LEPU MEDICAL

Vital Signs Monitor

(AIView VS)

Operator's Manual

I Preface

Copyright

This manual contains proprietary information protected by copyright law. All rights reserved. Without the prior written consent of the manufacturer, no part of this manual shall be copied or reproduced in any form or by any means.

Manual Purpose

The instructions for safe operation of the product in keeping with its function and intended use are contained in this manual. In order to operate the product properly, and protect patient and operator from injury, compliance with this manual is first priority.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. Please keep in touch with the manufacturer or your local distributor if you have any questions.

As an indispensable portion of the product, this manual should always be placed near the device so that it can be got easily when needed.

Intended Audience

This manual applies to clinical professionals with knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Only clinical professionals, anyone who are under their guidance or people who have been trained adequately can use this monitor. The unauthorized or the untrained are forbidden to operate the product.

About this Manual

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II Manual Conventions

Illustrations

Setup or data displayed on your monitor may not be necessarily showed in all illustrations in this manual, because they are used only as examples.

All names mentioned in this manual and illustrations are fictitious. Any similarity is purely coincidental.

General Notes

- *Italic* text is used to indicate prompt information or quote the referenced chapters or sections.
- [XX] is used to indicate the character string in the software.
- → is used to indicate operational procedures.

Special Notes

The warnings, cautions and notes in this manual are used to remind readers of some specific information.

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	Provides application tips or other useful information to ensure that you get the most from your product.

Table of Contents

Chapter 1 Safety

1.1 Safety Information

This chapter provides important safety information related to the use of the device. In other chapters, it also contains relevant safety information for specific operations.

1.1.1 Warning

Warning	Before putting the system into operation, the operator must verify that the device, connecting cables, and accessories are in correct working order and operating condition.
Warning	The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.
Warning	To avoid explosion hazards, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.
Warning	Using the device in the environment of flammable anaesthetic agents may be at risk of explosion.
Warning	Please peruse the relative content about the clinical restrictions and contraindication.
Warning	If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.
Warning	This device is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this operator's manual before operation, especially all the contents with warnings and attention signs.
Warning	To prevent the risk of the short circuit and to ensure the ECG signal quality, the device must be properly grounded.
Warning	The summation of leakage current should never exceed leakage current limits while several other devices are used at the same time.
Warning	Make sure that the applied parts never contact other conductive parts.

Warning	Equipments connected to the device must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment).
Warning	The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify that it can run normally in the configuration in which it is used.
Warning	Do not touch the patient or metal parts in contact with the patient during defibrillation. Otherwise serious injury or death could result.
Warning	The monitor is defibrillation-proof. Verify that the accessories can function safely and normally, and the monitor is grounded correctly before conducting defibrillation. Operate the device on battery power if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.
Warning	This device is used for a single patient at a time.
Warning	Disconnect the monitor and sensors from the patient before MRI scanning. Using them during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.
Warning	If you are in doubt about the accuracy of any measurement, firstly check the patient's vital signs by any alternative means, and then make sure the monitor is functioning properly.
Warning	The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
Warning	Do not place the device or accessories in any position that might cause it to fall on the patient.
Warning	All the connecting cables and tubes of the applying parts should be kept away from the patient's neck to prevent any possible suffocation of the patient.
Warning	Before each use, check the device and its accessories for safe and normal operation. Do not use this device to monitor the patient if there are indications of damage or reminders of error. Please contact your local distributor or the manufacturer.
Warning	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

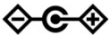
1.1.2 Caution

Caution	All the parts of the monitor should not be replaced at will, substitution of a component different from that supplied by the manufacturer might result in measurement error. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused. No modification of this device is allowed.
Caution	Do not immerse the monitor or its accessories in liquid to clean.
Caution	Connect only approved equipments to this device. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance with IEC 60601-1-1.
Caution	Store and use the device in specified environmental condition. The monitor and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.
Caution	If the monitor falls down accidentally or has other functional failures, it cannot be used any more. The safety performance and technical indicators must be tested in detail, and it can be used only after the test results are qualified.

1.1.3 Notes

Note	The software copyright of the monitor is solely owned by the manufacturer. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
Note	All combinations of equipment must be in compliance with the standard IEC 60601-1.
Note	The device and accessories must be disposed of in compliance with local regulations at the end of their service lives.
Note	Put the device in a location where it can be easily viewed and operated. Do not locate the device in a place difficult to access the mains plug.
Note	The monitor can be configured with different parameters. This manual describes all features and options. The monitor you purchase may not cover all functions described below.
Note	All illustrations in this manual serve as examples only and may differ from what is seen.

1.2 Device Symbols

Symbols	Function	Symbols	Function
	Power switch		USB connector
	Serial number		Direct current power connector
	General warning sign (Background: yellow; Symbol and line: black)		Device or part of CF type with defibrillation proof
	Refer to Operator's Manual (Background: blue; Symbol: white)		Non-ionizing electromagnetic radiation
	Manufacturer		Date of Manufacture
	Dispose of in accordance to your country's requirements		

Note	Your device does not necessarily have all of the above symbols.
Note	This manual is printed in Black and White.

Chapter 2 Product Introduction

2.1 Intended Use

The monitor is intended to be used for monitoring, displaying, reviewing, and storing multiple physiological parameters including ECG, body temperature (Temp), pulse oxygen saturation (SpO_2), pulse rate (PR), and non-invasive blood pressure (NIBP). The monitor is to be used for triage and ward rounds in hospitals, clinics, community health centers, or other medical care facilities by qualified clinical professionals or under their guidance.

The NIBP and ECG are intended for adult and pediatric.

The Temp, SpO_2 and PR are intended for adult, pediatric and neonate.

2.2 Contraindication

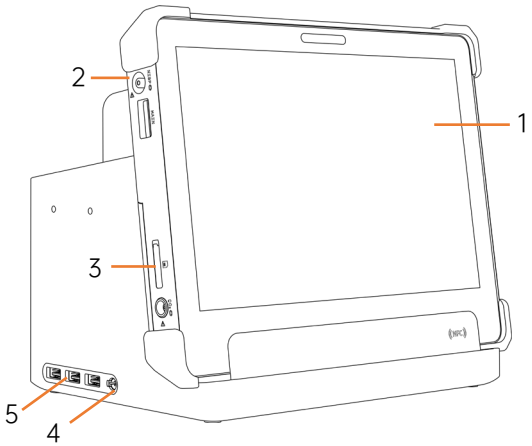
No contraindication.

2.3 Features

- The view can be flexibly configured.
- Lead-off detection function.
- Support the commonly used clinical tool of early warning score (EWS).
- Support large-capacity storage.
- Support touch screen, multi-touch (zoom, multi-finger slip, etc.).
- Protection against defibrillator discharge, resistance against the interference from electro-surgical unit.
- Support a variety of operating modes, such as demonstration mode, ward round mode, spot-check mode.
- USB data export function and application software upgrade are available.
- Support HL7 communication protocol.
- Provide a recorder for thermal print.

2.4 Product View

2.4.1 Front Right View



1 Touchscreen

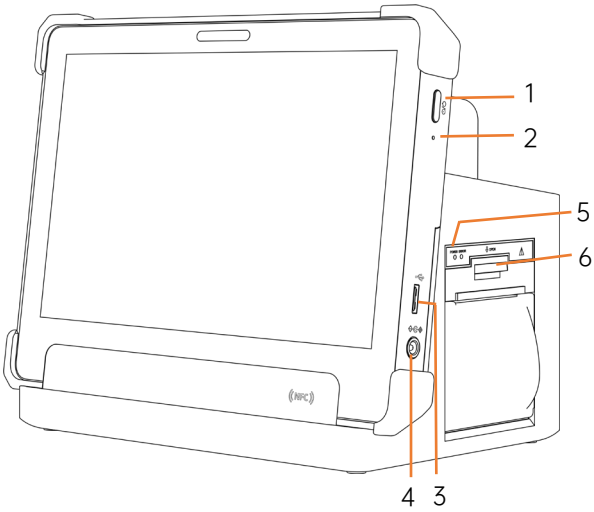
2 NIBP cuff connector

3 Adapter connector: Connect the multi-functional adapter which connects the accessories of multiple parameters (ECG, SpO_2).

4 Temperature probe connector

5 USB connectors (Base)

2.4.2 Front Left View



1 Power switch: Turn on/off the monitor.

2 Power switch indicator:

Green (Flashing)	In the state of power-on, the battery is fully charged
Yellow (Flashing)	In the state of power-on, the battery is not fully charged
White (Flashing)	In the state of power-on, no external DC power is connected
Green (Steady)	In the state of power-off, the battery is fully charged
Yellow (Steady)	In the state of power-off, the battery is not fully charged
Off	In the state of power-off, no external DC power is connected

3 USB connector (Main Unit)

4 DC adapter connector

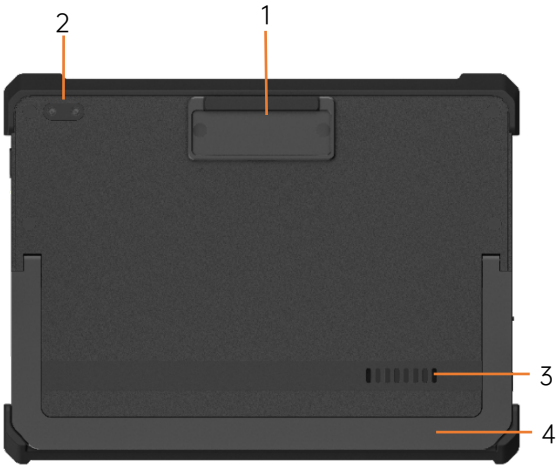
5 Recorder indicator

Green light	On	Normal recorder power supply
	Off	Abnormal recorder power supply
Red light	On	The recorder is out of paper, or the thermal paper is not loaded

		properly
	Off	The recorder work normally

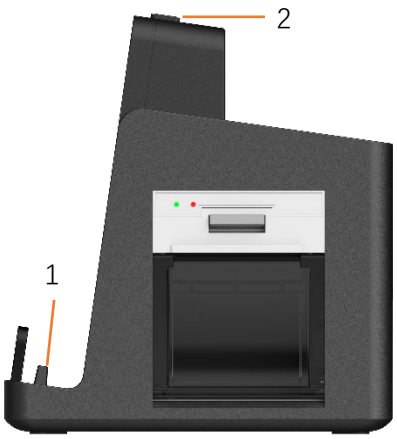
6 Open button for recorder door

2.4.3 Rear View of Main Unit



1 Latch for main unit and base
2 Camera and flash
3 Speaker
4 Main unit support

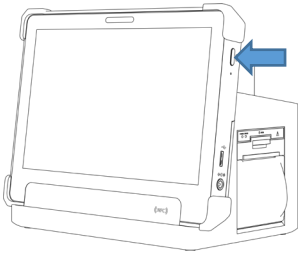
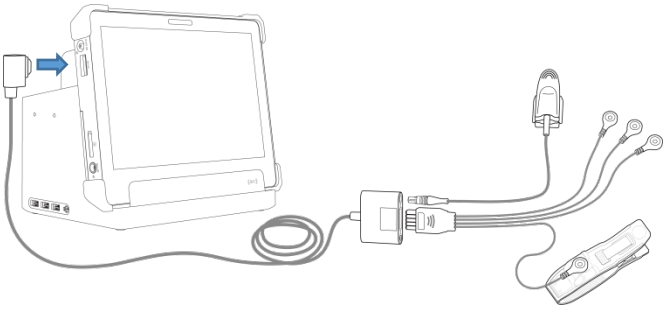
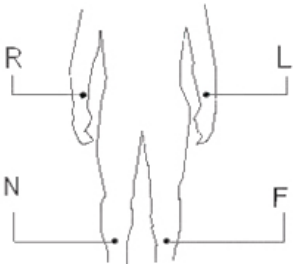
2.4.4 Base View

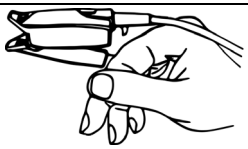
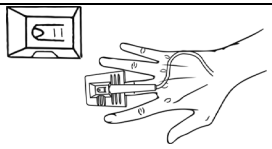
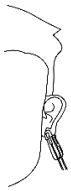
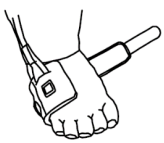


1 Main unit/base connector

2 Main unit release button: When the main unit is connected to the base, press this button to release the main unit.

Chapter 3 Quick Start

1. Turn on the monitor	
2. Connect	• Connect monitor, multi-functional adapter, and accessories (ECG, SpO_2).  • Connect the NIBP cable with the NIBP connector. • Connect the wired infrared thermometer to the temperature probe connector on the base, or pair and connect the Bluetooth thermometer to the monitor.
3. Apply accessories	ECG  SpO_2

<table>
<tr><td></td><td colspan="2"> 
(Finger clip)
 
(Finger cot)
 
(Earlobe)
 
(1)
 
(2)
(Wrapper)

Temp
Measurement site: forehead or earhole.

NIBP
  </td></tr>
<tr><td>5. Enter new patient information</td><td colspan="2">Select the patient information area.</td></tr>
<tr><td>6. Select operating mode</td><td colspan="2">Select [Menu] →[Work Mode] tab.</td></tr>
<tr><td>7. Measure and save records</td><td>Spot-check mode:
1. Take measurements
2. Select the [Next] on the main screen.</td><td>Ward round mode:
1. Select a patient from [Pat. List].
2. Select [Start] and take measurements.
3. Select [Save] on the main screen.</td></tr>
</table>

Chapter 4 Installation and Connection

4.1 Environment Requirements

The monitor can be installed on a wall, desktop, or a trolley. Select a place where the infrastructure and mains supply are well set up. Place the monitor in a safe and stable location where it can easily be viewed and operated.

The operating environment of the device must meet the requirements specified in this manual. Otherwise, unexpected consequences, e.g. damage to the device, could result.

The environment where the monitor is used shall be reasonably free from noise, vibration, dust, corrosive, flammable, and explosive substances.

When the monitor is moved from one place to another, condensation may occur as a result of temperature or humidity differences. In this case, never start the system before the condensation evaporates.

Note Place the monitor in a location from direct sunlight to avoid abnormal internal temperature rise

Note Do not immediately turn on the monitor when it is damp. Wait till it air dries before use.

4.2 Power Supply

4.2.1 Connecting the DC Power

1 Take out the accompanying DC power connector from the package.

2 Insert one end of the DC power adapter into the DC power connector on the main unit, and the other end into the three-wire outlet of a power source with protected-earth.

3 Verify that the power switch indicator is On.

4.2.2 Using the Battery

The device will automatically run from battery power in case of power failure of the DC power supply.

Note Because of the power consumption during storage and transportation, the monitor may run out of battery power. The battery

must be charged when the monitor cannot be turned on.

Note

The battery is charged whenever the device is connected to the DC power source regardless of whether or not the device is currently turned on.

4.3 Preparing Recorder

You can use the recorder to print patient information, data, and ECG reports.

To load the recording paper, follow the steps below:

1 Press and hold down the “Open” button to open the recorder door.

2 Insert a new roll of paper into the paper compartment properly, with the printing side facing upwards.

3 Pull about 2 cm of the paper out, and then close the recorder door.

Chapter 5 Functions

5.1 Turning On/Off Monitor

Turning On the Monitor

Press the power switch for about 2-3 seconds.

After the monitor runs, it displays a start-up screen and then jumps to the main screen. This indicates that the monitor is started successfully.

Turning Off the Monitor

Press the power switch for about 1-2 seconds, and a window will pop up and select [**Power off**].

You can press and hold the power switch for 10 seconds to forcibly shut down when it cannot be shut down normally. However, this operation may cause loss or corruption of patient data.

5.2 Work Modes

The monitor provides the operating modes as listed in the following table. Each mode is specially designed to meet the needs of different clinical scenarios.

Select [**Menu**] → [**Work Mode**] tab to select the desirable mode. The default mode is spot-check mode.

Mode	Scenario	Remarks
Spot-check mode	Spot-check mode is used for triage. In this mode, you can quickly adjust patient type and take measurements.	/
Ward round mode	Round mode is used for ward rounds. In this mode, a patient list is provided and you can easily take measurements for each patient.	If no patient is selected, the measurements cannot be saved.
Demo Mode*	Demo mode is only used for demonstration purpose. The data and waveform in demo mode are generated by the system, and cannot be used to evaluate the physiological condition of patients.	/

Warning <Demo Mode> In clinical use, do not set the device to Demo mode, to avoid stimulated data being mistaken for a monitored patient's data, which may cause improper monitoring and delayed treatment.

Work Process for Spot-Check Mode

In spot-check mode, you can quickly take measurements for a patient only with the patient type selected.

If you want to save the measured record, follow the steps below:

1 Enter patient information through any of the methods described in *5.4 Entering Patient Information.*

2 Take measurements.

3 Select the [**Next**] button on the main screen. All the conducted measurements are saved in a record in [**Review**].

Work Process for Ward Round Mode

1 Select [**Pat. List**] button on the main screen.

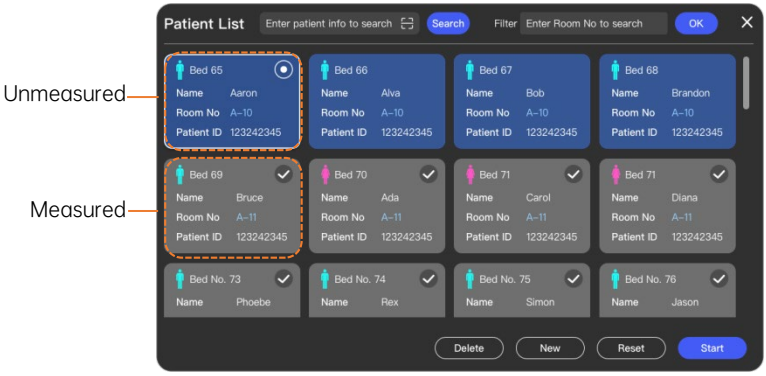
2 Select a patient from the pop-up window.

- Double-click the patient card in deep blue.

  Unmeasured: background in deep blue

  Measured: background in grey

- When the patient card background is in deep blue, select the [**Start**] button at the bottom of the window.



Then the screen will automatically skip to the main screen.

3 If the patient is not listed in the window, you can select [**New**] to create the patient file and select it.

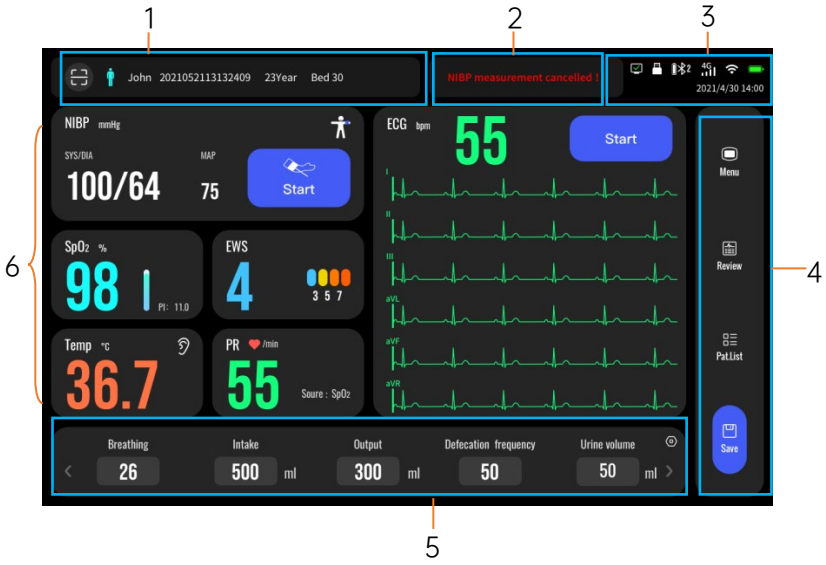
4 Take measurements.

5 Select the [**Save**] button on the main screen. All the conducted measurements are saved in a record in [**Review**].

5.3 Main Screen

The display content of the main screen is slightly different between spot-check mode and ward round mode.

The following screen is in ward round mode for illustration.



No.	Description
1	**Patient information area**: displays the patient name, gender, identifier, and so on, as well as the barcode or QR code scanning icon . Selecting this area to pop up the Patient Info window. Patient gender description: • Male (blue): Adult /Pediactric /Neonate • Female (pink): Adult /Pediactric /Neonate • Unknown gender (white): Adult /Pediatric /Neonate
2	**Prompt message area**: displays the last technical prompt message. Selecting the area to pop up the prompt message window.
3	**System status area**: Displays network status, battery status, Bluetooth status, and system time. **Network icon**:

No.	Description
	•  Indicates Wi-Fi signal strength Selecting one of the icons to display the **[Wireless]** or **[Connection]** tab. **Bluetooth icon:** •  Indicates monitor's Bluetooth is turned on **Battery icon**: •  Indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the device will automatically shut down after 5 minutes. •  Indicates that no battery is installed or battery fault. •  Indicates that the battery is being charged. The filled portion represents the remaining capacity of the battery. •  Indicates current battery capacity. The filled portion represents the remaining capacity of the battery. **USB drive icon**: •  indicates that a USB drive is connected. Selecting the icon to display the **[Detect Info]** tab. **Base icon**: •  indicates that the main unit is on the base.
4	**Button area:** displays the system buttons. The buttons are slightly different between spot-check mode and ward round mode. Spot-check mode buttons: **[Menu]**, **[Review]**, **[Switch Patient]**, **[Next]**. Ward round mode buttons: **[Menu]**, **[Review]**, **[Pat. List]**, **[Save]**.
5	**Observation parameter area**: displays the observation parameters and the entered values.
6	**Numerics and waveform area**: displays the parameter numerics of NIBP, Temp, SpO_2, and PR, and can also display the selectable EWS area, ECG area, observation parameters, or SpO_2 Pleth waveform.

5.4 Entering Patient Information

In the [**Patient Info**] screen, an asterisk (*) is placed behind the required information. Use any of the following methods to enter patient information:

- Enter patient information manually
- Read patient ID with the device's camera
- Read patient ID with a barcode reader

Note: You can save patient information only when all the required patient information is entered.

Note: After camera scanning, please check the scanning result to ensure that the correct patient information is entered.

Entering Patient Information Manually

1 Select any part of the patient information area other than  icon.

2 In the pop-up window, enter the patient information manually. For the Patient ID, you can switch on [**Auto encoding**] to have an automated patient ID.

Reading Patient ID with the Device's Camera

1 Click the  icon to start scanning with the built-in camera.

2 Use the camera to scan the linear barcode or QR code, and enter the decoded content into the patient ID text box.

3 Enter other patient information manually.

4 Click the [**OK**] button to save the patient information.

Reading Patient ID with a Barcode Reader

1 Connect the barcode reader to the USB connector on the main unit.

2 Press down the button on the reader handle, and target the reader to the barcode. Then the [**Patient Info**] menu pops up with the patient ID entered.

5.5 Settings and Operation Overview

Note An item marked with * indicates that it is followed by relevant warning or prompt information at the end of this section.

5.5.1 Setup

Items	Function	Entry
Date & Time	Set system date, time, as well as date and time format.	Select [Menu]→ [System] → [Setup] tab.
Language	Set the system language.	Select [Menu]→ [System] → [Setup] tab.
Brightness	Set screen brightness	Select [Menu]→ [System] → [Setup] tab.
QRS Mode and Volume*	Select QRS mode, and set QRS volume.	Select [Menu]→ [System] → [Setup] tab.
Key Volume	Switch On/Off to key volume.	Select [Menu]→ [System] → [Setup] tab.
Wireless network	Set wireless network IP address.	Select [Menu]→ [System] →[Wireless] tab.
Display of patient information field	Customize the required fields and other displayed fields in the [Patient Info] screen when adding a patient.	Select [Menu] → [System] → [Patient Info] tab.
Recorder setup	Set the paper speed of the recorder.	Select [Menu]→ [System] → [Print] tab.
ECG layout in the output	Set the ECG waveform layout as 6×1 or 3×2 in the PDF file.	Select [Menu]→ [System] → [Print] tab.

Warning <QRS Volume> It is not recommended to set the QRS volume to 0. Pay attention to potential risks.

5.5.2 Operations

Operations	Functions	Entry
Editing Patient Information	Modify the current patient information, including patient type, name, age, etc.	Select patient information area→modify patient information→[OK].
Pairing the Bluetooth thermometer	Pair the detected Bluetooth device with the monitor	Select [Menu] →[System] →[Detect Device] → select the device in [Unbound devices].
Enabling ECG	Make the ECG function available.	Select [Menu] → [Parameters] → switch on [Parameter On/Off] of ECG
Enabling EWS	Make the EWS function available.	Select [Menu] → [Parameters] → [EWS›] →switch on [Parameter On/Off]
Enabling observation parameters	Make the function of the observation parameter group available.	Select [Menu] → [Parameters] → [More parameters›] → switch on [Parameter On/Off] → enter the maintenance password
Scoring in EWS	Calculate a score in the selected EWS tool.	Select [Menu] → [Parameters] → [EWS›]
1 mV calibration	Calibrate for the amplitude of 1 mV.	Select[Menu] → [System] → [Setup] tab → [ECG Setup].

Chapter 6 ECG Acquisition

The monitor provides 4-electrode ECG acquisition if your device is configured with this function.

The function is intended for adult and pediatric patients.

6.1 Safety Information

Warning	Only use the lead wires provided by the manufacturer. Using those from other suppliers may cause improper performance or poor protection during defibrillation.
Warning	Check if the patient category setting is correct for the patient.
Warning	Ensure that the conductive parts of ECG electrodes and associated connectors, including the neutral electrode, do not come into contact with any other conductive parts including earth. Make sure that all electrodes are connected to the patient correctly.
Warning	Do not use dissimilar metal electrodes, otherwise it will cause high polarization voltage. Reusable electrodes will withstand a large bias potential due to polarization, and the recovery time after defibrillation will be particularly long (more than 10 seconds). It is recommended to use disposable electrodes.
Warning	To minimize the hazard of burns during use of high-frequency surgical unit (ESU), the ECG electrodes should not be located between the surgical site and the ESU return electrode.
Warning	To minimize the hazard of burns during high-frequency surgical procedures, ensure that the monitor's cables and transducers never come into contact with the electrosurgery unit (ESU).
Warning	The improper connection with the electrosurgical unit may not only cause burns but also damage the monitor or arouse deviations of measurement. You can take some steps to avoid this situation, such as do not use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electro-surgical return electrodes and connecting them with the patient properly.
Warning	If any side-effect such as allergic or itchy reaction is found, remove the electrodes from the patients immediately.
Warning	Use only the same type of electrodes recommended by the manufacturer on the same patient to avoid the change of resistance.
Note	Interference from an ungrounded instrument near the patient or electrosurgery usage can induce noise and artifact into the

waveforms.

Note When the monitor is inoperable due to overload of ECG signal or saturation of any part of the amplifier, it will prompt "*Lead off*" to remind the operator.

Note Transient caused by cable circuitry blocks while monitoring may cause artifact on ECG signals yielding wrong heart rate reading and even triggering false alarm. If the electrodes and cable are located in proper places according to this manual's instructions for using electrodes, the chance of this transient occurrence will be decreased.

6.2 ECG Measurement Preparation

6.2.1 Preparing the Patient's Skin

The state of the patient's skin directly affects the strength of the ECG signal and the accuracy of monitoring information. To properly prepare the patient's skin, please refer to the following steps:

1 Select sites with intact skin, without impairment of any kind. Shave hair from sites, if necessary.

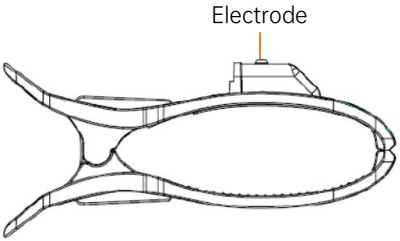
2 Wash sites thoroughly with soap and water (Never use ether or pure alcohol, because this increases skin impedance).

3 Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

6.2.2 Connecting ECG Cable and Applying Electrodes

1 Connect the ECG cable to the multi-functional adapter installed on the main unit.

2 Connect the electrode with the electrode connector on the lead wire.



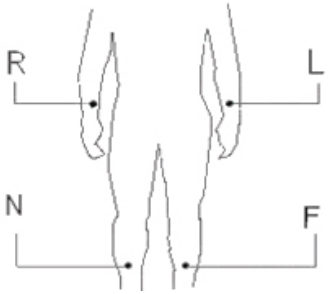
3 Daub a thin layer of conductive paste on the metal part of the limb electrode clamp.

4. Connect the electrode to the limb, and make sure that the metal part is placed on the electrode area above the ankle or the wrist. Refer to the following section for ECG electrode placements, or follow the doctor's instructions.

The electrode identifier and color code are classified into IEC (European standard) and AHA (American standard). The electrode identifier and color are shown below:

IEC Standard		AHA Standard	
Identifier	Color Code	Identifier	Color Code
R	Red	RA	White
L	Yellow	LA	Black
F	Green	LL	Red
N or RF	Black	RL	Green

The 4-electrode are limb electrodes and should be placed on the upper part of the forearm wrist joint and the ankle joint inside the calf (avoiding the bones), and the electrodes should be placed in close contact with the skin.



- R placement: right arm.
- L placement: left arm.
- N placement: right leg.
- F placement: left leg.

6.2.3 Factors Affecting ECG Signal

- Interference from electrosurgical units.
- Unreasonable filter mode setting.
- Poor grounding.

- Incorrect placement of electrodes.
- Use expired electrodes or use disposable electrodes repeatedly.
- The skin on which the electrodes are placed is unclean or poor contract caused by scurf and hair.

6.3 ECG Display

The ECG area can be set to be displayed on the main screen.

To display the ECG area, select [**Menu**] → [**Parameters**] → enable [**Parameter On/Off**] of ECG, and the ECG area will display on the main screen.

In the ECG area, the HR value and ECG waveform are displayed.

6.4 Acquiring ECG

On the ECG area, you can acquire at most 10 s waveforms.

You can select the [**Start**] button to initiate the acquisition and then it automatically stops when 10 seconds elapse.

6.5 Generating an ECG Report

To diagnose the acquired ECG, follow the steps below:

1 Select the [**Review**] button on the main screen.

2 Select the desired record of a patient.

3 Select [**Waveform**] in the ECG parameter panel.

4 In the pop-up ECG waveform screen, select [**Diagnose**].

5 In the field of [**Diagnosis**], enter or edit the analysis result.

6 Select [**OK**]. The diagnosis is saved.

7 Select [**Export**] to export a PDF report to a USB drive, or select [**Print**] to print the report in the printer or recorder.

6.6 ECG Setup

Items	Functions	Details
Speed	Set ECG waveform speed.	Options: 50 mm/s, 25 mm/s, 12.5 mm/s, 6.25 mm/s. The default is 25 mm/s.
EMG Filter	Filter the electromyogram noise.	Options: 25 Hz, 35 Hz, 45 Hz, Off. The default is 45 Hz.
Sensitivity*	Set ECG waveform amplitude.	Options: 40 mm/mV, 20 mm/mV, 10 mm/mV, 5 mm/mV, 2.5 mm/mV, 1.25 mm/mV. The default is 10 mm/mV.
QTc Formula	The monitor uses the formula to correct the QT interval for heart rate.	The monitor provides four formulas: Hodeges: $QTc = QT+1.75 \times (HR-60)$ Bazett: $QTc = QT \times (HR/60)^{1/2}$ Fredericia: $QTc = QT \times (HR/60)^{1/3}$ Framingham: $QTc = QT+154 \times (1-60/HR)$ The default is Hodeges.
Notch Filter	Filter the interference from the power line frequency.	Filter the waveform at 50 Hz or 60 Hz frequency.
Filter	Select a ECG filter in different range.	Options: 0.05 Hz-150 Hz, 0.67 Hz-150 Hz, Off.
ECG standard	Determine the lead label following IEC or AHA standard.	The monitor will follow the selected ECG standard concerning lead labels in the technical prompt.

Note If the amplitude of the ECG waveform is too large, the wave peak or

the wave valley might not be displayed. In this case, you should change the waveform gain appropriately.

Chapter 7 Measuring Pulse Oxygen Saturation (SpO_2)

SpO_2 monitoring is intended for adult, pediatric, and neonatal patients.

7.1 Safety Information

Warning	Check the SpO_2 sensor and cable before use. Do not use the damaged SpO_2 sensor.
Warning	Check the compatibility of the monitor, probe, and cable before use to avoid patient injury.
Warning	Do not stare into the light of the SpO_2 sensor (infrared light is invisible) when it is on, as the infrared light can cause damage to the eyes.
Warning	SpO_2 measuring site must be examined more carefully for some special patient. Do not place the SpO_2 sensor on the site with edema or fragile tissue.
Warning	Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should not be applied to the same site for over two hours.
Warning	Inspect the SpO_2 sensor application site every one to two hours to ensure skin quality and correct optical alignment, and change the measuring site periodically if necessary. If the skin quality changes, move the sensor to another site.
Warning	If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema, hypoxia, tissue ischemia, and inaccurate oxygen saturation measurements.
Warning	Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements.
Warning	At elevated ambient temperatures, be careful with measurement sites that are not well perfused, because this can cause burns after prolonged application.
Warning	For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements.
Warning	Please do not use the SpO_2 sensor and the monitor when doing the

MRI imaging, or burn may be caused by faradism.

Caution	For disposal SpO_2 sensor, if the sterile packaging is damaged, do not use it any more.
Caution	When the temperature of SpO_2 sensor is abnormal, do not use it any more.
Note	The clinical study for SpO_2 measurement accuracy was done on human subjects according to Standard ISO 80601-2-61.
Note	A functional tester or SpO_2 simulator cannot be used to assess the accuracy of the oximeter or a SpO_2 sensor. However, it can be used to check how accurately a particular oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.
Note	The SpO_2 calibration of the monitor has been carried out before delivery, and user does not need to calibrate it again during the operation.

7.2 Measurement Interferences

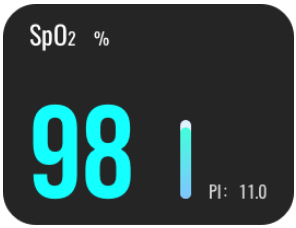
- The SpO_2 measurement of the monitor may not work effectively for all kinds of patients, for whom with weak pulse due to shock, low ambient / body temperature, major bleeding, or use of vasoconstriction medications, the measurement will be more sensitive to interference, if stable readings cannot be obtained at any time, stop using the SpO_2 monitoring function.
- For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 measurements may be inaccurate.
- The medicines such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measurements.
- As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO_2 value.

- The high-pressure oxygen environment can affect measurement accuracy.
- Peripheral vasospasm, or constriction of blood vessels caused by a decrease in temperature, can affect measurement accuracy.
- Avoid placing the sensor on extremities with an arterial catheter, an NIBP cuff or an intravascular venous infusion line.
- Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate oxygen saturation measurements.
- Excessive ambient light may affect the measurement result, including includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
- The fingernail should be of normal length when use the finger clip or finger cot sensor.
- Please do not use nail polisher or other cosmetic product on the nail.
- Vigorous patient movement, strong ambient light, or extreme electrosurgical interference may also affect the SpO_2 measurement accuracy.
- Low perfusion may affect the measurement accuracy.

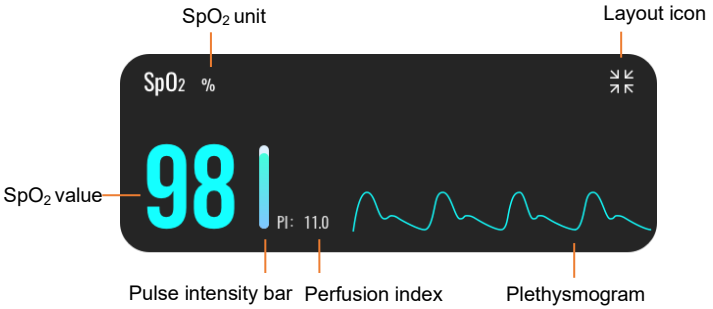
7.3 SpO_2 Display

The SpO_2 area has the following two types of layout. When any of the EWS area and ECG area is enabled, the SpO_2 area is displayed according to Layout 1.

Layout 1: SpO_2 area (Only parameter)



Layout 2: SpO_2 area (Parameter and Plethysmogram)



- Layout icon: Select the layout icon to display the plethysmograph or not.

Note

The Plethysmogram (Pleth) waveform is processed by amplitude normalization.

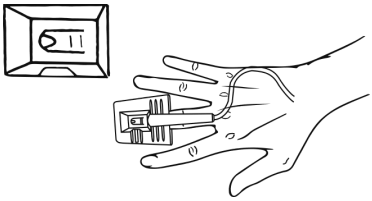
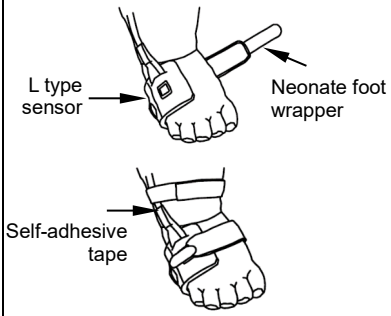
7.4 PR Display

Note

When the measured value exceeds the measurement range, “--” is displayed in the numerics area.

7.5 SpO_2 Monitoring

1 Select the proper SpO_2 sensor according to the characteristics of each type, and then place the sensor according to the following.

<table>
<tr>
<td>Finger clip
(Middle finger preferred, index or ring finger)
  </td>
<td>Finger cot
(Middle finger preferred, index and ring finger)
  </td>
</tr>
<tr>
<td>Ear clip
(Earlobe)
  </td>
<td>L-type Wrapper
(Foot)
 
</td>
</tr>
</table>

2 Connect the SpO_2 extension cable to the multi-function adapter installed on the main unit.

3 Connect the sensor to the extension cable.

7.6 SpO_2 and PR Setup

Item	Functions	Details
Speed	Set the Pleth waveform sweeping speed.	The larger the value, the faster the sweeping speed.
PR source	Set the source where the pulse rate value comes from.	The source can be Auto, SpO2 or NIBP.

Chapter 8 Measuring Temperature (Temp)

The monitor supports two types of infrared thermometers. You can select one of them to measure the ear or forehead temperature, and the measurement will transfer to the monitor.

The thermometer type and measurement site are as follows:

- Bluetooth thermometer (Ear/Forehead)
- Wired thermometer (Ear)

Temperature measurement is intended for adult, pediatric, and neonate patients.

8.1 Safety Information

Caution	The user is responsible for checking the compatibility of the monitor, the probe, and probe cable before use.
Caution	Incompatible components can result in degraded performance.
Note	There is a range of normal body temperature. At the same time, the temperature of different measurement sites is different. Therefore, the readings of different sites should not be compared directly.

8.2 Using the Wired Thermometer (THP59JU)

The thermometer uses a disposable probe cover. Keep the probe cover holder nearby the monitor.

1 Insert the thermometer cable into the connector on the base.

2 Press the probe tip into the probe cover until you hear a click.

3 Apply the thermometer probe to the measurement site.

4 Press the measurement button on the thermometer. The measurement will be displayed on the monitor screen.

For more information, refer to thermometer THP59JU instructions for use.

8.3 Using the Bluetooth Thermometer (AOJ-20A)

For the first use, you need to bind and connect the Bluetooth thermometer to the monitor.

1 Make sure your thermometer is powered on.

2 Select [**Menu**] →[**System**] →[**Detect Device**].

3 Select your device in the area of [**Unbound devices**].

4 Select [**Bind**]. Then the device will appear in the area of [**Bound devices**].

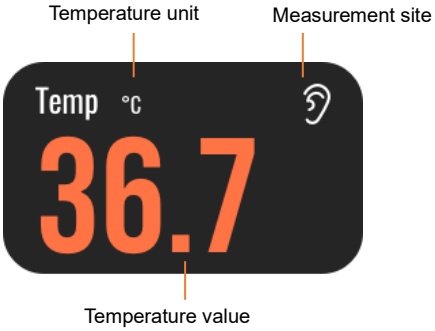
5 Select the device and then select [**Connect**]. The device connection status will turn to *Connected*.

6 Apply the thermometer probe to the measurement site.

7 Press the measurement button on the thermometer. The measurement will be displayed on the monitor screen.

For more information, refer to thermometer AOJ-20A instructions for use.

8.4 Temp Display



8.5 Temp Setup

Item	Functions	Details
Unit	Select temperature unit.	Options are ℃ and ℉. (℉ = ℃×9/5+32)

Chapter 9 Measuring Non-Invasive Blood Pressure (NIBP)

The monitor uses the oscillometric method to measure non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. A cuff is used to occlude the artery by inflating it above the patient's systolic pressure, the oscillometric devices measure the amplitude of pressure changes with pulsation in the cuff as the cuff pressure decreases. The pulsations increase in amplitude, and reach a maximum, then diminish along with the decrement of cuff pressure. The cuff pressure at the pulse amplitude backward reduced according to proper proportion is defined as systolic pressure (SYS), and the cuff pressure at the pulse amplitude forward reduced according to proper proportion is defined as diastolic pressure (DIA).

NIBP monitoring is intended for adult and pediatric patients.

9.1 Safety Information

Warning	Before the measurement is carried out, select an appropriate measuring mode depending on the patient type.
Warning	If any abnormality occurs, move the cuff to another place or stop the blood pressure measurement immediately.
Warning	If the patient is moving or suffering tremble, hyperkinesia or arrhythmia, it may cause the inflation time of inflatable balloon endures longer, which may not only prolong the measurement time, but also result in the body wrapped by the cuff is troubled by purpura, hypoxemia and neuralgia because of the friction.
Warning	The monitor can be used on the patients who are pregnant or pre-eclamptic, but close attention should be paid to such patients.
Warning	Do not wrap the cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, injury may be caused to the limbs.
Warning	The air-hose which connects the cuff and monitor should be straightway without any tangle.
Warning	The measurement site, patient position, motion, and physiological status can all affect the NIBP reading. If you have doubts about the accuracy of the measurement results, please use other methods to check the patient's vital signs first, and then check whether the monitor's function is abnormal.

Warning	NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, otherwise, partial bleeding will appear.
Warning	Do not apply or pressurize the cuff on the arm on the side of a mastectomy or lymph node clearance.
Caution	Do not take the measurement when the patient uses diuresis or vasodilator.
Caution	The blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers.
Caution	Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.
Caution	The NIBP measurement will not be affected when the monitor is connected to the patient on whom the electro-surgical unit and defibrillator is being used.

9.2 Measurement Interferences

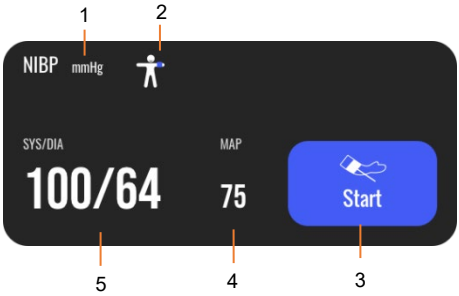
- Do not apply cuff on the limb where skin damage has occurred or is expected.
- For patients with severe coagulation disorders, it is necessary to determine whether to carry out automatic blood pressure measurement according to clinical evaluation, because there is a risk of hematoma at the friction between the limb and the cuff.
- The patient has serious angiospasm, vasoconstriction, or weak pulse.
- When extremely low or high heart rate or serious arrhythmia of the patient occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
- When the patient is suffering from massive hemorrhage, hypovolemia, shock and other conditions with rapid blood pressure change or when the patient has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
- The cuff should be at the same level with the heart. If not, the measurement may be inaccurate.

- Speak or motion during measurement may affect the measurement accuracy.
- The measurement interval should not be too short (should be greater than 2 minutes). For continuous blood pressure measurements, if the interval is too short, it can cause the arm to be compressed, resulting in a decrease in blood volume and thus a decrease in blood pressure.

Requirements for patient posture, setting and operation:

- The patient should be positioned in a supine position with legs uncrossed, so that the cuff and the heart are in a horizontal position and the most accurate measurement is taken. Other postures may lead to inaccurate measurement.
- Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects. The air tube which connects the cuff and monitor should be straight without any tangles.
- It is recommended to take the first reading after the device runs for at least 5 minutes to ensure the stability of the measurement.
- The measurement should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measurement of blood pressure. It is recommended the measurement be taken at intervals of more than two minutes.
- Patients should be measured in a relaxed and calm state, otherwise the accuracy of blood pressure measurement data will be affected.
- When taking NIBP measurements on adult patients, the monitor may fail to give the blood pressure measurement if the pediatric patient type is selected. When taking NIBP measurement on pediatric or neonatal patients, the operator must select the correct patient type depending on different patients and do not operate with the adult patient type setting. The high inflation pressure for an adult is not suitable for pediatric patients.
- If the original parts are replaced with parts not provided by the manufacturer, it may cause measurement errors.

9.3 NIBP Display



1 NIBP unit

2 Measurement site

3 Start/Stop measurement button

4 Mean arterial pressure

5 Systolic/diastolic pressure

Note

If NIBP measurement fails, “XX” is displayed in the numerics area; if NIBP measurement is untaken, stopped, reset is completed, no numerics is displayed.

9.4 NIBP Monitoring Preparation

Before starting the NIBP measurement, make sure that the patient remains calm and relaxed.

1 Make sure that the patient type setting is correct.

2 Select an appropriate cuff according to the patient's age and limb circumference. The width of the cuff should be 40% of the limb circumference or 2/3 of the length of the upper arm or the thigh. The inflatable part of the cuff should be long enough to encircle to overlap at least 50% to 80% of the limb.

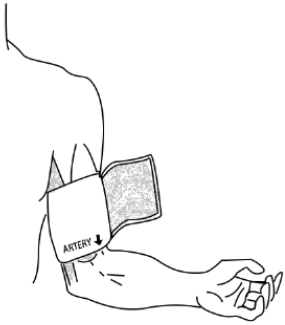
3 Empty the cuff until there is no residual air inside it to ensure accurate measurement.

4 Connect the cuff to the air tubing.

5 Connect the air tubing to the NIBP connector on the monitor.

6 Put on the cuff, unfold, and wrap it around the patient's upper arm or thigh evenly to appropriate tightness.

7 Locate the cuff in such a way that the "ARTERY" mark "⬇" is at a location where the clearest pulsation of brachial artery is observed. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm. The cuff should be at the same level with the heart, and the lower end of the cuff should be 2 cm above the elbow joint. As shown in the figure below: As shown in the figure below:



9.5 Starting and Stopping NIBP Measurements

Start NIBP measurement	• Select [**Start**] in the NIBP parameter area
Stop NIBP measurement	• Select [**Stop**] in the NIBP parameter area

9.6 Correcting the NIBP Measurements

The middle of the cuff should be at the level of the right atrium. If the limb is not at the heart level, the measurement should be corrected as follows:

- Add 0.75 mmHg (0.10 kPa) to the displayed value for each centimetre higher.
- Deduct 0.75 mmHg (0.10 kPa) to the displayed value for each centimetre lower.

9.7 NIBP Setup

Item	Functions	Details
Measurement Site	Set NIBP measurement site	NIBP measurement site includes left arm, right arm, left leg, right leg.
Initial Pressure	Set the initial cuff inflation pressure	See *A.6 NIBP Specifications* for inflation range.
Unit	Set the NIBP unit	mmHg or kPa, in which 1 kPa=7.5 mmHg

Chapter 10 Early Warning System

Early Warning System (EWS) is an evaluation system, that provides an overall score based on vital signs measurements and observation, followed by corresponding action suggestions.

Warning The EWS system is not applicable to pregnant women and people under 16 years old.

Warning NEWS is not applicable to spinal cord injury (SCI) patients.

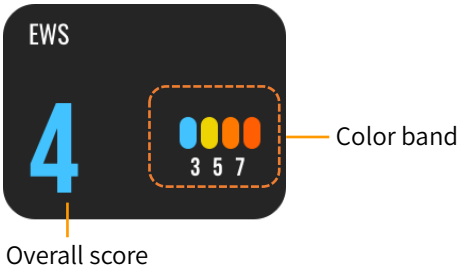
Warning The EWS scores and recommended actions are for reference only and cannot be directly used for diagnostic interpretation.

Warning EWS cannot be used as an index of prognosis. It is not a clinical judgement tool. Clinicians must use their clinical judgement in conjunction with the EWS tool at all times.

EWS Parameter Area

The EWS area is not displayed by default.

Select [**Menu**] → [**EWS>**] → Enable [**Parameter On/Off**], and then the area will display on the main screen.



- **Color band**: The top of the band shows the color indication, and the bottom shows the threshold value for each color. The risk is gradually increasing from blue to red.
- **Overall score**: The overall score is assessed on the criteria of each scoring system when individual score for each parameter is obtained. The numerical color of the overall score is displayed according to the color band. For example, when NEWS is adopted, 8-point is displayed in red.

Types of Scoring System

The monitor supports NEWS, MEWS, and CART scoring systems.

Scoring System	Scoring Parameters	Result Description
National Early Warning Score (NEWS)	Consciousness, Supply O_2 (oxygen supply status), RR, PR, SpO_2, Temp, SBP (systolic pressure)	• 0-4 points, with the numerics in blue: indicates a low risk • 0-4 points, with the numerics in yellow: indicates a medium-low risk, and the score of a certain parameter is high (3 points) • 5-6 points: indicates a medium risk • 7 points and above: indicates a high risk
Modified Early Warning Score (MEWS)	Consciousness, RR, Temp, SBP (systolic pressure), HR	• 0-3 points, with the numerics in blue: indicates a low risk • 0-3 points, with the numerics in yellow: indicates a medium-low risk, and the score of a certain parameter is high (3 points) • 4-6 points: indicates a medium risk • 7 points and above: indicates a high risk
Cardiac Arrest Risk Triage (CART)	RR, HR, DBP (diastolic pressure), Age	• 0-16 points, blue number: indicates a low risk • 17-20 points, yellow number: indicates a medium-low risk • 21-24 points: indicates a medium risk • 25 points and above: indicates a high risk

Calculate a Score

Select **[Menu]** → **[Parameters]** → **[EWS>]**, and you can enter the EWS screen.

1 Select the scoring tool.

2 Enter the required parameter value under the scoring tool.

3 Select **[Calculate]** to calculate a score.

4 The total score and a pattern based on individual parameter score will display.

Caution Before calculating the score, select [Clear] to clear the previous score.

Note You can get the score only when all required parameters have been measured or entered.

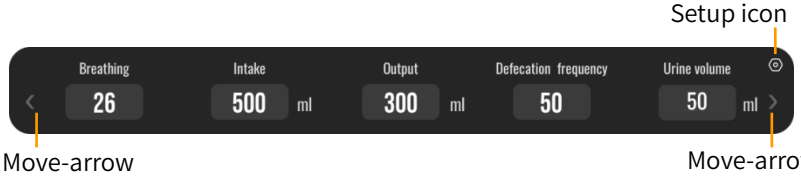
Chapter 11 Observation Parameters

The monitor provides a set of parameters from the physician's clinical observations or patient's complaints. Physicians can enter the values of these parameters and output them in a record.

Observation Parameter Area

The Observation Parameter area is not displayed by default.

Select [**Menu**] → [**More parameters>**] → enable [**Parameter On/Off**], and then the area will display on the main screen.



- Select the icon to pop up a window. In this window, you can select the parameter group to be shown in observation parameter area, and can also quickly enter the relevant measurements. The monitor is pre-configured with two sets of parameter groups for use in triage and general wards. You select one for your needs.
- Select the arrows on the right and left ends to show more parameters in the group.

Customize Parameter Group

You can set up your observation parameter groups, and edit the parameters in the two defaultly configured parameter groups.

You can create up to 20 groups.

To create a new parameter group, follow the steps below:

1 Select [**Menu**] → [**More parameters>**] →[**New**].

2 Enter the group name and the required parameters.

3 Select [**OK**].

To edit the parameters in the preset [**Triage**] and [**General Ward**] groups, follow the steps below:

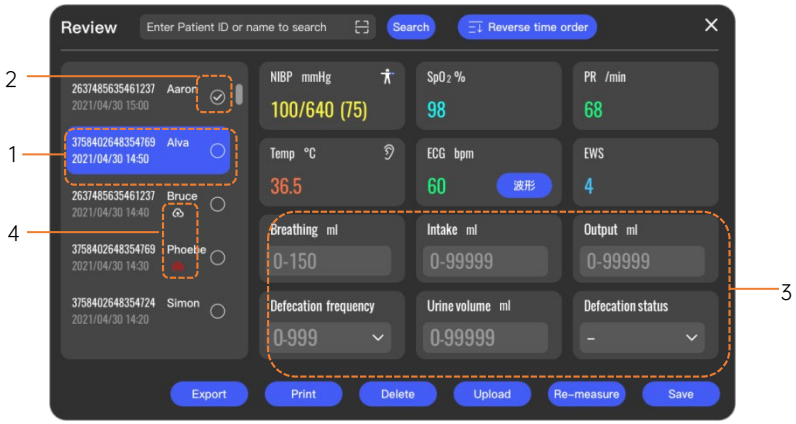
1 Select [**Menu**] → [**More parameters>**].

2 Select [**Edit**] and select the desired fields.

3 Select [**OK**].

Chapter 12 Review

Select **[Review]** to enter the Review screen. You can view all the measuring records of all patients.



1 **Current record**: Current record is in blue background. The measurements of this record display on the right side.

2 **Selected records**: The checked records are selected records. These selected records can be operated by exporting, deletion, and printing.

3 **Observation parameters**: These parameters' value is editable.

4 Upload status of records: When the records are manually uploaded in this screen, you can see their upload status.

 indicates that the upload failed.

 indicates that the upload succeeded.

 indicates that the upload is in process.

You can perform the following operations in review:

- View all the measurements of a specific record.
- View the ECG waveform and generate an ECG report.
- Select records to export to a USB drive.
- Select records to print by the thermal recorder.

- Delete the selected records.
- Modify the value of observation parameters.
- Re-measure the parameters.

Caution If the device storage has 20% remaining, it will promote insufficient storage space. If the device storage has 10% remaining, the earliest patient records will be automatically deleted.

Chapter 13 Cleaning and Disinfection

13.1 Safety Information

Warning Do not immerse the device and accessories in liquid.

Warning Do not pour liquid on the device or accessories. Do not allow the liquid permeate into the device.

Warning Do not use abrasive materials or any strong corrosive solvents for cleaning to avoid scratches or damages to the device.

Warning The parts contacted by the infected or suspected patient should be disinfected.

Warning The manufacturer is not responsible for the effectiveness of the disinfectant or disinfection method used as a means of infection control. Please consult your hospital's infection control director or epidemiologist for advice.

13.2 Recommended Cleaning and Disinfection Agents

Supported cleaning agents include:

- Water
- Mild soapy water
- Non-corrosive diluted cleaner

Supported disinfection agents include:

- Ethanol (70%-75%)
- Isopropanol (70%)
- Hydrogen peroxide (3%)

Supported cleaning and disinfection tools include cotton balls, soft gauze, soft brush, and soft cloth.

13.3 Cleaning

Clean the exterior surface of the monitor monthly or more frequently if needed.

To clean the monitor, follow the steps below:

1 Turn off the monitor and disconnect it from the DC power cable and accessories.

2 Clean the surface of the monitor with a clean soft gauze moistened with one of the recommended cleaning agents.

3 Wipe off all the cleaning agent residue with a clean dry cloth. Dry your monitor in a ventilated, cool place.

Caution Keep the cleaning agent away from the connectors of the monitor and accessories while cleaning the device housing.

Caution Use non-aggressive cleaning agent to clean the surface of the monitor and the display screen.

Caution Most cleaning agents must be diluted before usage.

13.4 Disinfection

Disinfect the monitor in accordance with the disinfection procedures of your hospital. Clean the monitor before disinfection.

Warning Ethanol is flammable. Please keep away from fire while using the ethanol disinfectant.

Warning People allergic to ethanol are forbidden to use the ethanol disinfectant.

Caution Rubber and plastic products will harden after prolonged contact with alcohol disinfectants, hence the residual disinfectant should be removed in time after disinfection.

Caution Do not use radiation or steam for disinfection.

Caution Please avoid contact with the metal parts when user disinfects the device with peroxide or chlorine-containing disinfectants.

13.5 Sterilization

It is not allowed to sterilize the monitor and related accessories unless stated in their operation instructions.

13.6 Cleaning the Thermal Print Head

If the thermal printer has been used for a long time, deposits of paper debris may collect on the print head, which may affect the print quality and shorten the lifetime of the roller.

Caution The thermal head may be hot after completing the recording task. Do not clean the thermal head of the recorder immediately.

Follow this procedure to clean the thermal print head:

1 Take measures against static electricity such as Disposable Wrist Strap for the work.

2 Open the printer door and take out the paper.

3 Gently wipe around the print head using cotton swabs dampened with Ethanol.

4 After the Ethanol has completely been dried, reload the paper and close the printer door.

13.7 Cleaning, Disinfection and Sterilization of Accessories

For the cleaning, disinfection, and sterilization methods of reusable accessories, refer to the instructions for use that accompany the accessories. If the accessories have no user manual accompanied, refer to this chapter for instructions on cleaning, disinfection, and sterilization of the monitor.

Chapter 14 Care and Maintenance

To ensure the normal operation of the monitor and maintain its service life, please pay attention to the maintenance of the monitor.

14.1 Safety Information

Warning	No modification of this device is allowed.
Warning	This device contains no user serviceable parts.
Warning	The safety checks or maintenance involving any disassembly of the device should be performed by professional service personnel. Otherwise, undue device failure and possible health hazards could result.
Warning	A comprehensive inspection for the monitor (including functions and safety inspections) should be carried out by qualified personnel every year or after each maintenance.
Warning	Do not open the device housings. All servicing and future upgrades must be carried out by trained and authorized personnel.
Caution	If the user does not regularly check or maintain the monitor, it may affect its performance and safety.
Caution	If the user cannot implement a satisfactory maintenance plan, it may disable the monitor functions and endanger human health.
Caution	If you discover a problem with any of the device, contact your service personnel or our company.
Caution	Use and store the device within the specified temperature, humidity, and altitude ranges.
Caution	When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of the reach of children.
Caution	At the end of its service life, the device, as well as its accessories, must be disposed of in compliance with the local regulations regarding the disposal of such products. If you have any questions concerning disposal of the device, please contact our company.
Caution	The device and accessories shall not be serviced or maintained while in use on a patient.
Note	Upon request, the manufacturer may provide necessary circuit diagrams, component part lists, and other technical information to assist qualified service personnel in parts repair.

14.2 Routine Inspections

Before using the monitor, the checks below should be carried out:

- Check the monitor for any mechanical damages.
- Inspect the exposed parts and the inserted parts of all the cables and the accessories.
- Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition.
- Make sure that the monitor is grounded properly.

14.3 Regular Inspections

The monitor is designed with a service life of 10 years.

It is strongly recommended to use the product within its life cycle, or it may cause inaccurate measurement. During the long-term use, it is recommended that the user check and calibrate the monitor once a year to ensure the measurement accuracy. Due to the high risk of product aging in the last year of the service life, please pay close attention to the inspection results. Dispose of the monitor and its accessories when their service life is reached.

The inspection items mainly include:

- Check whether the safety signs are damaged.
- Check the main unit and accessories for mechanical and functional damages.
- Carry out the protective grounding impedance, leakage current and insulation resistance test according to the requirements of IEC 60601-1.
- Verify the functions of the device according to the operator's manual.

The test and results recording should be carried out by trained and qualified personnel with the safety test knowledge. Please maintain the monitor if any problem is detected in the above tests.

14.4 Battery Maintenance

The performance of the battery deteriorates over time. It is recommended to check and condition the battery every three months.

Caution Do not condition the monitor battery while a patient is under monitoring.

Caution If the battery conditioning has not been conducted for a long time, the battery capacity display may be inaccurate, causing the incorrect judgment of remaining battery runtime.

Caution The operating time of the battery reflects its performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may have reached its service life or be malfunctioning.

Perform battery conditioning as follows:

1 Disconnect the monitor from the patient and stop all monitoring and measurements.

2 Allow the battery to be charged uninterruptedly until it is fully charged.

3 Allow the monitor to run on the battery until the battery is completely depleted and the monitor automatically shuts down.

4 Fully recharge the battery for use or charge it to 40%-60% for storage.

14.5 Storage, Packaging and Transportation

If the monitor will not be used for a long time, wipe it clean and keep it in the packaging, which shall be kept in a dry and well-ventilated room free from dust and corrosive gases.

The monitor is packed in high-quality corrugated cartons with foam inside to protect the monitor against damage during transportation. The outer packaging box is marked with gross weight and dimension.

The monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do not hit or drop it with force during transportation.

14.6 Viewing System Version

To see the software version, select **[Menu] →[System] →[Device Info]**.

When performing maintenance for the monitor, you may need to check the system and module information.

Select **[Menu]** →**[System]**→enter the password→**[Maint.]**, and you can view the system software version, hardware version, module version, etc.

Chapter 15 Troubleshooting

Status	Possible Causes	Handling Measures
Battery cannot be recharged and/or fully charged	Battery is defective	Contact the service personnel and replace the battery.
	Main board is defective	Contact the service personnel and replace the main board.
Excessive ECG signal interferences, or thick baseline	Check that the electrodes are properly located	Adjust the electrode placement
	Check that valid electrodes are being used	Replace the electrode
	Check if lead wires are properly inserted	Properly connect the cable
	Check that the mains outlet has standard grounding wire.	Replace the outlet with protective grounding wire.
No SpO_2 readings	Check that the SpO_2 sensor is properly connected to the SpO_2 connector.	Properly connect the cable
	Check that the indicator of the pulse oxygen sensor flashes	The SpO_2 sensor is defective. Replace the sensor.
No NIBP readings	Check that the blood pressure cuff is properly wrapped around the arm according to the instructions.	Properly wrap the cuff.
	Check that cuff is leaking	If there is leakage, replace the cuff.
	Check that inlet is firmly connected to the NIBP jack.	Properly connect the cable
Recorder produces unusual sounds	Check for a paper jam	Take out the paper and tear off the draped part. Reload the paper.

Chapter 16 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the monitor. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. 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 patient monitor or not meet the claimed specifications in this manual.
Warning	Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.
Warning	Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
Warning	Reuse of disposable accessories may cause a risk of contamination and affect the measurement accuracy.
Warning	Although the accessory material that contacts patients has been evaluated biologically and the biological safety meets the requirements of ISO 10993-1, very few people may have allergic reaction, and those with allergic reaction should stop using it!
Caution	The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.
Caution	Use the accessories before the expiration date if an expiration date is indicated.
Caution	Do not use expired accessories.
Caution	Discard disposable accessories according to your local regulations or hospital regulations.
Caution	The accessories which can be used repeatedly should be cleaned thoroughly before use on another patient. Please refer to the related chapter for maintenance method.
Note	Part No. is subject to change without prior notice, please refer to the label of parts or the supplied package list.
Note	This manual describes all the accessories that are validated for use. Not all accessories are available in every market. Please check

availability with your local supplier.

Note

For the replacement cycle and replacement method of the accessories, refer to the instructions for use provided with the accessory.

16.1 ECG Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	ECG lead wire	KE-DGB041	4-electrode, defibrillation-proof, reusable	Adult/ Pediatric
2	ECG clamp	15000078	With snap	Adult/ Pediatric

16.2 SpO_2 Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	SpO_2 sensor	KS-AE01	Ear-clip, reusable	Adult
2	SpO_2 sensor	KS-AC01	Finger-clip, reusable	Adult
3	SpO_2 sensor	KS-AR01	Large finger-cot, reusable	Adult
4	SpO_2 sensor	KS-AR02	Small finger-cot, reusable	Adult/ Pediatric
5	SpO_2 sensor	KS-ALW02	L-type, with wraps, reusable	Neonate
7	SpO_2 sensor	L-type, with wraps, disposable, non-sterile	L-type, with wraps, disposable, non-sterile	Neonate

16.3 Temp Accessories

No.	Accessories	Model/Part No.	Applicable Patient
1	Temp probe	AOJ-20A	Adult/ Pediatric/Neonate
2	Temp probe	THP59JU	Adult/ Pediatric/Neonate

16.4 NIBP Accessories

No.	Accessories	Model/Part No.	Description	Applicable Patient
1	Cuff	KN-231	10 cm-19 cm, reusable	Adult/ Pediatric
2	Cuff	KN-233	18 cm-26 cm, reusable	
3	Cuff	KN-241	25 cm-35 cm, reusable	
4	Cuff	KN-243	33 cm-47 cm, reusable	
5	Cuff	KN-114	7.1 cm-13.1 cm, disposable	
6	Cuff	KN-115	8 cm-15 cm, disposable	

16.5 Other Accessories

No.	Accessories	Specification/Model
1	Multi-functional adapter (VX)	15010070
2	DC power adapter	LXCP40-01233
3	Monitor base	V-Base

Appendix A Technical Specifications

A.1 Overall Specifications

Classifications

Anti electric-shock type	Class I and internally powered device
Anti electric-shock degree	Type CF with defibrillation protection
Degree of protection against harmful ingress of water	Main unit: IPX2 Main unit + base: IPX1
Disinfection/sterilization method	Refer to *Chapter 13 Cleaning and Disinfection.*
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Operation mode	Continuous
Installation method	Non-permanent installation device
Electromagnetic compatibility	Group I, Class A

Environmental Specifications

Main unit

Environment	Temperature	Relative Humidity (Non-condensing)	Atmospheric pressure
Operating	0℃ - 40℃	15% - 95%	57.0 kPa -107.4 kPa
Transport & Storage	-20℃ - +60℃	10% - 95%	50.0 kPa-107.4 kPa

Power Supply Specifications

External power supply	
Input voltage	AC 100-240 V
Input power	0.6 A-0.2 A
Frequency	50/60 Hz
Battery	
Type	Built-in lithium-ion rechargeable battery
Rated voltage	DC 7.4 V
Battery capacity	5000 mAh
Run Time	≥ 360 min (standard operating mode) Standard operating mode: With a fully charged battery, NIBP measurement every 15 minutes, ECG, SpO_2, and temperature monitoring in continuous operation.
Charging Time	• When charged by the external power supply, after the device is turned off, the charging time is as follows: Time of charging to 90% is less than 4 hours. The time of charging to 100% is less than 5 hours. • When charged by the external power supply, after the device is turned on, the charging time is as follows: Time of charging to 90% is less than 10 hours. The time of charging to 100% is less than 13 hours.
Low-Battery prompt	With a new battery, NIBP measurement every 15 minutes, ECG, SpO_2, and temperature monitoring in continuous operation, the lowest screen brightness. At least 20 minutes since the first low battery prompt. At least 5 minutes since the battery depleted prompt.
Data	This monitor protects your data from shutdown due to battery

protection from power failure	depletion. The monitored information will be automatically saved. Upon recharging or reconnecting to external power, the monitor will return to its pre-shutdown state.

Physical Specifications

Main unit size	254 mm×185 mm×28 mm
Weight	Main unit: 1.4 kg Base: 1.2 kg
Display screen	10.1 inches, 1280×800, color LCD screen with multi-touch capacitive touch panel.
Main Unit Indicators	Power/switch indicator: 1 (green, yellow, and white)
Speaker	Support key tone, QRS tone. Support pitch tone and multi-level tone modulation.
Main unit connectors	Multi-functional adapter connector: 1 NIBP cuff connector: 1 Power adapter connector: 1 PogoPin connector: 1 USB connector: 1
Camera	Color CMOS camera, 8 M pixels, 3264×2448
Base connectors	USB connector: 3 PogoPin connector: 1 (for communication with the main unit) Temp probe connector: 1
Thermal recorder	Recorder Indicator: • 1 power indicator (Green) • 1 error indicator (Red) Horizontal resolution: 8 dots/mm Vertical resolution: 8 dots/mm Paper width: 50 mm±1 mm Paper speed: 25 mm/s, 50 mm/s

Data Storage

Records (with ECG)	70,000 sets
Records (without ECG)	550,000 sets

Wi-Fi Module

Frequency	2.4 G/5 G dual-band WLAN communication
Standard compliance	802.11 a/b/g/n and 802.11 ac
Transmission rate	≥2 MB/s

Bluetooth

Version	Support BT 5.0
Communication distance	10 m

Network Security

<table>
<tr><td>Network condition</td><td colspan="2">The monitor is connected to LAN through a wireless module and TCP/IP protocol.</td></tr>
<tr><td>Security software</td><td colspan="2">The monitor is of an independent embedded software with communication protocol and verification, and does not support the use of other security software.</td></tr>
<tr><td>Data and device interface</td><td colspan="2">• USB interface: With USB 2.0 protocol, it supports batch export of patient data through USB drive, including patient information, vital signs parameters and reports. The data storage format is dat and pdf. Support the use of USB drive for system upgrade and for connection of barcode scanner.
• Wireless network: The device uses Wi-Fi, and TCP/IP standard protocol for updating software and connecting to central monitoring system.</td></tr>
<tr><td rowspan="3">Network security measures</td><td>Functions provided by the monitor through the network</td><td>Security measures</td></tr>
<tr><td>The monitor sends patient information, measurement data through network.</td><td>Standard HL7 protocol (Version 2.7)</td></tr>
<tr><td colspan="2">The general network service function is not provided on the monitor, and the general network service port is closed.</td></tr>
<tr><td>User access control</td><td colspan="2">User types: medical staff, manufacturer maintenance personnel.
User permissions:</td></tr>
</table>

mechanism	• Permission of medical staff: No password. The monitor automatically enter the monitoring screen after starting up, and can be set according to requirements, for example, all the modules can be accessed and set except maintenance functions. • Permission of manufacturer's maintenance personnel: Enter the maintenance menu by inputting the manufacturer's maintenance password. In addition to the permissions of the hospital equipment maintenance personnel, you can also export the original data collection and upgrade the software and parameter board.

A.2 ECG Specifications

ECG	
Lead	• 4-electrode leads: I, II, III, aVR, aVL, aVF
Waveform sweeping speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error ≤±5%
Sampling rate	500 Hz
Display sensitivity	1.25 mm/mV(×0.125), 2.5 mm/mV(×0.25) 5 mm/mV(×0.5), 10 mm/mV(×1) 20 mm/mV(×2), 40 mm/mV(×4) Error <±5%
Common mode rejection ratio	≥90 dB
Differential input impedance	≥10 MΩ
Input signal range	-10.0 mV to +10.0 mV (peak-to-peak value)
Electrode polarization voltage range	±800 mV
Input offset current	≤0.1 μA
System noise	≤30 μVp-p
Time constant	≥3.2 s
Skew between channels	<2%
Frequency response	0.05 Hz-150 Hz
Filter	EMG filter 25 Hz, 35 Hz, 45 Hz

	Notch filter	50 Hz/60 Hz
	Filter	0.05 Hz-150 Hz, 0.67 Hz-150 Hz, Off
HR		
Measurement range and error	Adult: 15 bpm-300 bpm Pediatric: 15 bpm-350 bpm Error: ± 1% or ± 1 bpm, whichever is greater	

A.3 SpO_2 Specifications

Compliant standard	ISO 80601-2-61: 2017
SpO_2 measurement range	0%-100%
SpO_2 measurement accuracy	70%-100%: ±2% 50%-69%: ±3% 0%-49%: not defined
Sensor	Wavelength: Red light: 660 nm, Infrared light: 905 nm Maximum optical output power: ≤2 mW Note: The accuracy of the measurement may be affected when clinicians operate devices involving peak wavelengths (such as photodynamic therapy devices).
Data update cycle	SpO_2 < 30 s
SpO_2 accuracy test	The SpO_2 measurements are statistically distributed, only about 2/3 of SpO_2 measurements can be expected to fall within ±Arms of the value measured by a CO-Oximeter.
Perfusion index (PI) display range	0.1%- 20% Error: not defined

A.4 PR Specifications

Display range	30 bpm-250 bpm
PR from NIBP module	
Measurement range and accuracy	30 bpm-250 bpm, error ±3 bpm or ±3%, whichever is greater
PR from SpO_2 module	

Measurement range and accuracy	30 bpm-250 bpm, error ±2 bpm or ±2%, whichever is greater

A.5 Temp Specifications

Compliant standards	ISO 80601-2-56: 2017	
Measurement method	Infrared thermal temperature	
Measurement mode	Direct mode	
Measurement range	0.0℃ - 50.0℃	
Measurement accuracy	AOJ-20A	THP59JU
	0℃ - 42℃, error ±0.2℃	5.5℃ - 42.0℃(95.9°F-107.6°F), error ±0.2℃(0.4℉). Other Measurement range, error ±0.3℃(0.5℉).
Measurement time	1 s	

A.6 NIBP Specifications

Compliant standards	IEC 80601-2-30: 2018			
Maximum single measurement	Adult / Pediatric‹180 s			
Static measurement range and accuracy	0 mmHg-300 mmHg (0.0 kPa-40.0 kPa) Error: ±3 mmHg (±0.4 kPa)			
Initial inflating pressure	Adult: 80 mmHg-280 mmHg (10.6 kPa-37.2 kPa) Pediatric: 80 mmHg-210 mmHg (10.6 kPa-27.9 kPa)			
Overpressure protection	Adult: ≤297 mmHg (39.5 kPa) ±3 mmHg (±0.4 kPa) Pediatric: ≤247 mmHg (32.9 kPa) ±3 mmHg (±0.4 kPa)			
Measurement range	Blood Pressure		Adult	Pediatric
	SYS	mmHg	25-290	25-240
		kPa	3.3-38.6	3.3-31.9
	MAP	mmHg	15-260	15-215

		kPa	2.0-34.6	2.0-28.6
	DIA	mmHg	10-250	10-200
		kPa	1.3-33.3	1.3-26.6
Measurement accuracy	The measurement error of blood pressure simulator should be ≤ 8 mmHg (1.07 kPa)			

Appendix B Prompt Messages

Parameter-related prompts

Prompt Messages	Causes
ECG lead off	All ECG leads fall off or ECG cable is not connected.
ECG xx lead off	The electrode is not firmly connected with the patient or falls off, resulting in the corresponding ECG lead falling off.
SpO_2 sensor off	The SpO_2 sensor detaches from the patient.
SpO_2 sensor disconnected	The SpO_2 main cable is disconnected from the multifunctional adapter, or the SpO_2 sensor is disconnected from the main cable.
SpO_2 no pulse	The PR from SpO_2 module cannot be detected.
SpO_2 sensor error	The SpO_2 sensor is faulty.
SpO_2 search pulse	The monitor is searching for SpO_2 pulse.
SpO_2 low perfusion	The SpO_2 sensor is placed incorrectly or the patient's perfusion index is too low. Position SpO_2 sensor correctly or replace the measuring site.
Temp module error	Temperature module self-test fails.
Temp X probe off	Temperature probe detaches from the patient.
NIBP too loose or disconnected	Please check the cuff and air tubing for air leakage.
NIBP cuff or tubing leakage	Please check the cuff and air tubing for air leakage.
NIBP signal too weak	The patient's pulse is too weak or the cuff is too loose.
NIBP over range	The patient's blood pressure may exceed the measurement range.
NIBP excessive motion	The patient's arm is not still.
NIBP overpressure protection	The cuff may be squeezed or the module may be faulty.
NIBP measurement	If the measurement time is over 120 seconds in adult or

Prompt Messages	Causes
timeout	pediatric mode and over 90 seconds in neonatal mode. The blood pressure cannot be obtained.
Cuff and patient type mismatch	The cuff used does not match the preset patient type: use neonatal cuff in adult mode.
NIBP airway leak	Air moving part, tube, or cuff leak air.
NIBP airway occlusion	• Check whether the air tube is bent or squeezed • Check whether the patient is lying on the cuff • Check whether the cuff is wrapped in the correct position • Check whether the valve is open normally
NIBP measurement failed	• At the beginning of the measurement, the cuff pressure is greater than 15 mmHg and does not drop below 15 mmHg within 5 s • Failed or incomplete extraction of blood pressure parameters • Other
NIBP module error	• Sensor or A/D sampling error • EEPROM error • Not calibrated • Auto zeroing failed

System-related prompts

Prompt Messages	Causes
Low battery	Low battery (after the first alarm of low battery, it supports no less than 20 minutes of work)
Battery depleted	Too low battery (The battery power is seriously low, it supports no less than 5 minutes of monitoring)
Battery error	Battery temperature is too high or voltage is too high
Power supply error	The AC voltage is too high/low, the voltage of the system power is too high/low
XXX bluetooth disconnected	The Bluetooth device is bound to the monitor, but the connection between Bluetooth device and monitor is not set up or off.
XXX bluetooth poor signal	The Bluetooth signal of bluetooth device and monitor is low.
XXX low battery	Bluetooth device battery power <5%

Prompt Messages	Causes
Recorder error!	Recorder initialization error, communication error, or recorder unavailable
Recorder out of paper	Recorder runs out of paper, or recorder door not closed.
Recorder not exist	Recorder not connected
Parameter board communication error	Communication error with parameter board

Appendix C EMC Compliance

Table 1

Guidance and manufacturer's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group I	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	

Table 2

Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material,

			the relative humidity should be at least 30%.
Electrostatic transient / burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz-80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz-800 MHz $d=2.3\sqrt{P}$ 800 MHz-2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol. ((•))
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.5 GHz	3 V/m	

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

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

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

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter/m		
	150 kHz-80 MHz $d=1.2\sqrt{P}$	80 MHz-800 MHz $d=1.2\sqrt{P}$	800 MHz-2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Appendix D Abbreviations

AC	alternating current
A/D	analog to digital
AHA	American Heart Association
CART	Cardiac Arrest Risk Triage
CF	cardial floating
CMOS	complementary metal oxide semiconductor
DC	direct current
Demo	demonstration
ECG	electrocardiogram
EEPROM	electrically erasable programmable read-only memory
EMC	electromagnetic compatibility
EWS	early warning system
HIS	hospital information system
HL7	Health Level Seven
ID	identification
IEC	International Electrotechnical Commission
IP	internet protocol
IPXX	ingress protection rating
ISO	International Organization for Standardization
LAN	local area network
LCD	liquid crystal display
MEWS	Modified Early Warning Score
NEWS	National Early Warning Score
NIBP	non-invasive blood pressure
Pleth	plethysmogram
PR	pulse rate
SpO_2	arterial oxygen saturation from pulse oximetry
TCP/IP	Transmission Control Protocol / Internet Protocol

Temp	temperature
USB	universal serial bus
WLAN	wireless local area network
EMG	electromyogram

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