

BERRY®

User Manual

BERRY HSAT

PM50 series

Shanghai Berry Electronic Tech Co., Ltd.

Instructions

This user manual provides instructions for the use of the BERRY HSAT. Before use, please read and understand the contents of this manual carefully to ensure the correct usage of the product, maximize its performance, and ensure the safety of both patients and operators.

Please keep this manual near the device for easy and timely access when needed.

Any changes to the content of this manual will not be notified in advance, as long as they do not affect the normal use by users.

User Manual Release Date: 2026/XX/XX

Please refer to the label for the production date.

Statement

The manufacturer is only responsible for the safety, reliability, and performance of the product under the following conditions:

- Assembly, expansion, readjustment, improvement, and repair are carried out by personnel authorized by the manufacturer.
- Relevant electrical equipment complies with national standards.
- The product is used in accordance with the "User Manual".

The manufacturer may provide circuit diagrams, component lists, annotations, calibration guidelines, or other information that is useful for qualified technicians authorized by the manufacturer to repair the designated repairable components of the device.

Warranty

Free service coverage:

- Any product that meets the requirements specified in the manufacturer's warranty service regulations is eligible for free service.

Paid service coverage:

- Any product that exceeds the scope defined in the manufacturer's warranty service regulations will be subject to paid service.
- Even within the warranty period, the manufacturer will provide paid service in the following situations: intentional damage, improper use, unavoidable natural disasters, use of unauthorized accessories not approved by the manufacturer, or repairs performed by unauthorized personnel.

Returns

In the event that it becomes necessary to return a unit to the manufacturer, please obtain a return authorization first. Please contact the manufacturer and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible. The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

Transportation

After the product is properly packaged, it can be transported using common means of transportation. However, it is important to avoid exposure to rain, snow, and mechanical collisions during transportation.

Safety Information

This chapter outlines the basic safety Attention information that users should be aware of and follow when operating the BERRY HSAT. Additional Attention information related to specific operation and use of the BERRY HSAT will appear in various sections of this user manual. Users must strictly adhere to these safety Attention instructions.

The following safety symbols, Attentions, and cautions are used in conjunction with text to alert users to potential hazards during use.

 Caution	This message contains information that may cause minor harm to the human body or damage to the product.
 Attention	This is to emphasize important precautions, provide instructions, or provide explanations.

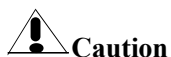
Attention



- Personnel using this device must receive sufficient training before use.
- This device is a monitoring device, not a therapeutic device. It should be used in conjunction with specific clinical symptoms.
- Before using this device, users should check and ensure that the device and accessories are functioning properly and safely. If you cannot access the measurement interface properly, please do not use this device.
- When using this device in conjunction with electro-surgical equipment, users should pay attention to and ensure the safety of the monitored patients.
- Do not use this device in places where flammable substances such as anesthetics are present to prevent fires or explosions.
- This device should not be used in Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) systems.
- This device is calibrated to display functional oxygen saturation.
- This device does not have an alarm function.
- The measured area should be free from dirt or wounds.
- Please use the accessories, sensors, and cables provided by the manufacturer or those authorized by the manufacturer. Before use, please check the compatibility between the sensor and this device. Using unspecified accessories, sensors, and cables may enhance electromagnetic radiation or reduce anti-electromagnetic interference performance.
- Before cleaning this device and its accessories, please ensure that the power is turned off.
- This device is a typical sealed device. Users should ensure that its surface is dry and clean, and prevent any liquids from entering the interior.
- Users should place this device properly to prevent it from falling from high places, being subjected to strong vibrations, or other mechanical forces that may cause damage. Care must be taken to prevent harm to the product and the patient from external forces during use.
- Do not modify this device or its accessories without authorization. Repairs should be carried out by professional repair personnel recognized by the manufacturer. Do not modify this device without manufacturer authorization.
- If modifications are made to this device, appropriate inspections and tests must be conducted to ensure its

continued safe use.

- Unauthorized disassembly and replacement of the internal lithium battery are strictly prohibited. When the battery is low, please recharge it in a timely manner. If the device has not been used for 6 months or longer, the user should charge the battery.
- To avoid contamination or infection of others, the environment, or other equipment, please dispose of this device and its accessories according to the relevant national regulations or the hospital's disposal regulations.
- If the accessories used with this device are disposable, please dispose of them promptly according to the relevant regulations. They should only be used for a single patient and must not be reused.
- Static electricity should be avoided. Before using this device, ensure that direct or indirect electrostatic charges on the operators and patients who come into contact with the device are minimized.
- During use, try to keep this device away from radio receivers.
- If this device is not used with the specified and EMC-tested system configuration, it may enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration only.
- Portable and mobile RF communication devices may affect the normal use of this device.
- This device should not be placed near or stacked with other devices. If it must be placed near or stacked with other devices, observe and verify that it can operate properly in the configuration being used.
- Except for the accessories and cables sold by the manufacturer as spare parts for the internal components of this device, the use of non-prescribed accessories and cables may increase the emissions of the device or reduce its immunity to interference.
- The highest temperature for the contact between the blood oxygen saturation sensor and the human skin should not exceed 41°C.
- This device is not edible. Do not inhale or swallow any part of this device. If such a situation occurs, seek medical attention immediately.
- Contact with the human body may cause sensitization. The biological safety meets the standard requirements, but individual users may have allergic reactions. Use should be discontinued for patients with allergic reactions!
- The optimal measurement site for blood oxygen saturation is the index finger. This is not a continuous monitoring product, and the measurement at the same location should not exceed 10 hours. If long-term monitoring is required, please change the measurement site in a timely manner.
- This device should be placed out of reach of children, pets, and insects.
- The performance degradation of this device may be caused by the aging of accessories such as the blood oxygen saturation sensor, ECG lead cable, and electrode pads. In such cases, the accessories can be replaced before use.
- When the ambient temperature is 20°C, the time required for this device to reach the expected state of readiness from the lowest storage temperature or the highest temperature after use does not exceed 3 minutes.



Caution

Before using this product, please read this user manual, all safety information, and technical specifications carefully.

Patients may also be expected operators, and both the functionality and maintenance of this product can be safely performed.

A functional tester can't be used to assess accuracy. The accuracy of this device's SpO₂ measurements has been verified through human oxygen saturation clinical studies.

Product Features

1. The product is easy to use, with one-key operation.
2. It has a small size and light weight, making it easy to carry.
3. The product has low power consumption and can sustain 10 hours of continuous use with the included 3.7V lithium-ion battery.
4. When the battery voltage is too low to affect normal operation, the display screen will show a low voltage reminder indicator  and blink.
5. No daily maintenance or calibration is required.
6. Real-time clock.
7. Continuous data storage for over 10 hours.
8. Data can be synchronized with the application.
9. It is rechargeable.

Device Identification

Models:	PM50, PM50-B
Trade/Common name:	BERRY HSAT
Device Classification Name	Ventilatory Effort Recorder

Intend use

The BERRY HSAT device aid in the diagnosis of sleep disordered breathing for adult patients. The BERRY HSAT records the following data: patient respiratory nasal airflow, snoring, SpO₂, PR, HR, respiratory effort and body position during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.

Applicable People

The target audience includes individuals who need preliminary screening for sleep apnea and respiratory-related disorders.

Intended operating environment

The device is intended for home and hospital use under the direction of a HCP.

Components

The BERRY HSAT consists of the main unit, Multi-Functional Sensor, ECG lead cable, ECG electrode patches, SpO₂sensor, nasal cannula, thoracic-abdominal belt and multi-functional sensor fixing shell, and charging cable.

Contraindications

The measurement site in contact with the blood oxygen saturation sensor should not have any skin tissue damage. The skin where the electrocardiogram (ECG) electrodes are applied should be free from damage or scars.

Measurement Principle

This product records and analyzes the changes in respiration, Pulse oxygen saturation, pulse rate, heart rate, snoring, and body position during a single sleep session.

Reprocessing

1. Scope and classification

This section applies to the cleaning and disinfection processing of this product. This product is a non-critical medical device (contact with intact skin only). Processing is performed by manual cleaning and intermediate-level disinfection.

2. Processing location and personnel requirements

- ◆ Applicable environment: Medical institution consultation room, ward or home environment.
- ◆ Personnel requirements: The operator shall be trained in basic device cleaning and disinfection.
- ◆ Personal protective equipment (PPE): Disposable medical gloves shall be worn during processing; eye protection is recommended if there is a risk of splashing of body fluids.

3. Initial treatment at the point of use

After each use, if visible contamination is present on the surfaces, perform immediate local wiping to remove it and prevent the soil from drying.

4. Cleaning Procedure

4.1 Preparation before cleaning

- ◆ Disconnect the patient connection, switch off the device.
- ◆ Prepare cleaning tools and consumables (see table below).

Tool / Consumable	Specification Requirements
Lint-free cloth	Lint-free and chemical-resistant
Soft-bristle brush	Soft bristles that will not scratch device surfaces

4.2 Cleaning Agent

Parameter	Requirement
Type	Neutral or weakly alkaline medical detergent (pH 6.5-8.5), or enzyme-containing detergent

Parameter	Requirement
Recommended Product	[Brand / Model, if applicable]
Concentration	Follow the detergent manufacturer's instructions (typically 0.5%-2%)
Water Temperature	30 °C-35 °C (shall not exceed 40 °C)
Water Quality	Potable water

4.3 Cleaning Steps

- 1) Moisten a soft cloth with detergent solution and wipe all external surfaces of the main unit housing from top to bottom.
- 2) For the display screen area, gently wipe with dedicated screen-cleaning cloth; avoid applying excessive pressure.
- 3) Use a soft-bristle brush to assist cleaning of crevices around buttons, knobs and ports.
- 4) For accessories:
 - ❖ Wipe length-wise from one end to the other; avoid knotting.
 - ❖ Focus cleaning on patient-contact surfaces.
 - ❖ Cleaning duration: No less than 5 minutes (from start of wiping to completion).
 - ❖ Wipe the device with a clean lint-free cloth dampened with purified water to remove detergent residues.
 - ❖ Rinse step: Perform a secondary wipe using purified water wipes to eliminate residual detergent.

4.4 Prohibited Actions

- ◆ Do not immerse any part of the device in liquid.
- ◆ Do not use chlorine-containing disinfectants, toluene or abrasive materials (steel wool, sandpaper).
- ◆ Prevent liquid ingress into electrical ports, vents or internal components.
- ◆ Do not use high-pressure water jets or ultrasonic cleaning.
- ◆ Do not use ammonia- or acetone-containing cleaners to avoid probe damage.

5. Disinfection Procedure (Intermediate-Level Disinfection)

5.1 Recommended Disinfectants

Disinfectant	Effective Concentration	Contact Time	Remarks
Ethanol	75% (v/v)	≥ 1 minute	Preferred for routine disinfection
Isopropyl Alcohol (IPA)	70% (v/v)	≥ 1 minute	For routine disinfection

5.2 Disinfection Steps

- ◆ Confirm that cleaning has been completed and no visible soil remains on device surfaces.
- ◆ Take a new lint-free cloth and saturate thoroughly with disinfectant (moist but not dripping).
- ◆ Systematically wipe all external surfaces from clean areas to contaminated areas in a top-down sequence:
Main unit: Display screen → front panel → sides → rear → bottom Base: All surfaces Accessories:
Inner and outer cuff surfaces → full length of lead cables → patient-contact surfaces of each probe.
- ◆ Ensure all surfaces are fully wetted by disinfectant.
- ◆ Maintain required wet contact time on surfaces (see table above; minimum 1-3 minutes).
- ◆ If required by the disinfectant manufacturer's instructions, wipe with purified-water dampened cloth after contact time to remove residues.
- ◆ Use a new lint-free cloth for each device to prevent cross-contamination.

6. Drying Procedure

- ◆ Air-dry naturally: Place the device in a clean, well-ventilated area for natural air-drying.
- ◆ Assisted drying: Gently wipe surfaces dry with clean, dry lint-free cloth.
- ◆ Ensure complete drying of the following locations before power-on use: All electrical ports and connectors
Crevices surrounding buttons / touchscreen Vents
- ◆ Drying time: Typically no less than 15 minutes (adjust according to ambient temperature and humidity);
no visible residue shall remain after drying.
- ◆ Compressed-air blowing-dry is prohibited (may force contaminants into device interior).

7. Inspection and Maintenance

7.1 Visual Inspection

Perform the following inspections after each reprocessing cycle:

Inspection Item	Acceptance Criteria	Action for Non-conformance
Main host	No cracks, damage or deformation	Discontinue use and contact service
Display screen	No reading-impairing scratches; no liquid ingress traces	Evaluate before continued use
Buttons / knobs	Proper function, no looseness	Contact service

Inspection Item	Acceptance Criteria	Action for Non-conformance
accessories	No damage, fracture or exposed conductors	Replace immediately
	Intact contact surfaces; no cracks	
Labels / markings	Clearly legible	Contact manufacturer for replacement

7.2 Functional Check

- ◆ Apply power and confirm normal device startup.
- ◆ Run built-in self-test routines (if available).
- ◆ Verify normal display of all monitoring parameters.

7.3 Periodic Maintenance

- ◆ Perform routine maintenance per the manufacturer's recommended maintenance schedule.
- ◆ Professional electrical safety inspection is recommended every 6 months.

8. Packaging Requirements

- ◆ Non-critical devices do not require sterile packaging after cleaning and disinfection.
- ◆ Cleaned and disinfected devices may be stored in a clean and dry environment.
- ◆ For transport to other clinical departments, cover with a clean dust cover or transport bag.

9. Storage and Shelf-Life

9.1 Storage Conditions

Parameter	Requirement
Temperature	-10 °C ~ +50 °C
Relative Humidity	10%-90% (non-condensing)
Atmospheric Pressure	700 hPa ~ 1060 hPa
Environment	Clean, dry, well-ventilated; protect from direct sunlight

9.2 Shelf-Life after Cleaning and Disinfection

- ◆ The storage duration between completion of cleaning-disinfection and subsequent reuse shall be established by the healthcare facility via its own risk-assessment-based policy.
- ◆ Reference recommendation: When stored in a clean and dry environment, the shelf-life shall not exceed 7 days. If covered with a protective cover, the shelf-life may be extended to 30 days.
- ◆ If the post-reprocessing shelf-life is exceeded, the device shall be re-cleaned and re-disinfected prior to use.

10. Maximum Reprocessing Cycles

Component	Maximum Reprocessing Cycles
Main Unit	Unlimited reprocessing cycles within the device's design service life
accessories	500 cycles

Basic Specifications

Display: OLED screen

Product Dimensions: 46mm (L) × 34mm (W) × 13mm (H) (Main Unit)

Product Weight: Approximately 77g (Excluding accessories)

Electrical Specifications

Battery Type: 3.7V 250mAh lithium-ion battery.

Operating Voltage: DC 3.4V to DC 4.3V.

Operating Current: Less than 50mA.

Charging Time: 3 hours.

Charging Method: When the low voltage reminder indicator appears on the display screen  , it indicates that the battery level is low. Connect one end of the charging cable to the device and the other end to the power adapter. When the charging indicator on the display screen shows continuous increase in battery level  , it indicates that the battery is charging. When the full charge indicator appears on the display screen  , it indicates that the battery is fully charged.

Parameter Specifications

SpO2

Measurement Range: 0%~100%

Measurement Accuracy: ±2% (80%~100%), ±3% (70%~79%), Not defined (<70%)

Measurement Resolution: 1%



Note

- The accuracy of the pulse rate has been validated and compared with a blood oxygen saturation simulator.
- The BERRY HSAT accuracy was tested in 24 healthy subjects, aged 22~47 with skin tones varying from MONK 1-10. The following tables show the bias and accuracy by skin pigmentation.

Pigmentation Group	MST Range
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Light	1–4
Medium	5–7
Dark	8–10
Overall	1–10

Table 1:Pigmentation Group_light

Sao2 range (%)	70-100 (Overall)	70-80	80-90	90-100
# of data pairs	302	96	100	106
Bias	-0.4371	-1.9917	0.373	0.2066
Arms	2.366	3.5496	1.8382	1.1619

Table 2:Pigmentation Group_Medium

Sao2 range (%)	70-100 (Overall)	70-80	80-90	90-100
# of data pairs	116	41	36	39
Bias	0.3534	-0.341	1.0868	0.3333
Arms	1.6454	1.977	1.6974	1.156

Table 3:Pigmentation Group_Dark

Sao2 range (%)	70-100 (Overall)	70-80	80-90	90-100
# of data pairs	120	37	41	42
Bias	0.49	0.2946	0.7293	0.4286
Arms	2.4347	1.9161	3.4934	1.3372

Table 4:Pigmentation Group_Overall

Sao2 range (%)	70-100 (Overall)	70-80	80-90	90-100
# of data pairs	538	174	177	187
Bias	-0.0533	-1.05	0.6	0.2556
Arms	2.2276	2.9167	2.2913	1.1795

Pulse Rate

Measurement Range: 25bpm~250bpm

Measurement Accuracy: ± 2 bpm (25 bpm to 150bpm); ± 3 bpm (151bpm to 250bpm)

Measurement Resolution: 1bpm

Nasal Airflow

Measurement Range: 10rpm to 40 rpm

Measurement Resolution: 1rpm

Measurement Accuracy: ± 2 rpm

Respiratory Effort

Measurement Range: 0 rpm~60rpm

Measurement Resolution: 1rpm

Measurement Accuracy: ± 2 rpm (10rpm to 60rpm,)

Heart Rate

Measurement Range: 25bpm to 250bpm

Measurement Resolution: 1bpm

Measurement Accuracy: ± 3 bpm

Body Position

The application can detect five sleep positions: supine (lying on the back), standing/sitting, left lateral (lying on the left side), right lateral (lying on the right side), and prone (lying face down).

Snoring

Recording snoring signals and extracting snore characteristics.

Sensor Disconnection

The application can display the status of finger/probe detachment.

Configuration Table for Various Models

Feature Models	SpO ₂	Pulse Rate	SpO ₂ Waveform	Bluetooth	Respiratory Effort	Heart Rate	Body Position	Nasal Airflow	Snoring
PM50	●	●	●	●	●	●	●	●	●
PM50-B	●	●	●	●	—	—	—	—	—
Note: In the table, "●" indicates the presence of a particular feature, while "—" indicates the absence of that feature.									

All patients can safely use the BERRY HSAT with the above-mentioned features.

The peak wavelengths of the emitted light from the blood oxygen saturation sensor are 660nm/905nm, with a maximum optical output power of ≤ 10 mW.



Note

- Clinical operations involving devices with peak wavelengths (e.g., photodynamic therapy devices) may affect the accuracy of the measurements taken by the BERRY HSAT.

Wireless Bluetooth Parameters

Bluetooth Protocol Version: 5.0 and above

Wireless Frequency: 2400-2483.5MHz

Transmit Power: ≤ 20 dBm

Frequency Range: 2400-2480MHz

Channel Spacing: ≤ 3 MHz

Modulation Type: GFSK

Maximum Output Power: <100 mW

Note:

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

- Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Environmental Requirement

Temperature Range

Operation: +5°C~+40°C

Transportation and Storage: -20°C~+55°C

Relative Humidity Range

Operation: ≤80% (non-condensing)

Transportation and Storage: ≤95% (non-condensing)

Atmospheric Pressure Range

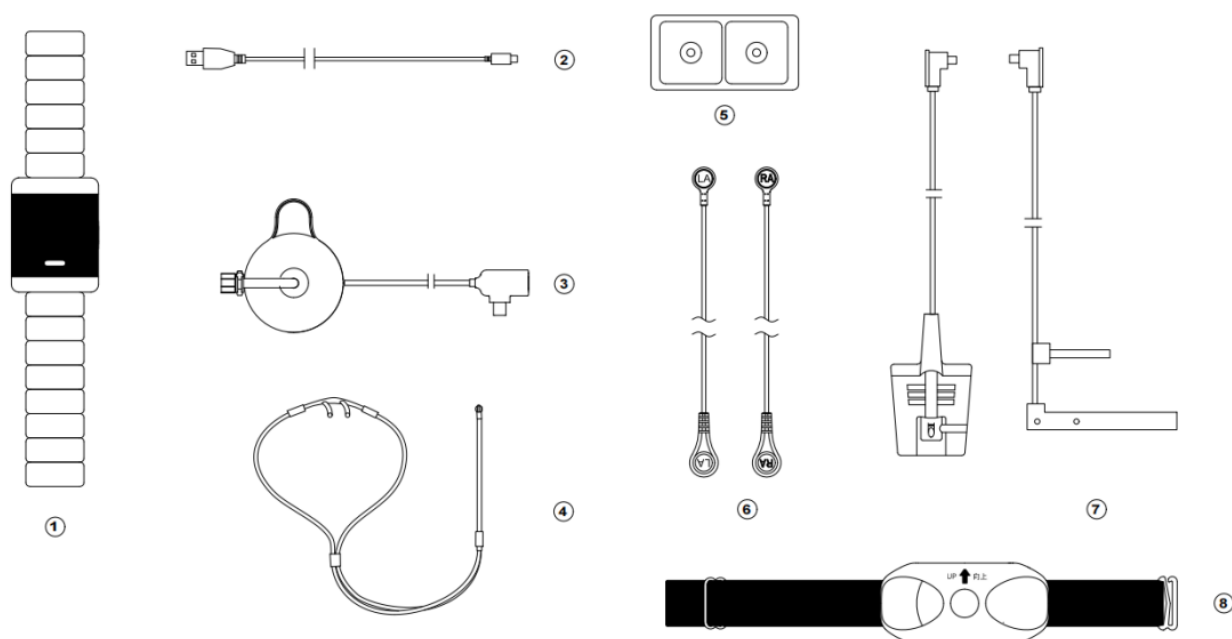
Operation: 70kPa to 106kPa

Transportation and Storage: 70kPa to 106kPa

The environmental conditions for transportation and storage between two uses after removing the protective packaging should be within the aforementioned ranges.

Product and Accessories List

1. Product Component Diagram



Number	Component Name
①	the main unit
②	Charging cable
③	Multi-functional Sensor
④	Nasal cannula
⑤	ECG electrode patches
⑥	ECG Lead Cable
⑦	SpO ₂ Sensor
⑧	Thoracic-abdominal belt and multi-functional sensor fixing shell

2. Composition of Various Models

Accessories	①	②	③	④	⑤	⑥	⑦	⑧
Model	①	②	③	④	⑤	⑥	⑦	⑧
PM50	√	√	√	√	√	√	√	√
PM50-B	√	√	-	-	-	-	√	-

Among them, the SpO₂ sensor is available in various models and specifications, and users can select and configure it according to their needs. The optional SpO₂ sensor provided by this product are shown in Table 2.

Table 2 Specifications of SpO₂ sensor Models

Model	Usage Times
BST-50-1	Reusable
BSA-50-1	Disposable

3. Accessories List

	Name	Quantity
	BERRY HSAT(the main unit)	1

Main Unit and Accessories	SpO ₂ Sensor	1
	ECG Lead Cable	1
	ECG electrode patches	2
	Multi-functional Sensor	1
	Thoracic-abdominal belt and multi-functional sensor fixing shell	1
	Charging Cable	1
Others	User Manual	1

Expected service life of the device is 5 years.

Operating Instructions



Attention

- Before measurement, check if the multi-lead respiratory monitor is functioning properly. Do not use if it is damaged.
- Handle the cables with care, similar to other medical devices, to avoid possible entanglement or strangulation of the patient. The cables of the electro-surgical equipment should not be tangled with the cables of the multi-lead respiratory monitor.
- Do not place the multi-lead respiratory monitor on limbs with arterial catheters or venous injection tubes.
- Do not place the pulse oximetry sensor and blood pressure measurement on the same limb, as occlusion during blood pressure measurement can affect the accuracy of the oxygen saturation readings.
- This multi-lead respiratory monitor cannot monitor patients with a pulse rate below 25bpm, as it may result in inaccurate PR (pulse rate) readings.
- Strong light can cause inaccurate measurements. If the lighting is too intense, use non-transparent material to cover the sensor.
- Ensure that the measurement site is free from dirt or scars, as they may result in weak signals and inaccurate measurements.
- When using the multi-lead respiratory monitor on different patients, there is a risk of cross-infection. Users should take precautions and control measures. It is recommended to clean or disinfect the multi-lead respiratory monitor before use on different patients.
- The site for measuring oxygen saturation should be well-perfused and fully covered by the sensor's detection window. Clean the measurement site before placing the oxygen saturation sensor and ensure it is dry.
- Minimize movement of the oxygen saturation sensor's measurement site. Keep the patient as still as possible, particularly at the measurement site.
- Improper placement of the oxygen saturation sensor can affect measurement accuracy. The best measurement results are obtained when the sensor is at the same level as the heart.
- Select the appropriate oxygen saturation sensor based on the patient and measurement site. If the sensor is too tight, it may cause venous pulsation, obstruct blood circulation, leave pressure marks, result in pressure necrosis, introduce artifacts, and cause inaccurate measurements. If the sensor is too loose, it may compromise optical alignment or even detach. If the sensor is oversized due to improper placement or swelling at the placement site, excessive pressure can cause venous congestion at the distal end, leading to interstitial edema and tissue ischemia.
- The thoracic and abdominal belt and multi-functional sensor fixing shell must not be worn directly on the skin.

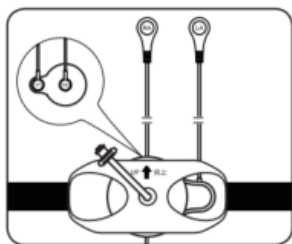
Factors Affecting Measurement Accuracy

- The measurement values depend on the absorption of oxyhemoglobin and deoxyhemoglobin at specific wavelengths of light. The presence of non-functional hemoglobin species such as carboxyhemoglobin (COHb) and methemoglobin (MetHB) can affect the accuracy of the measurements.
- Conditions such as shock, anemia, hypothermia, and the use of vasoconstrictor drugs can reduce arterial blood flow to a level that cannot be measured.
- Dyes within blood vessels or external use of colored substances (such as nail polish, fuels, or colored

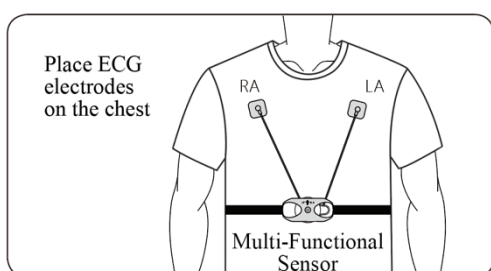
skincare products) can lead to unreliable measurement values.

Measurement Steps and Wear Instructions

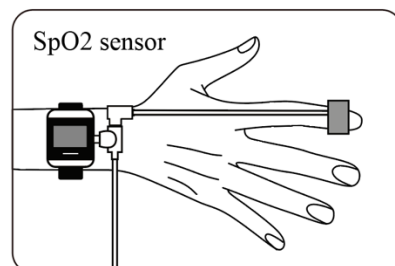
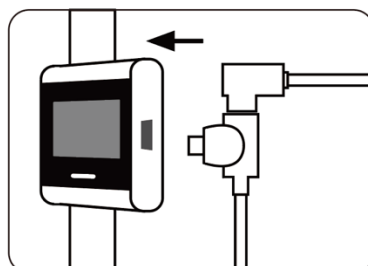
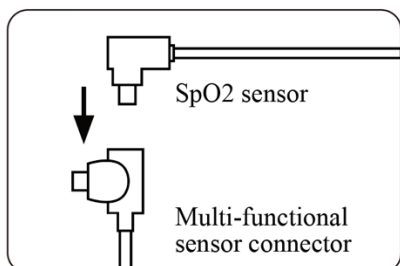
1. Connect the ECG lead cable and Ruhr connector to the multi-functional sensor.



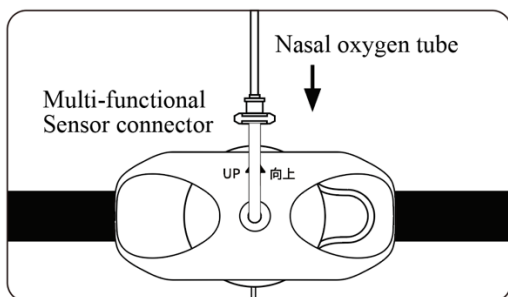
2. Tear off the protective film of the electrode pads and wear the thoracic and abdominal belt as shown in the diagram.



3. First, connect the oxygen saturation sensor to the multi-function sensor, then connect it to the main unit. Then, wear the SpO2 sensor to your finger.



4. Connect the nasal oxygen tube to the multi-functional sensor.



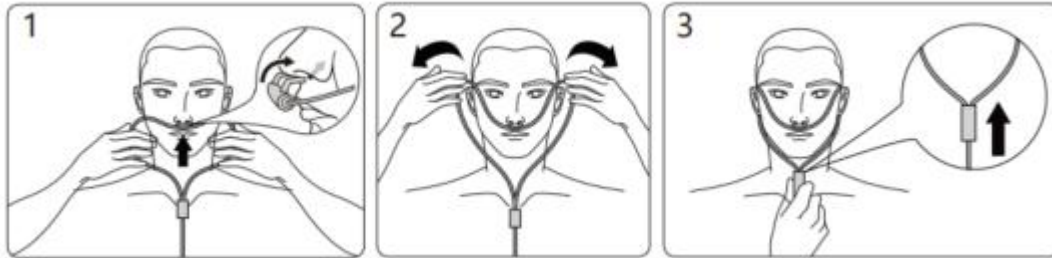
5. Wear the nasal oxygen tube:

- a. Insert the nasal oxygen tube's vent into the nostril.
- b. Route the tubing around and hang it over the ear.
- c. Secure the slider to the chin, adjusting it to a comfortable and secure position.

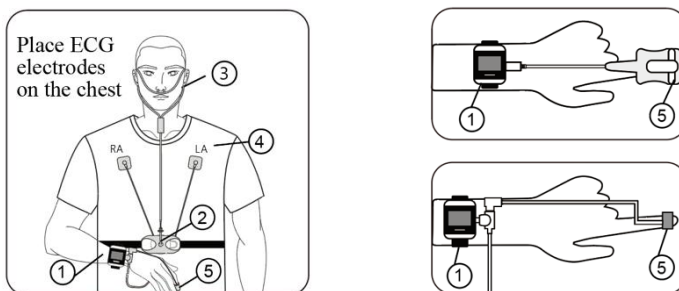
6. The Berry Smart Health Application is a proprietary mobile-application. It may be downloaded from the web page: <https://web.berry-med.com/#/app>. For details regarding the use of this Application, please see the *Berry*

Note

Do not bend the nasal oxygen tube to avoid obstructing airflow.



6. Wearing the BERRY HSAT



PM50

PM50-B

Number	Component Name
①	Main Unit
②	Multi-Functional Sensor
③	Nasal cannula
④	ECG electrode patches
⑤	SpO ₂ Sensor

7. Automatic Recording of Measurement Data

- Wear the BERRY HSAT before going to bed and start the measurement.
- When the SpO₂ and PR icons change to timestamps, automatic recording begins.
- If the measurement time exceeds fifteen minutes, the recorded data for this session is considered valid.

8. Uploading Records

- After completing the measurement, restart the device and enter the upload interface.
- The device establishes a Bluetooth connection with the phone and begins transferring data.
- Once the transfer is complete, the device automatically shuts down.

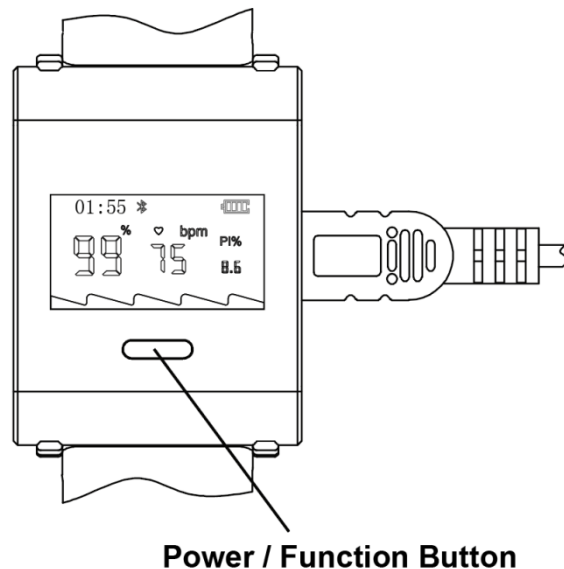
Caution

- The placement of the blood oxygen saturation sensor on the finger has a specific orientation. The light emitter of the sensor should be on the side of the back of the hand, and the light receiver should be on the side of the palm. The depth of inserting the finger should ensure that the nail completely covers the light from the blood oxygen saturation sensor.
- To obtain accurate readings, please wait until the monitor is properly stabilized before recording the data.

- The accuracy of the readings may be affected when using the monitor or when the patient is in a state of motion.
- Applying nail polish, wearing artificial nails, or having excessively long nails can lead to incorrect readings.
- Failure to use the control or adjustment devices as specified, or to perform each step of the operation, may result in harmful radiation exposure.

Operation Button Instructions

1. Power On: Press the power/function button briefly. The screen will light up, and you will enter the measurement interface.
2. Power Off: If there is no button operation for 10 minutes during the measurement, or if you long-press the power/function button, the screen will display "Shutting Down."
3. Screen Wake-up: In the powered-on state, if there is no button operation for 30 seconds, the screen will automatically turn off to save power. Press the power/function button briefly to activate the display.
4. Interface Switching: When the sensor is connected, press the power/function button briefly to switch between parameter display interfaces.



Application Program Data Upload

Step 1: Application Installation

1. Search for and download the “Berry Smart Health” application from your mobile device’s app store.
2. Complete application installation and initial permission configuration (Bluetooth, storage, etc.).

Step 2: User Registration and Log-in

1. Launch the “Berry Smart Health” APP.
2. Enter your account (email or phone number) and password, then tap the Log In button.
3. If you do not have an account, tap Sign Up. Enter required information following on-screen prompts. You will be automatically redirected to the login page upon successful registration.
4. If you forget your password, tap Forgot Password? on the login page. Enter your email address and tap send. Access your email inbox and click the link to reset your password.

Step 3: Data Upload

1. Perform overnight sleep monitoring with the Berry sleep device.
2. Ensure normal Bluetooth connection before upload.
3. Select Sleep Monitor inside the APP to enter the data-upload page.
4. Tap the device-search button and wait patiently for data upload to the server.
5. A prompt will indicate successful upload once completed.

Note: Data shall be uploaded upon completion of each recording. The next measurement can only be performed after upload finishes. Uploading data during measurement will terminate the ongoing recording.

Step 4: Data Review and Report Generation

1. Tap the username to view and edit user profile information.
2. View uploaded monitoring records on the APP Historical Data page.
3. Select monitoring records for a specific date to inspect detailed numerical statistics.
4. Share reports as needed.

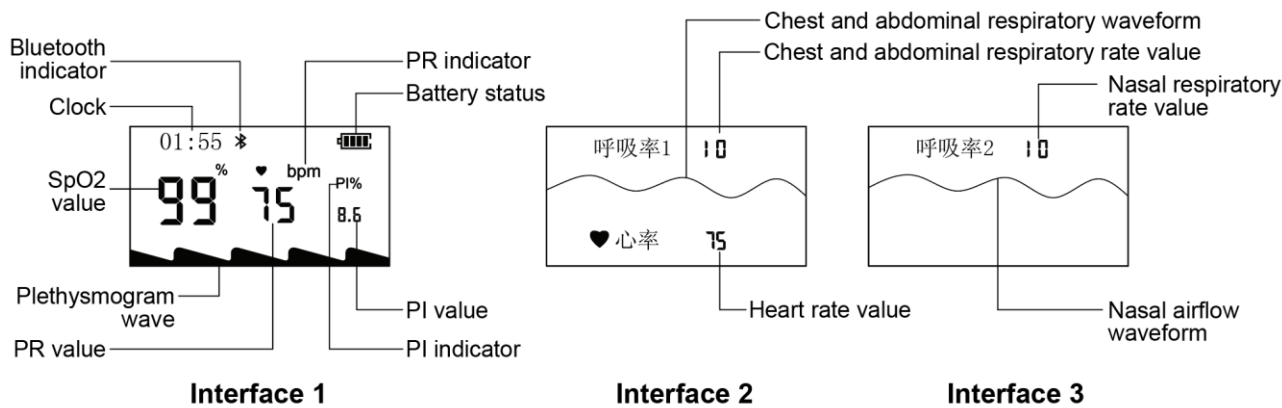
Interface Display Information Explanation

Note: Under various physiological and environmental conditions, the accuracy of SpO₂ measurement may decrease due to reduced signal integrity. This product indicates signal integrity through the following methods:

1. Pulse Volume Graph (Non-normalized): The pulse volume graph is displayed with scaling, where waveform amplitude reflects the strength of the patient's pulse signal;
2. Perfusion Index (PI): This index reflects the strength of the blood oxygen signal.
3. Symbol “-----”: When signal noise is excessive, the signal quality deteriorates, or the signal disappears, numerical values are not displayed, and “-----” is shown.

In practice, numerous factors can compromise signal integrity and reduce measurement accuracy. These factors may include, but are not limited to: ambient light (including photodynamic therapy), body movement (patient and externally imposed), diagnostic procedures, poor perfusion, electromagnetic interference, high-frequency surgical equipment, abnormal hemoglobin, certain dyes, improper placement of pulse oximetry probes, signal strength, noise frequency and amplitude, and noise sources.

Record Interface



Upload Interface



Troubleshooting

Malfunction	Causes of Malfunction	Solution
Abnormal display or disappearance of blood oxygen saturation or pulse readings	1. The finger is not properly placed in the appropriate position of the blood oxygen saturation sensor. 2. The patient's blood oxygen saturation level is extremely low and cannot be measured. 3. The plug of the blood oxygen saturation sensor is loose or detached. 4. The Bluetooth signal is interrupted.	1. Please correctly place your finger in the appropriate position of the blood oxygen saturation sensor and try again. 2. Try a few more times. If you confirm that the product has no quality issues, please seek medical attention promptly. 3. Please tighten the connection of the blood oxygen saturation sensor. 4. Check the Bluetooth connection and reconnect if necessary.
Unstable display of blood oxygen saturation or pulse readings.	1. The finger may not be inserted deeply enough. 2. The finger is trembling or the patient is in a state of motion.	1. Please correctly place your finger in the appropriate position of the blood oxygen saturation sensor and try again. 2. Avoid moving during use and maintain a quiet state.
Unstable display of nasal airflow or respiratory rate.	1, Connection issue. 2, Issue with the way it is being worn. 3, The patient is in a state of motion.	1, Ensure proper connection. 2, Use the correct wearing method. 3, Try to maintain a stable state.
Unable to power on	1. The battery may be low or completely drained. 2. The product may be damaged.	1. Please charge the device. 2. Please contact your local customer service center.
The display screen suddenly went blank.	1. The device is set to automatically shut down after 10 minutes of no signal detection. 2. If there is no operation for more than 30 seconds during operation, the screen will enter the sleep mode. 3. Battery power may be low.	1. This is a normal function. 2. Press the "Power/Function" button briefly. 3. Charge the device.

Symbolic significance

Symbol	Significance
	According to the user manual (Background: Blue; Symbol: White)
	BF type device
Rx Only	Federal law restricts this device be sold by the order of a licensed healthcare practitioner only.
FCC ID	Federal Communications Commission-ID
	Medical device
	Non-ionizing electromagnetic radiation
	This device does not have an alarm function
	The waste generated from the use of the device, accessories, and packaging materials should be properly handled according to local disposal regulations or rules
	Manufacturing date
	Made in china
	Serial number
	Product model
IP22	Protection level of the casing
 小心轻放	Handle with care
 向上	Keep upright
 防晒	Avoid direct sunlight
 防潮	Avoid rain



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If you need additional information, please contact with the manufacturer.