, and bed…For further introduction and installation instruction, please refer to the operation manual of the related products.

2.1.3 Connecting Accessories

Please insert the SpO2 sensor into the corresponding socket on the top of the instrument.

Confirm the right connection by plug in and pull out the sensor.

If any function is not needed, take off the related sensor or cable.

2.1.4 Connecting Power Source

Plug the output terminal of the DC power line into the input port of the desktop charger, and the DC input terminal into the 220V AC power supply

Caution:

- **The instrument cannot be used in the environment with inflammable gases or corrosive gases.**
- **The instrument should be protected from the liquid and conductive materials.**
- **The charger of the instrument should be used under the AC of 100-240. Please make sure the input voltage under the above range before plug into the power supply.**
- **The instrument should be earthed correctly.**
- **When connected to the patient with other devices, the connection must be proved no danger to the patient and environment by the qualified technician.**

Note:

Do not put the heavy stuff on the instrument.

When moving the instrument, please:

- **Power off and pull out the AC power line.**
- **Take care of the accessories to avoid the falling damages.**

2.1.5 Battery and Charging

If the instrument is configured with battery, the instrument will work with internal power of the battery if not connected to the DC power supply. If connected with the DC power supply, the instrument will work with the DC power and get the battery charged.

Caution:

- **If the instrument configured with a battery, please make sure the battery is well assembled and the back cover of the battery is tightly bitten.**
- **The instrument should be taken away from the charger or the pull out the DC power line when assemble and change the battery.**

The battery module is assembled on the bottom of the back cover. Make sure the instrument is taken away from the charger, or the DC power line is pulled out when disassemble the battery. Slide the buckle located on the bottom of the back cover to the right end, and both the cover and the battery can be removed.

When assemble the battery, the charging electrodes should match the contact pin of the charger. Push the battery into the battery jar and lock the back cover/

Insert the instrument into the slot of the desktop charger and plug into the DC power supply

to charge the battery. There are 3 status of the charging indicator:

Yellow: the DC power connected but charging not initiated

Green: Charging

Blue: Full of power

Considering the unique feature of the rechargeable battery, please get the battery charged at least once a half year, or the capability of the battery might be affected.

Caution:

- **The battery used for this instrument is the specified rechargeable battery with high capability. Do not use the battery not approved by BLMed, or the damages for the instrument might be caused.**
- **The short circuit, burning, excessive squeezing and disassemble of the battery might cause fire or explosion.**
- **Dispose of the used batteries according to the local environmental regulations or by handing over to the manufacture for recycling disposal.**

2.2 Description of the Appearance

2.2.1 Front Panel

Figure 2.1 Front Panel

Figure 2.1 shows the front panel of PMSH series Handheld Patient Monitor (NESO). The alarm indicator located on the left top of the panel used as the visible warning for alarms. The middle of the panel is the touch screen with all parameters, waveforms, operation menu and system status is displayed. On the bottom of the touch screen, there are three functional buttons which are: “Main Menu” button, “Alarm Mute” button and “Event Record” button.

2.2.1.1 Alarm Indicators

The alarm indicator turns different color (Red, Yellow, and Green) and flash in different frequency according to the different alarm level. For more information, please refer to the related description in Chapter 5 “Alarm Function”.

2.2.1.2 Touch Screen

The touch screen used for this instrument is the resistive touch screen. Please try using the solid stuff and touch by single point.

2.2.1.3 Functional Button

There are 3 functional buttons at the bottom of the front panel, defined as follows:

	MENU	Call out main menu of software
	MUTE	Mute or turn on or suspended the alarm sound
	REVIEW	Call out data review function

2.2.2 Power On/Off

A button located on the right side is the button used for power on and power off. When powered off, long press the power on/off button to start the instrument. When powered on, long press the power on/off button to shutdown the instrument.

2.2.3 Signal Interface

Figure2.2 Signal Interface on the top

Figure 2.2 is the description for the interfaces on the top of the instrument which are the sockets for the accessories.

Description for Symbols:

Anti-defibrillation BF Type (SpO2, CO2 module)

2.2.4 Battery Slot

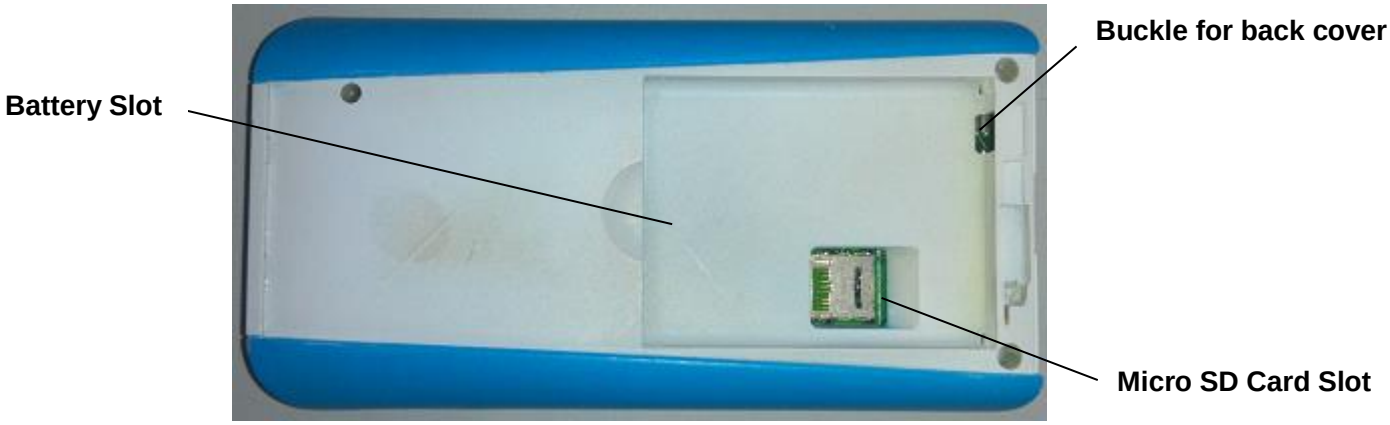

Figure 2.3 Rear Panel

Figure 2.3 shows the rear panel of the monitor.

The lower half of the real panel is the battery slot with the fool proof design. When the battery is incorrectly placed, it cannot be insert into the slot. In the battery slot located a MicroSD card slot which can be used for the storage of the monitor settings and patients' data by SD card.

2.2.5 Back Cover for Battery

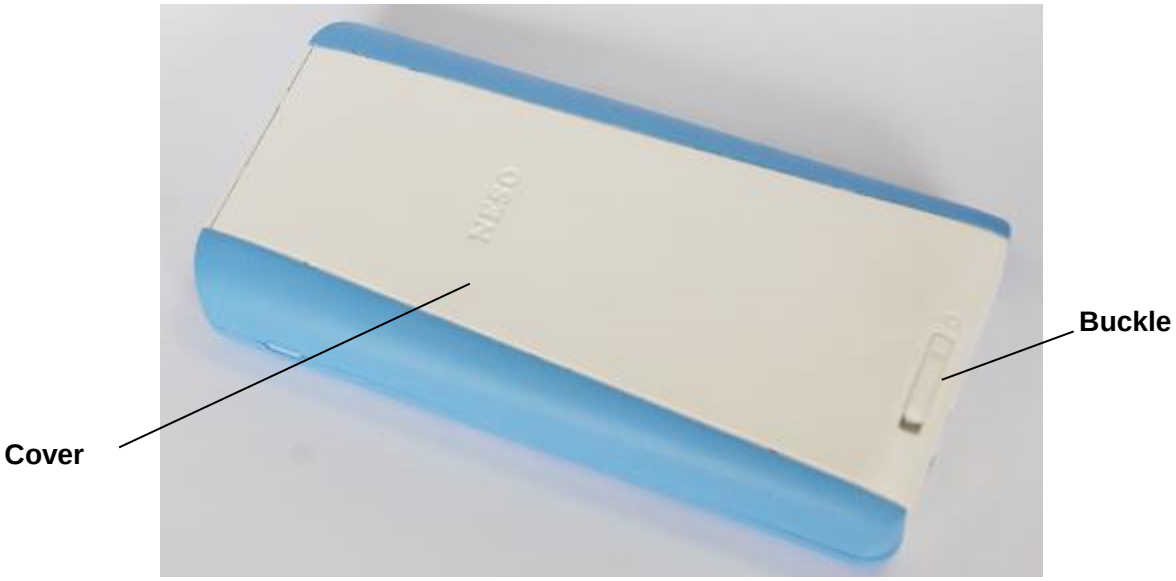

Figure 2.4 Back Cover for the battery

Figure 2.4 shows the back cover of the battery, including the nameplate and the brand information.

2.2.6 Desktop Charger

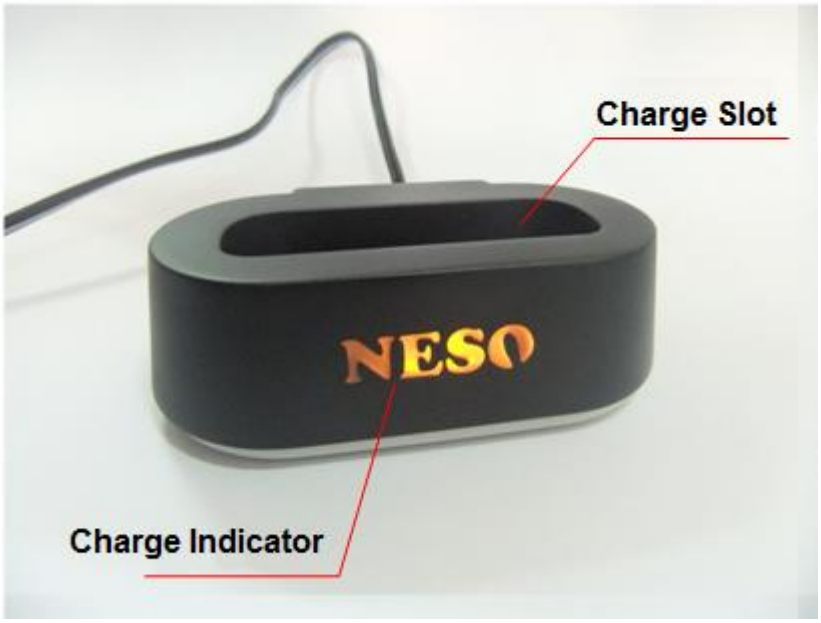

Figure 2.5 Desktop Charger

Figure 2.5 is the design of the desktop charger. When the charger is connected to the DC power, the charging indicator in front will turn yellow. When the monitor was inserted, the charging indicator turns green. When the battery of the monitor is full charged, the charging indicator turns blue. The bottom of the charger is a fixed slot used for the ambulance.

3 OPERATIONS

Please read the information in this chapter carefully so as to operate the instrument more effectively, to get more successful measurement, and to get more accurate results.

3.1 Power On and Power Off

Power on and power off function can only be operated when the instrument is insert into the charger or the battery still has power. When powered off, long press the power on/off button about 2-3 seconds until the power indicator lights to start the instrument. When powered on, long press the power on/off button until the monitoring pictures disappear to shutdown the instrument.
If the instrument has a internal power supply, the instrument will use internal power supply when not connected to the AC power and use the AC power supply and charge the battery when connected to the AC power.

Caution:

When the instrument using the internal power supply, it will automatically shut off when the internal power is used out.

3.1.1 Power On

Press the button "⏻" for several seconds, the indicator of the monitor will be lightened. The monitor begins its self-test. The main interface will be displayed after a few seconds.

The instrument will enter the monitoring status without any setting. The Phisilogical parameters like SpO2, PR and the waveforms like AwRR, CO2 can be displyed on the screen according to the modes preset.

Press the system"HOME" buttton to bring up the function menu for the setting of the parameters and data review.

3.1.2 Power Off

Please confirm whether the monitoring is finished and whether the patient date needs to be saved or eliminated before turning off the monitor.

Take off the cables and sensors connected between the patient and the monitor.

Press the button "⏻" for several seconds, until the monitoring pictures disappear to shutdown the instrument.

3.2 Monitoring Interface

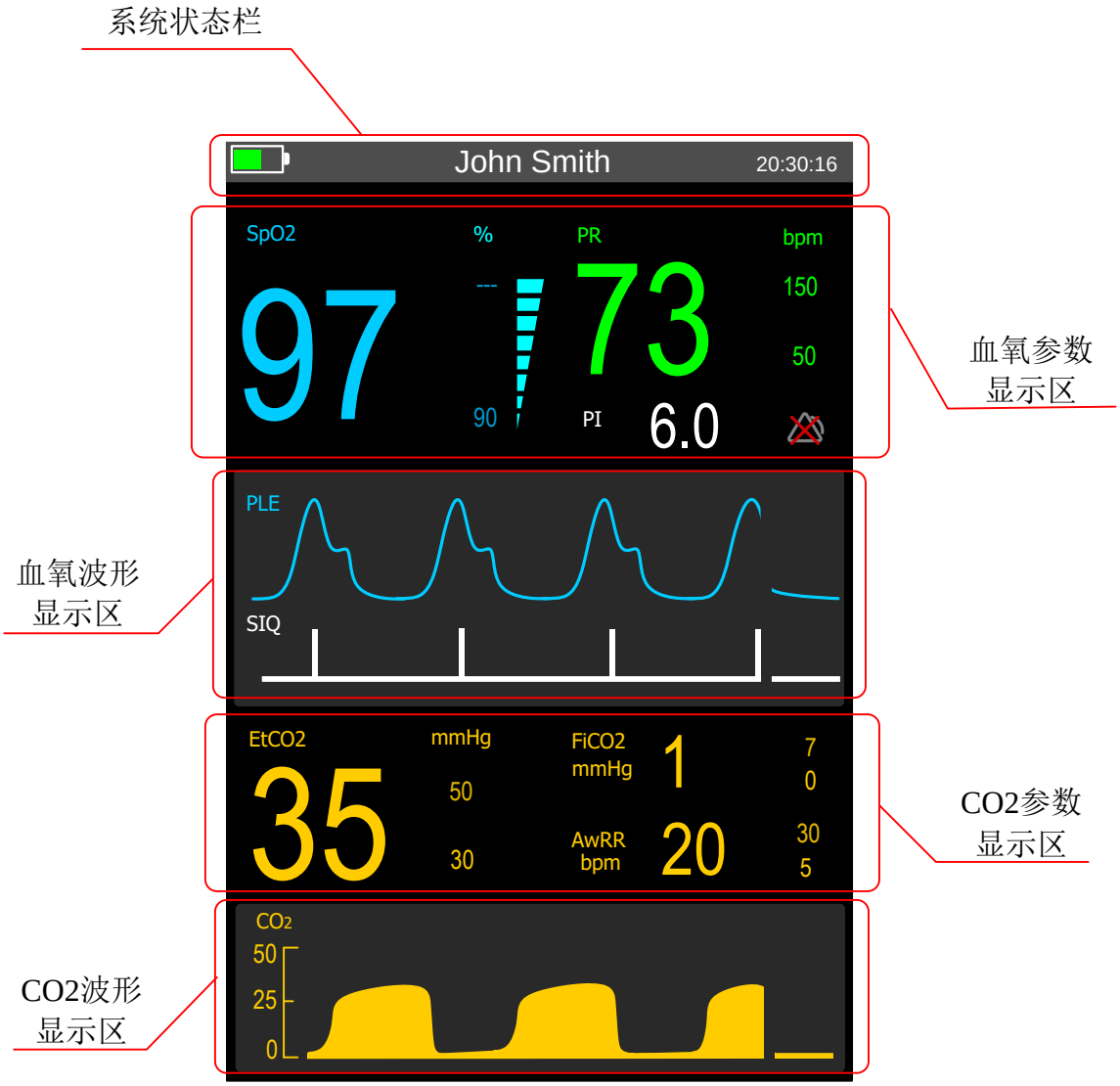

Figure 3.1 Monitoring Interface

Figure 3.1 shows the monitoring interface of the instrument.

The system status bar indicates the current time, battery power and paitent's name.

The display area of parameters shows the measured value, parameter name, unit, alarm limits and bar graph in the SpO2 display area.

The display arean of waveforms shows the waveform of the current measurement.

3.3 Patient Data Management

Caution:

When monitor a new patient, a new patient set up procedure should be finished to eliminate the date of the previous patient. Or the data might be mixed.

Click the "PATIENT" button in the navbar under the main menu to enter the patient setting interface, as showed in figure 3.2

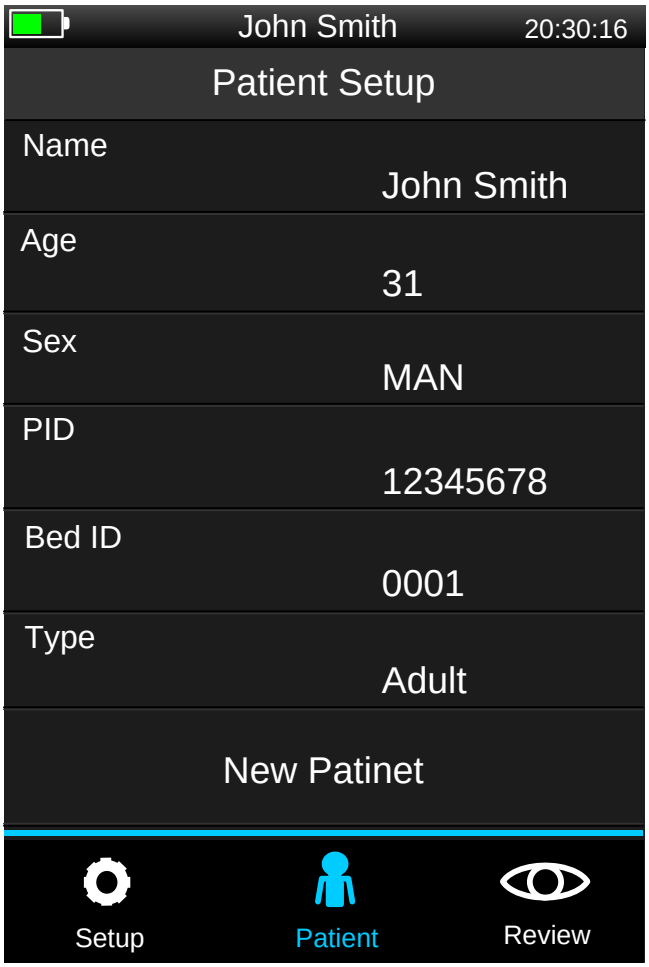

Figure 3.2 Patient Data Management

Under this interface, the user can input the patients' information like name, age, gender, patient number, bed number and patient type. Click the "new patient" can enter the new patient setup interface.

For more detailed description of patient data management, pls refer to the chapter4.1 "Patient Information Management".

3.4 Function Buttons

There are 3 function buttons for this instrument and can be defined as below:

Function Buttons	Descriptions
(MENU)	Call out main menu of software
(MUTE)	Mute or turn on or suspended the alarm sound
(REVIEW)	Call out data review function

3.5 Quick Reference Table

Main Menu

Menu	Description
SETUP	Enter the setup interface to set up all parameters and operations
PATIENT	Enter the patient information management interface to check, edit and operate the patients' data
REVIEW	Enter the data review interface to review the patients' data

SETUP

Menu	Description
SYSTEM	System setup like DATE, TIME, VOLUME…
SpO2	SpO2 setup like SpO2 alarm and SpO2 module
EtCO2	EtCO2 setup like EtCO2 alarm and EtCO2 module
ADVANCE	Setup by the developer, like the demo mode, system upgrading…

SETUP>System

Menu	Description
SYSTEM	System setup like DATE, TIME, VOLUME…
ABOUT	Check the current version information
DEFAULT	Reset the system to the factory settings
BACK	Back to the "setup" interface

SETUP>System > System

Menu	Description
TIME	Modify system time.
DATE	Modify system date.
LANGUAGE	Display system language
VOLUME	Set speaker volume including the alarm volume
BRIGHTNESS	Set the screen brightness
ALARM CTRL	Set the alarm response(alarm pause/ sound pause) for "MUTE"
PAUSE TIME	Set the interval time of alarm sound.
TECH ALARM	Start or close the technical alarm function

SETUP>System > About

Menu	Description
SOFTWARE	System Software Version
HARDWARE	System Hardware Version
RELEASE DATE	The release date of the system software
FACTORY	The name of the manufacturer

MODEL	The model of the patient monitor

SETUP>SpO2

Menu	Description
ALARM	Set the alarm of SpO2
MODULE	Set he SpO2 module
DEFAULT	Reset the SpO2 module and alarm to the factory settings
BACK	Back to the “setup” interface

SETUP>SpO2 > Alarm

Menu	Description
SpO2	Set the alarm switch, alarm level and the upper limit and lower limit of alarm
PR	Set the alarm switch, alarm level and the upper limit and lower limit of alarm
PI	Set the alarm switch, alarm level and the upper limit and lower limit of alarm

SETUP>SpO2 > Module

Menu	Description
AVERAGE TIME	Set the average data processing time
SENSITIVITY	Set the sensitivity of sampling
FREQUENCY	Set the frequency of sampling
FASTSAT	Set the switch of the FastSat mode
SMARTTONE	Set the switch of the SmartTone function
BEEP	Set the switch of the BEEP
SPEED	Set the sweep speed of the PLE waveform

SETUP>EtCO2

Menu	Description
ALARM	Set the alarm of EtCO2
MODULE	Set the EtCO2 module
DEFAULT	Reset the EtCO2 module and alarm to the factory settings
BACK	Back to the “setup” interface

SETUP>EtCO2 >Alarm

Menu	Description
EtCO2	Set he alarm switch, alarm level and the upper limit and lower limit of alarm
FiCO2	Set the alarm switch, alarm level and the upper limit and lower limit of alarm
AwRR	Set the alarm switch, alarm level and the upper limit and lower limit of alarm

SETUP>EtCO2 >Module

Menu	Description
WORK MODE	Set the working mode of the CO2 module: Measurement/Self Test/Sleep
SCALE	Set the scale range of the CO2 waveform: 0-30/ 0-50
BREATH OUT	Set the standard for the judgment of the respiration arrest
UNIT	Set the unit displayed: mmHg/ kPa
SetO2	SetO2 setup: high/ medium/ low
SetN2O	SetNO2 setup: high/ medium/ low
PERFORMZERO	Compulsive zero calibration

SETUP>Advance

Menu	Description
RUNNING MODE	Set operation mode of the monitor: monitoring/ demo
PASSWORD	Reset the password for advance setup
PASS CHECK	Set the switch of the authorization for alarm setting
UPGRADING	Upgrading the software version
BACK	Back to the “setup” interface

PATIENT>Patient Setup

Menu Item	Function Description
NAME	Set patient name.
AGE	Set patient age.
SEX	Set patient sex.
PID	Set patient ID
BED ID	Set bed number of the patient
TYPE	Set patient type: Adult/ Pediatric/ Neonates
NEW PATIENT	Set up a new patient and eliminate all data of the previous patient

REVIEW

Menu Item	Function Description
TREND	Trend review, like trend table and trend chart
ALARM	Alarm review, like alarm list
BACK	Back to the “setup” interface

4 WORKING STATUS SETUP

4.1 System Parameters Setup

The system menu of this instrument provides many setups for users by which the instrument can be adjusted to the particular status the user needed. Besides, the separate setup menu is available for each different module.

This chapter briefly introduces the method of setting the monitor working status by the system setup. The setup for each functional module will be introduced in the chapter introducing the functions of the monitor.

4.2 System Setup

Select **"SYSTEM"** under the "SETUP" menu to enter the system setting interface showed below in the Figure1.

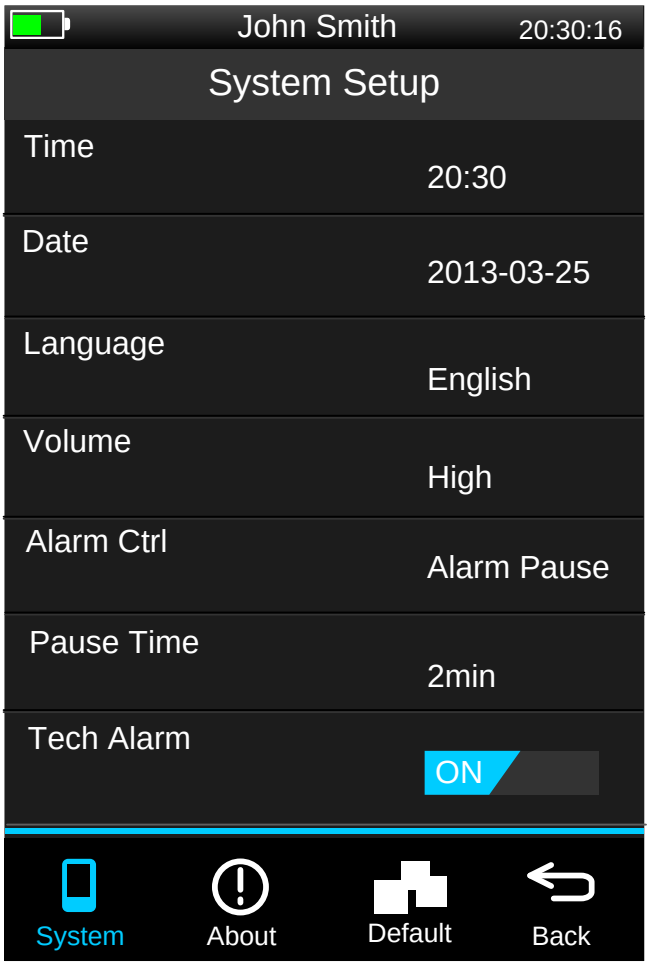

Figure4.1 System setting menu

Under the system setting menu, the following setups can be conducted:

Menu	Description
TIME	Modify system time.
DATE	Modify system date.
LANGUAGE	System language setup
VOLUME	Set speaker volume including the alarm volume
ALARM CTRL	Set the alarm response(alarm pause/ sound pause) for “MUTE”
PAUSE TIME	Set the interval time of alarm sound.
TECH ALARM	Start or close the technical alarm function
BRIGHTNESS	Set the screen brightness
DEFAULT	Reset the system setting to the factory settings

4.2.1 System Time

Caution:

The setup of the system time and date should be conducted when start the monitor, or the incorrect time and date might be provided when reviews the data with time and date related information.

4.2.2 System Volume

The “Volume” here not only indicates the “system volume”, but also the “alarm volume”

The volume rated in 5 levels: “0”、“1”、“2”、“3” and “4”, in which “0” means all sound is muted.

Caution:

When the alarm volume is muted (volume set to “0”), the monitor will not warn with sound if any alarm happens. Please use this function with great caution.

4.2.3 Alarm Ctrl

“Tech alarm” means to choose the response mode from “alarm pause” and “sound pause”. When an alarm happens, the monitor enters the “alarm status”, if the user press the “mute” button on front panel at this time, the monitor will response according to the setup of “tech alarm”.

For more information regarding the alarm, please refer to the chapter5, Alarm.

4.2.4 Pause Time

There are three options under the “alarm pause” and “sound pause” status:

1min/ 2min/ 3min

For more information regarding the pause time, please refer to the chapter 5, Alarm.

4.2.5 Tech Alarm

Set the switch the tech alarm function.

For more information regarding the alarm, please refer to the chapter 5, Alarm.

4.2.6 Default

When the user selects “default”, the interface as Figure4.4 shows will be pop up.

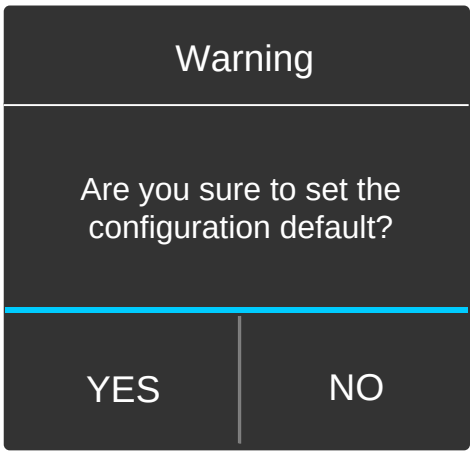

Figure4.2 Default

Choose “YES”, the setup for the current patient will be set to the default setup.

Choose “NO”, give up the current operation, and keep the original system settings.

NOTE:

When select any item under the default setting, a dialogue box will be pop up to confirm the operation. Choose “Yes” to confirm the operation and choose “NO” to give up.

Caution:

When choose “YES”, all settings will be replaced with the default settings.

4.3 About

Select “About” under “system setup” menu, the version information can be checked as showed in figure 4.3

Figure4.3 Version information

4.4 Patient Management

NOTE:

When monitor a new patient, a new patient set up procedure should be finished to eliminate the date of the previous patient. Or the data might be mixed.

Select “Patient” under the “Setup” menu to enter the “patient setup” interface as figure 4.4 shows below:

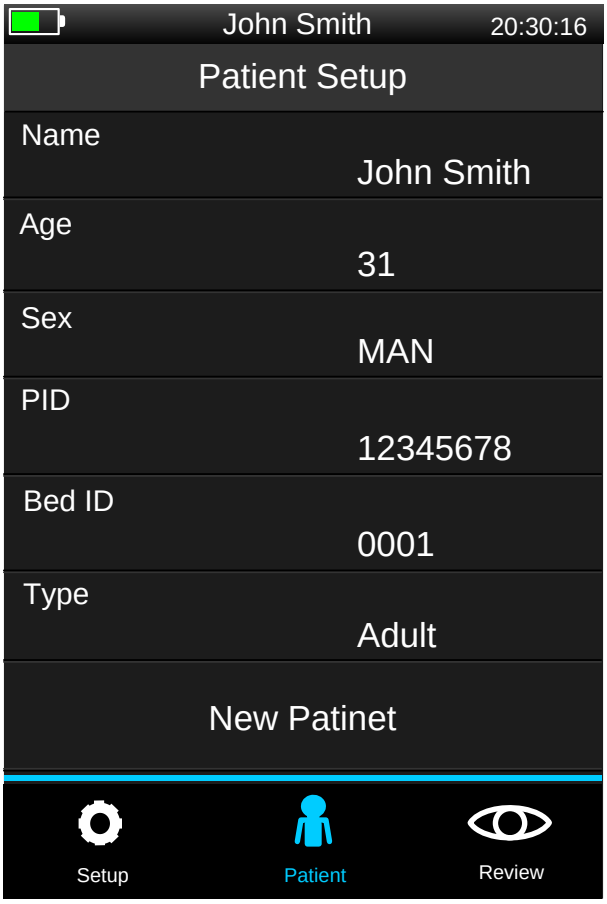

Figure4.4 Patient Management

Under the “patient setup” interface, the following settings can be conducted:

Menu Item	Function Description
NAME	Set patient name.
AGE	Set patient age.
SEX	Set patient sex.
PID	Set patient ID
BED ID	Set bed number of the patient
TYPE	Set patient type: Adult/ Pediatric/ Neonates
NEW PATIENT	Set up a new patient and eliminate all data of the previous patient

Select “New Patient” to enter the new patient setup interface as figure 4.5 shows below

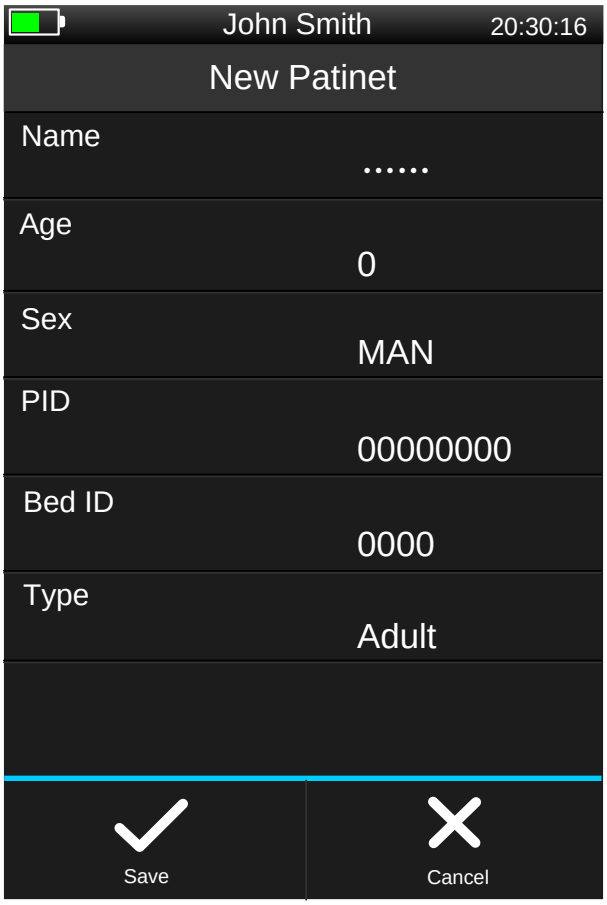

Figure4.5 New Patient Setup Interface

Select “Save” to delete the data of the current patient and save the data of the new patient;

Select “Cancel” to keep the data of the current patient and back to the patient setup interface of the current patient.

NOTE:

If select “Save”, the data of the current patient will be saved to the SD card and deleted from the system memory.

4.5 DEMO

The Demo function is designed for the manufacturer to demonstrate the performance of the instrument and help the user with the product training. The function allows the demonstration of all functions without the actual patient and the waveforms and data shows under demo are all created by the system automatically.

During the clinical uses, the demo function is forbidden to use. Considering the medical staffs may mistaken the data shows under the demo mode for the patient data under monitoring and delay the diagnosis and treatment, the user need a password to enter the demo function.

Select “Advance” under the “Setup” interface and enter the “Please input the password” interface as figure 4.6 shows below:

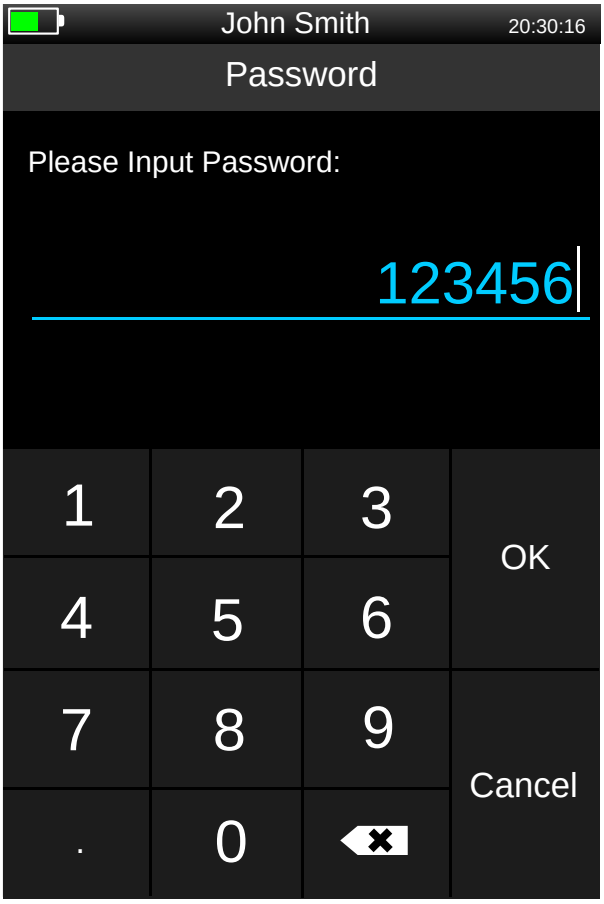

Figure4.6 Password input

The user can only enter the “advance” interface after input the correct password.

Select “demo” after enter the “Running mode” interface under “advance” menu

Figure 4.7 Advance Setup

Then the main interface will turn to demo interface.

After enter the demo mode, the information “demo” will displayed on top of the interface as showed below to indicate the current status.

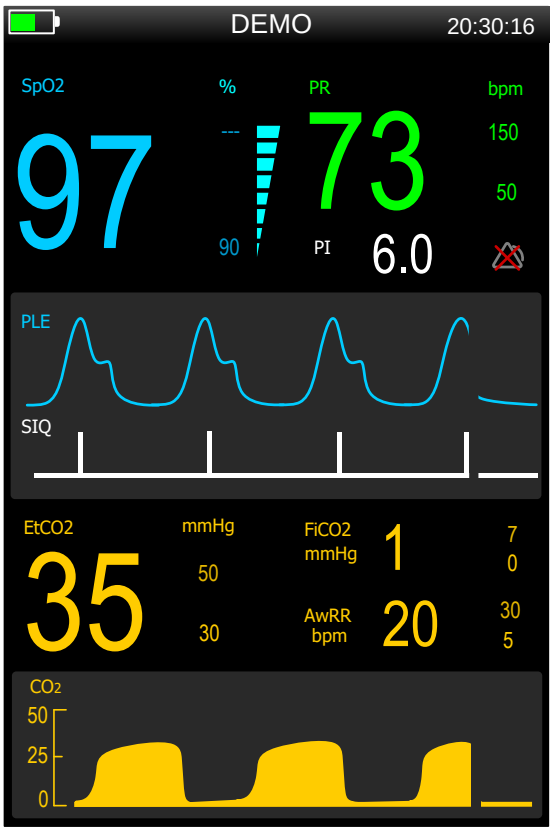

Figure 4.8 Demo Interface

5 ALARMS

- This chapter introduces the general documents related to alarm and the measurement should be taken when alarm happens.
- The user could learn more information regarding the parameter alarm and the alarm prompt in each chapter describe parameter settings.

5.1 Alarm

The alarm means the warning of the monitor to the user when any changes of vital signs or any malfunction of the instrument which might cause the failure monitoring.

The alarm system of the instrument is classified into two classes: Technical Alarm (TA) and Physiological Alarm (PA).

TA is a signal that indicates the instrument or parts of the monitor, which is not capable of accurately monitoring the patient's condition, such as SPO2 probe off, blood pressure measure failure, etc.

PA is a signal, which indicates the patient's physiological parameters abnormal. Such as rhythm of the heart overflow, SPO2 overflow, premature, etc. And it also indicates that a monitored physiological function is out of specified limits or indicates an abnormal patient condition, such as rhythm of SPO2 overflow, etc.

Below are some examples for TA and PA:

Status of the Patient or Monitor	Alarm Type
PR measured is 114BPM which exceed the preset PR alarm limit	PA
SpO2 measurement is 88% which is lower than the preset alarm limit	PA
SpO2 sensor off	TA
EtCO2 module failure	TA

5.1.1 Technical Alarm

Technical alarm means the instrument detect the technical failures like sensor off, etCO2 malfunction, and so forth.

5.1.2 Physiological Alarm

Physiological alarm means the instrument detect the abnormal parameters of the patient, like over-limit PR and over-limit SpO2.

5.1.3 Alarm level

Each alarm, no matter TA or PA has its level specialty. The higher alarm level means more apparent system alarm method of warning. The user can not change the setup of all TA level but some of the PA level can be set by the user except the ones specified by the system and not allowed to be changed.

5.2 Alarm Indicators

When alarm occurs, the instrument will indicate users by visual and auditory alarm. There are three types of alarm indicates.

Auditory: Alarm speaker send audio alert. The volume can be adjusted. In accordance with different audio frequency and duration, users can distinguish whether the alarm is PA or TA.

Visual: The alarm signal and parameter will display in relevant area. In PA, the related parameter will flash to increase the marked degree.

Assistant visual: Alarm lights. There is an alarm light on the top of the instrument. When PA occurs, they will glitter to arouse attention.

Caution:

When more than one alarm rated in different levels happens, the monitor will choose the alarm with the highest level to indicate the user.

5.2.1 Sound Alarm Features and Light Alarm Features

6-2 Sound Alarm Features and Light Alarm Features in Different Levels

ALARM LEVEL	SOUND FEATURE	LIGHT FEATURE
HIGH	“toot-toot-toot---toot-toot-------toot-toot-toot---toot-toot”，Sound every 9.3 seconds.(The interval calculated from the sound start to the next sound start)	Alarm light flash in red with high frequency
MEDIUM	“toot-toot-toot”， Sound every 25 seconds.(The interval calculated from the sound start to the next sound start)	Alarm light flash in yellow with high frequency
LOW	“toot-”， Sound every 25 seconds. (The interval calculated from the sound start to the next sound start)	Alarm light keep in yellow with no flash

5.2.2 Visual Alarm Features

Background color: Red for high level, yellow for both medium level and low level.

Color of the string: Always black regardless the alarm level. When the parameter measured exceeds the preset alarm limit and cause an alarm, the value of the parameter will start flashing. And the information in black with yellow background will show up on top of the screen for both low level and medium level alarm. The “*”、“**”and“***” shows before the alarm information indicated the low , medium, high alarm. If the alarm is a technical alarm, it will be indicated in the windows of the waveform without “*” before the alarm imessage.

5.3 Alarm Status

5.3.1 General

There are two statuses for each alarm: trigger status and cleared status

The alarm can only in one status at one time.

Trigger status: the status when the alarm exist

Cleared status: the status when the alarm not exist

All possible alarms will be in cleared status when the instrument initially started. During the following working time, when meet the conditions for alarm, it enters the trigger status.

For the whole alarm system (all alarms), there are following status:

Normal Status: means all indications (sound, light and message) started when an alarm is triggered.

Pause Status: means the indications (sound, light and message) not started when an alarm is triggered.

The whole alarm system can only in one status at one time.

5.3.2 Alarm Pause

Under the alarm pause status, the system will be set as below:

Stop all alarm sound and light indication.

Stop all message indication for physiological alarm.

Show the rest time for alarm pause in the display area of physiological alarm description

5.3.3 Status Switching

Under the normal status: Select “MUTE” to enter the alarm pause status.

Under the alarm status: Select “MUTE” to enter the alarm pause status.

Under the alarm pause status:

(1) Select “MUTE” to enter the normal status.

(2) If not select “MUTE”, the system will enter the normal status after the pause time.

(3) If any new TA happens under the pause status, the system will be back to the normal status.

(4) If any new PA happens under the pause status, the system will be back to the normal status.

5.4 Alarm Setup

Select “System” under the “setup” menu, the system will enter the interface as figure 5.1 shows. We could conduct the general alarm setup under this interface.

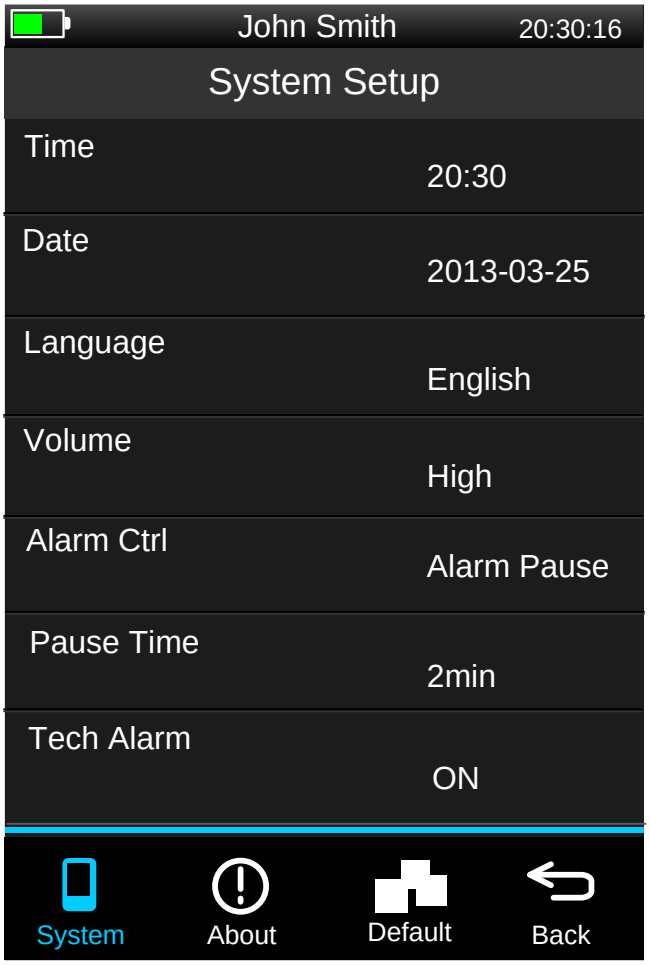

Figure5.1 Monitor System Setup

Genera Alarm Setup

- Alarm limit display: The user will see the preset alarm limit in the parameter display area when select “on”.
- Alarm record time: 3 options: 8 seconds/ 16 seconds/ 32 seconds.
- Alarm pause time: 3 options: 1min/ 2min/ 3min
- Alarm Volume: Indicate the sound volume when alarm happens.

  5 options: 0/ 1/ 2/ 3/ 4

Alarm setup for each parameter

The alarm setup for each parameter can be conducted under the related module setup menu. For more detailed information, please refer to the related chapters introducing alarm setup of different modules.

5.5 Parameter Alarm

The parameter alarm can be set separately under the related parameter menu. The user may set the alarm limit and alarm status.

When a parameter alarm is closed, a  will be displayed beside this parameter in the parameter display area. The user could set the parameter alarm for each separate parameter.

For parameters set with an alarm, when the value measured of one or more parameters exceed the alarm limit, the monitor will alarm automatically and proceed as below:

1) Indications on the screen, the mode as mentioned in the alarm indicators
2) Sound in accordance with the preset alarm level and alarm volume.
3) Light flashing in accordance with the alarm level.

5.6 Measures after Alarm

NOTE:

When an alarm happens, the patient should be the first to be checked.

The alarm information displays in the system information area and the corresponding measures should be taken according to the alarm mode and the alarm reason

1) Check the patient
2) Recognize the alarm parameter or the type of alarm
3) Find the alarm reason
4) Alarm mute if needed
5) Check the alarm status after the alarm disappears

The alarm information and the alarm indications can be find in separate parameter monitoring chapters.

5.7 Alarm Details

5.7.1 Physiological Alarm (PA)

INDICATION	CAUSE	ALARM LEVEL
SpO2 Module		
High SPO2	SpO2 exceeds the high limit	selectable
Low SpO2	SpO2 under the low limit	selectable
High PR	PR exceeds the high limit	selectable
Low PR	PR under the low limit	selectable
High PI	PI exceeds the high limit	selectable
Low PI	PI under the low limit.	selectable
Cardiac Arrest	SpO2 signal not detected for long time	advance
CO2 Module		
High EtCO2	EtCO2 exceeds the high limit	selectable
Low EtCO2	EtCO2 under the low limit.	selectable
High FiCO2	FiCO2 exceeds the high limit	selectable
Low FiCO2	FiCO2 under the low limit.	selectable
High AwRR	AwRR exceeds the high limit	selectable
Low AwRR	AwRR under the low limit.	selectable
Asphyxia（CO2）	Patient stop breathing	advance

5.7.2 Technical Alarm (TA)

INDICATION	CAUSE	LEVEL	MEASURES
SpO2 Module			
Sensor Off	SpO2 Sensor fall off from the patient or the patient monitor	low	Make sure the sensor connected to the monitor and placed appropriately on the patient figure or other positions
Module Initialization Error	SpO2 module error	high	Stop the SpO2 monitoring and inform the biomedical engineer or the service department of the company to solve the problem
Module Communication	SpO2 module error or communication error	high	Stop the SpO2 monitoring and inform the biomedical

Failure			engineer or the service department of the company to solve the problem
CO2 Module			
Module not Connected	Module not successfully connected to the patient monitor	high	
Software Error	CO2module error or communication error	high	Stop the EtCO2 monitoring and inform the biomedical engineer or the service department of the company to solve the problem
Hardware Error	CO2module error or communication error	high	Stop the EtCO2 monitoring and inform the biomedical engineer or the service department of the company to solve the problem
Over Speed Motor	CO2 module error	high	Stop the EtCO2 monitoring and inform the biomedical engineer or the service department of the company to solve the problem
Factory Calibration Value Lost	CO2module error	high	Stop the EtCO2 monitoring and inform the biomedical engineer or the service department of the company to solve the problem
Change the Adaptor			
Sampling Line Clogs			
No Adaptor			
No Sampling Line			
O2 interface Error			
Over the Specified range			

6 SpO2 MONITORING

This chapter describes the operation of SpO2 monitoring function in details.

NOTE:

- **The SpO2 function of this monitor will be not suggested to used for the SpO2 monitoring for apnea monitor**
- **Do not monitor SpO2 in the environment with mixed gases like flammable anesthetic, nitrous oxide and the oxygen-enriched environment.**

6.1 SPO2 Monitoring Description

6.1.1 The Definition of SpO2 Monitoring

SpO2 measures the arterial oxygen saturation which means the percentage of the oxyhemoglobin.

6.1.2 Measuring Method

SPO2 monitoring is a non-invasive technology. SPO2 and pulse rate is measured by the measurement of absorbability of wave with special wavelength. The LED of the probe emits light through the tissue, and the light is detected by the sensor that changes it to electrical signal. The monitor disposes the signal and displays the pulse wave, SPO2 and pulse rate on the main interface.

Normally, there is relation between oxygen parameter value and pulse waveform. Typically good SPO2 wave as follows. (Figure 6.1)

Figure 6.11

Principles of operation

The oxygen saturation (SpO2) is measured with a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side. The sensor measurement wavelengths are nominally 660nm for the red LED and940nm for infrared LED. The maximum optical power output for LED is 4 mW.

The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time regularly, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to calculate the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate value.

Caution:

The SpO2 value can be overestimated in the presence of Hb-CO, Met-Hb ot dye dilution chemicals.

SpO2 measurement

- SpO2 Value and plethysmography waveform can be displayed on the main screen.
- SpO2 mentioned in this menu indicate the oxygen saturation (SpO2) measured by non-invasive method.

Caution:

ES (Electrosurgery) equipment wire and SpO2 cable must not be tangled up.

Do not put the SpO2 sensor on extremities with arterial catheter or venous sytinge.

NOTE:

Do not perform SpO2 monitoring and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the SpO2 reading.

- Make sure the fingernail is just opposite to the light emitted from the sensor.
- Place the SpO2 sensor cable at the backside of the patient hand.
- SpO2 waveform is not proportional to the pulse volume

Caution:

- **Check if the sensor is in normal condition before monitoring.**
- **After unplugging the SpO2 sensor cable from the connector of the monitor, the system shall display the alarm message “SPO2 Sensor off” and give the audible alarm.**
- **Do not use the SpO2 sensor once the package or the sensor is found damaged.**
- **During prolonged and continuous monitoring, check the sensor placement regularly to ensure proper attachment, and move to another location if the skin deteriorates. More frequent examinations may be required for different patients, like neonates and patients of poor perfusion or skin sensitive to light.**

6.1.3 Measurement Limitations

Caution:

- **Do not place the blood oxygen probe on the fingers with injured skin, edema or fragile finger.**
- **Do not to place the probe on the same finger over 2 hours to prevent the finger discomfort.**
- **Use the neonatal SPO2 probe to measure the neonatal blood oxygen.**

In order to achieve more accurate SpO2 measurements and PLE, the user should pay attention to the following:

- Use probes specified by the manufacturer.
- The clip should be placed on the finger correctly, do not reverse the placement (see Figure 6.2), otherwise the measurement result will be incorrect.

- The light between the blood oxygen saturation sensor and the light-electric receiving tube must pass through the small artery bed of the patient.
- Avoid placing the blood oxygen probe to the same limb with artery catheter, blood pressure cuff or venous infusion.
- Improper fixing the probe with band will cause the venous pulse that induces the incorrect value.
- Do not place things like band to hinder the light way in the probe.
- Strong environmental lighting will affect the blood oxygen test, such as fluorescence light, double ruby light, infrared heater or direct sunshine.
- If the patient move intensely and there is interfereance by an electrosurgic, it will affect the accuracy.
- If blood oxygen monitoring is not wanted in the monitoring processes turn off this module in system setting. After turning off this module, neither shows the pulse waveform nor measures the blood oxygen value.

Inaccurate Measurements may be caused by:

- The measurement may be incorrect. It may be due to patients or mechanical influence. The conditions include but not limit to: vein beat, low blood pressure, serious anemia, low temperature, shock, tight sensor.
- Interfering substance may lead to incorrect SPO2 reading
- incorrect sensor application or use

Caution:

Considering the MRI Interference, do not monitoring SpO2 during MRI. The induced current might cause the skin scalding.

NOTE:

In following cases, their measurement should be limited:

1. Since the measurement is based on the small artery pulse, minimum artery flow is required. The weakness of the pulse or the micro-circulation disorder due to shock, cool, too low body temperature, massive hemorrhage or vasoconstrictor will decrease the pulse wave, and make the measurement more sensitive to the interference; Too much dye agent (methylene-blue, indocyamine, indigo carmine), carboxyhemoglobin (COHb), methionine (Me+Hb), sulfhemoglobin in body or in some patients with jaundice, the value may be incorrect when use this machine.
2. Drugs such as dopamine, procaine, prilocaine, lidocaine and buzucaine may induce bigger blood oxygen measurement deviation.
3. Patents with Parkinson’s disease.
4. In patients with anemic hypoxia and toxic hypoxia, the pulse blood oxygen is only of reference value, for in some severe anemic patients, their blood oxygen value may also be quite normal.

6.2 Preparation

6.2.1 SpO2 Sensor selection

Caution:

- **Use the sensor provided by the manufacturer or authorized agency.**
- **The normal lifetime for the SpO2 sensor is one year.**
- **Use the particular adhesive SpO2 sensor for neonates. Choose from finger wrap SpO2 sensor and finger clip SpO2 sensor for pediatric and adult.**

6.2.2 Sensor Placement

- Connect the cable end of the sensor to the monitor.
- Place the finger sensor as figure6.2 shows
- Do not place the blood oxygen probe on the fingers with injured skin, edema or fragile finger.
- Do not to place the probe on the same dinger over 2hours to prevent the finger discomfort.
- Make sure the cables of the sensor is not tangled up.

Caution:

Before the monitoring, the function of the SpO2 should be checked carefully. If the screen shows “sensor off” when the sensor is disconnected, the function is working normally.

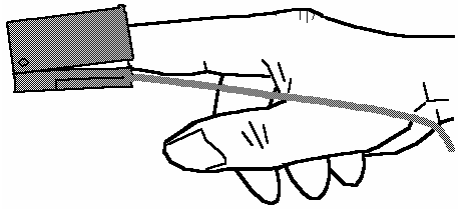

Figure6.2 Sensor Placement

Caution:

Place the SpO2 sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.

6.3 Parameters and Pulse Waveform

The display window of the SpO2 monitoring is as figure 6.3 shows:

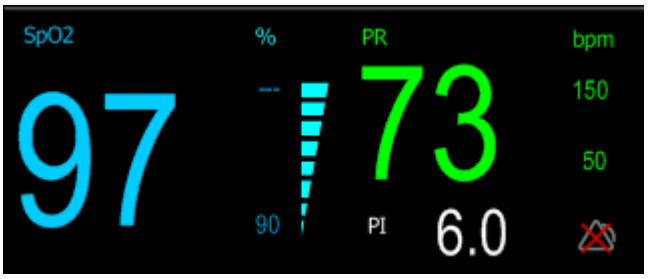

Figure 6.3 SpO2 Display

Description:

Each parameter has a name, unit and alarm limit;

Different parameter marked with different color: Blue for SpO2, Green for PR, White for PI;

When the alarm function of a parameter is closed, "  " will be displayed the corresponding alarm limit area;

The triangle ladder icon displayed in the middle is the pulse force icon which changes with the dynamic pulse force changes.

The SpO2 waveform is as showed in figure 6.4 below:

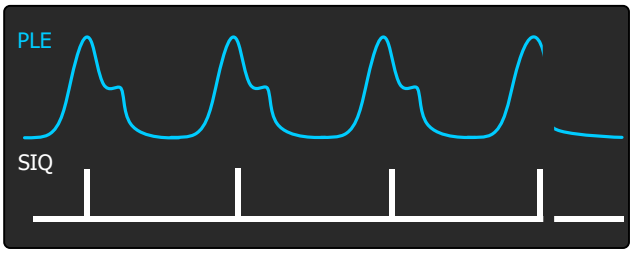

Figure6.4 SpO2 Waveform Display

6.4 SpO2 Parameter Setup

Select "SpO2" under the "Setup" menu to enter the SpO2 parameter setup interface. There are two setups for SpO2 parameter setup which are "Alarm setup" and "Module setup"

Caution:

If the high limit of the SpO2 alarm is set to 100%, it means the high limit alarm closed. Since the high SpO2 might lead to the retrolental fibroplasias disease to the premature infant, the setup of the high limit of SpO2 should be careful and in accordance with the acknowledged clinical practice.

6.4.1 SpO2 Alarm Setup

Select "SpO2" under the "Setup" interface to enter the SpO2 alarm setup interface as the figure 6.5 shows below:

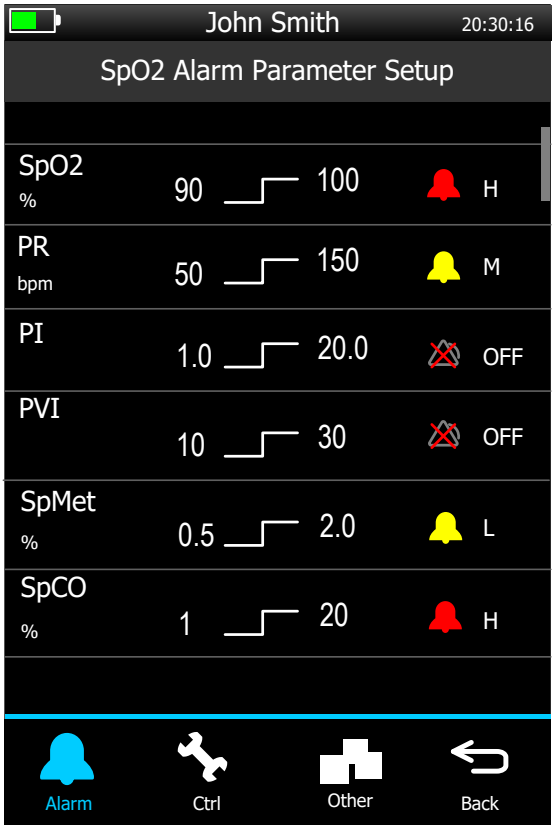

Figure 6.5 SpO2 alarm

This interface displays the parameter name, current unit, low limit of alarm, high limit of alarm, alarm level and the alarm status (the alarm function is closed when the alarm level shows “OFF”) of the parameter need to be set. Select any of the parameter to enter the parameter alarm editing interface as the figure 6.6 shows below:

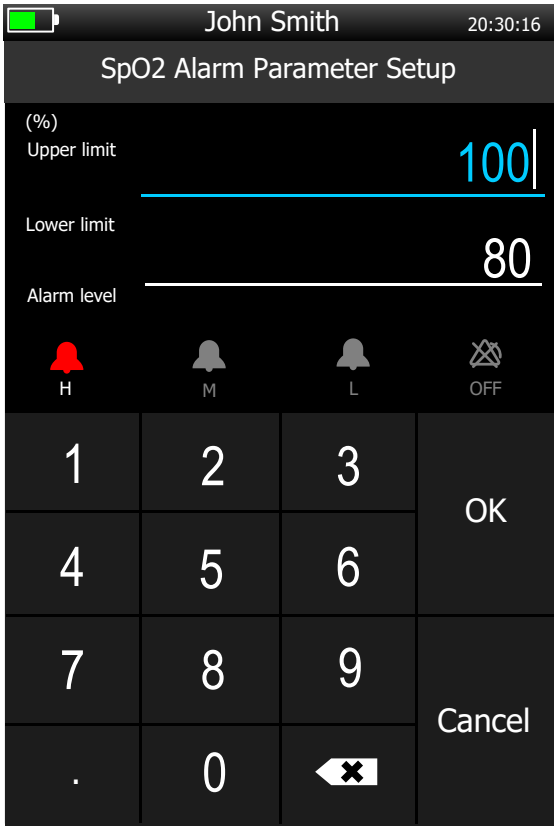

Figure 6.6 Parameter Alarm Editing

Description for the setup:

- High limit of the alarm

  Set the high limit of the parameter alarm. Alarm will be triggered when the measurements higher than this value. The user could edit this value by clicking the digital virtual keyboard.

- Low limit of the alarm

  Set the low limit of the parameter alarm. Alarm will be triggered when the measurements lower than this value. The user could edit this value by clicking the digital virtual keyboard.

- Alarm level

  Set the alarm level from “H”, “M”, “L” which indicate the levels of high, medium and low (H: red, L:yellow). “H” indicates the most serious alarm event. The user could edit the level by clicking the corresponding icon. The parameter alarm function is closed when the alarm level shows “OFF”

6.4.2 SpO2 Module Setup

The interface for the SpO2 parameter setup as is as the figure6.7 shows

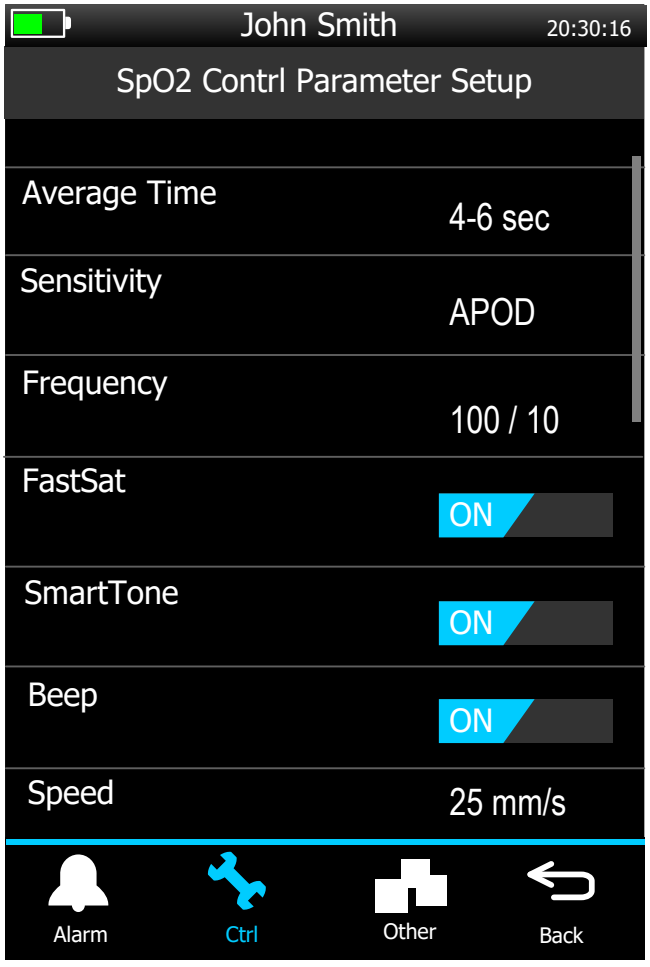

Figure6.7 SpO2 Parameter Setup

- Waveform Speed

  The waveform scanning speed of the PLETH has 2 options: 12.5mm/s and 25.0mm/s

- PR Sound

  On/ Off

- Sensitivity

  Choose the average time needed for SpO2 calculation from three options: high, medium and low which indicate the average SpO2 value in 4 seconds, 8 seconds and 16 seconds;

- Default: enter the default interface to choose the system default setup.

6.5 Alarm and Indications

When the physiological alarm is triggered by an over-limit parameter, the value of the parameter will be recorded automatically.

To know more information regarding the possible indications for PA and TA during SpO2 monitoring, please refer to “5.7 Alarm Details” in the chapter5, Alarm.

6.6 Maintenance and Cleaning

Caution:

Make sure the monitor is powered off before cleanning the monitor and sensors.

Caution:

Do not sterilize or use autoclave sterilization for the SpO2 sensor.

Do not dip the SpO2 sensor in the liquid

Stop using the sensor if any symptom of damages found for the sensor or the cable.

Cleaning

Use the tampons or the soft cloth with ethanol to clean the surface of the reusable SPO2 sensor. The cleaning of the LED and receiver is the same.

Sterilization

Sterilize the cables with the 3% hydrogen peroxide, 70% isopropyl alcohol or active reagents. Please note that the joint cannot dip in the above solution.

NOTE:

Do not leave the antibacterial solution recidual on the surface of the sensor

7 EtCO2 MONITORING

7.1 General

EtCO2

End-tidal CO2 monitoring is a continuous technique that determines the concentration of carbon dioxide in respiration gas by measuring the absorption of the CO2. NESO handheld patient monitor adopts the mainstream CO2 module. EtCo2 monitoring applied to both intubated and normal spontaneously breathing patients in ICU, OR, Anesthesiology Dpt., emergency and so on.

7.1.1 Measuring Method

There are two measuring methods for EtCO2 measurement which are mainstream measurement and sidestream measurement. Mainstream is invasive while the sidestream is noninvasive. EtCO2 of BLMed adopts microstream measurement (kind of sidestream) for the CO2 monitoring. The sample frequency of EtCO2 module is very low (50ml/min) which effectively prevent the sample line from moisture clogging and guarantee the measurement accuracy of the neonates and the pediatrics.

The measuring principle of the microstream measurement is the infrared emission. The photodetector measures the infrared irradiance through the respiratory system. Since part of the infrared is absorbed by the CO2 molecular, the light pass through the gas sensor depends on the CO2 concentration measured.

7.1.2 EtCO2 Parameters

The parameters can be measured by EtCO2 module:

1) EtCO2 partial pressure waveform
2) Maximum value for CO2 partial pressure (EtCO2)
3) Minimum value for CO2 partial pressure (FICO2)
4) AwRR

7.2 Preparation

To make sure the instrument working normally and achieve the expected measurement, the following should be assured before start monitoring.

7.2.1Preparation for CO2 Monitoring

Caution:

EtCO2 will work normally only by using the particular airway adaptor.

All accessories are disposable not reusable. Do not reuse the accessories.

Various accessories applied to:

- Patient type (Adult/ pediatric/ Neonates)
- Ventilation (including humidification)
- Working time: short term use: less than 24 hours (mostly in operation room) , or long term use (usually in ICU)

7.2.2 Waste Gas Treatment

Caution:

When monitorng CO2 on the patient in anesthesia, the gas outlet should be connected to the effluent treatment system or anaesthesia machine/ breathing machine to protect the medical stuff exposed in the anesthetic.

7.3 EtCO2 Monitoring

7.3.1 Module Connection

Insert the Metal joint of the EtCO2 module into the CO2 interface on top of the instrument. The interface will be self locked if confirm correctly connected.

The working indicator will be lightened after the connection is confirmed. The green indicator means the normal communication between the module and the instrument while the red indicator means the abnormal status and the measurement should be stopped immediately.

7.3.2 CO2 Parameter and Waveform Display

EtCO2 parameter display is as the figure 7.1 shows below:

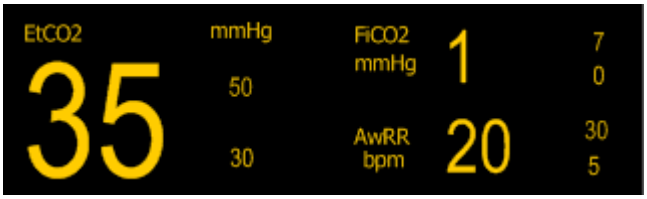

Figure7.1 EtCO2 Parameter Display

In which:

(1) Each parameter has a corresponding parameter name, unit, alarm limit.

(2) The alarm limit of each parameter can be edit under “EtCO2 setup” menu.

(3) Definition of the parameters as below:

EtCO2: Maximum value for CO2 partial pressure, unit can be chosen from mmHg/kPa

FiCO2: Minimum value for CO2 partial pressure, unit can be chosen from mmHg/kPa

AwRR: Airway respiratory rate, unit is bpm

The waveform of EtCO2 is as figure 7.2 shows below:

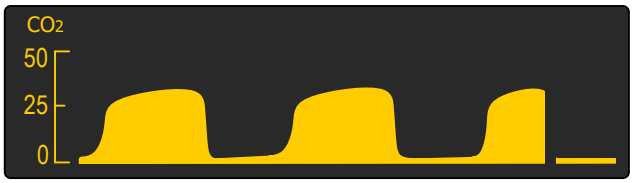

Figure7.2 EtCO2 Waveform Display

In Which:

(1) “CO2” indicate the name of the waveform;

(2) The scale label is under the name of the waveform;

7.4 CO2 Parameter Setup

Select “EtCO2” under the “Setup” menu to enter the CO2 parameter setup interface. There are two setups for CO2 parameter which are “alarm setup” and “module setup”. The default setup is the “alarm setup”.

7.4.1 CO2 Alarm Setup

Select “EtCO2” under the “Setup” interface to enter the CO2 alarm setup interface as the figure 7.3 shows below:

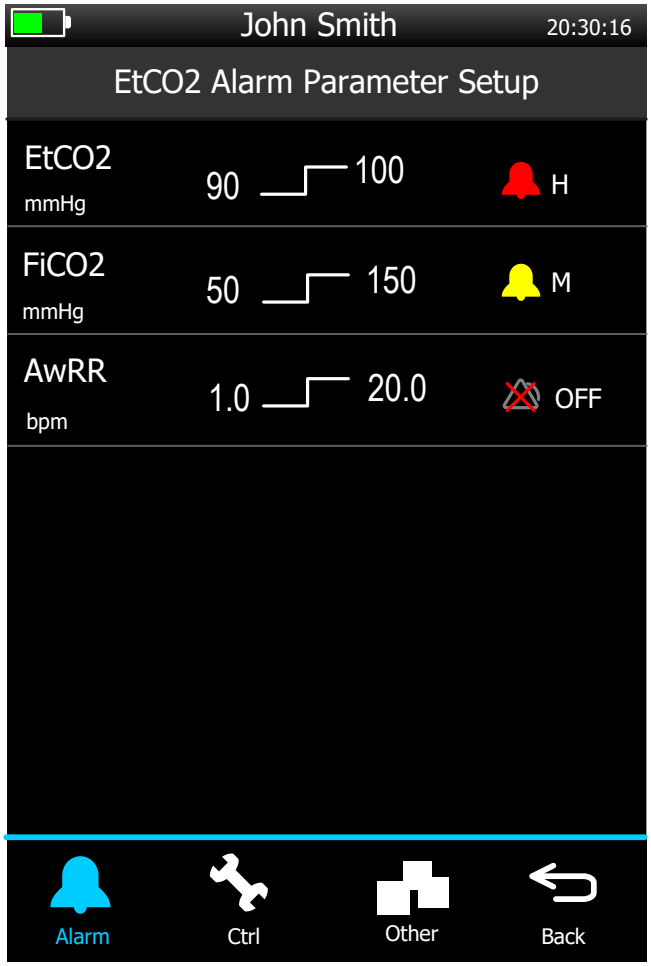

Figure 7.3 EtCO2 Alarm Setup

The above interface displays the preset parameter name, unit, low limit of alarm, high limit of alarm and the alarm status (the alarm is closed when the alarm level is “OFF”). Select any of the parameter to enter the parameter alarm editing interface as the figure 7.4 shows below:

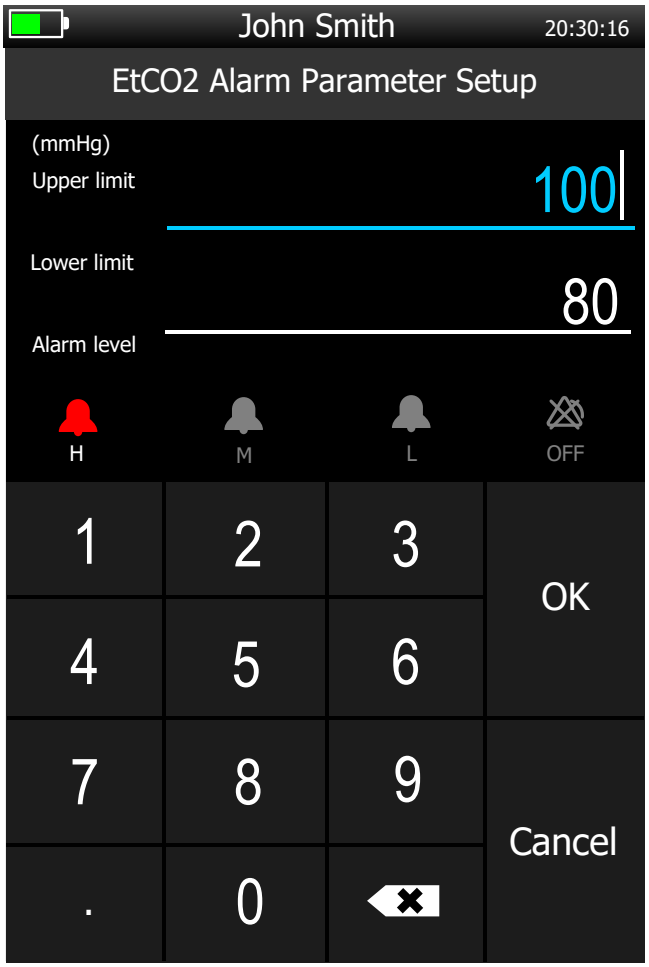

Figure7.4 EtCO2 Parameter Alarm Editing Interface

Description for the setup:

- High limit of the alarm

  Set the high limit of the parameter alarm. Alarm will be triggered when the measurements higher than this value. The user could edit this value by clicking the digital virtual keyboard.

- Low limit of the alarm

  Set the low limit of the parameter alarm. Alarm will be triggered when the measurements lower than this value. The user could edit this value by clicking the digital virtual keyboard.

- Alarm level

  Set the alarm level from “H”, “M”, “L” which indicate the levels of high, medium and low (H: red, L:yellow). “H” indicates the most serious alarm event. The user could edit the level by clicking the corresponding icon. The parameter alarm function is closed when the alarm level shows “OFF”

7.4.2 CO2 Module Setup

Select “EtCO2” under the “Setup” menu to enter the CO2 alarm setup interface. Click the “Ctrl” button to enter the CO2 module setup interface as the figure 7.5 shows below:

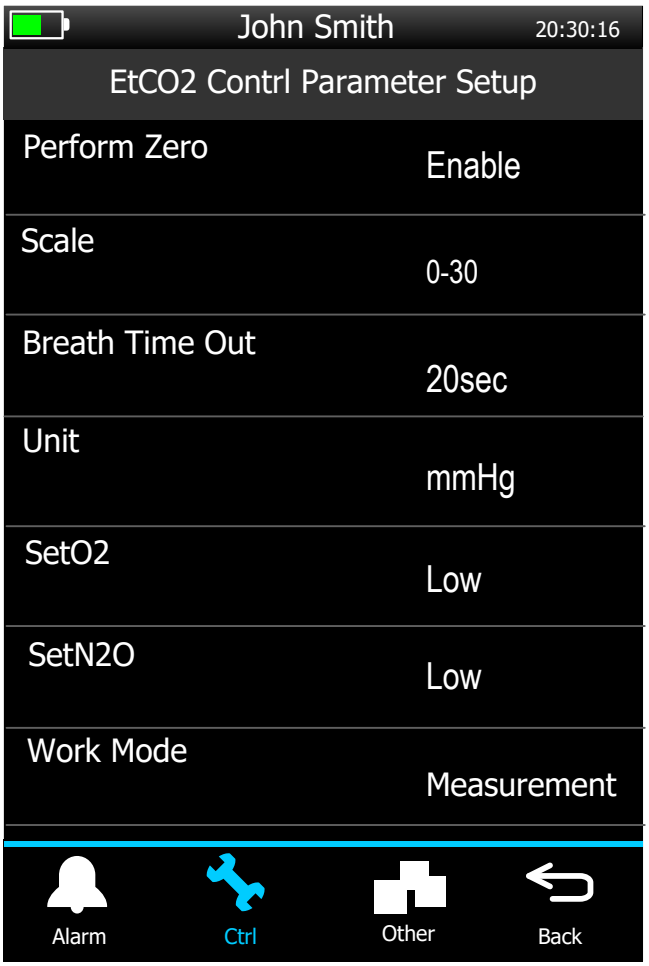

Figure 7.5 CO2 Parameters Setup

Setup descriptions:

- Perform Zero: Executive the module calibrations function.
- Scale: Set the scale of the waveform displayed between 0-30%, 0-60%.
- Breath Time Out: Choose from 20 seconds/ 40 seconds/ 60 seconds
- Unit: Choose from mmHg and kPa
- SetO2: Choose from Low/ medium/ high
- SetN2O: Choose from Low/ medium/ high
- Work Mode: Choose from measurement/ Testing/ Static

7.5 EtCO2 Alarm and Indications

When the physiological alarm is triggered by an over-limit parameter, the value of the parameter will be recorded automatically.

To know more information regarding the possible indications for PA and TA during CO2 monitoring, please refer to “5.7 Alarm Details” in the chapter5, Alarm.

7.6 Maintenance and Cleaning

Please check whether the disposable accessories are still within the effective period and check whether the sensors and the cables are intact before monitoring. Do not use the damaged accessory.

Caution:

The gas exhaust line is the disposable accessory which is not allowed for reuse.

To prevent environment pullution, the disposable accessories should be handled as the medical waste according to the local regulation.

8 DATA REVIEWING

8.1 Reviewing Guidance

NESO hand held patient monitor allows 100 patients' data (720 hours' trend data for each) storage. The user may review the patient data by select "Review" under the "Setup" menu as the figure 8.1 shows below:

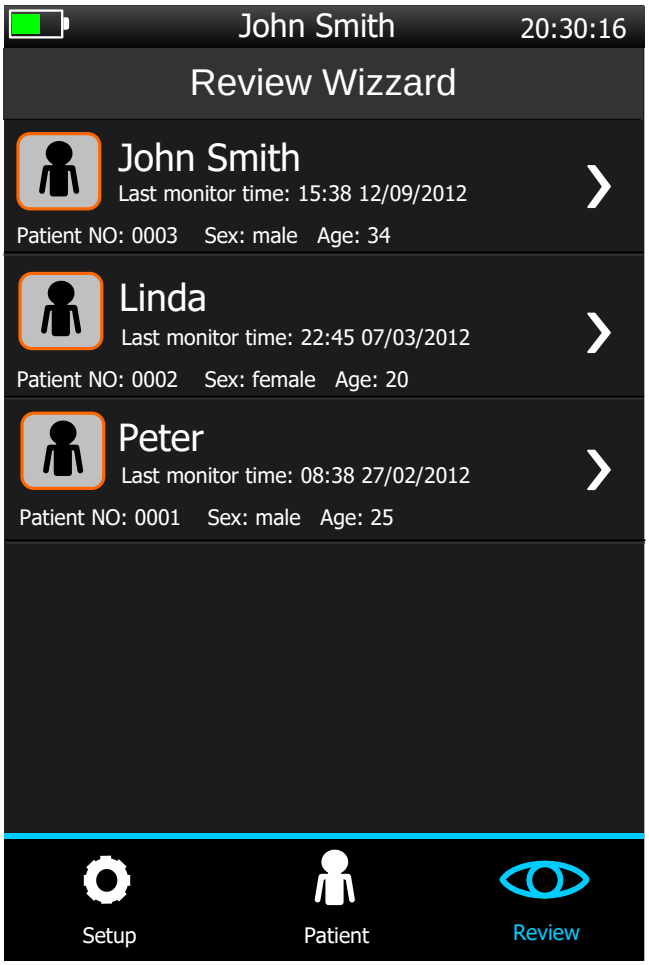

Figure8.1 Data Review

Under this "Review" interface, the user may review the patient data by selecting the patient recorded. Besides, the trend diagram and trend table for each parameter can also be created and reviewed.

8.2 Trend Table Review

After enter the review interface, the default display will be the review of the trend table as the figure 8.2 shows below:

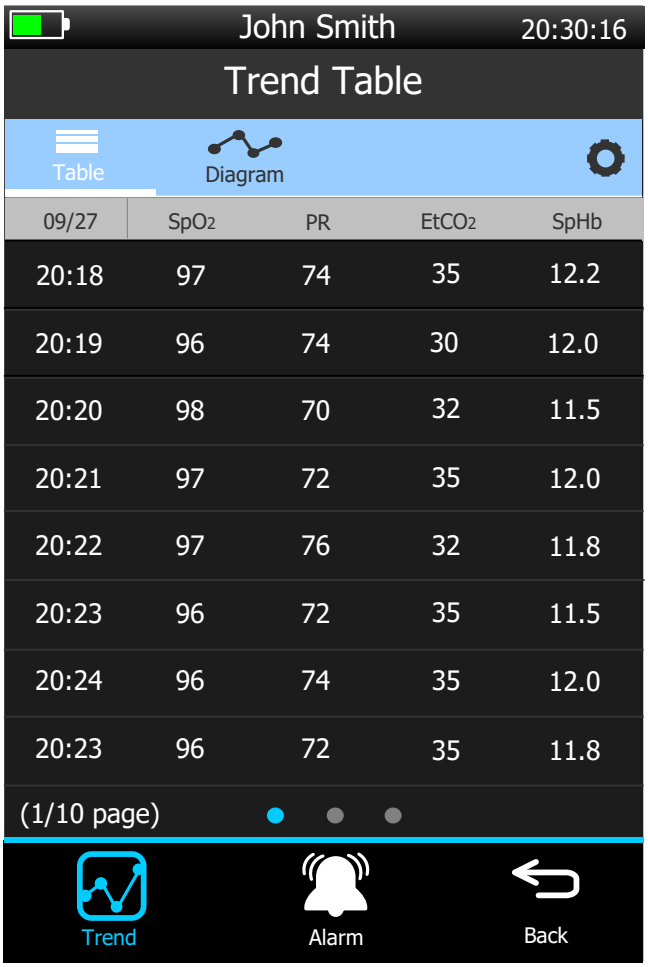

Figure8.2 Trend Table

In the trend table, the user may review the information like the recording time and the measurements. The records will be ranked in chronological order with the latest record on top. 8 groups of record can be displayed in each screen including the data of SpO2, PR, PI, EtCO2, FiCO2, AwRR. Slid screen (up and down) to review the next page. The instrument can review at least data of 720 hours.

8.3 Trend Diagram Review

Select the “graph” under the label page to check the trend chart. The user may review the measurements of each parameter within the latest 720 hours (the minimum resolution is 1 second). The Trend Diagram is as the figure8.3 shows below:

Figure8.3 Trend Diagram

The trend diagram of each parameter will be displayed in different lists. The graph of each parameter has a scale to display the effective range of the measurement. The user may slide the cursor in the graph to check the corresponding measurements. Slide the screen (up and down) to review the trend diagram of other parameters.

9 MAINTENANCE

In order to assure normal operation, test precision and life of the instrument, please pay attention to the maintenance of the instrument.

9.1 Clean and Sterilize

The user should clean the patient monitor in the specified method and using suggested material to prevent the instrument from contamination and the damages. To make sure the safety of the patient, do not use the damaged cables, sensors and accessories. And for the abandoned accessories, please handle according to the local regulation.

9.1.1 Cleaning

Use the soft cloth to clean the instrument;
Use the soap, amino and ethanol material to clean the main unit and power supply;
Use the soap, amino and ethanol material to clean the reusable SpO2 sensor;
Description:
Ammonia water: diluted ammonia water <3%; Ethanol70%; isopropanol 70%;
Do not use the abrasive material like steel brush or polishing compound;
Do not let the cleanout fluid into the instrument or soak the accessories need to be cleaned.

9.1.2 Sterilization

Besides cleaning, the sterilization is sometimes necessary;
Use the ethanol and ethanal detergent;
Use the ethanol and ethanal detergent for the reusable SpO2 sensor.
Description:
Ethanol: 70%
Ethanal: (35%-37%)

Decolorizer: sodium hypochlorite diluents, concentration: 500ppm-5000ppm. Do not let the antibacterial solution into the instrument or soak the instrument or the accessories
Do not leave the residual antibacterial solution on the surface.

9.1.3 Disinfection

Besides cleaning, the disinfection is sometimes necessary;
Since the disinfection is always completed, please conduct the procedure under the regulation of the hospital. ETO is always needed for disinfection.

9.1.4 Others

1) Do not put under direct sunlight, to avoid damages by high temperatures in the monitor enclosure
2) Do not use the instrument in an environment with poisonous, flammable or caustic gas
3) Place the instrument on firm and flat desk or shelf
4) Pay attention to any voltage fluctuations. If the voltage exceeds the permitted range, we advise the use of a voltage-stabilizing device.
5) If the instrument requires repair, one of our technicians or a company-designated representative must repair it. Do not tear down, maintain, debug the instrument, replace components or change electrical wires by an unauthorized technician. Otherwise, our company is not responsible for the resulting consequences.
6) Do not use keyboard in order to avoid damage to internal information and procedures
7) Use the soft cloth to clean the display.

9.2 Power Supply and the Battery

9.2.1 Charge up the Internal Battery

- When the instrument is supplied with an external AC power, the internal battery will charge. The indicatorwill remain illuminated until the battery is full.
- Charging time is based on the electrical capacity, when the battery is exhausted at least 4~8 hours of charging is needed. In a normal situation, the battery can be used for 5~10 hours if it is fully charged.
- Internal battery models are divided into two types, one is the standard, and the capacity is 2200mAh. The other is optional, the capacity is 4650mAh.

9.2.2 Install and Replace the Battery

The battery is at the bottom of the instrument with two screws for fixation. It is connected with the internal modules by connectors.

Installing and replacing the battery, please pull the power line first.

Because of the characteristic of the battery, it needs to be charged up at least once every six months. Otherwise, the battery performance will be affected or invalid. The battery is charged up via plug power for about 3 hours.

Scrap batteries are disposed of in accordance with local environmental requirements or may be recycled by returning to the manufacturer.

Caution:

- **The battery used for this instrument is the specified rechargeable battery with high capability. Do not use the battery not approved by the manufacturer, or the damages for the instrument might be caused.**
- **The short circuit, burning, excessive squeezing and disassemble of the battery might cause fire or explosion.**
- **Dispose of the used batteries according to the local environmental regulations or by handing over to the manufacture for recycling disposal.**

9.3 Periodic Check

1) The designed lifecycle of the instrument is 5 years.
2) Check the instrument once a year.
3) Check the accessories every six months.
4) If the instrument with battery has not been used for a long time, then it needs to be charged up at least every six months. The battery performance will be affected or invalid if it is not charged regularly. The battery is charged via the AC plug into the power socket for about 4~8 hours at least

.

9.4 Service

1) If the instrument has some malfunctions, please contact with the dealer or our service department at once, we will remedy the problem as soon as possible.
2) If the instrument has some malfunctions to repair, one of our technicians must make repairs or a company designated repair person. Tearing down, maintaining, debugging the instrument, replacing components or changing electrical wires by anyone without our agreement or commission voids any warranty and our company is not responsible for the resulting consequences.
3) The components for replacement must be produced by our company or adaptable to use with our approval.
4) Necessary accessories for maintenance are supplied to an authorized service and supply representative.
5) If the customer wants to use the accessories as SPO2 probes, blood pressure sleeves which are not approved by our company, the user must contact our service department to confirm if they are compatible.
6) The manufacturer will provide, for a fee, the circuit diagrams, component part lists, etc.

9.5 Transportation and Storage

The transportation must be complied with the requirements of the ordering contract.

1) Environmental temperature: -40°C ~70°C
2) Environmental relative humidity: ≤95% (non-condensing)
3) The room is well ventilated and without caustic gas.

Note:

Please properly store the package. If the monitor needs to be returned, please use the package to protect the monitor.

10 TROUBLES SHOOTING

If the instrument has malfunctions in use, the problems can be addressed as shown in the table below. If the malfunction is not debugged, please contact our dealer or service department.

Warning

If there are signs of problems, such as fire or smoke, do not open the instrument to find the malfunctions. The best way is to contact with local dealer or service department of the manufacturer at once.

Caution

Only a manufacturer trained technician can open the monitor, replace or adjust the components

Do not open the instrument to or attempt to repair the, as it may lead damage to the instrument.

If there are no available manufacturer trained technicians, please contact with service department of the manufacturer.

10.1 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 is on the rechargeable battery)
2) If AC supplies it, check if the monitor is plugged in and if the power line is connected to the monitor.

10.2 Failure Instructions Displayed on the Screen

Failure indication	Possible reason	Solution
System boot failure, Please insert system disk	1.Failure Electronic Hard Disk 2.Failure CPU	1.Electronic Hard Disk Replacement; 2.CPU replacement
Hardware not assembled or hardware failure	1.Poor contact of the interface board 2.Failure interface board	1.replug the interface board; 2.interface board replacement
SpO2 failure	1.SpO2 Module Failure 2.Poor contact of the signal communication cable connected between the module and the interface cable	1.SpO2 module replacement 2.replug or replace the communication cable

SpO2 Sensor Off	1.Broken SPO2 Probe 2.SPO2 line slot failure 3.the SPO2 module failure	1.replace the SPO2 Probe 2.replace SPO2 line slot replace the SPO2 module 4.replace high quality electrode

10.3 Other Phenomena of Malfunctions

If the malfunctions must be disposed by replacing some components, please contact with local dealer or service department of the manufacturer.

Malfunction phenomena	Possible causes	Means to dispose
The screen is black when power on	1. the LCD is damaged 2. the lines of the LCD is loose contact or damaged	1. replace the LCD 2. re-plug or replace the lines
The color of the screen seems red	1. the backlight of the LCD is damaged	1. replace the LCD
Power-on Self-Test not passed	1. CPU malfunction	1. replace the CPU
Can't save system time	1. CMOS battery is invalid 2. malfunction of clock CMOS chip	1.replace CMOS battery 2.replace clock CMOS chip
The buttons and the knob are of no effect	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
SPO2 value can't be read or incorrect	1.the probe is placed reversely 2.the finger with the probe is moving 3.dirt on the finger with the probe 4.if the luminous diode does not flash, then it shows that the SPO2 probe is loose contact or damaged 5.the patients belongs to the ones who are not allowed the measure the SPO2	1.clip the probe correctly onto the finger 2.keep the patient quiet 3.clean the finger 4.re-plug or replace the probe or SPO2 signal lines. 5.do measurement after the patient is normal.

Appendix A Product Specifications

A.1 Safety Information

Class	Specification
Type of protection against electric shock	Class I, with internal power supply
Degree of protection against electric shock	Anti-defibrillation: BF type
Degree of protection against ingress of water as detailed in the current edition of IEC 529	Ordinary equipment (sealed equipment without liquid proof)
Degree of protection against hazards of ignition of flammable anesthetic mixtures with air, oxygen or nitrous oxide	Not suitable for use in the presence of a flammable anesthetic mixtures with air, oxygen or nitrous oxide
Mode of operation	Continuous

A.2 Technical Specifications

A.2.1 SpO2

SPO2	
Measuring method	Dual wave length infrared wave
Measuring Range	0~100%
Alarm setup range	70~100%
Resolution	1%
Precision	±2% (70~100% adult/ Pediatric)
	±3% (70~100% neonate)
	Unspecified (0~69%)
Pulse rate	
Measuring Range	20~250bpm
Alarm setup range	20~250bpm
Resolution	1bpm
Precision	±3bpm (Geostationary) or ±5 bpm (Campaign)
Alarm setup	SPO2 overruns, pulse rate overruns
Alarm method	Alarm with sound and lights, and record the alarm status for review

A.2.2 EtCO2

EtCO2 Module	
Parameters	**Technical Specifications**
Parameters	EtCO2 FiCO2 AwRR
CO2 Measurement Range	0-99mmHg
Accuracy	0-38 mmHg: ±3mmHg 39-99 mmHg: ±(when bigger than 38mmHg, the error is 5% of the reading, and the error will increase 0.08% every time when the reading increases 1mmHg)
Alarm range	0-99mmHg

A2.3 Others

Parameters	**Technical Specifications**
Harmonized Standards	GB9706.1(IEC60601-1)
Classification for the Electric Shock	Type I internal electric source
Input Power	10VA
Internal Battery	DC 3.7V(±0.5V)
Working Mode	Continuous operating
Display	3. color LCD with high luminance
Parameters	SpO2, EtCO2
Degree of the Electric Shock	Type BF(SpO2, EtCO2)
Protection degree for the harmful liquid	Usual device, not belong to AP type or APG type
Import and Export	Export part can be connected with BLMed's Central Monitoring Software.

Appendix B EMC

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

The equipment meets the requirements of EN 60601-1-2:2007/AC:2010.

Note

Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The equipment complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the monitor in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the monitor in extremely close proximity to other equipment.

B.1 Electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below.

The customer or user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC61000-3-3	Compliance	

B.2 Electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \times \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5GHz	3 V/m	

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a]. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

[b]. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication and the equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter W (Watts)	**Separation Distance According to Frequency of Transmitter M (Meters)**		
	150kHz -80MHz $d = 1.2 \times \sqrt{P}$	80MHz -800MHz $d = 1.2 \times \sqrt{P}$	800M Hz -2.5GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix C Accessoris

NO.	PN.	Description
1	M64-50-010	Adult SPO2 Finger Clamp Probe
2	M64-50-020	Adult SPO2 Finger Wrap Probe
3	M64-50-030	Pediatric SPO2 Finger Clamp Probe
4	M64-50-040	Neonatal SPO2 Finger Wrap Probe
5	M64-50-051	Masimo DCI Clip Sensor
6	M64-50-052	Masimo Extension cable
7	M64-50-091	DCI Adult Reusable Sensor(2501)
8	M64-50-092	DCIP Pediatric/Slender Digit Reusable Sensor(2502)
9	M64-50-093	Reusable Sensor, 3 ft. Multiple Foam and AdhesiveWraps(2505)
10	106210	IRMA Airway Adapter Adult, 25 pcs/per Box
11	106260	IRMA Airway Adapter Infant, 10 pcs/per Box
12	100250	IRMA` Holder Velcro
13	100845	ISA Analyzer Clamp Adapter
14	100840	ISA Analyzer Modura Holder
15	100801	ISA module tubing, (1.6 / 3.2 mm), per meter
16	100802	ISA module tubing Y-connector (1.6 mm), per meter
17	100270	RS-232-M, open end cable, Box of 25
18	100310	IRMA/ISA USB serial converter
19	900160	ISA Maintenance Toolkit

Appendix D Information of Manufacturer

(1) Manufacturer

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(2) Authorized EC Representative

EC REP

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Change Content		
Version	Date	Remark
A2	2017-09	Initial release
A3	2018-09	Company address change has been approved by JSFDA at April 2018.。