MULTIPARA MONITOR

MN 1031-3W

USER MANUAL

MANN ELECTRONICS INDIA PVT. LTD.

E-55, Road No. 3, Indraprastha Industrial Area, **KOTA**, **INDIA**-324005 | Ph. : 91-0744-2425779, 2980779 | Fax : 91-0744-2980779
Mob. : +91-98875 55889 | E-mail : mannelectronics@gmail.com | sales@mannindia.com

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1. Safety

1.1. Safety Information

1.1.1. Manual conventions

The following information is used in this manual to emphasize alarming about patient or equipment related information or potential risks, and users should pay attention to:

⚠ DANGER	You should be aware of urgent dangers, if not avoided, they may result in death, serious personal injury or property damage.
⚠ WARNING	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
⚠ NOTE	Emphasize important considerations、provides application tips or other useful information to ensure that you get the most from your product. This information will affect how to use this manual and this product, or be used to provide some additional information such as detailed explanations, alarms or reminders.

1.1.2. Dangers

This equipment does not involve information on the level of danger.

1.1.3. Warnings

⚠ WARNING ⚠

For clinical monitoring of patients, only professional clinicians or fully-trained nurses are allowed to use in designated use occasions.

Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.

To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.

The user should set the alarm according to the actual situation of the patient, and

ensure that the monitor can emit an alarm sound when the alarm is triggered.

Do not come into contact with the patient, beds and other medical electrical equipment during defibrillation, otherwise serious injury or death could result.

The user should ensure the safety of the patient being monitored when the monitor is shared with electrosurgical equipment.

To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.

This device should not be used in the presence of magnetic resonance imaging (MRI) equipment, otherwise the induced current will cause burns to the patient.

If the equipment does not work normally, please do not perform maintenance by yourself. Contact Witleaf authorized to repair the equipment. The authorized maintenance personnel can obtain the corresponding information from Witleaf, including circuit diagrams, component lists, etc.

Do not open the equipment housings in order to reduce the danger of electric shock. All servicing and future upgrades must be carried out by trained and authorized personnel. otherwise it may cause equipment safety issues.

The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.

1.1.4. Precautions

⚠ CAUTION ⚠

Use only parts and accessories specified in this manual to ensure the safety of operators and users.

Before use, the user must check the equipment and cables for no obvious damage that may affect patient safety or instrument performance. The recommended inspection cycle is once a day. If obvious damage is found, replace the damaged part before use.

Users should pay attention to whether the patient will cause biological incompatibility or toxicity due to consumables.

Disposable accessories can only be used once, and repeated use may cause performance degradation or cross-infection.

At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact us.

Before connecting the monitor to the power supply, please confirm that the voltage and

frequency of the power supply comply with the equipment label or the requirements specified in this manual.

Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. Ensure that the installation and use environment of this instrument is free from strong electromagnetic interference, such as wireless transmitters or mobile phones.

⚠ NOTE ⚠

Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.

Before use, the user should check whether the instrument and its accessories can work normally and safely.

Put the equipment in a location where you can easily view, operate and maintain the equipment.

Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

This manual describes all features and options. Your equipment may not have all of them.

Do not operate this equipment outside the limits of the operating environment, otherwise it will cause the equipment to work abnormally. The operating environment is limited as follows:

Working temperature: 5℃～40℃;

Relative humidity: 15%～95%(noncondensing);

Atmospheric pressure: 70.0kPa ～ 106.0kPa;

Voltage: 100～240V;

Rated power: 60VA;

All illustrations provided in this user manual are for reference only, and the actual product may not be exactly the same as the illustrations.

1.2. Equipment Symbols

	Power On/Off		General Warning Sign
	Alternating Current（AC）		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
	Direct Current		Description of the application components are BF type, F-type isolated (floating) application part.
	Alarm Stop		Equipotentiality
	Alarm Pause		Audio Off
	Alarm Reset		Nurse Call Interface
	NIBP Measure		Network Interface
	Graphical Record		USB Connector
	Freezes Waveforms		Gas Inlet
	Refer to Instruction Manual/Booklet		Gas Outlet

1.3. Transport symbol

	Fragile: Handle with care		Temperature Conditions: Do not expose the product to an environment that exceeds the displayed temperature limit
	Afraid of Rain		Location: Here up
	Humidity Storage Conditions: Do not expose the product to an environment that exceeds the displayed humidity value		Stacking Limit: up to 3 layers
	The atmospheric pressure during transportation shall not be higher than 106KPa or lower than 57.3KPa		

2. Equipment Introduction

2.1. Introduction

2.1.1. Safety Information

The patient multi-parameter monitor is used by medical institutions for the purpose of monitoring, collecting and processing information from the patient, providing the patient's ECG, respiration (RESP), blood oxygen saturation (SpO_2), pulse (PR), body temperature (TEMP), non-invasive blood pressure (NIBP), end-breathing carbon dioxide (ETCO2), invasive blood pressure (IBP) ,Anesthesia awareness index (Ai), EMG, BURST inhibition ratio (BSR), EEG, and EEG quality index (SQI) are used for monitoring.

This monitor is used by professional clinicians or under the guidance of professional clinicians in hospitals or healthcare environments.

2.1.2. Contraindications

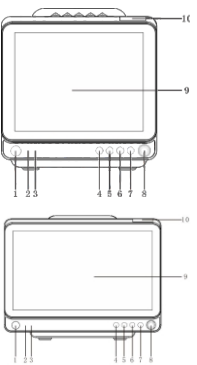
Not yet clear.

2.1.3. System Components

The monitor consists of the main unit, battery, bracket, parameter module, parameter module plug-in box and accessories. See the accessories section for details.

2.2. Main Unit

2.2.1. Front view



NO.	Icon Name	Description
1	Power Switch	On: pressing this switch turns on the monitor after the monitor is connected to AC power. Off: when the monitor is on, pressing and holding this switch for 2 seconds turns off the monitor.
2	AC Power Indicator	On: when AC power is connected. Off: when AC power is not connected.
3	Battery Indicator	On: the monitor operates on battery power. Flashing: low battery
4	Alarm Reset Key	Reset all on-going alarm currently occurring in the monitor.
5	Alarm Pause Key	Pauses or resume the current alarms.
6	Freezes Wave forms Key	Freeze or unfreeze the waveform.
7	NIBP Start/Stop Key	Starts an NIBP measurement or stops the current NIBP measurement.
8	Knob	Rotation: Rotate clockwise or counterclockwise to move the focus. Press: Press the knob to perform an operation, such as entering a menu or executing a command.
9	Displays	
10	Alarm Lamp	When a physiological alarm or technical alarm occurs, this lamp lights and flashes corresponding with the alarm priority: High priority alarms: the lamp quickly flashes red. Medium priority alarms: the lamp slowly flashes yellow. Low priority alarms: the lamp lights in yellow without flashing. Low-level technical alarms: the lamp lights off.

2.2.2. Rear view

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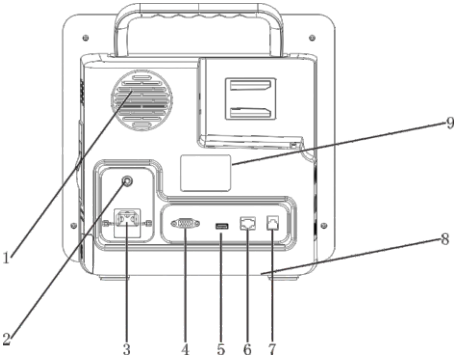

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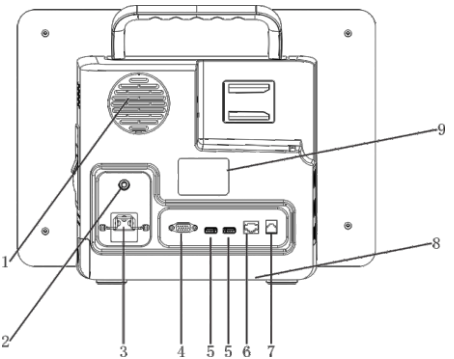
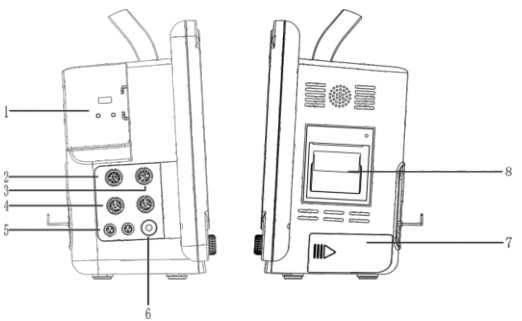


NO.	Icon name	Description
1	Loudspeaker Hole	Sound broadcasting.
2	Equipotential Grounding Terminal	When using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential difference between them.
3	AC Power Input	
4	Secondary Display Connector	The secondary display connected to the standard VGA interface is used for auxiliary display and monitoring through the secondary display. The display content of the secondary display is consistent with the main display of the monitor.
5	USB Connector	Connect U disk for software upgrade.
6	Network Connector	It is a standard RJ45 connector which connects the central monitoring system or other equipment.
7	Nurse Call Connector	It connects the monitor to the hospital's nurse call system through the nurse call cable. Alarms from the monitor are sent to the nurse station through the nurse call system.
8	Radiator	The gas outlet of the monitor is convenient for the machine to dissipate heat.
9	Label	Monitor Label.

2.2.3. lateral view



1: Slot **2**: ECG connector **3**: SpO_2 connector **4**: IBP connector
5: Temp connector **6**: BP connector **7**: Battery door **8**: Logger

2.2.4. Parameter module slot usage

Please refer to the following process to connect and remove the module:

Connect module: With the module properly oriented, align the module insertion guide slot with the insertion guide. Push the module until you hear a click. Push the lock at the bottom of the module inwards to lock the module. After inserting the module, please confirm whether the indicator light on the module is on, if it does not light up, please repeat the above operation.

Remove module: Release the lock at the bottom of the module and lift up the wrench. Pull outwards the module to remove the module.

2.2.5. Pluggable parameter module

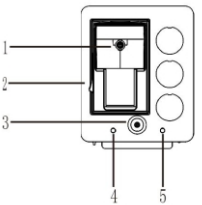
This monitor provides many parameter mode plugin packages for users to choose:

Module label	Description	Remarks
M401B	Mainstream CO2 Module	Individual parameter module
M402C	TiniStream5 CO2 external module	Individual parameter module, with module M402B described in “Genera product information” described in “Genera product information”
M402E	TiniStream8 CO2 external module	Individual parameter module, with module M402D
iM-MA	Plugin package	Connect with mainstream CO2 module (M401B)/TiniStream5 CO2 external module (M402C)/ TiniStream8 CO2 external module (M402E) and EEG Wave/Ai (Depth of anesthesia) (PK2.087.004)
iM-SA	Plugin package, with sidestream CO2 module M420B/M420D and sink integrated	Plugin package, with sidestream CO2 module M420B/M420D and sink integrated
iM-M	Plugin package	Connect with mainstream CO2 module(M401B) /TiniStream5 CO2 external module(M402C) / TiniStream8 CO2 external module(M402E)
iM-S	Plugin package, with sidestream CO2 module M420B/M420D and sink integrated	Connect with sidestream gas sample cannula
iM-A	Plugin package	Connect with EEG Wave/Ai (Depth of anesthesia) (PK2.087.004)

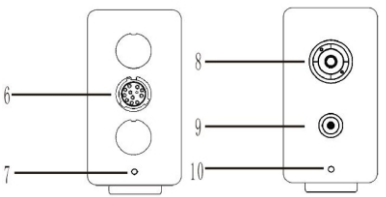
iM-T	Plugin package, with sidestream CO2 module M420D integrated	Connect with dry gas sample cannula

(*This plug-in package has an interface for CO2 only, with the option of connecting a Mainstream CO2 module and a TiniStream CO2 module, see appendix A.2 for details of the module types)

Main view of sidestream CO2 module



Main view of mainstream/ TiniStream CO2 module

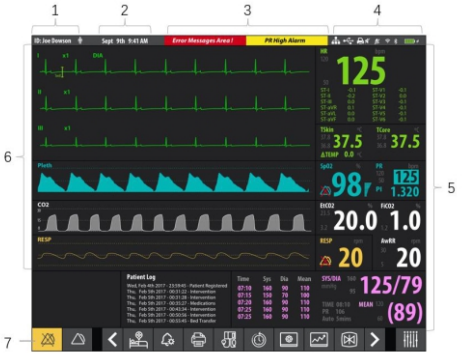


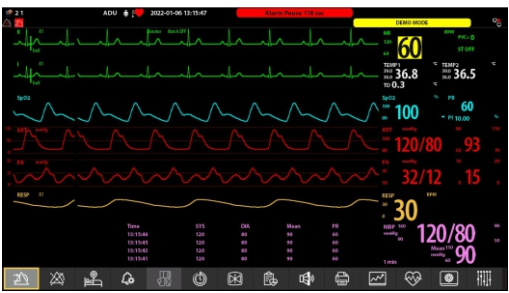
1: Sidestream sample line connector **2**: Sidestream sink base **3/9**: Gas outlet
4/5/7/10: Module work indicator **6**: Mainstream CO_2 module interface
8: TiniStream sample line connector

2.3. Display

The display of monitor is a color high-resolution TFT LCD display, which can clearly display various physiological parameters of the patient, waveforms, etc. The following figure shows

the interface of the monitor in the monitoring state. The display content of the interface is different when the monitors of different configurations are selected.





1: Patient information area **2**: Time area **3**: Alarm information area

4: System Information area **5**: Monitoring parameter area

6: Parameter waveform area **7**: Smart hot key area

2.4. Smart hot keys

Smart hot keys are graphical hotkeys displayed at the bottom of the main screen of the monitor, which enable you to access certain functions conveniently and quickly. Smart hot keys are as follows:

	Alarm Pause		Alarm Reset
	Patient Management		Alarm Off
	Alarm Setup		NIBP Measure
	Dynamic Minitrends		Volume Setup
	Manual Event		Main Screen Setup
	Main Menu		Freeze
	Default Main Interface Display		Data Review
	Next Page		Print Setup
	Previous Page		

3. Getting Started

3.1. Open the Package and Check

Before opening the packing case, please verify whether the packages are intact; If you find any damage to the package, please do not open the package and contact the transportation company or our company in time. Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list. Check for any mechanical damage. Check all the cables, modules and accessories. If there is any problem, contact the distributor immediately.

⚠WARNING

Save the packaging material and out of the reach of children as they can be used if the equipment must be reshipped. If the packaging materials are abandoned, be sure to observe the applicable waste control regulations.

The equipment may be contaminated by microorganisms during storage, transportation and use. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not use.

3.2. Monitor Installation

⚠ WARNING

The equipment should be installed by authorized Witleaf personnel.

Use only installation accessories specified by Witleaf.

If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, please consult the Witleaf or an expert in the field. A determination must be made that the proposed combination will not negatively affect the devices themselves or the patient's safety.

3.2.1. Environment

Make sure that the equipment operating environment meets the specific requirements.

The use environment of the monitor should also reasonably avoid the presence of noise, vibration, dust, corrosive or flammable, explosive substances, etc. If it is installed in a chassis, ensure that there is enough space at the front and rear of the chassis for operation, maintenance and repair; in

order to allow the normal circulation of air to achieve good heat dissipation, a gap of at least 5 cm should flow out of the equipment.

When the monitor is transferred from one environment to another, due to the difference in temperature or humidity, the monitor may have condensation. Make sure wait for the condensation to disappear before using the monitor.

3.3. Turning on / Turning Off the Monitor

3.3.1. Turning on the Monitor

Before turn on the monitor, perform the following inspections:

1. Check the monitor, SMR and modules for any mechanical damage. Make sure that all external cables, plugins and accessories are properly connected.
2. Connect the power cord to the AC power source. If you use a battery for power supply, make sure that there is enough power in the battery.
3. Press the power switch on the front panel of the monitor, the screen displays the startup screen, and how the alarm indicator and sound alarm change.
4. The startup screen disappears and enters the main interface, indicating that the startup is successful.

3.3.2. Turning Off the Monitor

Before turn off the monitor, perform the following check:

1. Ensure that the monitoring of the patient has been completed.
2. Disconnect the cables, sensors and accessories from the patient.
3. Make sure to save or clear the patient monitoring data as required.
4. Long press the power switch to enter the shutdown state, the interface shows that the system is shutting down.
5. The screen turns off, indicating that the shutdown is complete.

3.4. Operation and Navigation

3.4.1. Starting Monitoring a Patient

After turning on your monitor, follow this procedure to monitor a patient:

1. Decide which parameters need to be monitored or measured.

2. Install the required modules, patient cables and sensors, and ensure that the correct connection to the patient is made.
3. Check whether the monitor settings are correct. Especially [Patient Category] and [Paced].
4. For more information, see corresponding measurement chapters.

⚠ WARNING

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact customer service personnel approved by Witleaf immediately.

3.4.2. Using the Key

There are three different Categories of keys in the monitor:

Hard key: The tangible keys on the monitor are located on the front panel of the monitor to realize the corresponding operation functions of the monitor.

Eject key: The menu related to the task will automatically pop up on the monitor screen. For example, when confirming certain settings, a confirmation key pops up.

Soft key: The position where the cursor can stay on the interface. It is convenient for users to quickly enter certain menus or perform certain operations, including:

Parameter key: Select the parameter area or waveform area of the parameter to enter the corresponding parameter setting menu.

hot key: Quick hot keys at the bottom of the main screen.

3.4.3. Using the Soft Keyboard

When you click the editable box, the system will display a soft keyboard on the screen to facilitate you to input information. You can use the navigation knob or the touchscreen to select characters to enter data. Select the Enter key 

to confirm the entry and close the soft keyboard.

3.4.4. Using the Touchscreen

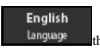
You can use the touchscreen to select a screen element by pressing directly on the monitor's screen.

3.4.5. Using the Secondary Display

In order to viewing or operation, the secondary display can be connected through the VGA interface on the rear of the monitor. The secondary display and the monitor display the same content. The display content is controlled by the monitor. The purpose of the secondary display is only for display.

3.5. Configuring Your Monitor

3.5.1. Selecting the Language

1. Select the hot key in Main Menu  turn to the [Settings]menu.
2. Select the key in [General Settings] , 

then select the [Language] in the pop-up list.

3.5.2. Setting the Date and Time

1. Select the hot key in Main Menu  turn to the [Settings] menu.
2. Select the key in [General Settings] , 

set [Date]、[Time]、[Date Format] and [Time Format] in the pop-up [System Time] window.

3.5.3. Adjusting the Screen Brightness

1. Select the hot key in Main Menu  turn to the [Settings] menu.
2. Select the key in [General Settings] 

, then select the [Screen Brightness] in the pop-up list.

3.5.4. Adjusting the Volume

1. Select the hot key in Main Menu  turn to the [Settings]menu.
2. Select the key in[General Settings] 

, then select the [Key Volume] in the pop-up list.

3.5.5. Setting the Monitor Information

1. Select the hot key in Main Menu  turn to the [Settings]menu.
2. Select the key in [System Settings] 

, then select the [Device Name]、[Department] and [Bed No.] in the pop-up list.

3.5.6. Setting the Parameter Display switch

1. Select the hot key in Main Menu  turn to the [Settings] menu.
2. For the keys for selecting different parameters in [Interface Settings], you can display or hide the waveform and parameter value of the parameter on the interface.

3.5.7. Setting the Demo Mode

1. Select the hot key in Main Menu  turn to the [Settings]menu.
2. Select the key in [System Settings] 

, can enter or exit [Demo Mode].

4. Managing Patients

4.1. Introduction

The patient information management system of the monitor is of great significance for historical data review. Connect the patient to the monitor, and the monitor can display and store the physiological data of the patient. Although the patient can be monitored without performing the operation of receiving the patient on the monitor, this will cause the stored historical monitoring data to not correspond to the patient one-to-one, so it is very important to admit the patient correctly.In the case of sudden power failure, the system will automatically switch from the network power state to the battery power supply to the monitor, and will not lead to the interruption of monitoring work.

⚠ WARNING

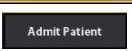
The settings of patient category and paced status always contain a default value, regardless of whether the patient is admitted or not. Check if the setting is correct for your patient.

For paced patients, you must set Paced to Yes. Otherwise, the ECG arrhythmia analysis will fail and the system will fail to alarm when the ECG signal is too weak.

For non-paced patients, you must set [Paced] to [No].

4.2. Admitting a Patient

1. Select the hot key in Main Menu  turn to the [Patient Management] menu.

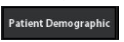
2. Select  to admit a new patient. If the monitor has received the patient, please select [OK] to discharge the current patient.
3. Complete patient information in the pop-up [Patient Information] window, especially:
   [Patient Category]: Determines the algorithm used by the monitor to process and

calculate certain measurements, as well as the safety limits and alarm limit ranges applicable to certain measurements.

[Paced]: Determines whether the monitor displays the pacemaker pulse mark. When set to [No], the pacemaker pulse mark will not be displayed on the ECG waveform.

4.3. Managing Patient Information

Edit patient information after a patient has been admitted, or when patient information is incomplete, or when you want to change patient information:

1. Entering the [Patient Management] menu.
2. Select the key 

, then make the required changes in the pop-up [Patient Information] window.
3. Select [OK].

4.4. Discharging a Patient

To discharge a patient:

1. Entering the [Patient Management] menu.
2. Select the key 

.
3. Select [OK] to discharge the patient, select [Cancel] to cancel this discharge operation.

NOTE

Discharging a patient deletes all history data from the monitor.

5. Screen Display

5.1. Introduction

The monitor supports a variety of styles of display interface. Select the hot key in Main Menu  , turn to the [Screen selection] menu, select the key 

select the appropriate [Screen Category] in the pop-up list. Supported screen Categories include:

Standard Screen
Dynamic Trend Screen
oxyCRG Screen
Big Numerics Screen
ECG full-screen 7-guide Screen
ECG half-screen 7-guide Screen

Through [Parameter switch] and [Parameter display switch], you can show and hide specific parameters.

3. Select the hot key in Main Menu  turn to the [Settings]menu. Select the [User Maintenance] in [System Settings], then select [Parameter control]. On the pop-up menu, you can set the switch state of the measurement parameter.

4. Select the hot key in Main Menu  turn to the [Settings]menu. For the keys for selecting different parameters in [Screen Settings], you can display or hide the waveform and parameter value of the parameter on the interface.

5.2. Standard Screen

5.3. Dynamic Trend Screen

Dynamic Trend Screen is located to the left of the corresponding waveform in the Waveform area, can display the trend of a series of parameters in the most recent period of time. The upper part of each trend screen shows the parameter label of the trend, and the left side shows the scale. The time is displayed at the bottom of the Dynamic Trend Screen.

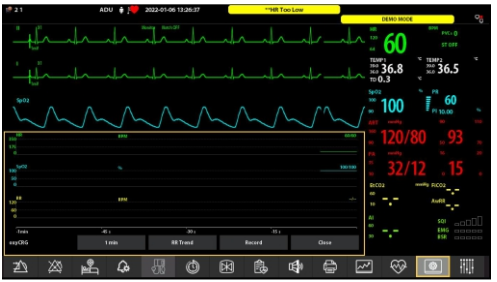
Select the Dynamic Trend Screen area, in the pop-up menu, you can:

In the [Parameter Settings], select the parameters to be displayed.

In the [More Settings], select the key , 

then select the appropriate time in the pop-up list.

5.4. oxyCRG Screen



Located at the lower part of the screen, oxyCRG screen consists of four trends: HR Trend, SpO2 Trend, RR Trend and Compressed Resp. Waveform. There are hot keys at the bottom part of the oxyCRG Screen:

Select OxyCRG trend length

Select to time lengths:[1MIN]、[2MIN].

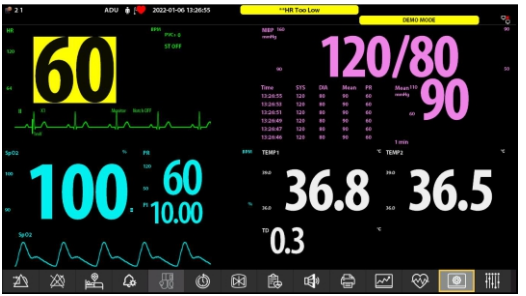
Parameter Settings

Two display modes can be selected, one to display HR Trend, SpO2 Trend and RR Trend, and the other to display HR Trend, SpO2 Trend and Compressed Resp. Waveform.

Record

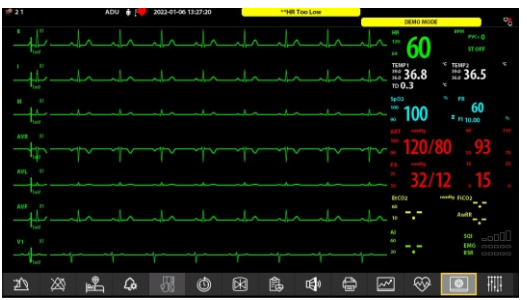
Use the recorder to output the three waveforms in the oxyCRG at the same time.

5.5. Big Numerics Screen

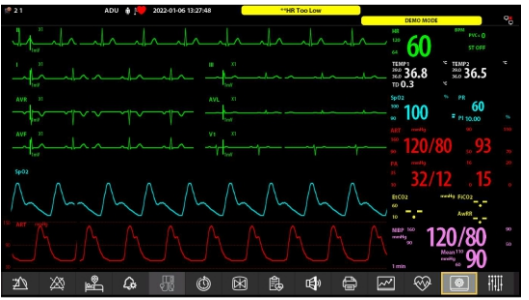


Select the hot key in Main Menu  ,enter the [Big Numerics] menu, Users can choose four parameters to observe according to their needs. For parameters with waveforms, a waveform will be displayed at the same time.

5.6. ECG full-screen 7-guide Screen



5.7. ECG half-screen 7-guide Screen



6. Alarms

6.1. Alarm Introduction

Alarm refers to when the patient being monitored has abnormal vital signs changes, or the monitor itself fails and the monitoring of the patient cannot be carried out smoothly, the monitor uses sound, light and other means to prompt the medical staff.

6.1.1. Alarm Categories

The monitor has two different Categories of alarms: physiological alarms and technical alarms.

1. Physiological Alarms

Physiological alarms are triggered by patient measurement exceeding the parameter limits, or by an abnormal patient condition. Physiological alarm information is displayed in the physiological alarm area.

2. Technical alarms

Technical alarms, also called system error messages, refer to alarms that are triggered when a certain monitoring function fails to operate normally due to improper operation or system failure, or when the monitoring result is distorted. Technical alarm information is displayed in the technical alarm area.

Apart from the physiological and technical alarms, the monitor can also prompt some messages telling the system status or patient status. Reminder information is generally displayed in the technical alarm area and the reminder information area, and the reminder information related to arrhythmia is displayed in the physiological alarm area. In addition, some prompt information is displayed in the parameter area, for example: the prompt information related to NIBP is displayed in the NIBP parameter area.

NOTE

when power alarm system, monitoring are saved before the power outage alarm.
The stored alarm information does not change with the time of outage.
When the product power off, will not form an alarm record and file

6.1.2. Alarm Priorities

By severity, the alarms are classified into high priority alarms, medium priority alarms and low priority alarms.

	Physiological Alarms	Technical Alarms
High	Indicates that the patient is in a critical state and may be in danger of life. Require an immediate response, such as arrest, ventricular fibrillation/ventricular tachycardia, etc.	Indicates a severe device malfunction. May not be possible to detect the critical state of the patient, making it life-threatening, such as low battery power.
Medium	Indicates abnormal vital signs. Require a prompt response.	Some machine failures or misoperations may not threaten the safety of patients, but also affect the normal monitoring of key physiological parameters.
Low	The patient's physical signs are abnormal, and corresponding measures or treatment may be needed.	Indicate a discomfort condition, a device malfunction, or an improper operation. But will not threaten patient safety.

6.1.3. Alarm Indicators

When an alarm occurs, the monitor indicates it to you through visual or audible alarm indications:

Visual Alarm: Different colors and flashing frequencies are used to prompt different levels of alarm information.

Alarm Description: Prompt the corresponding alarm information through the relevant alarm area.

Audible Alarm: Use different sound characteristics to prompt different levels of alarms.

Parameter flashing: When an alarm occurs for a certain physiological parameter of the patient, the parameter value in the parameter area will flash at a frequency of once per second, and the high or low limit of the parameter will also flash at the same frequency, indicating that the parameter exceeds the upper limit or the lower limit.

Among them, Visual Alarm、 Audible Alarm and Alarm Description distinguishes the level of the alarm in different ways.

	Visual Alarm	Audible Alarm	Audible Alarm Frequency	Alarm Description	Alarm light Frequency	sound pressure level range and measurement

						radius
High Priority Alarms	Flash in red with high frequency	Du-Du-Du---Du-Du------Du-Du-Du---Du-Du	90ms	Red, ***	2Hz	52dB-79dB 1m
Medium Priority Alarm	Flash in yellow with low frequency	Du-Du-Du	145ms	Yellow, **	0.5Hz	45dB-78dB 1m
Low Physiological Priority Alarm	Lights on in yellow	Du-Du	145ms	Yellow, *	Always	43dB-76dB 1m
Low Technical Priority Alarm	Lights off	Du-Du	145ms	Blue, *	Always	/

NOTE

When multiple alarms of different priority levels occur simultaneously, the monitor select the alarm of the highest priority to light the alarm lamp and issue the alarm tone.

When adjusting high-priority alarms, the alarm sound must not be adjusted less than the ambient background sound, otherwise the alarm sound will not be heard.

High priority alarm, the alarm occurs in the physiological signal, , the alarm signals at an interval of 5s.

Medium priority alarm, the alarm occurs after the physiological signal, the alarm signals at an interval of 10s.

6.1.4. Alarm Status Symbols

In the alarm state, the following four symbols will appear on the monitor screen to indicate the different states of the alarm.

 indicates that all the alarms are paused.

 indicates that the alarm system is reset.

 indicates that audible alarm tones are turned off.

 indicates that individual measurement alarms are turned off or the system is in the alarm off status.

6.2. Setting Alarm Tone Properties

6.2.1. Setting the Minimum Alarm Volume

1. Select the hot key in Main Menu  turn to the [Settings]menu.
2. Select [User Maintenance] in [System Settings], then select [Alarm Parameters] to enter the [Alarm Parameters] window.
3. Select the key 

, then select a volume value in the pop-up list, the range is 0 ~ 5.

The minimum alarm volume determines the minimum value of the alarm volume setting. It is not affected by user default configuration or factory default configuration. After the monitor is shut down and restarted, the minimum alarm volume setting will not change.

6.2.2. Setting Alarm Volume

The alarm volume can be set in three ways:

1. Select the hot key in Main Menu  turn to the [Settings]menu. Select [User Maintenance] in [System Settings], then select [Alarm Parameters] to enter the [Alarm Parameters] window.
2. Select the hot key in Main Menu  , turn to [Volume Settings] window.
3. Select the hot key in Main Menu  , then select [Other] to enter the [Other Alarm Settings] window.

Then select the key 

, then select a volume value in the pop-up list, the range is 0 ~ 5. But the minimum value cannot be lower than [Minimum Alarm Volume].

6.2.3. Setting the High Alarm Volume

1. Select the hot key in Main Menu  , then select [Others] to enter the [Other alarm settings] window.
2. Select the key 

, then select a [High Alarm Volume] in the pop-up list.

6.3. Setting Parameter Alarm Properties

Select the hot key in Main Menu  , open the [Alarm Settings] window. Including alarm settings for [Necessary Parameters], alarm settings for [Optional Parameters], settings for [ST Segment Alarms], and alarm settings for [Arrhythmia Diagnosis and Analysis].

1. You can set the alarm low limit, alarm high limit, alarm level and alarm record for each alarm.
2. Select [Switching Off all alarms] to close all alarms on the current page.
3. Select [Switching On all alarms] to open all current alarms.
4. Select [Auto Alarm Limit], the monitor will quickly set the alarm limit on the current page according to the patient's individual vital signs measurement results.
5. Select [Default Alarm Limit], the monitor will set all the alarms on the current page as the default configuration. Decide which parameters need to be monitored or measured.
6. Select [Important Alarm On], the monitor will turn on the default alarm on the [Arrhythmia Diagnosis and Analysis] page.

6.4. Setting alarm time

Select the hot key in Main Menu  turn to the [Settings]menu. Select [User Maintenance] in [System Settings], then select [Alarm Parameters] to enter the [Alarm Parameters] window.

Select the key 

, then select an appropriate time in the pop-up list as the

[Alarm Pause Time].

Select the key 

, then select an appropriate time in the pop-up list as the [Alarm Delay Time].

Select the key 

, then select an appropriate time in the pop-up list as the[ST Alarm Delay Time].

6.5. Pausing Alarms

Enter the interface of single parameter, click the icon  under the interface of single parameter, the parameter will enter the alarm shutdown state, and the icon will change to  :

Both the Visual Alarm and Audible Alarm are suspended.

The parameter and upper/lower limit of the physiological alarm will stop flashing.

Alarm Description will not be displayed.

The remaining alarm pause time is displayed in the physiological alarm information area.

The default alarm pause time is 2 min. The monitor returns to the alarm after 2 minutes. To set the alarm pause time, alarm pause time Optional: 1min, 2min, 3min, 4min, 5min, 10min, 15min, permanent.

After the alarm stops, the user clicks the icon  under the single parameter interface to cancel the alarm stop.

6.6. Switching Off Alarms

If [Alarm Pause Threshold]is set to [Permanent] (see 16.4), then uses the key on the monitor panel  or the hot key in Main Menu  ,The monitor enters the alarm off state.

Physiological alarms are switched off. The alarm lamp does not flash and alarm sound is not issued.

The parameter and upper/lower limit of the physiological alarm will stop flashing.

The message Alarm Off is displayed in the physiological alarm information area.

The physiological alarm information area display [Alarm Pause] with red background.

Alarm sound of technical alarms is switched off, but alarm lamp flashes and alarm messages are presented.

During the alarm off period, the monitor will beep continuously to indicate that the device has turned off the alarm. The set interval range is not 10-60s, and the default interval is 30s.

After the alarm stops, the user uses the key on the monitor panel  or the hot key in Main Menu  to cancel the Switching Off alarm.

⚠ **WARNING**

Pausing or switching off alarms may result in a hazard to the patient.

6.7. Resetting Alarms

Select the key in Main Menu  ,then reset all the alarms currently occurring in the monitoring.

For physiological alarms, after pressing the Alarm Reset hot key, all physiological alarms will enter the alarm reset state except for the physiological alarms related to NIBP.

The alarm sound is silenced.

Display symbols in the alarm status symbol area 

A √ appears before the alarm message, indicating that the alarm is acknowledged.

Parameter measurement value and alarm limit will still flash.

Resetting Technical Alarms:

Display symbols in the alarm status symbol area 

For some technical alarms, including technical alarms related to NIBP, the alarm is silenced and a √ appears before the alarm message, indicating that the alarm is acknowledged.

Some technical alarms are changed to the prompt messages.

Some technical alarms are cleared. The monitor gives no alarm indications.

6.8. Testing Alarms

The monitor automatically performs a selftest at startup. At this time, the screen displays the boot screen, the technical alarm indicator and the alarm indicator light up in blue and yellow respectively, and then the alarm indicator will turn from yellow to red again, and the system will beep “Do” at the same time as the technical alarm indicator. This indicates that the visible and audible alarm indicators function correctly.

To further test individual measurement alarms, perform measurements on yourself or using a simulator （Such as SpO_2 or NIBP）. Adjust alarm limits and check that appropriate alarm behavior is observed.

6.9. Actions When an Alarm Occurs

When an alarm occurs, observe the following steps and take proper actions:

1. Check the patient’s condition.
2. Confirm the alarming parameter or alarm category.
3. Identify the source of the alarm.
4. Take proper action to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

7. ECG

7.1. Introduction

Electrocardiogram (ECG) measures the electrical activity of the heart and displays the ECG waveform and parameter values on the screen. This monitor provides 3 / 5 / 12 lead monitoring.

7.2. Safety precautions

⚠ WARNING

This equipment is not intended for direct cardiac application.

Use only the designated ECG electrodes and cables by Witleaf.

When placing electrodes or connecting cables, ensure that there is no contact with other conductive parts or places. In particular, make sure that all ECG electrodes are connected to the patient.

Check the skin at the placement electrode regularly. If there are signs of allergy, change the electrode or change the placement location.

Non-defibrillation type ECG cables shall not be used when patient defibrillation is required.

Do not touch the patient, table nearby, or the equipment during defibrillation.

NOTE

Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

7.3. Monitoring Procedure

7.3.1. Basic steps

1. Skin preparation. Proper skin preparation is necessary for good ECG signal quality at the electrode sites, as the skin is a poor conductor of electricity. To properly prepare the skin, choose flat and less muscle areas then follow this procedure:
   Shave hair from skin at chosen electrode sites.
   Gently rub skin surface at sites to remove dead skin cells.
   Thoroughly cleanse the site with a mild soap and water solution. ((no ether and pure alcohol, which increase skin impedance)
   Dry the skin completely before applying electrodes.
2. Attach clip or snap to electrodes prior to placement.
3. Put the electrodes on the patient.
4. Connect the electrode lead to the patient's cable.

⚠ WARNING

Verify lead fault detection prior to the start of monitoring phase. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

NOTE

Pay attention to using the same type of electrode on the same patient to avoid problems that may be caused by impedance differences.

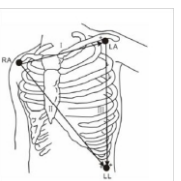
7.3.2. Choosing ECG lead

Select the ECG parameter area or waveform area, and open the [ECG setting] and [ECG alarm setting] menus.

In the [ECG setting] menu, select the button 

, then select the appropriate lead type in the pop-up list.

7.3.3. Installing electrodes



3-leadwire

Take American Standard as an example, the 3-lead electrode placement position is as shown:

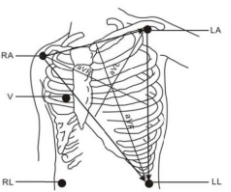
RA: directly below the clavicle and near the right shoulder.

LA: directly below the clavicle and near the left shoulder.

LL: on the left lower abdomen

5-leadwire

Take American Standard as an example, the 5-lead electrode placem ent position is as shown:



RA: directly below the clavicle and near the right shoulder.

LA: directly below the clavicle and near the left shoulder.

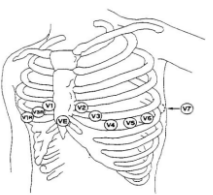
RL: on the right lower abdomen.

LL: on the left lower abdomen.

V: on the chest.

12-leadwire

Take American Standard as an example, the 12 conductive electrodes include the limbs and chest, the limbs should be placed on the soft skin of both hands and feet and the chest electrodes for the custody of the following positions:



V1 is between the fourth rib of the right margin of the sternum.

V2 is between the fourth corib of the left margin of the sternum.

V3 is in the middle position between V2 and V4.

V4 is between the fifth rib of the left collarbone midline.

V5 in left arm front, horizontal with V4.

V6 in the left arm midline, horizontal position equal to V4.

The V3R-V7R is located on the right side of the chest wall, and its position corresponds to the left side.

VE is located at the saber process uplift. For the back "V" lead placement,

To place the "V" electrode in one of the following locations.

V7 is on the back left armpit rear line between the fifth rib.

V7R is on the back right armpit rear line between the fifth rib.

⚠ WARNING

When using Electrosurgery equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

When using Electrosurgery equipment, never place an electrode near the grounding plate of the Electrosurgery device, otherwise there will be a great deal of interference with the ECG signal.

7.3.4. Checking Paced Status

It is important to correctly set the paced status before you start monitoring ECG. The **paced** symbol  is displayed when Paced is set to **Yes**. When the pacing signal is detected, the "|" symbol is marked at the ECG waveform baseline position, which is different from the waveform color. If Paced is set to No, there is no display in the pacing icon display area of the monitor.

To change the pacing state in either of the following ways:

Select the Patient Information Area, or:

Select [main menu] → [patient information],or:

Select the ECG numeric area or waveform area → [Other settings].

Then, select button 

, set [pacing] to [yes] or [no] in the pop-up menu.

If you do not set the pacing state, the monitor will give a prompt tone when detecting the pacing pulse, the pacing icon will flash, and" please confirm whether the patient has a pacemaker" will be displayed in the ECG waveform area. At this time, please check and set the pacing status of the patient.

⚠ WARNING

When connecting the ECG cable and performing an ECG test, a doctor is required to confirm that the patient has a pacemaker.

For paced patients, you must set Paced to Yes. Or, the monitor could mistake a pace pulse for a QRS complex and fail to alarm when the ECG signal is too weak. Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.

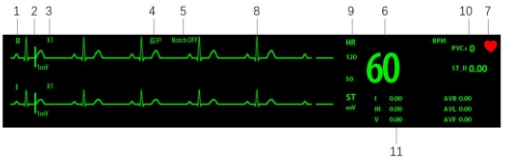
For non-paced patients, you must set Paced to No.

The auto pacer recognition function is not applicable to neonatal patients.

False low heart rate or false asystole alarms may result with certain pacemakers because of pacemaker artifacts, such as electrical overshoot of the pacemaker overlapping the true QRS complexes.

7.4. ECG Display

The following pictures show the 5-leadwire ECG monitoring interface, for reference only, your display may be configured to look slightly different.



1: ECG lead label of the displayed waveform

2: 1mv ruler

3: ECG waveform gain

4: ECG filter mode

5: Notch filter status

6: HR value

7: Pace pulse mark

8: ECG waveform

9: HR alarm limits

10: PVC value

11: ST value

7.5. Set up the ECG

7.5.1. Choose the ECG menu

Select the ECG numeric area and waveform area, choose the [ECG setting] menu.

7.5.2. Setting ECG Alarm

In most cases, the values of heart rate and pulse rate are the same. In order to avoid triggering heart rate and pulse rate alarms at the same time, the monitor can select one of them as the alarm source. To set ECG alarm properties, firstly enter the [SpO2 Setting] menu, select the [alarm source], then select:

[HR]: The monitor takes the heart rate as the alarm source of HR/PR.

[PR]: The monitor takes the pulse rate as the alarm source of HR/PR.

[Auto]: As long as ECG measurement is turned on and effective heart rate can be obtained, the monitor will take the heart rate measured by ECG as the alarm source. If the heart rate is not available, such as when the lead is disconnected, and a pulse source has been opened and available, the monitor will automatically take the pulse rate from the current measurement as the pulse source and switch the pulse to the alarm source. Then, if the heart rate can be obtained again, the monitor will automatically restore the heart rate to the alarm source.

7.5.3. Choosing the ECG Lead Type

In [ECG setting], choose 

, set [Lead Type].

7.5.4. Setting the ECG Screen

For 5-lead ECG monitoring, in [ECG setting], choose the key 

, then select an [ECG interface] from the pop-up list.

[Normal]: There is 2-lead ECG waveform is available.

[Full-Screen]: There is 7-lead ECG waveform is available, The waveforms of other parameters are not displayed.

[Half-Screen]: 7-lead half screen waveform is available.

For 12-lead ECG monitoring, only Full-Screen] is available.

7.5.5. Setting the ECG Filter

The setting of the ECG filtering mode determines how to smooth the ECG waveform.

In [ECG setting], choose the key 

, then select an [Filter] from the pop-up list.

[Diagnostic]: use when diagnostic quality is required. The unfiltered ECG waveform is displayed so that changes such as R-wave notching or discrete elevation or depression of the ST segment are visible.

[Monitor]: use under normal measurement conditions.

[Surgery]: Use when the signal is disturbed by high or low frequency. High-frequency interference usually causes high-amplitude spikes, causing the ECG signal to appear irregular. Low-frequency interference usually results in baseline

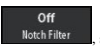
drift or thickening. In the operating room, selecting the [surgery] method can reduce the false difference and the interference from the electrosurgical equipment. In normal measurement situations, this selection may suppress the QRS wave group and disturb the ECG analysis.
[HARDEST]: is used with strong noise.

NOTE

It is recom mended to monitor the patient in a [standard] way when the interference is small.

7.5.6. Setting Notch Filter Frequency

When the filtering mode is diagnosis, the power frequency notch can be set.

In [ECG setting], select the [Other settings], choose the key 

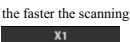
, select [close] [50Hz] [60Hz] [50/60Hz] from the pop-up list.

7.5.7. ECG Wave Settings

Select the ECG numeric area and waveform area, choose the [ECG setting] menu.

Choose the key 

: Select the appropriate setting in the pop-up list. The larger the value, the faster the scanning speed and the wider the waveform.

Choose the key 

: Select the appropriate setting in the pop-up list.

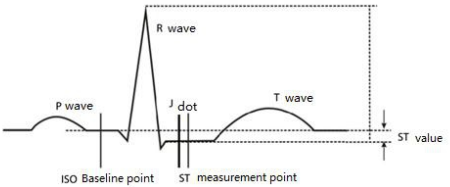
7.5.8. Set heartbeat volume

In [ECG setting] menu, select [Other setting], choose the key 

, Select the heartbeat volume from the pop-up list.

7.5.9. Setting HR limit

In [ECG alarm setting] menu, Heart rate alarm switch, alarm low limit and alarm high limit can be set. When the measured value of heart rate is higher or lower than the set value and the alarm is on, the advanced physiological alarm will be triggered to prompt [HR too high] or [HR too
low].



When you start monitoring or the patient's heart rate or ECG waveform changes significantly, you need to adjust the position of ISO and St points. Abnormal QRS complex is not considered in ST segment analysis.

⚠ WARNING

Please always ensure that the st measurement point is suitable for the monitored patient.

To adjust the ST segment analysis points:

1. In [ST Setting] menu, choose the key ST Position , enter the [st point setting] window, and the two vertical lines in the [ST point setting] window represent the positions of [ISO] and [St points] respectively.
2. Select the [ISO], [J] or [ST] option and then rotate the knob to adjust each point individually.

   The ISO-point cursor determines the position of the equipotential relative to the R peak. Position the ISO point in the middle of the flatter part of the baseline (located between the P and Q waves or between the P waves).

   The J point cursor determines the position of the J point relative to the R peak. He helps to locate the ST points correctly. Position the J point at the end of the QRS group, the beginning of the ST segment.

   "Point ST" is located at a fixed distance relative to Point J, J + 40, J + 60, and J + 80.

   Move the J point cursor to the ST point in the middle of the ST segment.

8. Respiratory

8.1. Overview

Impedance respiration is measured across the thorax. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the patient monitor screen.

8.2. Safety Information

⚠ WARNING

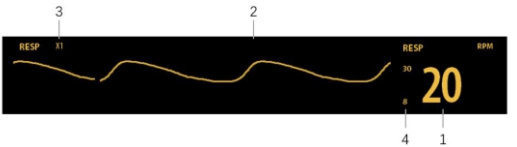
When monitoring the patient's respiration, do not use ESU-proof ECG cables.

If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the detection level too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.

The respiration measurement does not recognize the cause of apneas. It only indicates an alarm if no breath is detected when a pre-adjusted time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.

If operating under conditions according to the EMC Standard IEC 60601-1-2 (Radiated Immunity 3V/ m), field strengths above 3V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

8.3. Resp Display



1: Respiration rate (RR), **2**: Resp waveform, **3**: Resp waveform gain, **4**: Alarm limits

Select the ECG waveform area or numeric area to choose the [RESP setting] menu and [RESP alarm setting].

NOTE

Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

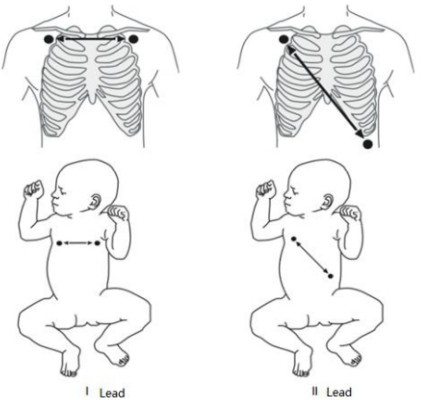
8.4. Placing the Resp Electrodes

Proper skin preparation is necessary for good signal quality at the electrode site, as the skin is a poor conductor of electricity. You can find out how to deal with the skin in the ECG section.

As the Respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables(3-lead 5-lead 12-lead). Since the respiration signal is measured between two ECG electrodes, if a standard ECG electrode placement is applied, the two electrodes should be RA and LA of ECG Lead I, or RA and LL of ECG Lead II.

NOTE

To optimize the respiration waveform, place the RA and LA electrodes horizontally when monitoring respiration with ECG Lead I; place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.



8.4.1. Adjust the Position of Respiratory Electrodes

If you want to measure breathing while measuring ECG, you may need to adjust the positions of the two electrodes that measure breathing. Adjusting the standard position of ECG electrode will lead to the change of ECG waveform and may affect ST arrhythmia analysis.

8.4.2. Cardiac activity superposition

The effect of cardiac activity on respiratory waveform is called cardiac activity superposition. This occurs when the respiratory electrode collects impedance changes caused by rhythmic blood flow. Correct electrodes placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.

8.4.3. Abdominal Beathing

Some patients with restricted movements breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

8.4.4. Thoracic Dilatation

In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform.

8.5. Select Calculation Channel

Select the key 

in [Resp Setting] menu, you can select [calculation Channel] as [I] or [II].

8.6. Set Suffocation Delay

Select the key 

in [resp setting] menu, set suffocation delay time, When the time of suffocation exceeds the set time, the monitor will trigger the alarm. The settings of [suffocation delay] in Resp and CO2 modules remain linked.

8.7. Setting the Resp Waveform

Open the [Resp setting] menu:

Select the key 

set waveform gain: The larger the gain, the higher the waveform amplitude. The user sets the respiratory calculation gain according to the current situation of the monitored patient. The higher the gain, the easier it is to detect the respiratory wave, and the weaker the anti-interference ability.

Select the key 

set scan speed: Select the appropriate setting in the pop-up list. The larger the value, the faster the scanning speed and the wider the waveform.

8.8. Setting the RR Source

Select the key 

in [resp setting] menu, then select a source or auto in the pop-up list.

This list displays the currently valid [RR sources]. When you select [Auto], the system automatically selects the [RR source] according to the priority. When the current [RR source] does not have valid measurement, the system automatically switches the [RR Source] to [Auto].

8.9. Set Calculation Sensitivity

Select the key 

in [Resp setting] menu, then select a sensitivity in the pop-up list.

8.10. Set Alarm Properties

In [Resp Alarm Setting] menu, alarm switch, alarm high limit and alarm low limit can be set. When the measured value of respiratory rate is higher or lower than the set value and the alarm is on, the advanced physiological alarm will be triggered to prompt [RR high limit] or [RR low limit].

the PR Alarm Source, then select:

[HR]: The monitor takes the heart rate as the alarm source of HR/PR.

[PR]: The monitor takes the pulse rate as the alarm source of HR/PR.

[auto]: As long as ECG measurement is turned on and effective heart rate can be obtained, the monitor will take the heart rate measured by ECG as the alarm source. If the heart rate is not available, such as when the lead is disconnected, and a pulse source has been opened and available, the monitor will automatically take the pulse rate from the current measurement as the pulse source and switch the pulse to the alarm source. Then, if the heart rate can be obtained again, the monitor will automatically restore the heart rate to the alarm source.

9.4. Set High and Low Saturation Limits

In the [SpO2 alarm setting] menu, the alarm switch and alarm low limit can be set. When the measured value of SpO2 is higher or lower than the set value and the alarm is on, the advanced physiological alarm is triggered.

9.5. QRS Volume

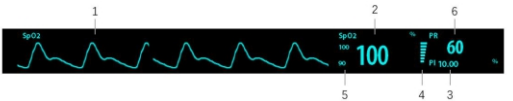
You can select the monitor to play the pulse sound by setting the pulse volume. When you select the pulse volume off, the monitor will stop playing the pulse sound. The setting process is as follows:

1. Enter [SpO2 setting] menu.
2. Select the key 2 Pulse Volume to Set QRS Volume.

10. SpO2

10.1. Introduction

SpO2 was measured by continuous and non-invasive pulsatile blood oxygen quantitative method. It measures the luminous flux of specific wavelength light emitted from the sensor light source, which is absorbed by oxygenated hemoglobin in the patient's tissue and reaches the photodetector end of the sensor, so as to obtain blood oxygen saturation and pulse rate. This monitor has been calibrated to display functional oxygen saturation.



1. Pleth waveform: The amplitude of Pleth waveform can directly reflect the strength of the patient's pulse signal. The waveform is not normalized.
2. Oxygen saturation of arterial blood (SpO2): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin. The update frequency is 1Hz.
3. Perfusion index(PI): Perfusion index is the percentage of pulsation volume and non-pulsation momentum caused by arterial blood flow change in blood oxygen signal. PI is an indicator of the pulsatile strength, and also use it to assess the quality of SpO2 measurement.

   Above 1 is optimal.

   Between 0.3 and 1 is acceptable.

   Below 0.3 indicates low perfusion. Reposition the SpO2 sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible.
4. Perfusion bar chart: proportional to pulse intensity.
5. Set the upper and lower limits of blood oxygen saturation.
6. Pulse rate: detected pulsations per minute (derived from the pleth wave).

10.2. Safety Information

⚠ WARNING

Use only SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.

Before use, the operator needs to verify the compatibility between the monitor, probe and cable, otherwise it may cause injury to the patient.

When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.

Do not use SpO2 sensors during magnetic resonance imaging (MRI). Induced current could potentially causes burns.

Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.

NOTE

Functional test equipment or blood oxygen simulator cannot be used to verify the accuracy of blood oxygen saturation monitor and pulse blood oxygen probe. The accuracy of oxygen saturation monitor and pulse oxygen probe needs to be verified by clinical data.

The blood oxygen probe and probe extension wire used with the monitor were confirmed and tested for the compliance of YY 0784-2010 together with the monitor.

10.3. Steps for SpO2 Monitoring

1. Select an appropriate sensor according to the module type, patient category and weight.
2. Clean the contact surface of the reusable sensor.
3. Apply the sensor to the patient according to the instruction for use of the sensor.
4. Select an appropriate extension cable according to the connector type and plug the cable into the SpO2 connector.
5. Connect the sensor to the extension cable.

10.4. SpO2 Settings

10.4.1. Open SpO2 Menu

You can select the SpO2 numeric area or waveform area to enter the [SpO2 setting] and [SpO2 alarm setting] menu.

10.4.2. Set High and Low Saturation Limits

In the [SpO2 alarm setting] menu, the alarm switch and alarm low limit can be set. When the measured value of SpO2 is higher or lower than the set value and the alarm is on, the advanced physiological alarm is triggered, it indicates that [blood oxygen concentration is too high] or [blood oxygen concentration is too low].

10.4.3. Set Sensitivity

The SpO2 value displayed on the monitor screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. For critically ill patients, selecting shorter averaging time will help understanding the patient's state.

In the [SpO2 alarm setting] menu, select the key 

, then select a sensitivity in the pop-up list. Set [sensitivity] to [low], [medium], [high], or [maximum], and the corresponding average time is 11 seconds, 9 seconds, 7 seconds and 5 seconds respectively.

10.4.4. Setting the Sweep Speed of the Pleth Wave

In the [SpO2 alarm setting] menu, you can set [waveform speed]. The larger the value, the faster the scanning speed and the wider the waveform.

10.4.5. Setting the Pleth Wave Mode

In the [SpO2 alarm setting] menu, you can set [waveform mode]. It includes [trace] and [fill] modes.

10.5. Limitations for Measurement

If you doubt the accuracy of the measurement results, first check the patient's vital signs by other methods, and then check the monitor and pulse oxygen probe. In operation, the accuracy of oximetry readings can be affected by:

External light radiation

Movement (Patient active or passive movement)

Diagnostic test

Weak perfusion

High-frequency electrical noise, Such as nuclear magnetic resonance equipment electrosurgical apparatus

Concentration of nonfunctional hemoglobin, such as carbon hemoglobin（COHb）and methemoglobin（MetHb）

Some kind of dyes, such as methylene blue and carmine indigo 一

Improper sensor installation or incorrect contact position of the patient

Shock, anemia, low temperature and application of vasomotor may all cause the arterial blood flow to reduce and hence make the measurement impossible.

11. NIBP

11.1. Introduction

The monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). It is applicable for adult, pediatric, and neonatal usage.

To understand how oscillation works, it can be compared with auscultation.

Auscultation: The doctor listens to the blood pressure through the stethoscope and obtains the systolic and diastolic blood pressure. As long as the arterial pressure curve is normal, the mean pressure can be calculated from systolic and diastolic blood pressure.

Oscillation method: The monitor cannot listen to blood pressure. It measures the vibration amplitude of cuff pressure. The change of blood pressure causes the vibration of the cuff. When the amplitude is the largest, the corresponding cuff pressure is the average pressure. After the mean blood pressure is measured, the systolic and diastolic blood pressure can be calculated.

Simply put, auscultation measures systolic and diastolic blood pressure and calculates the mean blood pressure. The mean blood pressure was measured by oscillation method, and the systolic and diastolic blood pressure were calculated.

NIBP can be measured during electrosurgery and during defibrillator discharge.

The clinical significance of NIBP measurement must be determined by the physician.

11.2. Safety Information

⚠ WARNING

Be sure to select the correct patient category setting for your patient before NIBP measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may present a safety hazard.

Do not measure NIBP on patients with sickle-cell disease or on the limb where skin damage has occurred or is expected.

Use clinical judgment to determine whether to perform frequent unattended

blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.

Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

If you doubt the NIBP measurements, determine the patient's vital signs by alternative means, and then verify that the monitor is working correctly.

11.3. NIBP Measurement Limitations

Measurements are impossible with heart rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

Regular arterial pressure pulses are hard to detect.

With excessive and continuous patient movement such as shivering or convulsions.

With cardiac arrhythmias.

With rapid blood pressure changes.

With severe shock or hypothermia that reduces blood flow to the peripheries

On an edematous extremity.

11.4. Measurement Modes

There are three NIBP measurement modes:

Manual: measurement on demand.

Auto: repeated measurements at set interval.

STAT: continually rapid series of measurements over a five-minute period.

11.5. Steps for NIBP Monitoring

11.5.1. Preparing for Measurements

1. If the monitor is off, turn on the monitor.
2. Verify that the patient category setting is correct. If not, make changes.
3. Connect the air tubing to the NIBP connector on the MPM module.
4. Select the cuff, confirm that the cuff has been completely deflated, and then tie it to the

patient's upper arm or thigh.

Determine the patient's limb circumference.

Select an appropriately sized cuff for the patient (The cuff is marked with the applicable limb circumference). The cuff width should be 40% of the limb circumference (50% for newborns) or 2 / 3 of the length of the upper arm. The length of the inflatable part of the cuff shall be enough to surround 50 ~ 80% of the limbs.

Apply the cuff to the patient's upper arm or leg and make sure the Φ marking on the cuff matches the artery location. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm (on adults), and loosely on neonates with little or no air present within the cuff. Otherwise it may cause discoloration and ischemia of the extremities. Make sure that the cuff index line falls within the range markings on the cuff.

5. Connect the cuff to the air tubing. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.

CAUTION

A wrong cuff size and a folded or twisted bladder can cause inaccurate measurements.

Do not touch the cuff or tubing during NIBP measurement.

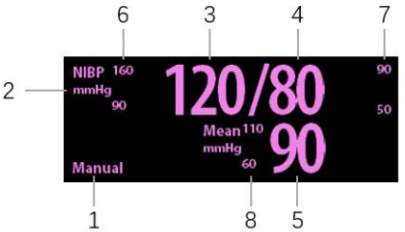
11.5.2. Starting and Stopping NIBP Measurements

You can use the key on the screen  NIBP measurement required for quick start, during measurement, and you can use the key on the screen  stop single NIBP measurement. You can also use the keys on the monitor panel  to start or stop NIBP measurement.

11.5.3. Changing Measuring Results

The part on the limb where blood pressure is measured shall be placed at the same level as the patient's heart. Otherwise, the following correction methods shall be used to correct the measurement results:

If the cuff is higher than the heart level, the measurement result shall be increased



1: Measurement mode

2: NIBP unit: mmHg or kPa

3: Systolic pressure

4: Diastolic pressure

5: Mean pressure displayed after measurement completed or cuff pressure displayed during the measurement.

6: Systolic pressure alarm limits

7: Diastolic pressure alarm limit

8: Mean pressure alarm limit

If NIBP measurement fails, “XX” is displayed; if NIBP measurement is not taken, “--” is displayed. If the measurement is stopped manually during the measurement, the last measured value is displayed.

11.7. NIBP Settings

Select the in the NIBP parameter area to open the [NIBP setting] menu and the [NIBP alarm setting] menu.

11.7.1. Setting the Initial Cuff Inflation Pressure

You can manually set the initial inflation pressure of the cuff. Open the [NIBP setting] menu and select the appropriate cuff pressure value in the [initial inflation pressure].

11.7.2. Setting the NIBP Alarm Properties

In the [NIBP alarm setting] menu, you can turn on or off the alarms of systolic blood pressure, diastolic blood pressure and average blood pressure, and set the alarm bottom limit and high

limit of systolic blood pressure, diastolic blood pressure and average blood pressure.

11.7.3. Setting the NIBP End Tone

The monitor can issue a reminder tone at the completion of NIBP measurement. The NIBP End Tone is off by default. You can turn on the NIBP completion tone in the [NIBP setting] menu.

11.7.4. Displaying the NIBP List

Under general interface, dynamic trend interface and large font interface, multiple groups of recent measurement results will be displayed, as shown in the following figure. The PR value comes from NIBP measurement.

Time	SYS	DIA	Mean	PR
19:28:59	250	250	250	250
19:28:57	250	250	250	250
19:28:55	250	250	250	250
19:28:53	250	250	250	250

Under [respiratory oxygenation interface], [ECG full screen 7-lead interface] and [ECG half screen 7-lead interface], NIBP cannot be displayed in [NIBP list].

11.7.5. Setting Pressure Unit

Select [unit setting] in the [user maintenance] menu, and the [pressure unit] can be set to [mmHg] or [kPa] in the pop-up menu.

11.8. Auxiliary venipuncture

Users can inflate with NIBP cuff to form a pressure close to diastolic pressure, block venous vessels and assist in venous puncture.

1. In the [NIBP setting] menu, confirm the value of [venipuncture pressure]. If not, adjust to the appropriate value.
2. Select [start auxiliary venipuncture].
3. Puncture the vein and draw a blood sample.
4. Select the onscreen button  or keys on the monitor panel  deflate the cuff. If the cuff is not deflated, the cuff will deflate automatically after a set time.

12. Temp

12.1. Introduction

Thermistor is used for temperature measurement, and its measurement principle is based on that the resistance value of thermistor will change with the change of temperature. Thermistors measure the resistance change and use it to calculate the temperature. The monitor measures temperatures of body surface and intracavity temperature. It can simultaneously monitor two temperature sites.

12.2. Safety Information

⚠ WARNING

Verify probe cables fault detection before beginning of monitoring phase. When the temperature probe cable of channel 1 or 2 is unplugged from the body temperature probe interface, the technical alarm will be triggered, and [T1 body temperature probe falls off] or [T2 body temperature probe falls off] will be prompted on the screen.

12.3. Temperature Measuring Steps

Please follow this procedure:

1. Select an appropriate probe for your patient according to patient category and measured site.
2. If you are using a disposable probe, connect the probe to the temperature cable.
3. Plug the probe or temperature cable to the temperature connector.
4. Follow the probe manufacturer's instructions to connect the probe to the patient.
5. The setting of the acknowledge alarm is applicable to the patient.

NOTE

The monitor supports body surface and body cavity probes. Please select the appropriate body temperature probe according to the patient type and

8.4.4. Thoracic Dilatation

In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform.

8.5. Select Calculation Channel

Select the key 

in [Resp Setting] menu, you can select [calculation Channel] as [I] or [II].

8.6. Set Suffocation Delay

Select the key 

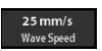
in [resp setting] menu, set suffocation delay time, When the time of suffocation exceeds the set time, the monitor will trigger the alarm. The settings of [suffocation delay] in Resp and CO2 modules remain linked.

8.7. Setting the Resp Waveform

Open the [Resp setting] menu:

Select the key 

set waveform gain: The larger the gain, the higher the waveform amplitude. The user sets the respiratory calculation gain according to the current situation of the monitored patient. The higher the gain, the easier it is to detect the respiratory wave, and the weaker the anti-interference ability.

Select the key 

set scan speed: Select the appropriate setting in the pop-up list. The larger the value, the faster the scanning speed and the wider the waveform.

measurement needs.

12.4. Temperature Display

The monitor can display the body temperature of the two channels (temp1 and temp2) and the difference between the two temperatures (TD).

Select temp parameter area to open [temp alarm setting] menu.

12.5. Temperature Settings

Setting the Temperature Unit

Click [unit setting] in the [user maintenance] menu, and the [temperature unit] can be set to [ºC] or [º F] in the pop-up menu.

13. CO2

13.1. Introduction

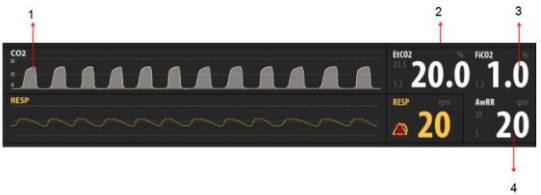
The monitor uses infrared absorption technology to measure the CO2 concentration in the patient's respiratory gas path. The principle is that CO2 molecules can absorb infrared light energy of specific wavelength, and the amount of absorbed energy is directly related to the concentration of CO2. When the infrared light emitted by the infrared light source penetrates the gas sample containing CO2, part of the energy will be absorbed by the CO2 in the gas. On the other side of the infrared light source, a photodetector is used to measure the remaining infrared light energy and convert it into an electrical signal. After the electrical signal is compared with the energy of the infrared light source and adjusted, it can accurately reflect the CO2 concentration in the gas sample.

The following two methods are used for measuring CO2:

Mainstream CO2 measurement: Directly insert a CO2 sensor into the patient's breathing system.

Sidestream/TiniStream CO2 measurement: Take a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO2 sensor built into the Sidestream or TiniStreamCO2 module.

13.2. CO2 Display



1: CO2 waveform

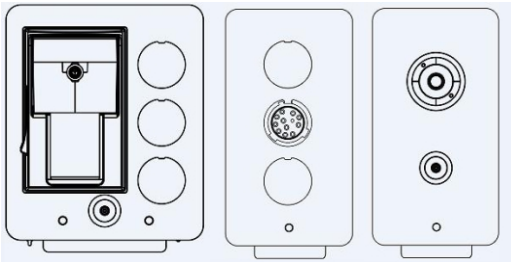
2: End tidal CO2 value (EtCO2): CO2 value measured at the end of expiratory phase.

3: Fraction of inspired CO2 (FiCO2): Minimum CO2 value measured during inhalation.

4: Airway respiration rate (awRR): Number of breaths per minute.

13.3. Identify CO2 Module

The CO2 module can be divided into side flow CO2 module, micro flow CO2 module and mainstream CO2 module. The plug-in box is divided into three, as shown in the figure below:



1: Side flow CO2 plug-in package with sink

2: Mainstream CO2 plug-in package or plug-in sidestream CO2 plug-in package

3: Microfluidic bypass carbon dioxide plug-in package

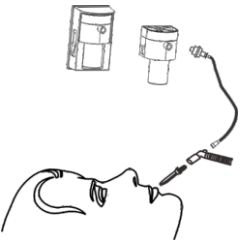
13.4. Preparing to Measure CO2

NOTE

CO2 measurement needs to be carried out in a well ventilated environment.

13.4.1. Sidestream CO2 Module

1. Install the water tank on the water tank fixing seat and connect the CO2 measurement assembly.



2. The bypass CO2 module defaults to the measurement mode. When the CO2 module is inserted, the screen will display [CO2 starting].
3. After startup, the screen displays [CO2 sensor preheating], and the module is in the quasi precision measurement state. At this time, the measurement can be carried out, but the accuracy is low.
4. After preheating, the module enters the full precision measurement state.

⚠ WARNING

Do not apply adult watertrap to the neonate patient. Otherwise, patient injury could result.

⚠ CAUTION

Connect the gas outlet to the scavenging system when measuring CO2 using the sidestream CO2 module.

The watertrap collects water drops condensed in the sample line and therefore prevents them from entering the module. To avoid blocking the airway, empty the watertrap container whenever half full.

The watertrap has a filter preventing bacterium, water and secretions from entering the module. After long-term use, dust or other substances may compromise the performance of the filter or even block the airway. In this case, replace the watertrap. Replacing the watertrap once a month is recommended.

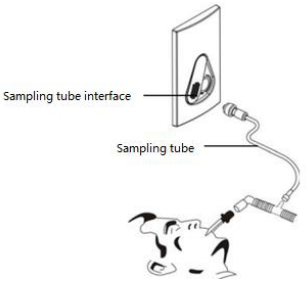
NOTE

When the CO2 monitoring function is not used, it is better not to connect the

water tank, and set the CO2 module to standby mode to improve the service life of the water tank and module.

13.4.2. TiniStream CO2 Module

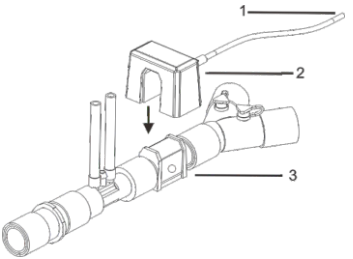
1. Connect one end of the sample line to the TiniStream CO2 module.



2. The microfluidic CO2 module defaults to the measurement mode. When the CO2 module is inserted, the screen displays [CO2 sensor preheating].
3. After preheating, the measurement can be started.

13.4.3. Mainstream CO2 Module

1. Connect the sensor to the CO2 module.
2. The mainstream CO2 module defaults to the measurement mode. When the CO2 module is inserted, the prompt message [CO2 sensor preheating] is displayed on the screen.
3. After preheating, connect the sensor to the gas path adapter.
4. Perform zero calibration as described in the zero calibration section.
5. After zero calibration, connect the gas circuit as shown in the figure below.
6. After confirming the tightness of the gas circuit, the measurement can be started.



Serial number	Name
1	Module connection end
2	Mainstream CO2 Module
3	Airway adapter

NOTE

Always position the sensor with the adapter in an upright position to avoid collection of fluids in the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.

13.5. Settings for All CO2 Modules

13.5.1. Enter CO2 Menu

Select the CO2 numeric area or waveform area to enter the [CO2 setting] menu and [CO2 alarm setting] menu.

13.5.2. Entering the Standby Mode

The standby mode of CO2 module is associated with the standby mode of monitor:

If the monitor enters the standby mode, the CO2 module also enters the standby mode.

If the monitor exits the standby mode, the CO2 module will also automatically exit the standby mode.

The CO2 module enters or exits the standby mode without affecting the monitor.

To manually enter or exit standby mode: Select the button 

in the [CO2 setting] menu, Set [operation mode] to [standby] or [measurement].

13.5.3. Setting the CO2 Unit

Click [unit setting] in the [user maintenance] menu, and the [CO2 unit] can be set to [mmHg], [%] or [kPa] in the pop-up menu.

13.5.4. Setting the Gas Compensation

⚠ WARNING

Make sure to use the appropriate compensations. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.

For the sidestream CO2 module:

1. Enter the [CO2 setting] menu.
2. Set the compensation according to the actual condition:

   [O2 concentration]

   [N2O concentration]

   [Anesthetic concentration]

For the TiniStream CO2 module, there is no need to set gas compensation.

For the mainstream CO2 module:

1. Enter the [CO2 setting] menu.
2. Set the compensation according to the actual condition:

   [Balance Gas]

   [Room Air]: When the main component of the patient's breathing gas is air.

   [N2O]: When the main component of the patient's breathing gas is N2O.

   [He]: When the main component of the patient's breathing gas is He.

   [O2 Compensation]

   [Off]: when the amount of O2 is less than 30%.

   Others: Select an appropriate setting according to the amount of O2 in the ventilation gas mixture.

   [AG Compensation]: enters the concentration of anesthetic gas present in the

ventilation gas mixture. This could compensate for the effect of AG on the readings.

13.5.5. Setting Humidity Compensation

The gas measured by CO2 module can be divided into two cases:

1. ATPD: Ambient Temperature and Pressure, Dry Gas
2. BTPS: Body Temperature and Pressure, Saturated, That is, humid gas with body temperature of 37 ° C, relative degree of 95% and partial pressure of water vapor of 47 mmHg.

The mainstream CO2 sensor has built-in heating devices to prevent water vapor condensation. Therefore, when using the mainstream CO2 module, it is not necessary to set humidity compensation. For side flow and micro flow CO2 modules, humidity compensation shall be turned on or off according to the actual situation. The setting method is:

1. Enter the [CO2 setting] menu.
2. In the case of BTPS or ATPD, select the button 

Set [BTPS compensation] to [on] or [off] respectively.

13.5.6. Setting Suffocation Delay

In the [CO2 setting] menu, select the button 

, [suffocation delay] can be set: The monitor will trigger an alarm when the time of asphyxia exceeds the set time. The monitor will trigger an alarm when the time of asphyxia exceeds the set time. The settings of [suffocation delay] in Resp and CO2 modules remain linked.

13.5.7. Setting Extraction Rate

For the bypass CO2 module, the sampling rate of respiratory gas in the patient's respiratory airway can be changed by setting the extraction rate. The setting method is: enter the [CO2 setting] menu and select the button 

, set the corresponding [extraction rate].

⚠ WARNING

When setting the extraction rate, please consider the actual bearing capacity of the patient and select the extraction rate suitable for the patient.

13.5.8. Setting the CO2 Waveform

Enter the [CO2 setting] menu.

1. Select button 

, set [waveform mode].

   [Tracing]: The CO2 waveform is depicted by lines.

   [filling]: The area below the CO2 waveform is filled.

2. Select button 

, set [waveform speed]: Select the appropriate setting in the pop-up list. The larger the value, the faster the scanning speed and the wider the waveform.

3. Select button 

, set [waveform ruler]: Adjust the position of the scale on the waveform to change the waveform amplitude accordingly.

13.6. Measurement Limitations

The following factors may influence the measurement accuracy:

Leaks or internal venting of sampled gas;

Mechanical impact;

Cyclic pressure up to 10 kPa (100 cmH2O);

Other sources of interference, if any.

13.7. Troubleshooting

When the sampling system of the bypass CO2 module is abnormal, first check whether the sampling pipes are wound together. When the sampling system of the bypass CO2 module is abnormal, first check whether the sampling pipes are wound together.

13.8. Exhaust gas emission

⚠ WARNING

When using side flow CO2 module or micro flow CO2 module to measure patients who are using anesthetics or have recently used anesthetics, the exhaust hole on

the module must be connected to the exhaust gas treatment system to prevent medical personnel from inhaling anesthetics.

An exhaust pipe is connected with the exhaust port on the module to exhaust the sample gas into the exhaust gas treatment system.

13.9. Zeroing

The purpose of zero calibration is to eliminate the influence of baseline drift on the results in the measurement process and ensure the correctness of the measurement results.

13.9.1. Sidestream/TiniStream CO2 Module

The sidestream or TiniStream CO2 module performs zero calibration automatically when needed. Users can also manually calibrate zero when they think it necessary: In the [user maintenance] menu, select [module maintenance > >] → [CO2 module maintenance > >] → [CO2 calibration > >], and then select [zero calibration]. During zero calibration, it is not necessary to disconnect the patient's air circuit.

13.9.2. Mainstream CO2 Module

For mainstream CO2 modules, the sensor should be zeroed in the following conditions:

1. A new adapter is used.
2. Reconnect the sensor to the module.
3. The message CO2 Zero Required displays. In this case, check the airway adapter for any blockage, e.g. mucus, etc. If a blockage is detected, clear or replace the adapter.

To zero the sensor, follow this procedure:

1. Connect the sensor to the module.
2. Select the CO2 parameter area, set the [operation mode] to [measurement] in the [CO2 setting] menu, and the screen will prompt [CO2 sensor preheating].
3. After warm-up is finished, connect the sensor to a clean, dry airway adapter. The adapter should be vented to the air and isolated from CO2 sources, such as ventilator, the patient's breathing, your own breathing, etc.
4. Select [Zero] in the [CO2 setting] menu. The message [Zeroing] is displayed.
5. It takes about 15 to 20 seconds. The message disappears when the zero calibration is completed.

⚠ WARNING

When perform a zero calibration during the measurement, disconnect the sensor from the patient's airway first.

Please do not rely on the readings during zeroing.

13.10. Calibration

For sidestream or TiniStream CO2 modules, a calibration should be performed once a year or when the readings go far beyond the range. The mainstream CO2 module does not require calibration. For details, see ***Maintenance***.

⚠ CAUTION

When calibrating the CO2 module, the calibration gas must be connected to the exhaust gas treatment system.

14. IBP

14.1. Overview

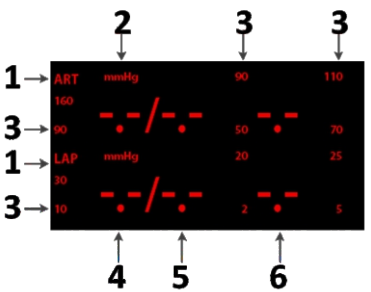
The device provides two channels for measuring the invasive blood pressure (diastolic pressure, systolic pressure and mean pressure) and displays two waveforms and parameter values on the screen, as shown below.

The options are: ART (Arterial Pressure), PA (Pulmonary Arterial Pressure), CVP (Central Venous Pressure), RAP (Right Atrial Pressure), LAP (Left Atrial Pressure), ICP (Intracranial Pressure) and P1, P2 (Inflation Pressure).

In addition, each waveform shows three ruler lines, and the scale is marked on the left of the upper and lower ruler lines.

14.2. Display of IBP parameters

The parameter window of the IBP is located on the right side of the IBP waveform as shown in the following figure.



SNumber	Figure name
1	Channel name；
2	Pressure Units：mmHg or kPa；
3	Alarm line；
4	Parameter values for channels, systolic pressure；
5	Parameter Values for Channel, Diastolic；
6	Parameter values for channels, mean pressure；

⚠ WARNING

Use only the pressure transducers specified in this insert. Do not reuse the disposable pressure transducers.

It is necessary to ensure that the accessories used meet the safety requirements for medical device.

Accessories and live parts shall be prevented from contact when they are connected and used.

When the monitor is connected to the high frequency surgical equipment, it is necessary to avoid contact between the sensor and cable of the monitor and the high frequency surgical equipment, so as to prevent leakage current from burning the patient.

Sensor cables should be checked for proper operation before starting monitoring. When the sensor is removed from the IBP interface, the monitor will prompt the message "IBP Sensor Disconnected" on the screen and issue an alarm tone.

The sensors (excluding ICT/B sensor) specified in this instruction have the function of preventing electric shock (especially preventing leakage current) and preventing the effect of cardiac defibrillator, so they can be used for surgical operation. When the patient is in defibrillation, the pressure wave may be temporarily disturbed. After defibrillation, the monitor will work normally. The operation mode and user configuration of the monitor will not be affected.

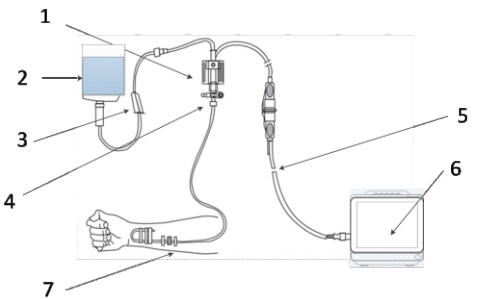
The sensor should be calibrated periodically per hospital procedures.

14.3. Monitoring procedures

1. Plug the pressure sensor cable into the corresponding IBP sensor interface, and power on the monitor;
2. Prepare the pressure tube and sensor by filling the system with normal saline solution to ensure that there are no bubbles in the catheter system;
3. Connect the arterial catheter to the pressure tube, and ensure that there is no air in the catheter and pressure tube as well as in the transducer;
4. The transducer is placed at the level of heart, approximately in the midaxillary line;
5. Confirm that the correct name has been selected;
6. Zero the sensor.

NOTE

If the pressure tube or sensor shows bubbles, the liquid perfusion system



SNumber	Figure name
1	Pressure transducer；
2	Anticoagulant saline；

3	Valve：
4	Three-way valve：
5	Pressure Sensor Interface Cable：
6	Monitor：

14.4. IBP Measurement Settings

The IBP setting menu is called up. The user may use the shuttle or touch screen to click the IBP display area to call up the IBP setting menu. The menu is as follows:

In this menu, the user can set the following items:

Alarm switch	On: alarm prompt and storage in case of IBP alarm; Off: no alarm prompt and storage in case of IBP alarm; When "OFF" is selected, icon " ⚠ "will appear in the "Alarm Line in IBP Parameter Display Area" area.
Alarm limit setting	Enter the menu as shown in the following figure to set the upper limit and lower limit for triggering alarm.
Amplitude regulation	For adjusting the amplitude of waveform, there are two options: manual and automatic;
Waveform speed	Three options: 6.25mm/s, 12.5mm/s, 25.0mm/s;
Pressure Units	Two options: mmHg, kPa;
Filtering mode	Set the filtering mode of IBP waveform, with two options:

	filtering 1: filtering at the frequency of 12.5Hz; f iltering 2: filtering at the frequency of 40Hz;
Indicate settings	The IBP channel can be selected as ART, PA, CVP, RAP, LAP, ICP, P1 or P2IBP measurement range to be adjusted through the Pressure Scale Adjustment > > item;
Zeroing	Zeroing the IBP

The set range of alarm limit is as follows:

Pressure Name	High alarm limit	Low alarm limit	Adjustment step
ART	(mmHg) (mmHg)	(mmHg) (mmHg)	(mmHg) (mmHg)
PA	120	-6	1
CVP	40	-10	1
RAP	40	-10	1
LAP	40	-10	1
ICP	40	-10	1
P1	300	-50	1
P2	300	-50	1

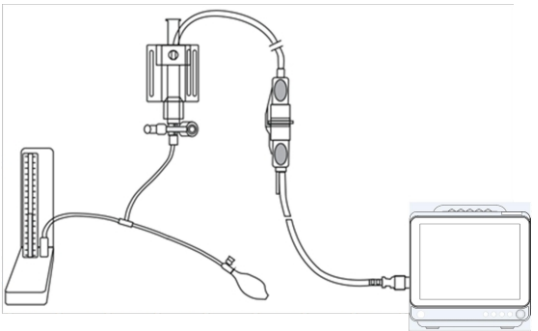
14.5. IBP Pressure Zeroing

In the IBP Settings menu, click IBP Pressure Zeroing to enter Zeroing for the current channel.

14.5.1. Zeroing steps

1. Disconnect the pressure sensor from the patient;
2. Close the channel from the three-way switch to the patient, so that the sensor passes through the three-way switch to the atmosphere;
3. Click Zero to begin Zeroing.

14.6.1. Calibration procedure



1. Disconnect the pressure transducer from the patient, and connect the three-way stopcock to the sphygmomanometer and inflated balloon with a T-shaped connector, as shown in the following figure;
2. First perform the zeroing operation. After successful zeroing, lead the three-way switch to the sphygmomanometer end;
3. Select the box on the right side of "Channel 1 Pressure Calibration Value" or "Channel 2 Pressure Calibration Value" in the "IBP Pressure Calibration" menu to set the pressure value calibrated by this channel;
4. Use an inflatable balloon for inflation, so that the pressure reading of

sphygmomanometer is close to the pressure value set in the menu;

5. Repeatedly adjust the calibration pressure value in menu and the pressure value of sphygmomanometer, until they are equal;
6. Select the "Calibrate" button, the monitor will start calibration;
7. Wait for the calibration results, and take the corresponding countermeasures according to the prompt message;
8. After calibration, remove the sphygmomanometer tubing and T-connector, and connect the sensor to the patient for monitoring according to the operating specifications.

NOTE

Calibration should be performed before using a new sensor, or per hospital procedures.

Calibration is to ensure that the monitor can provide accurate measurement results, and zero calibration should be performed before calibration.

⚠ WARNING

Do not perform calibration while monitoring a patient.

14.6.2. Calibration prompt

By Channel 1, after a calibration operation, the monitor may prompt the following:

"Channel 1 Calibration Successful!": Channel 1 works correctly and the user can use channel 1 to monitor the patient for IBP.

"The channel 1 sensor is off and cannot be calibrated!": Confirm that the channel 1 sensor is not off and calibrate again. If this prompt still appears, contact service.

"In Demo state, cannot calibrate": Observe whether the "Demo" text is displayed on the screen, cancel the Demo state and then calibrate; if this prompt still appears, please contact the service personnel.

"Pressure is out of range and cannot be calibrated": Confirm that the selected calibration value is reasonable before calibration. If this prompt still appears, contact the manufacturer's service personnel.

"Pulsatile pressure, cannot be calibrated": Confirm that the current pressure value of sphygmomanometer is constant, and then perform calibration. If this prompt still appears, contact the manufacturer's service personnel.

15. EEG

15.1. nomenclature

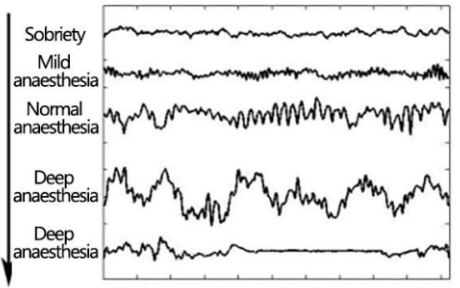
Ai	Anesthesia consciousness index: Based on multiple indicators of frequency, time domain, complexity and other indicators, a multivariate statistical method is used to quantify the brain waves from awake to the deepest degree of anesthesia
SQI	EEG signal mass index: values calculated based on electrode impedance changes, artifact signals, and other variables
EMG	EMG index: including EMG artifacts and other high-frequency interference signals
BSR	Outbreak inhibition ratio: indicates the proportion of the EEG burst and inhibition state during anesthesia, and the inhibition state when the EEG amplitude is very weak
EEG	EEG: Raw EEG signals are processed by filters at a scanning rate of 1 g / s and an amplitude of 25 microvolt / Gs
False trace signal	Interference signals of non-brain waves

15.2. introduce

15.2.1. principle

The monitor can record, display and analyze the EEG (EEG) signals, the main function is to be used in the operating room together with the anesthetic sedation drugs to monitor the patient's anesthesia status, and can also be used in the serious illness care unit and clinical research.The monitor includes the Ai index and other EEG process parameters that can effectively reflect the patient's EEG changes during anesthesia.

The brain is the main area of action of anesthetic drugs, and there are relatively obvious changes in the brain waves under different states of anesthesia, so the brain waves can be used to evaluate the patient's state of consciousness.Based on the large number of parameters derived from the brain waves, multivariate statistics were used to quantify the brain waves from the awake to the deepest degree of anesthesia (that is, the Ai index).The Ai index ranges from 0 to 99% (0 indicates the deepest degree of anesthesia), and the lower the value indicates the deeper the degree of anesthesia.



The EEG maps of the different anesthetic states

The Ai index depicted in time becomes the trend chart of the Ai index.It and the trend chart of some other parameters provide the user with the overall effect of the patient's state of consciousness during the procedure.

Imimpedance detection is used to check the sensor connectivity to ensure good signal quality.During the ongoing recording process, the system performs impedance testing at regular intervals.Interference detection uses a large number of mathematical algorithms for the automatic detection of non-brain waves (such as blink, electric knife).The SQI (signal quality index) provides users with the current signal quality.

15.2.2. Indications, scope of application, contraindications, and precautions

Indications: This monitor is used to collect and analyze the patient's EEG signals, and to automatically score the depth of anesthesia consciousness for the operating room, neurosurgery, intensive care unit and clinical research to evaluate the patient's EEG consciousness status.

Scope of application: clinically used for EEG signal acquisition and anesthesia status monitoring in adult patients.

Contraindications and precautions: Patients with known neurological disorders, psychotropic medication, central nervous system history or cerebrovascular diseases need a careful explanation of the Ai index.

Attachment: A disposable EEG sensor, a disposable accessory for the monitor, and must be replaced after each use.Refer to Figures 2 and Figure 3.

15.3. operate

15.3.1. Paste sensor

Follow the instructions on the sensor package, determine the location of the sensor (Figure 6) and secure the sensor to the patient's head.Note the following matters when pasting the sensor:

Avoid the distortion or bending of the sensor.

Avoid sticking the sensor to the skin damage.

Ensure that the surrounding adhesive ring is firmly pasted to avoid pressing the middle of the electrode.

The sensor part shall avoid contact with other conductive parts.

Please use the standard disposable EEG sensor.

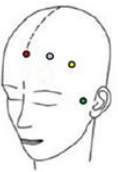


Figure 2 The EEG acquisition point

15.3.2. Connect the sensor to the anesthesia depth guide wire

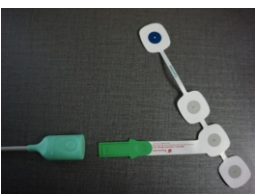


Figure 3 Connecting the anesthesia depth guide line

Each time the sensor is connected to the anesthesia depth guide wire, the monitor detects the integrity of the sensor to determine if the sensor is valid.

15.3.3. Sensor detection

The sensor detection function of the monitor detects the impedance on the electrode to verify that it is within an acceptable range.After connecting the anesthesia depth guide line to the host machine, and connecting the sensor to the anesthesia depth guide line, the monitor automatically performs impedance detection, and the user can also press the [impedance detection] button for impedance detection.

When connecting the anesthesia depth guide wire, try to ensure that the two cables before and after the anesthesia depth guide cable do not cross, and avoid the guide wire being pressed, moved or trampled, so as not to affect the EEG recording results.

The "impedance detection interface" is displayed.The interface displays each electrode on the sensor, indicated by color indicating each electrode status, with a corresponding text prompt below each electrode:

By: The electrode icon is green, indicating that the impedance is within an acceptable range and can begin monitoring.

High: The electrode icon is in red, indicating that the impedance is beyond the acceptable range.Press all sides of each electrode in turn to ensure a firm paste. If the impedance still does not pass, press the electrode with the appropriate strength (if the conductive glue does not overflow). If the impedance does not pass or even improve during the period, please remove the sensor and reuse a new sensor after cleaning the skin.

Noise: The electrode icon is gray, indicating that the electrode impedance cannot be measured.Monitoring can only begin if the interference is removed and all electrodes pass detection.

Loss: electrode icon is hollow circle indicating electrode loss or poor contact.

No text prompt: means that the electrode status is unknown, and when ready, the electrode logo will be displayed.

When the electrode state is through or high, the corresponding impedance value is shown above the electrode.

When all electrode detection passes, the main interface will be entered and the monitoring will begin.

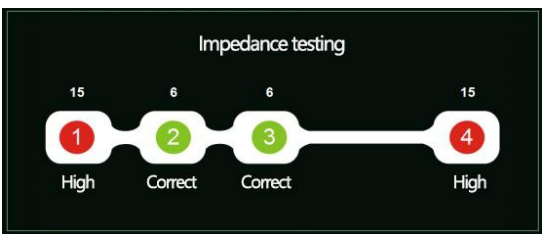


Figure 4. Sensor impedance detection

15.4. Home interface view

unit labels appear on the right coordinate axis line.The second parameter trend name is shown in the top right corner of the chart.

15.4.8. Impedance detection button

[Impedance Detection] Button 	[Impedance Detection] Button: This button is used to manually start the sensor impedance detection. Sensor detection will occur automatically when the anesthesia depth guide wire and the sensor are connected to the host.Select this option to perform another detection at any time. After the automatic detection passes, the detection interface is automatically withdrawn.Users can also press the lit [impedance detection] button again at any time to exit.Refer to No.3 Sensor Detection 3.3.3.

15.4.9. False trace signal

When the collected signal has interference, the artifact signal icon is displayed to the right of the signal mass index.

16. Freeze

16.1. Introduction

When monitoring a patient, you may freeze the waveforms of interest so as to view them carefully.

16.2. Enter Freeze Status

In the Non-Freeze status, press the button  on the front panel of the monitor, at the time, the interface is frozen, all the waveforms are frozen. The system will no longer refresh all other waveform, the data in the parameter area is refreshed normally.

16.3. Exit Freeze Status

In the Freeze status, press the button  on the front panel of the monitor, 此 the interface will discharge the Freeze status, all waveforms continue to refresh or scroll.

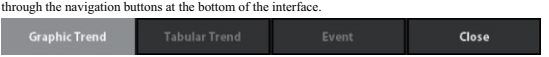
17. Review

17.1. Introduction

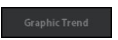
The multi parameter monitor supports trend review, which can view the monitoring information of the previous period. Trend review supports three forms: trend table review, trend chart review and event review.

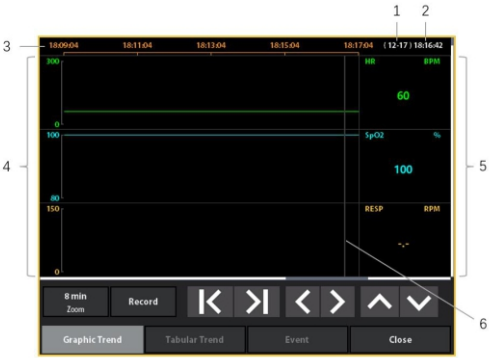
17.2. Enter the Review Window

enter the review window: Select the Review quick key  you can enter the trend review interface. You can freely switch the trend chart, trend table and event interfaces through the navigation buttons at the bottom of the interface.



17.3. Trend Graph

Select from the navigation button  at the bottom of the trend review window, you can enter the review trend chart interface as following:



1: Current date, **2**: Cursor time,**3**: Timeline,**4**: Waveform area, **5**: Numeric area, **6**: Cursor

Select 

, you can set the length of time for the review window.

Select 

, the trend graph displayed in the current window can be recorded.

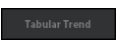
Select  and  , you can page left or right to move the waveform.

Select  and  , the trend cursor can be moved left or right.

Cursor time displays the time corresponding to the current cursor position, and the trend data area displays the parameter data at that time, which will change automatically with the movement of the trend cursor.

Select  and  , The trend display of different parameters can be switched up or down.

17.4. Trend Table

Select from the navigation button 

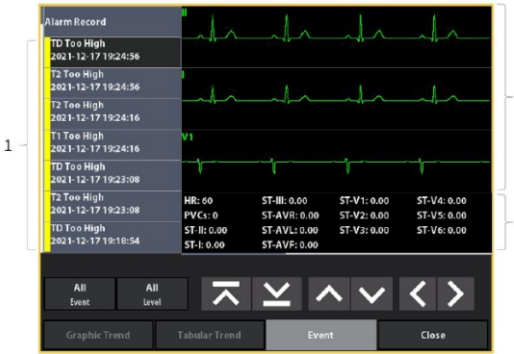
at the bottom of the trend review window, you can enter the review trend table interface as following:

1: Current date, **2**: Timeline,**3**: parameter list, **4**: Waveform area,

- Select 5 s Interval, the time resolution of the review window can be set.
- Select Record. The trend data displayed in the current window can be recorded.
- Select and , you can page left or right to browse the trend table.
- Select and , you can browse the trend table left or right.
- Select and , the trend data of different parameters can be switched up or down.

17.5. Events Review

Select from the navigation button Event at the bottom of the trend review window, you can enter the event review interface, as following:



1: Event list, **2**: Event waveform display, **3**: Event parameter value

- select 

, you can set events that display specific types, Including ECG events, SpO2 events, IBP events, NIBP events, resp events, temp events, CO2 events, manual events and all events.
- select 

, you can set and display specific levels of events, including low-level events, medium-level events, high-level events and all events.
- select  and  , you can page up or down to browse the event table and refresh the waveform and parameter value display.
- select  and  , you can browse the event table up or down and refresh the waveform and parameter value display.
- select  and  , different waveforms and parameters can be switched left or right.

18. Calculation

18.1. Calculation Overview

The monitor provides calculation functions. The calculated values, which are not directly measured, are computed based on the values you provide. The calculation function is independent of other monitoring functions and can therefore be used for patients being monitored by other monitors. Any operation in a calculation dialog does not affect the patient monitored by the current monitor.

You can perform the following calculate:

- Drug calculate
- Hemodynamic calculate
- Oxygenation calculate
- Ventilation calculate
- Renal calculate

18.2. Calculation Safety Information

⚠ **WARNING**

-
  - **Decisions on the choice and dosage of drugs administered to patients must always be made by thephysician in charge. The drug calculations are based on the values input; it does not check the plausibility of the calculation performed.**
  - **Check that the entered values are correct and the calculated values are appropriate. Witleaf assumes no responsibility for any consequences caused by wrong entries and improper operations.**

18.3. Dose Calculate

18.3.1. Dose Calculation Procedure

To perform drug calculations, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.

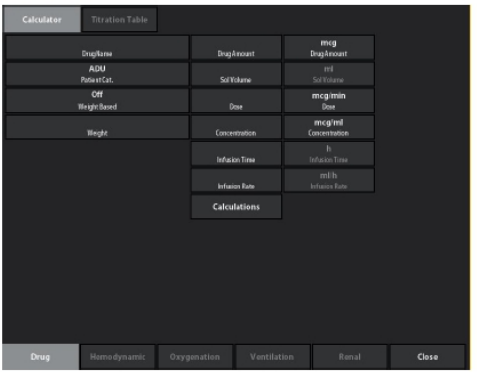
2. Select 

to enter the Calc interface.

3. Select the 

to set Drug Name, Drug Amount and PatientCat , etc.

As shown below:



NOTE

- **When you first enter medication calculation, the patient type and weight recorded in the Patient Management menu are automatically added to the medication calculation menu. You can change the patient type and weight, which does not change the patient type and weight recorded in the Patient management menu.**
-

18.3.2. Checking the Titration Table

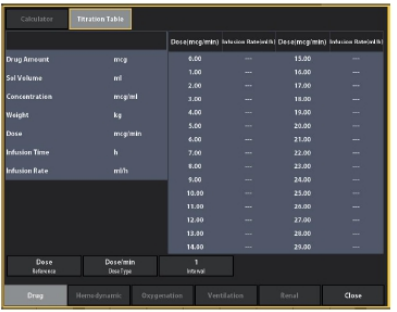
The titration table shows information on the currently used drugs. Use the titration table to see what dose of a drug your patient will receive at different infusion rates.

To access the titration table, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.

2. Select Calc to enter the Cals interface.

3. Select the Titration Table to checking the Titration Table. As shown below:



4. Select Dose Type to set the type of dose unit in the titration table.

5. Select Interval to set the interval between two adjacent titration table items.

6. You can select how to display the titration table:
   - Dose: the titration table is listed in the sequence of increased drug dose.
   - Infusion Rate: the titration table is listed in the sequence of increased infusion rate. By default the resolution of the infusion rate is one (1). By selecting Exact Rate the resolution of the infusion rate can reach 0.01 so that you can display the infusion rate more accurately.

18.3.3. Dose Calculation Formula

Description Unit Formula	Description Unit Formula	Description Unit Formula
Dose	G series：mcg、mg、g Unit series：unit、kU、MU mEq series：mEq	Dosage = dose x infusion time
Dose (weight based)	g series: mcg, mg, g unit series: Unit, KU, MU	Dose (weight dependent) = dose x infusion time x weight

	mEq series: mEq	
liquid volume	L、ml、μμ	Liquid volume = infusion speed x infusion time
dose	Dose /h Dose /min	Dose = infusion speed x drug concentration
dose(related to weight)	Dose /kg/h Dose /kg/min	Dose (weight dependent) = infusion speed x drug concentration/body weight
drug concentration	mcg/ml、mg/ml、g/ml、Unit/ml、kU/ml、mEq/ml	Drug concentration = dose/liquid volume
infusion time	h	Infusion time = dosage/dose
infusion time(related to weight)	h	Infusion time (weight dependent) = dosage/(dose x weight)
infusion speed	ml/h	Infusion speed = dose/drug concentration
infusion speed(related to weight)	ml/h	Infusion speed (weight dependent) = dose x weight/drug concentration

18.3.4. Titration Table Calculation Formula

Description Unit Formula	Description Unit Formula	Description Unit Formula
Infusion Rate	ml/hr	Infusion Rate = Dose/Concentration
Infusion Rate (weight based)	ml/hr	Infusion Rate = Weight × Dose/Concentration
Dose	Dose/hr Dose/min	Dose = Infusion Rate × Concentration
Dose (weight based)	Dose/kg/hr	Dose (weight based) = Infusion Rate × Concentration/Weight

18.4. Hemodynamic Calculate

18.4.1. Hemodynamic Calculations Procedure

To perform hemodynamic calculations, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.
2. Select 

to enter the Calc interface.

3. Select the Hemodynamic to setting relevant information . As shown below:

4. Enter the known values. For a patient who is being monitored, the currently measured values are automatically entered.
5. Select Calculations to calculate the value of each output parameter
6. Select【Range】to show the normal range of each parameter.
7. Select【units】to display the units for each parameter.

18.4.2. Input Parameters for Hemodynamic Calculations

Input Parameter	Label	Unit
cardiac output	C.O.	L/min
heart rate	HR	bmp
pulmonary artery wedge pressure	PAWP	mmHg
mean arterial pressure	AP-MAP	mmHg

pulmonary artery mean pressure	PA-MAP	mmHg
central venous pressure	CVP	mmHg
end-diastolic volume	EDV	ml
height	Height	cm
weight	Weight	kg

18.4.3. Calculated Parameters and Formulas for Hemodynamic Calculations

Calculated Parameters	Label	Unit	Formula
cardiac index	C.I.	L/min/m2	C.I.(L/min/m2)=C.O.(L/min)/BSA(m2)
body surface area	BSA	ml	BSA(m2)=W0.425(kg)xH0.725(cm)x0.007184
stroke volume	SV	ml	SV(ml)=1000xC.O.(L/min/m2)/HR(bpm)
stroke index	SVI	ml/m2	SVI(ml/beat・m2)=SV(ml/beat)/BSA(m2)
systemic vascular resistance	SVR	DS/cm5	SVR(Dyn/S/cm5)=79.96x[APMAP(mmHg)-CVP(mmHg)]/C.O.(L/min)
systemic vascular resistance index	SVRI	DS•m2/cm 5	SVRI(Dyn/S・m2/cm5)=SVR(Dyn/S/cm5)xBSA(m2)
pulmonary vascular	PVR	DS/cm5	PVR(Dyn/S/cm5)=79.96x[PAMAP(mmHg)-PAWP(mmHg)]/C.O.(L/mi

resistance			n)
pulmonary vascular resistance index	PVRI	DS•m2/cm 5	PVRI(Dyn/S・m2/cm5)=PVR(DS/cm5)xBSA(m2)
left cardiac work	LCW	kg•m	LCW(kg・m)=0.0136xAPMAP(mmHg)xC.O.(L/min)
left cardiac work index	LCWI	kg•m/m2	LCWI(kg・m/m2)=LCW(kg・m)/BSA(m2)
left ventricular stroke work	LVSW	g•m	LVSW(g・m)=0.0136xAPMAP(mmHg)xSV(ml)
left ventricular stroke work index	LVSWI	g•m/m2	LVSWI(g・m/m2)=LVSW(g・m)/BSA(m2)
right cardiac work	RCW	kg•m	RCW(kg・m)=0.0136xPAMAP(mmHg)xC.O.(L/min)
right cardiac work index	RCWI	kg•m/m2	RCWI(kg・m/m2)=RCW(kg・m)/BSA(m2)
right ventricular stroke work	RVSW	g•m	RVSW(g・m)=0.0136xPAMAP(mmHg)xSV(ml)
right ventricular stroke work index	RVSW I	g•m/m2	RVSWI(g・m/m2)=RVSW(g・m)/BSA(m2)
ejection fraction	EF	%	EF(%)=100xSV(ml)/EDV(ml)
end-diastolic volume index	EDVI	ml/m2	EDVI (ml/m2) = EDV (ml)/BSA (m2)
end-systolic volume	ESV	ml	ESV (ml) = EDV (ml) –SV (ml)
end-systolic	ESVI	ml/m2	ESVI (ml/m2) = ESV (ml)/BSA (m2)

volume index			

18.5. Oxygenation Calculate

18.5.1. Oxygenation Calculations Procedure

To perform Oxygenation calculations, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.
2. Select  to enter the Calc interface.
3. Select the  to set relevant information. As shown below:

4. Enter the correct values for each parameter. For the patient being monitored, the monitor takes the current measured value as input, and the height and weight are derived from the input patient information.
5. Select the 【Calculate】 button to calculate the value of each output parameter.
6. Select【OxyCont Unit】,【Hb Unit】and【Pressure Unit】. Then corresponding parameter values will be automatically converted and updated accordingly.
7. Select 【Range】to show the normal range of each parameter.

8. Select 【units】 to display the units for each parameter.

18.5.2. Input Parameters for Oxygenation Calculations

Input Parameter	Label	Unit
cardiac output	C.O.	L/min
percentage fraction of inspired oxygen	FiO2	%
partial pressure of oxygen in the arteries	PaO2	mmHg,kPa
partial pressure of carbon dioxide in the arteries	PaCO2	mmHg,kPa
arterial oxygen saturation	SaO2	%
partial pressure of oxygen in venous blood	PvO2	mmHg,kPa
venous oxygen saturation	SvO2	%
hemoglobin	Hb	g/L,g/dl, mmol/L
respiratory quotient	RQ	无
atmospheric pressure	ATMP	mmHg, kPa
height	Height	cm, inch
weight	Weight	kg, lb

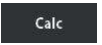
18.5.3. Calculated Parameters and Formulas for Oxygenation Calculations

Calculated Parameters	Label	Unit	Formula
body surface area	BSA	m2	BSA(m2)=Wt0.425(kg)*Ht0.725(cm)*0.007184
oxygen consumption	VO2	ml/min	VO_2(ml/min)=C(a-v)O_2(ml/L)*C.O.(L/min)
arterial oxygen content	CaO2	ml/L, ml/dL	CaO_2(ml/L)=10*(0.0134*Hb(g/dl)*SaO_2(%))+0.031*PaO_2(mmHg)
venous oxygen content	CvO2	ml/L, ml/dL	CvO_2(ml/L)=10*(0.0134*Hb(g/dl)*SvO_2(%))+0.031*PvO_2(mmHg)
arteriovenous oxygen content difference	C(a-v)O2	ml/L, ml/dl	C(a-v)O_2(ml/L)=CaO_2(ml/L)*CvO_2(ml/L)
oxygen extraction ratio	O2ER	%	O_2ER(%)=100*C(a-v)O_2(ml/L)/CaO_2(ml/L)
oxygen transport	DO2	ml/min	DO_2(ml/min)=C.O.(L/min)*CaO_2(ml/L)
partial pressure of oxygen in the alveoli	PAO2	mmHg, kPa	PA0_2(mmHg)=[ATMP(mmHg)*47mmHg]*FiO_2(%)/100*PaCO$_2$(mmHg)*[FiO_2(%)/100+(1*FiO_2(%)/100)/RQ]
alveolar-arterial oxygen difference	AaDO2	mmHg, kPa	$AaDO_2$(mmHg)=PAO_2(mmHg)*PaO_2(mmHg)
capillary oxygen content	CcO2	ml/L, ml/dl	CcO_2(ml/L)=Hb(g/L)*1.34+0.031*PAO_2(mmHg)
venous admixture	QS/QT	%	QS/QT(%)=100*[1.34*Hb(g/L)*(1*SaO_2(%)/100)+0.031*(PAO_2(mmHg)*PaO_2(mmHg))] /[1.34*Hb(g/L)*(1*SvO_2(%)/100)+ 0.031*(PAO_2(mmHg)*PvO_2(mmHg))]
oxygen transport index	DO2I	ml/min/m2	DO_2I(ml/min/m^2)=CaO_2(ml/L)*(C.O.(L/min)/BSA(m^2))
oxygen consumption	VO2I	ml/min/m2	VO_2I(ml/min/m^2)=C(a-v)O_2(ml/L)*(C.O.(L/min)/BSA(m^2))

18.6. **Ventilation Calculate**

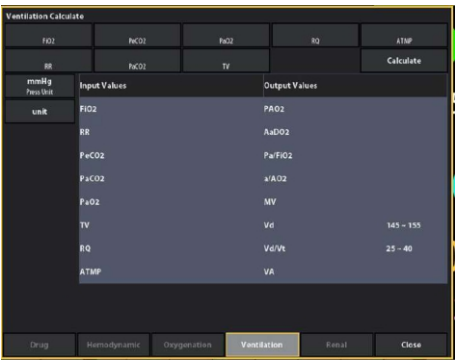
18.6.1. Ventilation Calculations procedure

To perform ventilation calculations, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.
2. Select 

to enter the Calc interface.
3. Select the 

to set relevant information. As shown below:



4. Enter the known values. For a patient who is being monitored, the currently measured values are automatically taken. If the anesthesia machine or ventilator is connected, measured values for ventilation calculation are also automatically entered.
5. Select the 【Calculate】button to calculate the value of each output parameter.
6. Select 【Pressure Unit】Then corresponding parameter values will be automatically converted and updated accordingly.
7. Select 【Range】to show the normal range of each parameter.
8. Select 【units】to display the units for each parameter.

18.6.2. Input Parameters for Ventilation Calculations

Input Parameter	Label	Unit
percentage fraction of inspired oxygen	FiO2	%
respiration rate	RR	rpm
partial pressure of mixed expiratory CO2	PeCO2	mmHg, kPa
partial pressure of carbon dioxide in the arteries	PaCO2	mmHg, kPa
partial pressure of oxygen in the arteries	PaO2	mmHg, kPa
tidal volume	TV	ml
respiratory quotient	RQ	None
atmospheric pressure	ATMP	mmHg, kPa

18.6.3. Calculated Parameters and Formulas for Ventilation Calculations

Calculated Parameters	Label	Unit	Formula
partial pressure of oxygen in the alveoli	PAO_2	mmHg,kPa	PAO_2(mmHg)=(ATMP(mmHg)-47 mmHg)× FiO_2(%)/100 - $PaCO_2$(mmHg) [FiO_2(%) /100+(1-FiO_2 (%) /100)/RQ]
respiratory quotient	RQ		RQ = VCO2/VO2
alveolar-arterial oxygen difference	$AaDO_2$	mmHg,kPa	AaDO2 (mmHg)= PAO2(mmHg)-PaO2(mmHg)

oxygenation ratio	Pa/FiO_2	mmHg,kPa	Pa/FiO_2 (mmHg)= 100 $ratio_2$(mmHg)/FiO_2 (%)
arterial to alveolar oxygen ratio	a/Ao_2	%	a/AO_2 (%) = 100 alveolar oxygen r_2(mmHg)
minute volume	MV	L/min	MV(L/min)=[TV (ml) r ox (rpm)]/1000
volume of physiological dead space	Vd	ml	vd (ml)= TV(ml)olo1 - $PeCO_2$(mmHg)/$PaCO_2$(mmHg)]
physiologic dead space in percent of tidal volume	VD/Vt	%	vd/vt (%)=100 ad space in perce
alveolar volume	VA	L/min	VA(L/min) = [TV (ml) e in percent of tidal v

18.7. Renal Calculate

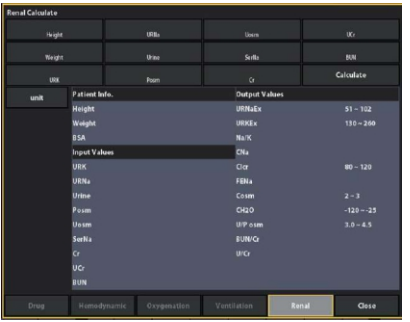
18.7.1. Renal Calculations Procedure

To perform ventilation calculations, follow this procedure:

1. Select the hot key in Main Menu  turn to the [General Settings] menu.
2. Select 

to enter the Calc interface.
3. Select the 

to set relevant information. As shown below:



4. Enter the known values. For a patient who is being monitored, the currently measured values are automatically taken. If the anesthesia machine or ventilator is connected, measured values for ventilation calculation are also automatically entered.
5. Select the 【Calculate】button to calculate the value of each output parameter.
6. Select 【Range】to show the normal range of each parameter.
7. Select 【units】to display the units for each parameter.

18.7.2. Calculated Parameters and Formulas for Renal Calculations

Input Parameter	Label	Unit
urine potassium	URK	mmol/L
urinary sodium	URNa	mmol/L
urine	Urine	ml/24 hrs
plasm osmolality	Posm	mOsm/kgH2O
urine osmolality	Uosm	mOsm/kgH2O
serum sodium	SerNa	mmol/L

creatinine	Cr	μmol/L
urine creatinine	UCr	μmol/L
blood urea nitrogen	BUN	mmol/L
height	Height	cm
weight	Weight	kg

18.7.3. Calculated Parameters and Formulas for Renal Calculations

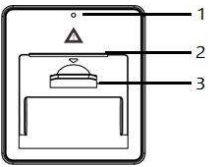
Calculated Parameters	**Label**	**Unit**	**Formula**
urine sodium excretion	URNaEx	mmol/24hrs	URNaEx (mmol/24hrs)=Urine(ml/24 h) for Renal Calculat
urine potassium excretion	URKEx	mmol/24hrs	URKEx(mmol/24hrs)= Urine(ml/24 h)) for Renal Calcu
sodium potassium ratio	Na/K	%	Na/K(%)= 100sium ratione(ml/24 h)) for
clearance of sodium	CNa	ml/24hrs	CNa (ml/24hrs)=URNa (mmol/L)24 h)) for Renal Calculationsr
creatinine clearance rate	Clcr	ml/min	Clcr (ml/min)= Ucr(μmol/L)×Urine (ml/24 h)/[Cr(μmol/L)×(BSA(m^2)/1.73)l/min)
fractional excretion of sodium	FENa	%	FENa (%)= 100cretion of sodiumneμmol/L)/[SerNa (mmol/L)×Ucr(μmol/L)]
osmolar clearance	Cosm	ml/min	Cosm (ml/min)=Uosm (mOsm/kgH_2O)sm (ml/min)=Uosm (mOsm/kgHumneμm$_2$O)sm 40)
free water clearance	CH2O	ml/hr	CH_2O (ml/hr)= Urine (ml/24 h)×[1-Uosm (mOsm/kgH_2O)/Posm(mOsm/kgH_2O)]/24
urine to plasma osmolality ratio	U/P osm	无	U/Posm= Uosm (mOsm/kgH_2o)/Posm (mOsm/kgH_2o)

blood urea nitrogen creatinine ratio	BUN/Cr*	无	BUN/Cr= 1000itrogen creatininμmol/L)
urine-serum creatinine ratio	U/Cr	无	U/Cr (mmol/L) = Ucr(μmol/L)/Cr(μmol/L)

19. Recording

19.1. Recorder

The plug-in thermal recorder records patient information, it supports multiple recording types, and can output patient information, measurement data, review data and up to 3 waveforms.



1: indicator light

- On: when the recorder works correctly.
- Off: when the monitor is switched off.
- Flashes: if an error occurred to the recorder, for example: lack of paper.

2: Paper outlet

3: Recorder latch

19.2. Recording Type

According to the triggered mode, records can be divided into:

1. Manually initiated real-time recording.
2. The recorder automatically starts timing recording according to the set interval.
3. Alarm records triggered by parameter overrun or arrhythmia.
4. Manually initiated records related to a specific function.

19.3. Starting /Stopping Recordings

To manually start a recording, you can:

1. Select the key on the monitor panel, Start real-time recording.
2. Select [record] in the upper left corner of the current menu or window, start records

related to specific functions.

Automatic recordings will be triggered in the following conditions:

1. Timed recordings will start automatically at preset intervals.
2. When Print on Alarm is set to Recorder and Print on Alarm for a measurement are set to on, if On/Off for an alarm is set to on, an alarm recording will be triggered automatically as alarms occur.

During recording, you can manually stop recording in the following ways:

1. Select the key  on the monitor panel.
2. Select [stop] in the [print setting] menu.

Recordings stop automatically when:

1. A recording is completed.
2. The recorder runs out of paper.
3. A technical failure occurred that caused the recorder to fail to work properly.

19.4. Setting the Recorder

19.4.1. Enter the Settings Menu

Select the key  in [main menu], The [print setting] menu can be opened.

19.4.2. Select the Recorded Waveform

The recorder can output up to 3 waveforms at a time.

1. Enter the [record setting] menu.
2. In the [print setting] menu, you can select [waveform 1], [waveform 2] and [waveform 3] successively, and then select the label of the waveform in the pop-up list.

19.4.3. Set up Real-time Recording

When starting a real-time recording, the length of recording depends on your settings for the monitor.

1. Enter the [record setting] menu.
2. Set [length] to:

   [10 seconds]: record the waveform for 5 seconds before and after the current time.

   [continuous]: record the waveform after the current time until the user stops recording.

door and take out the printing paper roll.

2. Cut off the draped part.
3. Reload the paper and close the recorder door.

19.7. Clean Recorder

After long-term use of the recorder, paper scraps and impurities will accumulate on the print head, affecting the quality of the record and the service life of the print head and roller shaft. Please clean as follows:

1. Before cleaning, take measures to prevent static electricity from damaging the recorder, such as wearing a disposable anti-static bracelet.
2. Open the recorder door and take out the recording paper to avoid interfering with cleaning.
3. Use a cotton ball to dip an appropriate amount of alcohol, and then gently wipe the surface of the thermal parts of the print head.
4. After the alcohol is completely dry, reinstall the recording paper and close the recorder door.

⚠ CAUTION

- **Do not use anything that will damage thermal components, such as sandpaper.**
- **Do not squeeze the thermal print head.**

20. Nurse Call

20.1. Introduction

The monitor provides a nurse call connector to output nurse call signal when a user-defined alarm occurs. To obtain nurse call signal, use the nurse call cable to connect the hospital nurse call system with the monitor's nurse call connector.

Alarms are indicated on the nurse call device only when the following conditions are met:

1. The nurse call system is enabled.
2. A user-defined alarm occurs.
3. Alarms are not paused or reset.

The setting method is as follows:

4. Select the[Main Menu] key →[Maintenance]→[Nurse Call Settings], open the [Nurse Call Settings] menu.
5. Set various options in the pop-up menu.。

- 【Trigger type】
  - [Open]: select this option when the hospital's call system is set to [Open].
  - [Closed]: select this option when the hospital call system is set to [Closed].
- [Alarm Level]: select the alarm level that triggers the nurse call signal.
- [Alarm Type]: select the alarm type that triggers the nurse call signal.

If no selection is made for [Alarm Level] or [Alarm Type], any alarm will not trigger the nurse call signal.

⚠ WARNING

- **The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the monitor, used in conjunction with clinical signs and symptoms, are the primary source for notifying medical personnel that an alarm condition exists.**

21. Battery

21.1. Battery Introduction

The monitor is equipped with one removable rechargeable lithium batteries. The function of lithium batteries is to ensure the normal use of the monitor in case of power failure or no network power. This type of rechargeable lithium battery cannot be charged by external charging equipment. When the monitor is connected to AC power supply, start charging the battery. In case of sudden power failure, the system will automatically switch from network power state to battery power supply for the monitor, and will not cause interruption of monitoring work.

The battery can maintain the normal operation of the monitor for about four hours under the new state.

It takes six hours for the battery to go from empty to 90 per cent full.

On-screen battery power indicator indicates the battery status:

-  : The battery works correctly. The green portion represents the remaining charge.
-  : The battery power is low and needs to be charged.
-  : The battery is being charged.
-  :
-  :
-  : No battery is installed.

⚠ WARNING

- **Do not disassemble the battery, put it into a fire or short it. Battery burning, explosion and leakage may cause personal injury. Do not directly touch the leaking battery.**
- **Keep batteries out of children's reach.**
- **Use only specified batteries, otherwise it may cause unexpected harm to users and patients.**

- **If the battery shows signs of damage or signs of leakage, replace it immediately.**
- **Do not use the faulty battery for the monitor, otherwise it may cause unexpected harm to users and patients.**

NOTE

- **The capacity of the battery is limited. When the battery is low, the technical alarm will be triggered and the message [Low Battery Power] will be displayed. In order to ensure the normal operation of the monitor, connect the monitor to AC power supply and charge the battery in time or replace a full battery.**
- **If the battery is obviously damaged or cannot store electricity, replace it and recycle it correctly.**
- **To dispose of the batteries, follow local laws for proper disposal.**

21.2. Checking Battery Performance

The performance of a rechargeable battery may deteriorate over time.To condition a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Connect the monitor to AC power supply and charge the battery continuously for more than 6 hours.
3. Allow the monitor to run on the battery until the battery is completely depleted and the monitor automatically shuts down.
4. The operating time of the batteries reflects their performance directly.
5. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may reach its service life or malfunction. Contact your service personnel.

NOTE

- **Life expectancy of a battery depends on how frequent and how long it is used. When properly used, the lithium-ion battery has a useful life of approximately three years. If improperly used, its life expectancy can be shortened. We recommend replacing lithium-ion batteries every three years.**
- **Battery operating time depends on equipment configuration and operation. For**

example, high display brightness or measuring NIBP repeatedly will shorten the battery operating time.

21.3. Conditioning Battery Performance

When the battery is used for the first time, it shall ensure at least two complete battery conditioning cycles. A battery conditioning cycle is one uninterrupted charge of the battery, followed by an uninterrupted discharge of the battery. Batteries should be conditioned regularly to maintain their useful life. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To condition a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.
2. Insert the battery in need of conditioning in the battery slot of the monitor.
3. Apply AC power to the monitor and allow the battery to charge uninterrupted for 6 hours.
4. Remove AC power and allow the monitor to run from the battery until it shuts off.
5. Apply AC power again to the monitor and allow the battery to charge uninterrupted for 6 hours.
6. This battery is now conditioned and the monitor can be returned to service.

21.4. Recycling Batteries

When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

22. Care and Cleaning

22.1. Care and Cleaning Safety Information

⚠ WARNING

- **When monitoring the patient's breathing, anti electric knife ECG cable can not be used.**
- **Before cleaning the monitor or the sensor, make sure that the equipment is switched off and disconnected from the power line.**

⚠ CAUTION

- **If you spill liquid on the equipment or accessories, disconnect the power supply, dry the equipment, and contact your service personnel.**

NOTE

- **Use only Witleaf approved cleaners and disinfectants and methods listed in this chapter to clean or disinfect your equipment.**
- **For the cleaning and disinfection of reusable accessories, please refer to the relevant accessories manual.**
- **Never immerse any part of the equipment or accessories in liquids.**
- **Never allow liquid to enter the interior of equipment.**
- **Do not press the display during cleaning, otherwise the display glass will be damaged.**

22.2. Cleaning Methods

Clean your equipment on a regular basis. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment. To clean the monitor, follow this procedure:

1. Turn off the power and disconnect the power cord.
2. Clean the dust on the monitor and cable line with a clean lint-free cloth.
3. Use gauze stained with an appropriate amount of detergent to wipe the surface and

cable of the monitor.

4. Use a lint-free cloth to wipe the cleaner on the monitor and cable line.
5. Allow the monitor air dry in a ventilated and cool place.

NOTE

The following are the cleaning agents available for cleaning:

- Sodium hypochlorite (bleaching powder for washing)
- Hydrogen Peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

22.3. Disinfection Methods

The disinfectant used for disinfection will damage the surface of the monitor shell and the cable to a certain extent, such as leaving spots on the plastic surface of the shell. Therefore, this operation manual recommends that you disinfect the monitor when you think it is necessary.

NOTE

Disinfectant recommended in this Operation manual:

- Ethanol (70%)
- Isopropanol (70%)
- Shuanmei active oxygen disinfectant (grade C / D)

23. Accessories

The accessories listed in this chapter comply with the requirements of corresponding standards when in use with the patient monitor. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with standards. For details about the accessories, refer to the instructions for use provided with the accessory.

⚠ WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the monitor or not meet the claimed specifications.**
- **The accessories listed in this chapter must be used together with the company's monitoring equipment. The user is responsible for reading the operation manual of the equipment (including accessories) or contacting the company for consultation before use to confirm the matching between the accessories and the equipment. Otherwise, it may cause injury to the patient.**
- **Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**

⚠ CAUTION

- **If the use or storage environment of accessories exceeds the specified temperature or humidity range, the performance of accessories may not meet the claimed specifications. If the performance of accessories decreases due to aging or environmental conditions, please contact our company or maintenance personnel.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if their expiry date is indicated.**
- **The disposable accessories shall be disposed of according to hospital's regulations.**

NOTE

- **Use the accessories before the expiry date if their expiry date is indicated.**
- **For sterilization accessories, please refer to the package of accessories.**

23.1. ECG、RESP Accessories

Name	PN	Description
10-lead ECG Leadwires（IEC）	E10R-WTL-P/I-Z	Used for 10-lead ECG monitoring.
10-lead ECG Leadwires（AHA）	E10R-WTL-P-Z	Used for 10-lead ECG monitoring.
5-lead ECG Leadwires（IEC）	25126EP-I	Used for 5-lead ECG monitoring(Resistance to electric knife).
5-lead ECG Leadwires（IEC）	25126RP-I-Z	Used for 5-lead ECG monitoring.
5-lead ECG Leadwires（AHA）	25126RP-Z	Used for 5-lead ECG monitoring.
3-lead ECG Leadwires（IEC）	23126RP-I-Z	Used for 3-lead ECG monitoring.
3-lead ECG Leadwires（AHA）	23126RP-Z	Used for 3-lead ECG monitoring.

23.2. SpO2 Accessories

Name	PN	Specifications	Description
SpO2 Extension Cables	U708-257	Reusable	
SpO2 Probes	U403-01	Adult	Reusable
SpO2 Probes	U103-01	Children	Reusable
SpO2 Probes	F543-01	Adult/Neonate Foam Adhesive/	Disposable
SpO2 Probes	U403S-01	Adult Soft Silicone	Reusable
SpO2 Probes	U303-01	Neonate,Foot Wrap	Reusable
SpO2 Probes	U603-01	Adult/Neonate Y-Type Wrap Silicon	Reusable
SpO2 Probes	U543-01	Pediatric	Reusable
SpO2 Probes	AMD-RS-AC6501-S	Adult	Reusable
SpO2 Probes	AMD-RS-AC0014-L	Children	Reusable
SpO2 Probes	AMD-RS-AC0022-L	Adult/Neonate Foam Adhesive/	Disposable

23.3. NIBP Accessories

NIBP External Tube	HS30-16-15	

NIBP Cuff	U1869S-C12	Reusable-Large Adult (Range 33-47cm)
NIBP Cuff	U1880S-C12	Reusable-Adult (Range 25-35cm)
NIBP Cuff	U1885S-C12	Reusable-Small Adult (Range 20-28cm)
NIBP Cuff	U1881S-C12	Reusable-Pediatric (Range 18-26cm)
NIBP Cuff	U1882S-C12	Reusable-Infant (Range 10-19cm)
NIBP Cuff	U1883S-C12	Reusable-Neonate (Range 6-11cm)
NIBP Cuff	U1685S-C12	Disposable-Infant (Range 8-15cm)
NIBP Cuff	U1684S-C12	Disposable-Infant (Range 7-13cm)
NIBP Cuff	U1683S-C12	Disposable-Infant (Range 6-11cm)
NIBP Cuff	U1682S-C12	Disposable-Infant (Range 4-8cm)
NIBP Cuff	U1681S-C12	Disposable-Infant (Range 3-6cm)
NIBP Cuff	V0115C	Reusable-Large Adult (Range 33-47cm)
NIBP Cuff	V0114C	Reusable-Adult (Range 25-35cm)
NIBP Cuff	V0113C	Reusable-Pediatric (Range 20-28cm)
NIBP Cuff	V0112C	Reusable-Pediatric (Range 18-26cm)
NIBP Cuff	V0111C	Reusable-Infant (Range 10-19cm)
NIBP Cuff	V0110C	Reusable-Neonate (Range 6-11cm)
NIBP Cuff	V2115N	Disposable-Infant (Range 8-15cm)
NIBP Cuff	V2114N	Disposable-Infant (Range 7-13cm)
NIBP Cuff	V2113N	Disposable-Infant (Range 6-11cm)
NIBP Cuff	V2112N	Disposable-Infant (Range 4-8cm)
NIBP Cuff	V2111N	Disposable-Infant (Range 3-6cm)
NIBP Cuff	WL-RNP-05	Reusable-Large Adult (Range 33-47cm)
NIBP Cuff	WL-RNP-04	Reusable-Adult (Range 25-35cm)
NIBP Cuff	WL-RNP-03	Reusable-Pediatric (Range 20-28cm)
NIBP Cuff	WL-RNP-02	Reusable-Pediatric (Range 18-26cm)
NIBP Cuff	WL-RNP-01	Reusable-Infant (Range 10-19cm)
NIBP Cuff	WL-RNP-00	Reusable-Neonate (Range 6-11cm)
NIBP Cuff	WL-NP-05	Disposable-Infant (Range 8-15cm)
NIBP Cuff	WL-NP-04	Disposable-Infant (Range 7-13cm)
NIBP Cuff	WL-NP-03	Disposable-Infant (Range 6-11cm)
NIBP Cuff	WL-NP-02	Disposable-Infant (Range 4-8cm)
NIBP Cuff	WL-NP-01	Disposable-Infant (Range 3-6cm)

23.4. TEMP Accessories

Name	PN	Description
Adult Body Surface TEMP Probes	TWTL-AS	Reusable

23.5. IBP/ICP Accessories

Name	PN	Description
IBP Cables	BC-WTL-MX	/
IBP Cables	BC-WTL-UT	/
IBP sensor	JIBPT-01-YP	Disposable
IBP sensor	JIBPT-01-UT	Disposable

23.6. CO2 Accessories

23.6.1. Sidestream CO2 Accessories

Name	PN	Description
Ordinary gas sample cannula	Sidestream-line	Sidestream Luer Sample Line
Ordinary gas sample cannula	Sidestream-AAA	Sidestream Adult/Pediatric Airway Adapter Sample Line
Ordinary gas sample cannula	Sidestream-IAA	Sidestream Infant Airway Adapter Sample Line
Ordinary gas sample cannula	Sidestream-3LM	Adult Nasal CO2 Cannula
Ordinary gas sample cannula	Sidestream-3MF	Pediatric Nasal CO2 Cannula
Ordinary gas sample cannula	Sidestream-3SM	infant Nasal CO2 Cannula
Ordinary gas sample cannula	Sidestream-4LMS	Adult Nasal CO2 Cannula With O2
Ordinary gas sample cannula	Sidestream-4MFS	Pediatric Nasal CO2 Cannula With O2
Ordinary gas sample cannula	Sidestream-4SMS	Infant Nasal CO2 Cannula With O2
Ordinary gas sample cannula	Sidestream-LAAM	Analyzer Mask, Large Adult
Ordinary gas sample cannula	Sidestream-SAAM	Analyzer Mask, Small Adult
Ordinary gas sample cannula	Sidestream-PAM	Analyzer Mask, Pediatric

23.6.2. TiniStream CO2 Accessories

Name	PN	Description
Dry gas sample cannula	TiniLine	TiniLine Luer Sample Line
Dry gas sample cannula	Tiniline-AAA	TiniLine Adult/Pediatric Airway Adapter Sample Line
Dry gas sample cannula	Tiniline-IAA	TiniLine Infant Airway Adapter Sample Line
Dry gas sample cannula	Tiniline-3LM	Adult Nasal CO2 Cannula
Dry gas sample cannula	Tiniline-3MF	Pediatric Nasal CO2 Cannula
Dry gas sample cannula	Tiniline-3SM	Infant Nasal CO2 Cannula
Dry gas sample cannula	Tiniline-4LMS	Adult Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline-4MFS	Pediatric Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline-4SMS	Infant Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline-LAAM	Analyzer Mask, Large Adult
Dry gas sample cannula	Tiniline-SAAM	Analyzer Mask, Small Adult
Dry gas sample cannula	Tiniline-PAM	Analyzer Mask, Pediatric

23.6.3. Mainstream CO2 Accessories

Name	PN	Description

Adult adapter	M401B-RA	Reusable
Adult adapter	M401B-A	Disposable
Pediatric adapter	M401B-N	Disposable

23.6.4. TiniStream 8 CO2 Accessories

Name	PN	Description
Dry gas sample cannula	TiniLine 8	TiniLine 8 Luer Sample Line
Dry gas sample cannula	Tiniline 8-AAA	TiniLine 8 Adult/Pediatric Airway Adapter Sample Line
Dry gas sample cannula	Tiniline 8-IAA	TiniLine 8 Infant Airway Adapter Sample Line
Dry gas sample cannula	Tiniline 8-3LM	Adult Nasal CO2 Cannula
Dry gas sample cannula	Tiniline 8-3MF	Pediatric Nasal CO2 Cannula
Dry gas sample cannula	Tiniline 8-3SM	Infant Nasal CO2 Cannula
Dry gas sample cannula	Tiniline 8-4LMS	Adult Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline 8-4MFS	Pediatric Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline 8-4SMS	Infant Nasal CO2 Cannula With O2
Dry gas sample cannula	Tiniline 8-LAAM	Analyzer Mask, Large Adult
Dry gas sample cannula	Tiniline 8-SAAM	Analyzer Mask, Small Adult
Dry gas sample cannula	Tiniline 8-PAM	Analyzer Mask, Pediatric

23.7. EEG Accessories

Name	PN	Description
Depth of anesthesia lead	PK2.087.004	Reusable
EEG sensor	ConViewYY-105	Disposable

24. Maintenance

24.1. Introduction

Before the monitor is used, continuously used for 6-12 months, repaired or upgraded, a comprehensive inspection shall be conducted by qualified maintenance personnel to ensure the normal operation and work of the monitor. The inspection items shall include:

- The environment and power supply meet the requirements。
- No mechanical damage to equipment and accessories.
- The power line shall be free of wear and good insulation performance.
- Use specified attachments
- The function of the alarm system is normal.
- The recorder works normally and the recording paper meets the specified requirements.
- Battery performance.
- Various monitoring functions are in good working condition.
- The grounding impedance and leakage current meet the requirements

If any damage or abnormality is found, please do not use the monitor, and immediately contact the medical engineer of the hospital or the maintenance personnel of the company.

⚠ WARNING

- **Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If necessary, please contact our company for product circuit diagram, parts list, calibration instructions or other information related to equipment maintenance**
- **If you discover a problem with any of the equipment, contact your service personnel or Witleaf.**

24.2. Maintenance Schedule

Except for visual inspection, startup detection, touch screen calibration, battery inspection and recorder inspection, the following tasks can only be completed by professional maintenance personnel. When the following maintenance is required, please contact the maintenance personnel in time. Make sure to clean and disinfect the equipment before taking any tests and maintenance.

<table>
<tr><th colspan="2">Test/Maintenance Item</th><th>Recommended Frequency</th></tr>
<tr><td colspan="3">Preventive Maintenance</td></tr>
<tr><td colspan="2">Visual Inspection</td><td>First installation, or after each reinstallation</td></tr>
<tr><td rowspan="2">NIBP Test</td><td>Pressure test</td><td rowspan="5">■ If users suspect that the measurement values are incorrect.
■ Follow any repairs or replacement of relevant module.
■ Once a year</td></tr>
<tr><td>Leakage test</td></tr>
<tr><td rowspan="3">Sidestream/TiniStream CO2 Test</td><td>Leakage test</td></tr>
<tr><td>Performance tests</td></tr>
<tr><td>Module calibration</td></tr>
<tr><td colspan="3">Performance Tests</td></tr>
<tr><td rowspan="2">ECG Test</td><td>Performance tests</td><td rowspan="12">■ If users suspect that the measurement values are incorrect.
■ Follow any repairs or replacement of relevant module.
■ Once a year</td></tr>
<tr><td>Calibration test</td></tr>
<tr><td colspan="2">RESP Performance Tests</td></tr>
<tr><td colspan="2">SpO2 Test</td></tr>
<tr><td rowspan="2">NIBP Test</td><td>Pressure test</td></tr>
<tr><td>Leakage test</td></tr>
<tr><td colspan="2">TEMP Test</td></tr>
<tr><td rowspan="2">IBP Test</td><td>Performance tests</td></tr>
<tr><td>Pressure calibration</td></tr>
<tr><td colspan="2">Mainstream CO2 Test</td></tr>
<tr><td rowspan="3">Sidestream/TiniStream CO2 Test</td><td>Leakage test</td></tr>
<tr><td>Performance tests</td></tr>
<tr><td>Module calibration</td></tr>
<tr><td colspan="2">Nurse Call Test</td><td>If you suspect that the nurse call function does not work properly</td></tr>
<tr><td colspan="3">Electrical Safety Tests</td></tr>
<tr><td colspan="2">Safety inspection according to IEC 60601-1</td><td>■ After repairing or replacing the power module
■ After the monitor falls.
■ once every two years or as required.</td></tr>
</table>

Other Tests		
Power-on test		■ First installation, or after each reinstallation. ■ After each repair or replacement of host parts.
Touchscreen calibration		■ When the touchscreen appears abnormal. ■ After the touchscreen is replaced.
Recorder check		Follow any repair or replacement of the recorder.
Battery check	Functionality test	■ When first installed. ■ When battery is replaced.
	Performance tests	Every three months or if the battery runtime reduced significantly

24.3. Checking Information

Select the [Main Menu] quick key → [monitor information]. In the pop-up menu, you can view the monitor configuration and system software version information.

24.4. NIBP Leakage Test

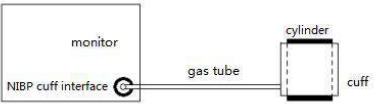
The NIBP leakage test checks the integrity of the system and of the valve. If the leakage test passes, the system will not give any prompt. if not, there are corresponding prompt messages in NIBP information area. The NIBP leakage test should be performed once every two years or when you doubt the NIBP measurements.

Before testing, the following materials shall be prepared:

- Adult sleeve: one
- Inflation tube: one
- Cylinders: one

The detection steps are as follows:

1. Set [patient type] to [adult].
2. Connect the cuff with the NIBP cuff interface of the monitor.
3. Wrap the sleeve around a cylinder of appropriate size; As shown in the figure.



4. Select [main menu] → [user maintenance] → [blood pressure maintenance].
5. Select [leakage test], and the NIBP parameter area will display [leakage test...].
6. After about 20 seconds, the system will automatically deflate and mark the completion of air leakage detection. If there is no prompt in NIBP parameter area, it indicates that there is no air leakage in the system. If [NIBP pump leakage] is displayed, it indicates that there may be an air leakage fault in the air circuit. At this time, the operator shall check whether the whole connection is loose. After confirming that the connection is correct, the air leakage detection shall be carried out again.

If there is still a fault prompt, please contact the manufacturer for maintenance.

24.5. NIBP Pressure Calibration

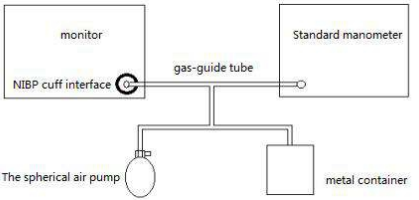
The NIBP pressure calibration should be performed once every year or when you doubt the NIBP measurements.

Before testing, the following materials shall be prepared:

- T-connector
- Airway
- Spherical air pump
- Metal container：500±25 ml
- Standard pressure gauge: calibrated with an accuracy higher than 1 mmHg

The verification steps are as follows:

1. Connect the monitor, pressure gauge, spherical air pump and metal container as shown in the figure below.



2. The pressure gauge should read zero before inflation. If it is not zero, open the valve of the spherical air pump to make the whole air circuit open to the atmosphere, make the reading of the standard pressure gauge zero, and then close the valve.
3. Select [main menu] → [user maintenance] → [blood pressure maintenance].
4. Set the value of [pre inflation pressure] to 200mmhg.
5. Select the appropriate [calibration mode]:
   - If the [calibration mode] is set to [manual mode], select [start calibration], use the spherical air pump to inflate the rigid container to make its internal pressure reach 200mmhg, stop inflation and wait for 10s to stabilize the measured value.
   - If the [calibration mode] is set to [automatic mode], after selecting [start calibration], the sphygmomanometer air pump will automatically start inflation to make its internal pressure charge to 200mmhg, stop inflation and wait for 10s to stabilize the measured value.
6. Fill the cuff pressure displayed on the monitor into [calibration pressure] and the reading on the standard pressure gauge into [reference pressure].
7. Select [set coefficient] to complete pressure calibration.

24.6. ECG Calibrating

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG waveform amplitude becomes greater or smaller. In that case, you need to calibrate the ECG module.

1. Select ECG waveform or parameter area, and change [filter] as [standard].
2. Select [main menu] → [user maintenance] → [ECG calibration signal], the [ECG calibration signal] will be displayed as [on], the square wave signal will appear on the screen, and the [ECG calibration in progress] will be displayed in the technical alarm

area.

3. Comparing the amplitude of square wave with the scale, the error range should be within 5%.
4. After the calibration is completed, select [ECG calibration signal], then the [ECG calibration signal] will be displayed as [off], and the ECG calibration will be stopped.

you can output square wave and ruler through recorder, and then measure more accurate error. If the error exceeds 5%, please contact the maintenance personnel.

24.7. CO2 Calibration

Daily calibration of CO2 module is not required, but it shall be conducted at least once a year or when the measured value deviation is large. users cannot calibrate CO2 by himself. Please contact the maintenance personnel when calibration is required. The CO2 module shall be checked and calibrated by qualified professional maintenance personnel.

24.8. Touchscreen Calibration

1. Select [main menu] → [user maintenance] → [touch screen calibration].
2. It will appear  in different positions on the screen
3. Click the center point of this mark  in turn.
4. After calibration, [screen calibration succeeded!] will be prompted, select [confirm] to complete the calibration.

24.9. Set IP Address

1. Select the [Main Menu] → [Maintenance] → [Network Settings].
2. Set [IP Address] and [Port Number].

24.10. Modify User Maintenance Password

1. Select the [Main Menu] → [Maintenance] → [Change Password].
2. After entering the new password, select [OK].

A Product Specification

A. 1 Security Features

A.1.1 Product classification

According to the classification of China State Food and Administratio, this monitor is a class II device

The main safety features of the monitor are as follows:

a）According to the anti-shock type, it is into class I and internal power supply

b）According to the degree of anti-shock classification: CF anti-fibrillation application part and BF anti-fibrillation application part(Only EEG parameters fit this category)

c）Classified according to the degree of protection against liquid intake：IPX2。

d）In the case of flammable anesthetic gas mixed with air or nitrous oxide security level classification: non-AP and APG devices

e）Classification by operation mode: continuous operation of equipment

A.1.2 Environment condition

Work environment:

a）Operating temperature：5℃～40℃;

b）Relative humidity：15%～95%;

c）Barometric pressure：70.0kPa～106.0 kPa。

Storage environment:

a）Temperature：-20℃～60℃;

b）Relative humidity：10%～95%，non-condensing;

c）Barometric pressure：57.3kPa ～106.0kPa;

A.1.3 Power information

a）Interflow：(100 - 240) V ~ (±10%)

b）Input power：110VA

c）Input frequency：（50Hz/60Hz）±3 Hz;

d）removable lithium batteries：11.1 V D.C.5200mAh;

e）Fuse specification：T3AH,250V。

A. 2 Component information

The host unit	Specification and models
Main control panel	/
Rechargeable lithium battery	/
Viewing screen	12.1inches/15.6 inches
Mainstream CO2	M401B
TiniStream 5 CO2	M402C&M402E
Integrated multi-parameter measuring board	M001(M301+M201)

A. 3 Hardware parameter

Parameter	Specification
Size	（length×width×height）
Weight	（contains no attachment）
Viewing screen	
Type	Color TFT LCD
Size	12.1inches diagonal,15.6 inches diagonal
Audio instructions	
Loudspeaker	Alarm sound, heartbeat sound/pulse sound; The alarm tone conforms to IEC60601-1-8 standard
Control	
key	There are five buttons and a shuttle. The Keys are: Power switch, quotation pause, alarm close, blood pressure control, waveform freezing
Port	
Power supply	One power port
Parameter measurement	ECG、RESP、NIBP、SpO2、TEMP1、TEMP2、CO2、IBP
port	VGA output port、USB port、network port、nurse call port
Exhaust gas emission	one exhaust outlet, equipped with microfluidic CO2 configuration

A. 4 Data storage

Trends	A minimum of 120 hours trend data with the resolution no less than 1 minute.
Events	1000 events When the data is full, the new data overwrites the old data
NIBP measurements	1000 events When the data is full, the new data overwrites the old data
Alarm Events	200 events When the data is full, the new data overwrites the old data
Interpretation of resting 12-lead ECG results	20 sets

A. 5 Parameter information

The adjustable range of the alarm limit is the same as the measuring rang of the signal useless otherwise specified in the specifications below

A.5.1 ECG Specifications

ECG	
Standard	IEC 60601-2-27
Lead set	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V 12-lead: I, II, III, aVR, aVL, aVF, V1 to V6
ECG standard	AHA 、IEC
Display sensitivity	2.5 mm/mV (X0.25), 5 mm/mV (X0.5), 10 mm/mV (X1), 20 mm/mV (X2), 40 mm/mV (X4), Auto, less than ±5% error
Sweep speed	6.25 mm/s、12.5mm/s、25mm/s、50mm/s,less than ±5% error
Bandwidth	standard mode: 0.05Hz～130Hz+0.4dB -3.0dB； Monitor mode: 0.5Hz～40Hz+0.4dB -3.0dB； Surgery mode: 1Hz～25Hz+0.4dB -3.0dB； HARDEST:5Hz～20Hz+0.4dB -3.0dB
Common mode rejection ratio	standard mode: ＞90dB； Other mode: ＞105dB(with notch filter on)
Notch filter	50Hz/60Hz
Differential input impedance	≥5MΩ
Input signal range	±5mV
Accuracy of signal reproduction	Use A and D methods based on IEC 60601-2-27 to determine frequency response.

Electrode offset potential tolerance	±400mV
Input offset current	≤0.1uA
Defibrillation protection	<3s
Patient leakage current	<10uA
Calibration signal	1mV (peak-to-peak value) ±5%
ESU protection	Cut mode: 300W Coagulate mode: 100W Recovery time: ≤10s
Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labeled with a PACE marker: Amplitude:±2mV～±700mV Width:0.1ms～2ms Rise time: 10us～100us No overshoot
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2mV to ±700 mV; Width: 0.1ms to 2 ms; Rise time: 10µs to 100 µs (< 10% of pulse width); No overshoot
HR	
Measurement range	15～300bpm（adult） 15～350bpm（pediatric/neonate）
Resolution	1bpm
Accuracy	±1 bpm or ±1%, whichever is greater.
Sensitivity	0.2mV
HR averaging method	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27: 2011, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging the remaining 10 RR intervals. The HR value displayed on the monitor screen is updated no more than one second.
Response to irregular rhythm	Figure 3a (Ventricular Bigeminy)： 80±1 bpm; Figure 3b (Slow Alternating Ventricular Bigeminy) ： 60±1 bpm; Figure 3c (Rapid Alternating Ventricular Bigeminy) ： 120±1 bpm; Figure 3d (Bi-directional Systoles) ： 90±2 bpm;
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 10 s; From 80 to 40 bpm: less than 10 s;
Time to alarm for	< 10S

tachycardia	
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate calculation is not affected for QRS of 1 mV amplitude and 100 ms duration, T-wave duration of 180 ms and amplitude lower than 1.2 mV,
Arrhythmia Analysis Classifications	1 Asystole 2 VF 3 ventricular tachycardia 4 R ONT 5 Multiple VPB 6 couple VPB 7 accidental VPB 8 bigeminy 9 trigeminy 10 tachycaridia 11 bradycaridia 12 multiform VPB 13 pace not capture 14 pacer not paced 15 Irregular rhythm 16 missed beat
ST Segment Analysis	
Measurement range	-2.0mV～+2.0mV
Accuracy	-0.8 mV to 0.8 mV: ±0.02 mV or ±10%, whichever is greater. Beyond this range: Not specified.
Resolution	0.01mV
Alarm limit	
ST High	（Low limit+0.1）～2.0mV
ST Low	-2.0mV～（High limit-0.1）
HR High	（HR Low limit+1bpm）～300bpm
HR Low	15bpm～（HR High limit-1bpm）

A.5.2 Resp Specifications

Technique	Trans-thoracic impedance
Lead	Options are lead I and II.
Respiration excitation waveform	＜300μA RMS,39kHz（±10%）
respiration impedance range	0.3～5Ω
Baseline impedance range	200～2000Ω(using an ECG cable with 1kΩ resistance)
Bandwidth	0.2～2Hz（-3 dB）
Sweep speed	6.25 mm/s、12.5mm/s、25mm/s、50mm/s

A.5.3 SpO_2 Specifications

SpO2	
Standard	ISO 80601-2-61
Measurement range	0～100%
Accuracy	70 to 100%: ±2% (adult/pediatric, without motion) 70 to 100%: ±3% (neonate, without motion) 0 to 69%: Not specified.

Resolution	±1%	
Alarm limit	Range	Step
SpO2 High	（Low limit+1%）～100%	1%
SpO2 Low	0～（High limit-1%）	

A.5.4 PR specification

Standard	ISO 80601-2-61	
Measurement range	25bpm～250bpm	
Accuracy	±3bpm	
Resolution	1bpm	
Alarm limit	Range	Step
PR High	（PR Low limit+1bpm）～250bpm	1bpm
PR Low	25bpm～（PR High limit-1bpm）	

A.5.5 CO2 specification

Measurement mode	Sidestream, TiniStream Mainstream	
Technique	Infrared absorption	
Zero RR delay	20s、25s、30s、35s、40s、45s、50s、55s、60s	
Alarm limit	Range	Step
EtCO2 High	（EtCO2 Low limit+1mmHg）～150mmHg	1 mmHg
EtCO2 Low	0～（EtCO2 High limit−1mmHg）	
FiCO2 High	0～150mmHg	
AwRR High	（AwRR Low limit+1 rpm）～120rpm	1 rpm
AwRR Low	0～（AwRR High limit-1 rpm）	
Sidestream CO_2 Module		
Standard	ISO 80601-2-55	
CO2 Measurement range	0.0-20.0% Percentage of volume.	
Accuracy	0.0vol % - 12 .0vol %: ±(0.2 vol % +2 % of readings) 12.1vol % - 20.0vol %: ±(0.2vol % +6 % of readings)	
Accuracy drift	Meets the requirements for measurement accuracy within 6 hours	
Resolution	1mmHg	
Sample flowrate	50ml/min	
Maximum disposal interval of effluent equipment	16H(Sampling gas temperature 37 C, room temperature 23 C and sampling relative humidity of 100 %)	
Sample flowrate tolerance	±8ml/min	
Start-up time	20s（typical）	
Response time	Use water tank, 2m sampling tube:≤2s @ 120ml/min	
Total system response rime	Use water tank, 2m sampling tube:＜2s @ 120ml/min	
awRR		

Range of Measurement	0-150 rpm	
Accuracy	≤70 rpm: ±1 rpm；no definition in other ranges.	
Resolution	1 rpm	
TiniStream CO2 external module		
Standard	ISO 80601-2-55	
CO2 Measurement range	0.0-20.0% Percentage of volume.	
Accuracy	0.0vol % - 12 .0vol %: ±(0.2 vol % +2 % of readings) 12.1vol % - 20.0vol %: ±(0.2vol % +6 % of readings)	
Accuracy drift	Meets the requirements for measurement accuracy within 6 hours	
Resolution	1mmHg	
Sample flowrate	50ml/min	
Maximum disposal interval of effluent equipment	16H(Sampling gas temperature 37 C, room temperature 23 C and sampling relative humidity of 100 %)	
Sample flowrate tolerance	±8ml/min	
Start-up time	20s（typical）	
Total system response rime	2m sampling line applies in sample drawn when pumping flow under the condition of 50 ml/min，total system response time ＜3s	
awRR		
Range of Measurement	0-150 rpm	
Accuracy	≤70 rpm: ±1 rpm；no definition in other ranges.	
Resolution	1 rpm	
Effect of interference gases on CO2 measurements		
Gas	Concentration (%)	Quantitative effect*
N2O	≤60	±2mmHg
HAL	≤5	
SEV	≤5	
ISO	≤5	
ENF	≤5	
DES	≤15	
*: means an extra error should be added in case of gas interference when CO2 measurements are performed between 0 to 40mmHg. Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15BPM and I:E ratio smaller than 1:1 relative to the gas readings without breath.		
Mainstream CO2 Module		
Standard	ISO 80601-2-55	
CO2 Measurement range	0.0-20.0% Percentage of volume.	
Accuracy	0.0vol % - 12 .0vol %: ±(0.2 vol % +2 % of readings) 12.1vol % - 20.0vol %: ±(0.2vol % +6 % of readings)	
Accuracy drift	Meets the requirements for measurement accuracy within 6 hours	
Resolution	1mmHg	
Rise time	≤90ms	
awRR		
Range of Measurement	0~150 rpm	

Accuracy	±1rpm	
Resolution	1 rpm	
Effect of interference gases on CO2 measurements		
Gas	Concentration (%)	Quantitative effect*
N2O	≤60	±2mmHg
HAL	≤5	
SEV	≤5	
ISO	≤5	
ENF	≤5	
DES	≤15	

*: means an extra error should be added in case of gas interference when CO2 measurements are performed between 0 to 40mmHg. Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15BPM and I:E ratio smaller than 1:1 relative to the gas readings without breath.

A.5.6 NIBP specification

Meet a criterion	IEC 80601-2-30				
Measure method	Automatic oscillation method				
Work pattern	Manual measurement, automatic measurement, continuous measurement				
Automatic mode measurement interval	1min/2min/3min/4min/5min/10min/15min/30min/60min/90min/2h/3h				
Continuous mode measurement time	5 min				
Maximum single measurement time	180s				
Measure range	Blood pressure(unit)		Adult	Pediatric	Infants
	Systolic pressure	mmHg	40～270	40～235	25～130
		kPa	5.3～36.0	5.3～31.3	3.25～16.9
	Diastolic pressure	mmHg	10～210	10～220	10～90
		kPa	1.3～28.0	1.3～29.3	1.3～11.7
	Mean pressure	mmHg	20～230	20～225	15～100
		kPa	2.7～30.7	2.7～30.0	2～13
Measuring precision	Maximum mean error：±5mmHg Maximum standard deviation：8mmHg				
Static pressure measuring rang	0 mmHg（0kPa）～300mmHg（40kPa）				
Static pressure measuring accuracy	±2mmHg or ±1% of reading，whichever is greater.				
Resolution ratio	1mmHg or 0.1kPa；				
Initial charging pressure setting norm（mmHg）	Adult：80mmHg、100mmHg、120mmHg、140mmHg、160mmHg、				

	180mmHg、200mmHg、220mmHg、240mmHg、250mmHg、260mmHg、270mmHg、280mmHg； Pediatric：80mmHg、100mmHg、120mmHg、140mmHg、160mmHg、180mmHg、200mmHg、220mmHg Infants：60mmHg、80mmHg、100mmHg、120mmHg	
Default initial inflation pressure（mmHg）	Adult：160 Pediatric：140 Infant：120	
Software overvoltage protection	Adult：297±5mmHg Pediatric：240±5mmHg Infants：150±5mmHg	
Alarm limit specification	Range （mmHg）	Step size（mmHg）
Systolic pressure high limit	Adult：（Systolic pressure low limit +1mmHg）～270mmHg Pediatric ：（Systolic pressure low limit +1mmHg）～235mmHg Infants：（Systolic pressure low limit +1mmHg）～130mmHg	1
Systolic pressure low limit	Adult/Pediatric：40mmHg～（Systolic pressure high limit -1mmHg） Infants：25mmHg～（Systolic pressure high limit -1mmHg）	
Average pressure height limit	Adult：（Mean depression limit +1mmHg）～230mmHg Pediatric：（Mean depression limit +1mmHg）～225mmHg Infants：（Mean depression limit +1mmHg）～100mmHg	
Mean depression limit	Adult/Pediatric：20mmHg～（Average pressure height limit -1mmHg） Infants：15mmHg～（Average pressure height limit -1mmHg）	
Diastolic pressure high limit	Adult：（Diastolic pressure low limit +1mmHg）～210mmHg Pediatric ：（Diastolic pressure low limit +1mmHg）～220mmHg Infants：（Diastolic pressure low limit +1mmHg）～90mmHg	
Diastolic pressure low limit	10mmHg ～（Diastolic pressure high limit -1mmHg）	

A.5.7 Temp specification

Standard	ISO 80601-2-56	
Technique	Thermal resistance	
Measurement range	0℃～50.0℃	
Resolution	0.1℃	
Accuracy	±0.2℃	
Refresh rate	1s	
Minimum time for accurate measurement	≤150s	
Alarm limit	Range	Step
Temp High	（low limit+0.1℃）～50.0℃	0.1℃
Temp Low	0℃～（high limitt-0.1℃）	

A.5.8 IBP specification

Standard	IEC 60601-2-34	
Technique	Direct invasive measurement	
Number of channels	2	
Measurement range	–50～300 mmHg（-6.7kPa～40.0kPa）	
Resolution	1 mmHg（0.1kPa）	
Accuracy	±2% or ±1 mmHg, whichever is greater (excluding sensor error)	
Refresh rate	1s	
Pressure transducer		
Excitement voltage	5VDC,±2%	
Sensitivity	5μV/V/mmHg	
Zero adjustment range	±200 mmHg	
Impedance range	300～3000Ω	
Volume displacement	＜0.04mm³/100mmHg	
Alarm limit	Range (mmHg)	Step (mmHg)
Sys High	（low limit +2）～300	1
Mean High		
Dia High		
Sys Low	-50～（high limit-2）	
Mean Low		
Dia Low		

A 5 9 EEG.specifications

Standard	IEC 60601-2-26 EN 60601-2-26
Input signal range (linear interval)	±1mV

noise	≤ 5μVpp 2 Hz–45 Hz
input impedence	≥ 10MΩ
sampling rate	500 Samples / sec
Module-to-digital conversion resolution	At 24
Frequency / bandwidth	2 Hz – 45 Hz
EEG scale	25 V / grid (± 50 V full range)
Analyze the parameters obtained	Anesthesia Consciousness Index (Ai), Outbreak Suppression ratio (BSR), Electromycle Index (EMG), Signal Quality Index (SQI)
Customize the display	Real-time EEG waveform and parameter trend maps
report to the police	The target range of the desired Ai value can be set (upper limit 5-100, lower limit 0-95, minimum adjustment step of 5) for a visual or auditory alarm when the Ai value exceeds the target range

B EMC

IEC 60601-1-2:2014/AMD1:2020 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class A product

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Patient Monitor (model name MN-1031-1, MN-1031-2, MN-1031-3W, MN-1031-3E, MN-1031-3L), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals
(CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this
equipment might not offer adequate protection to radio-frequency communication services. The user might need to
take mitigation measures, such as relocating or re-orienting the equipment.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV ±4 kV ±6 kV ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s)：±0.5, ±1 kV line(s) to earth：±0.5, ±1, ±2	line(s) to line(s)：±0.5, ±1 kV line(s) to earth：±0.5, ±1, ±2

	kV For signal input/output port: ±2 kV (Line to Ground)	kV For RJ 45 network port: ±2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz 80 MHz – 2,5 GHz 80 % AM at 2 Hz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF	Test	Band	Service	Modulation	Maximum	Distance	IEC 60601-1-2	Compliance

IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Frequency** (MHz)	(MHz)			**Power**(W)	(m)	**Test level** (V/m)	**level** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	28
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	28
	5240 5500	5 100 – 5 800	WLAN 802.11	Pulse modulation	0,2	0,3	9	9

	5785		a/n	217 Hz				

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation [a] 2,1 kHz	65 [b]
13,56 MHz	Pulse modulation [a] 50 kHz	7,5 [b]

a) The carrier shall be modulated using a 50% duty cycle square wave signal.
b) r.m.s., before modulation is applied.

C Configuring default information

This chapter lists some important factory defaults for monitoring configuration management. Users cannot change the Setting in the factory default configuration, but can modify the Setting as required and save Setting. The last column of form is left blank fir your record and review
The default alarm Settings and information of product startup are as follows：

C. 1 Parameter configuration

C.1.1 ECG

Name:		Default value	User custom
Lead type		Single track	
Alarm switch		on	
Alarm level		Middle	
HR high limit	Adult	120	
	Pediatric	160	
HR low limit	Adult	50	
	Pediatric	75	
Waveform speed		25mm/s	
Pace-making		no	
Power frequency notch		50Hz	
Gain		X1	
Filtering		Diagnose	
ECG interface		Display conventions	
ST-segment analysis			
ST-segment analysis		Close	
Alarm switch		Close	
Alarm level		Middle	
ST high limit		0.3 mV	
ST low limit		-0.2 mV	
ISO point		-80 ms	
J point		48 ms	
ST point		J+60 ms	
Arrhythmia analysis			
Premature beat	Alarm switch	Return on	
	Alarm level	High	
Fibrillation	Alarm switch	Return on	
	Alarm level	High	
Ventricular	Alarm switch	Return on	

tachycardia	Alarm level	High	
R on T	Alarm switch	Close	
	Alarm level	Middle	
Multiple ventricular premature beat	Alarm switch	Close	
	Alarm level	Middle	
Secondary ventricular premature beat	Alarm switch	Close	
	Alarm level	Middle	
Occasional ventricular premature beat	Alarm switch	Close	
	Alarm level	Middle	
Name:		**Default value**	**User custom**
Duplex rate	Alarm switch	Close	
	Alarm level	Middle	
trigeminy	Alarm switch	Close	
	Alarm level	Middle	
Supraventricular tachycardia	Alarm switch	Close	
	Alarm level	Middle	
Supraventricular bradycardia	Alarm switch	Close	
	Alarm level	Middle	
Pleomorphic PVC	Alarm switch	Close	
	Alarm level	Middle	
Pacemaker end capture	Alarm switch	Close	
	Alarm level	Middle	
Pacemaker end pacing	Alarm switch	Close	
	Alarm level	Middle	
Irregular rhythm	Alarm switch	Close	
	Alarm level	Middle	
Missed beat	Alarm switch	Close	
	Alarm level	Middle	

C.1.2 RESP

Name:		**Default value**	**User custom**
Alarm switch		Return on	
Alarm level		Middle	
Waveform speed		6.25mm/S	
Respiratory lead		Adult、Pediatric：Automatic Neonatal： II	
Increase		X2	
PR High	Adult 、 Pediatric	30	

	Neonatal	100	
PR Low	Adult 、Pediatric	8	
	Neonatal	30	
Asphyxiation delay	Adult 、Pediatric	20	
	Neonatal	15	

C.1.3 PR

Name:		Default value	User custom
Alarm switch		Return on	
Alarm level		Middle	
PR High	Adult	120	
	Pediatric	160	
PR Low	Adult	50	
	Pediatric	75	
Heartbeat sound source		Automatic	
Pulse volume		3	

C.1.4 SpO2

Name:	Default value	User custom
Alarm switch	Return on	
Alarm level	Middle	
SpO2 High	Adult、Pediatric：100	
SpO2 Low	Adult、Pediatric：90	
Waveform speed	25mm/s	

C.1.5 Temp

Name:	Default value	User custom
Alarm switch	Return on	
Alarm level	Middle	
Temp High	39.0℃	
Temp Low	36.0℃	

C.1.6 NIBP

Name:	Default value	User custom
Alarm switch	Return on	
Alarm level	Middle	
Measurement mode	manual	

Venous puncture pressure（mmHg）	Adult	80	
	Pediatric	60	
Initial inflation pressure（mmHg）	Adult	160	
	Pediatric	140	
Alarm limit setting			
SYS High	Adult	160	
	Pediatric	120	
SYS Low	Adult	90	
	Pediatric	70	
Mean High	Adult	110	
	Pediatric	90	
Mean Low	Adult	60	
	Pediatric	50	
DIA High	Adult	90	
	Pediatric	70	
DIA Low	Adult	50	
	Pediatric	40	

C.1.7 CO2

Name:	Default value	User custom
Alarm switch	Return on	
Alarm level	Middle	
Operation Mode	Measure	
Waveform speed	6.25mm/s	
Waveform spacing	40	
Asphyxiating delayed	20s	
Oxygen compensation concentration	16%	
nitrous oxide concentration	0%	
Anesthetic gas compensation	0%	
Bypass CO2 setting		
Suction rate	70 ml/min	
Alarm limit setting		
EtCO2 High limit（mmHg）	50	
EtCO2 Low limit（mmHg）	15	
FiCO2 High limit（mmHg）	8	
awRR High limit	30	
awRR Low limit	8	

C.1.8 IBP

Name:		Default value	User custom
Alarm switch		Turn-On	
Alarm Level		Medium	
Operation mode		Measurement:	
Measurement mode		Manual	
Waveform velocity		25 mm/s	
Filter		12.5 Hz	
Sensitivity		Medium	
Alarm limit setting			
IBP-S High Limit (mmHg)	Adult	160	
	Children	120	
	Neonate	90	
IBP-S Low Limit (mmHg)	Adult	90	
	Children	70	
	Neonate	55	
IBP-M High Limit (mmHg)	Adult	110	
	Children	90	
	Neonate	70	
IBP-M Low Limit (mmHg)	Adult	70	
	Children	50	
	Neonate	35	
IBP-D High Limit (mmHg)	Adult	90	
	Children	70	
	Neonate	60	
IBP-D Low Limit (mmHg)	Adult	50	
	Children	40	
	Neonate	20	

C. 1. 9 EEG

name	Windows default	User Custom
alarm switch	close	
Alarm level	centre	
High limit	60	
lower limit	40	

24. Maintenance

24.1. Introduction

Before the monitor is used, continuously used for 6-12 months, repaired or upgraded, a comprehensive inspection shall be conducted by qualified maintenance personnel to ensure the normal operation and work of the monitor. The inspection items shall include:

- The environment and power supply meet the requirements.。
- No mechanical damage to equipment and accessories.
- The power line shall be free of wear and good insulation performance.
- Use specified attachments
- The function of the alarm system is normal.
- The recorder works normally and the recording paper meets the specified requirements.
- Battery performance.
- Various monitoring functions are in good working condition.
- The grounding impedance and leakage current meet the requirements

If any damage or abnormality is found, please do not use the monitor, and immediately contact the medical engineer of the hospital or the maintenance personnel of the company.

⚠ WARNING

- **Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If necessary, please contact our company for product circuit diagram, parts list, calibration instructions or other information related to equipment maintenance**
- **If you discover a problem with any of the equipment, contact your service personnel or Witleaf.**

24.2. Maintenance Schedule

Except for visual inspection, startup detection, touch screen calibration, battery inspection and recorder inspection, the following tasks can only be completed by professional maintenance personnel. When the following maintenance is required, please contact the maintenance personnel in time. Make sure to clean and disinfect the equipment before taking any tests and maintenance.

<table>
<tr><th colspan="2">Test/Maintenance Item</th><th>Recommended Frequency</th></tr>
<tr><td colspan="3">Preventive Maintenance</td></tr>
<tr><td colspan="2">Visual Inspection</td><td>First installation, or after each reinstallation</td></tr>
<tr><td rowspan="2">NIBP Test</td><td>Pressure test</td><td rowspan="5">■ If users suspect that the measurement values are incorrect.
■ Follow any repairs or replacement of relevant module.
■ Once a year</td></tr>
<tr><td>Leakage test</td></tr>
<tr><td rowspan="3">Sidestream/TiniStream CO2 Test</td><td>Leakage test</td></tr>
<tr><td>Performance tests</td></tr>
<tr><td>Module calibration</td></tr>
<tr><td colspan="3">Performance Tests</td></tr>
<tr><td rowspan="2">ECG Test</td><td>Performance tests</td><td rowspan="12">■ If users suspect that the measurement values are incorrect.
■ Follow any repairs or replacement of relevant module.
■ Once a year</td></tr>
<tr><td>Calibration test</td></tr>
<tr><td colspan="2">RESP Performance Tests</td></tr>
<tr><td colspan="2">SpO2 Test</td></tr>
<tr><td rowspan="2">NIBP Test</td><td>Pressure test</td></tr>
<tr><td>Leakage test</td></tr>
<tr><td colspan="2">TEMP Test</td></tr>
<tr><td rowspan="2">IBP Test</td><td>Performance tests</td></tr>
<tr><td>Pressure calibration</td></tr>
<tr><td colspan="2">Mainstream CO2 Test</td></tr>
<tr><td rowspan="3">Sidestream/TiniStream CO2 Test</td><td>Leakage test</td></tr>
<tr><td>Performance tests</td></tr>
<tr><td>Module calibration</td></tr>
<tr><td colspan="2">Nurse Call Test</td><td>If you suspect that the nurse call function does not work properly</td></tr>
<tr><td colspan="3">Electrical Safety Tests</td></tr>
<tr><td colspan="2">Safety inspection according to IEC 60601-1</td><td>■ After repairing or replacing the power module
■ After the monitor falls.
■ once every two years or as required.</td></tr>
</table>

Other Tests		
Power-on test		■ First installation, or after each reinstallation. ■ After each repair or replacement of host parts.
Touchscreen calibration		■ When the touchscreen appears abnormal. ■ After the touchscreen is replaced.
Recorder check		Follow any repair or replacement of the recorder.
Battery check	Functionality test	■ When first installed. ■ When battery is replaced.
	Performance tests	Every three months or if the battery runtime reduced significantly

24.3. Checking Information

Select the [Main Menu] quick key → [monitor information]. In the pop-up menu, you can view the monitor configuration and system software version information.

24.4. NIBP Leakage Test

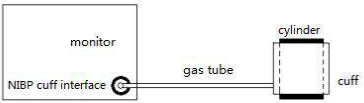
The NIBP leakage test checks the integrity of the system and of the valve. If the leakage test passes, the system will not give any prompt. if not，there are corresponding prompt messages in NIBP information area. The NIBP leakage test should be performed once every two years or when you doubt the NIBP measurements.

Before testing, the following materials shall be prepared:

- Adult sleeve: one
- Inflation tube: one
- Cylinders: one

The detection steps are as follows:

1. Set [patient type] to [adult].
2. Connect the cuff with the NIBP cuff interface of the monitor.
3. Wrap the sleeve around a cylinder of appropriate size; As shown in the figure.



4. Select [main menu] → [user maintenance] → [blood pressure maintenance].
5. Select [leakage test], and the NIBP parameter area will display [leakage test...].
6. After about 20 seconds, the system will automatically deflate and mark the completion of air leakage detection. If there is no prompt in NIBP parameter area, it indicates that there is no air leakage in the system. If [NIBP pump leakage] is displayed, it indicates that there may be an air leakage fault in the air circuit. At this time, the operator shall check whether the whole connection is loose. After confirming that the connection is correct, the air leakage detection shall be carried out again.

If there is still a fault prompt, please contact the manufacturer for maintenance.

24.5. NIBP Pressure Calibration

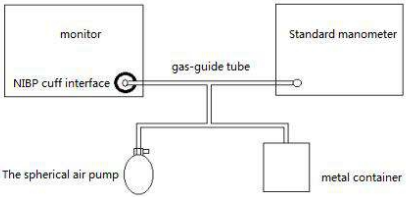
The NIBP pressure calibration should be performed once every year or when you doubt the NIBP measurements.

Before testing, the following materials shall be prepared:

- T-connector
- Airway
- Spherical air pump
- Metal container：500±25 ml
- Standard pressure gauge: calibrated with an accuracy higher than 1 mmHg

The verification steps are as follows:

1. Connect the monitor, pressure gauge, spherical air pump and metal container as shown in the figure below.



2. The pressure gauge should read zero before inflation. If it is not zero, open the valve of the spherical air pump to make the whole air circuit open to the atmosphere, make the reading of the standard pressure gauge zero, and then close the valve.
3. Select [main menu] → [user maintenance] → [blood pressure maintenance].
4. Set the value of [pre inflation pressure] to 200mmhg.
5. Select the appropriate [calibration mode]:
   - If the [calibration mode] is set to [manual mode], select [start calibration], use the spherical air pump to inflate the rigid container to make its internal pressure reach 200mmhg, stop inflation and wait for 10s to stabilize the measured value.
   - If the [calibration mode] is set to [automatic mode], after selecting [start calibration], the sphygmomanometer air pump will automatically start inflation to make its internal pressure charge to 200mmhg, stop inflation and wait for 10s to stabilize the measured value.
6. Fill the cuff pressure displayed on the monitor into [calibration pressure] and the reading on the standard pressure gauge into [reference pressure].
7. Select [set coefficient] to complete pressure calibration.

24.6. ECG Calibrating

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG waveform amplitude becomes greater or smaller. In that case, you need to calibrate the ECG module.

1. Select ECG waveform or parameter area, and change [filter] as [standard].
2. Select [main menu] → [user maintenance] → [ECG calibration signal], the [ECG calibration signal] will be displayed as [on], the square wave signal will appear on the screen, and the [ECG calibration in progress] will be displayed in the technical alarm

area.

3. Comparing the amplitude of square wave with the scale, the error range should be within 5%.
4. After the calibration is completed, select [ECG calibration signal], then the [ECG calibration signal] will be displayed as [off], and the ECG calibration will be stopped.

you can output square wave and ruler through recorder, and then measure more accurate error. If the error exceeds 5%, please contact the maintenance personnel.

24.7. CO2 Calibration

Daily calibration of CO2 module is not required, but it shall be conducted at least once a year or when the measured value deviation is large. users cannot calibrate CO2 by himself. Please contact the maintenance personnel when calibration is required. The CO2 module shall be checked and calibrated by qualified professional maintenance personnel.

24.8. Touchscreen Calibration

1. Select [main menu] → [user maintenance] → [touch screen calibration].
2. It will appear  in different positions on the screen
3. Click the center point of this mark  in turn.
4. After calibration, [screen calibration succeeded!] will be prompted, select [confirm] to complete the calibration.

24.9. Set IP Address

1. Select the [Main Menu] → [Maintenance] → [Network Settings].
2. Set [IP Address] and [Port Number].

24.10. Modify User Maintenance Password

1. Select the [Main Menu] → [Maintenance] → [Change Password].
2. After entering the new password, select [OK].

A Product Specification

A. 1 Security Features

A.1.1 Product classification

According to the classification of China State Food and Administratio, this monitor is a class II device

The main safety features of the monitor are as follows：

a）According to the anti-shock type, it is into class I and internal power supply

b）According to the degree of anti-shock classification: CF anti-fibrillation application part and BF anti-fibrillation application part(Only EEG parameters fit this category)

c）Classified according to the degree of protection against liquid intake：IPX2。

d）In the case of flammable anesthetic gas mixed with air or nitrous oxide security level classification: non-AP and APG devices

e）Classification by operation mode: continuous operation of equipment

A.1.2 Environment condition

Work environment：

a）Operating temperature：5℃～40℃;

b）Relative humidity：15%～95%;

c）Barometric pressure：70.0kPa～106.0 kPa。

Storage environment：

a）Temperature：-20℃～60℃;

b）Relative humidity：10%～95%，non-condensing;

c）Barometric pressure：57.3kPa ～106.0kPa;

A.1.3 Power information

a）Interflow：(100 - 240) V～(±10%)

b）Input power：110VA

c）Input frequency：（50Hz/60Hz）±3 Hz;

d）removable lithium batteries：11.1 V D.C.5200mAh;

e）Fuse specification：T3AH,250V。

A. 2 Component information

The host unit	Specification and models
Main control panel	/
Rechargeable lithium battery	/
Viewing screen	12.1inches/15.6 inches
Mainstream CO2	M401B
TiniStream 5 CO2	M402C&M402E
Integrated multi-parameter measuring board	M001(M301+M201)

A. 3 Hardware parameter

Parameter	Specification
Size	（length×width×height）
Weight	（contains no attachment）
Viewing screen	
Type	Color TFT LCD
Size	12.1inches diagonal,15.6 inches diagonal
Audio instructions	
Loudspeaker	Alarm sound, heartbeat sound/pulse sound; The alarm tone conforms to IEC60601-1-8 standard
Control	
key	There are five buttons and a shuttle. The Keys are: Power switch, quotation pause, alarm close, blood pressure control, waveform freezing
Port	
Power supply	One power port
Parameter measurement	ECG、RESP、NIBP、SpO2、TEMP1、TEMP2、CO2、IBP
port	VGA output port、USB port、network port、nurse call port
Exhaust gas emission	one exhaust outlet, equipped with microfluidic CO2 configuration