

FORA[®] VSM100 Pro

Vital Signs Monitor

(Blood Glucose, Blood Pressure, Temperature, SpO₂ and ECG Measurement)



Operator's Manual

FORA Vital Signs Monitor VSM100 Pro

About the Manual

The precautions, warnings and notes throughout this manual are very important. Please read this manual carefully before using **VSM100 Pro** Vital Signs Monitor.

SAFETY INFORMATION



WARNING!

- A warning statement in this manual identifies hazards that could lead to patient injury, illness or death. These warnings pertain to the entire **VSM100 Pro** Vital Signs Monitor.



CAUTION!

- A caution statement in this manual identifies hazards that could lead to minor personal injury, product damage or property damage.

General Warnings and Cautions

The information in this manual is a comprehensive guide to the operation of the monitor. For the best results, read this manual thoroughly before using the monitor.



WARNING!

- Use this monitor only for the intended use described in this manual.
- The monitor is not intended for use without healthcare practitioner's supervision.
- If the monitor cannot take a measurement or the measurement readings seem dubious, check the condition of the patient first.
- If any abnormality is found in the patient or the monitor, take appropriate measures, such as stopping the monitor, to ensure the safety of the patient.
- This monitor is not suitable to use around flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may occur.
- Do not let the monitor or its flexible cord come into contact with surfaces which are too hot to touch.
- To ensure patient safety, use only the accessories and supplies (i.e., cuffs, hoses, temperature probes, SpO₂ probe, test strips, etc.) recommended for or supplied with this monitor. Using unapproved accessories with this monitor can affect patient and/or operator safety.
- Avoid water or any fluid from leaking the connectors (especially AC power input socket). Should this occur, dry the connectors with a clean cloth immediately. For the monitor, remove the battery right away and do NOT turn on the monitor, then contact the customer service for assistance.
- Use with the specified AC voltage and frequency.
- Do not plug/unplug the AC adapter cable into an AC outlet with wet hands.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not obstruct the mains power switch or position the equipment where the connection to the mains line can be accidentally disconnected.
- No modification of this equipment is allowed.



MR UNSAFE!

- Do not use the VSM100 Pro during a magnetic resonance imaging (MRI) scanning, computed tomography (CT) screening, diathermy, radio-frequency identification (RFID), and electromagnetic security systems.



CAUTION!

- Every three months, inspect the blood pressure cuff, SpO₂ cable, and other accessories for fraying or other damage. Replace if necessary.
- Electric shock hazard: An operator may only perform maintenance procedures specifically described in this manual. For service, contact the customer service.
- This monitor complies with the current applicable standards for electromagnetic interference. As a precaution, avoid using this monitor close to other equipment.
- This monitor is composed of high-quality precision parts. Protect it from severe impact and shock. If it is dropped or damaged, it should be checked by a qualified service technician for proper operation prior to further use. Do not use this monitor if you notice any signs of damage. Contact the customer service for assistance.
- Do not use the SpO₂ probe with the blood pressure cuff simultaneously on the same limb. Doing so may result in inaccurate pulse rate and perfusion readings.
- Do not use the SpO₂ probe during a magnetic resonance imaging (MRI) scanning.
- The monitor is waterproof IPX2 degree. However, do not immerse it in water or drip fluids on heat exhale holes on the rear panel.
- When storage space is less than 20 records, the **VSM100 Pro** will display the reminder information.
- The use of this device is restricted to one patient at a time.

Blood Pressure Warnings and Cautions

These warnings and cautions pertain to the blood pressure feature of this monitor.



WARNING!

- Do not wrap the cuff around any of the following locations. Doing so can cause an accident. Anywhere on the four limbs that a venous pulse is secured, such as where there is an IV or blood transfusion. Any limb with an artificial dialysis shunt.
- When the cuff hose is bent or blocked, there could still be air in the cuff even though the pressure display reads 0mmHg. This may block the blood flow in the arm, which may in turn cause peripheral function disorders. In addition, make sure the cuff is deflated before use.
- Avoid compression of the blood pressure hose or cuff tubing. This may cause system errors to occur in the monitor.
- This monitor does not operate effectively on patients who are experiencing convulsions or tremors.



CAUTION!

- When several blood pressure measurements are taken on the same patient, regularly check the cuff site and extremity for possible ischemia, purpura, and/or neuropathy.
- Wrapping the cuff too loosely may lead to inaccurate results.

ECG Warnings and Cautions

These warnings and cautions pertain to the ECG warnings and cautions.



WARNING!

- In order to minimize interference and the danger of burns to the patient, only use FORA ECG cables. Keep the ECG cable as far away as possible from any electrosurgical cables. Make sure that the electrosurgical return conductor (neutral) is properly attached to the patient.
- Danger of destroying the monitor during defibrillation! The monitor is type CF protected only when the original FORA patient cables are used.
- Patients with a pacemaker must be observed continuously because the heart rate from the pacemaker might still be registered in case of a cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarm signals. Keep pacemaker patients under close surveillance.
- Pacemaker monitoring is not possible with ECG cables that have unshielded lead wires. Ensure that only shielded lead wire ECG cables are used when monitoring patients that have a pacemaker.
- FORA recommends to apply a SpO₂ sensor in addition to the ECG measurement and to set the alarm range for the peripheral pulse (PP) in the range of the heart rate (HR), or to set the HR source in the SpO₂ menu to SpO₂.



Caution!

- The guidelines in this section are for overview only. They are not a substitute for, nor do they overrule manufacturers' documentation and instructions or departmental procedures.

SpO₂ Warnings

These warnings and cautions pertain to the SpO₂ feature of this monitor.



WARNING!

- The SpO₂ probe and extension cables are intended for use only for pulse oximeter measurements. Do not attempt to connect these cables to a PC or any other monitor.
- Do not use a damaged probe or extension cables.
- Incorrect application or extended use of a SpO₂ probe on the same sensor site may cause incorrect readings. Inspect the sensor site periodically as directed in the

probe's directions for use.

- Certain ambient environmental conditions, probe application errors, and certain patient conditions may affect SpO₂ readings and pulse signal.



CAUTION!

- The SpO₂ probe is not intended for use as an apnea monitor.
- Do not immerse the probe or patient cables in water, solvents, or cleaning solutions (the sensors and connections are not waterproof).
- Do not use irradiation, steam, or ethylene oxide for sterilization.
- Consider the SpO₂ as an early warning monitor. As a trend toward patient deoxygenation is indicated, use laboratory instruments to analyze blood samples to completely understand the patient's condition.
- The Following Factors May Lead to Inaccurate Results:
 - ▶ Excessive ambient light
 - ▶ Excessive motion
 - ▶ Anemia or low hemoglobin concentrations
 - ▶ Fingernail polish
 - ▶ Arterial catheters, blood and infusion lines, etc.
 - ▶ Cardiovascular dyes
 - ▶ Improper sensor use
 - ▶ Incorrect sensor
 - ▶ Electrosurgical interference
 - ▶ Venous pulsations

Infrared Thermometer Warnings



CAUTION!

- Always store the thermometer in a cool and dry place: temperatures between -4°F to 140°F (-20°C to 60°C), relative humidity 10% to 85%, non-condensing. Avoid direct sunlight.
- Avoid dropping the thermometer from a height or strongly hitting it with a hard object.
- Only use the probe covers provided by the manufacturer. For proper hygiene, do not share probe cover. Damaged probe cover may result in error display.
- Do not disassemble the thermometer.
- Basic safety precautions should always be observed, especially when the thermometer is used on or near children and disabled persons.
- This thermometer is not intended to be a substitution for consultation with your physician.
- Keep probe covers out of reach of children.
- Temperature of left and right ear may differ. Always measure the same ear.

Blood Glucose Warnings



WARNING!

- Carefully read the owner's manual of the blood glucose monitoring system before use.

IMPORTANT SAFETY PRECAUTIONS

Read Before Use

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”
<http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>
- The meter should be disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
- Only auto-disabling, single use lancing devices may be used with this device.

For more information on the risk of blood-borne pathogen transmission from blood glucose meter and lancing devices, please refer to:

“FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

“CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

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INTRODUCTION

Intended Use

The Vital Signs Monitor is intended for the monitoring of parameters such as ECG, non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, body temperature, blood glucose, and oxygen saturation of arterial hemoglobin (SpO₂) of adult patient. The monitor is intended to be used by clinicians and medically qualified personnel and trained users.

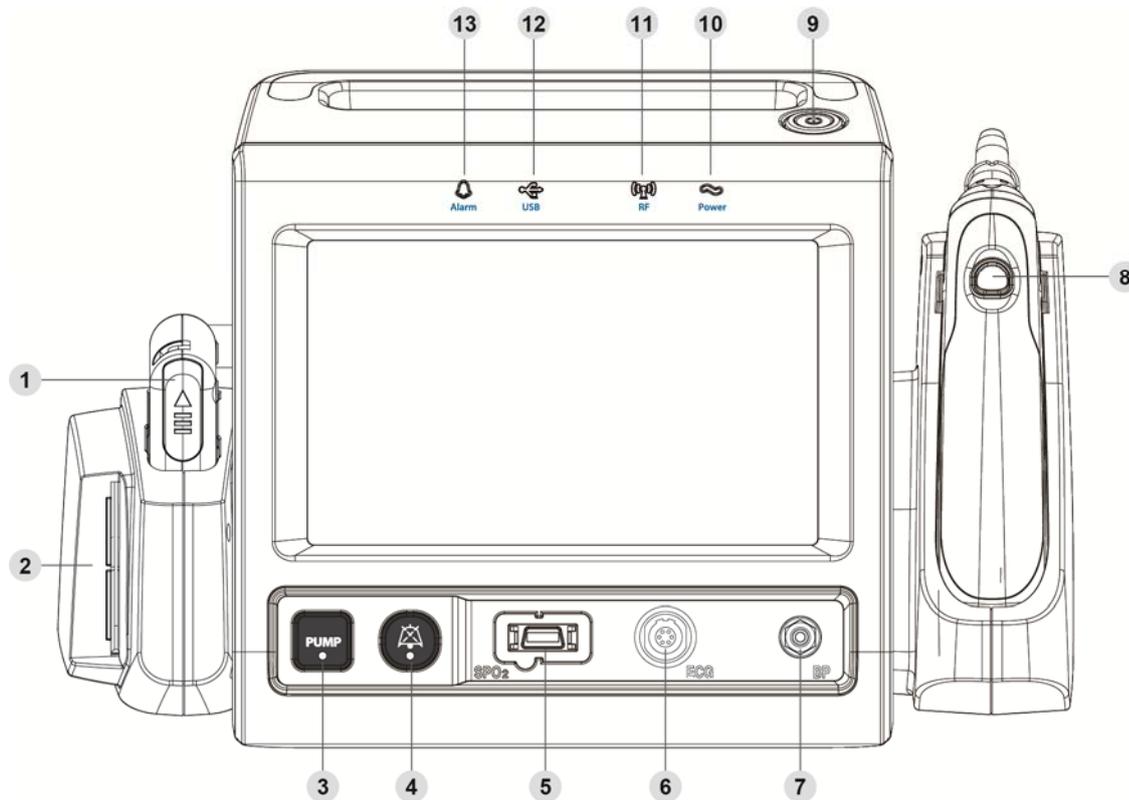
Main measurement function

- NIBP (Non-Invasive Blood Pressure)
- SpO₂
- Infrared thermometer
- Blood glucose Meter
- ECG

Contents of System

1. Main monitor
2. Infrared thermometer
3. Probe cover of infrared thermometer
4. Blood glucose meter
5. Blood glucose test strip (10 strips)
6. Safety lancet (10 pieces)
7. SpO₂ sensor and extension cable
8. ECG cable
9. NIBP upper arm cuff and extension hose
10. AC power cord
11. Warranty card
12. ECG electrode pads (5 pieces)
13. SD memory card
14. Probe cover cassette (16 pcs)

Monitor Overview



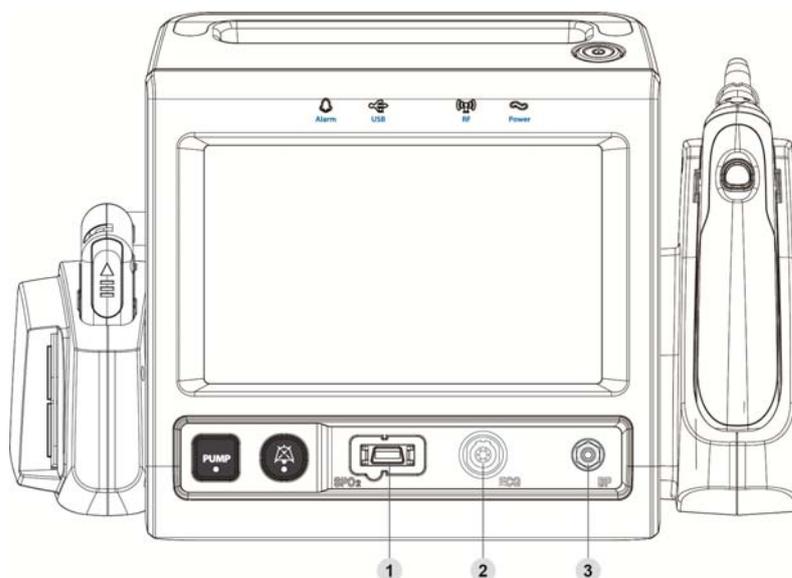
1. Blood glucose meter
2. Smart card reader
3. Non-invasive blood pressure (NIBP) measurement button
(When PUMP indicator lights up, press the button to start a NIBP measurement. For emergency stop during the measurement, press this button again)
4. Silence button (When the alarm sounds, press this button to temporarily mute the audio. Refer to page 73 for more information.)
5. SpO₂ sensor connection port
6. ECG cable connection port
7. NIBP pressure hose connection port
8. Infrared thermometer
9. Power On/Off button
10. Power display LED
11. RF LED
12. USB LED
13. Alarm LED

Before Measurement - Connecting Accessories

Start with the monitor off, and connect all accessories to the monitor. The following figures show the accessory ports on the front and back panels. (For reference only, some of the accessories show may differ from actual products).

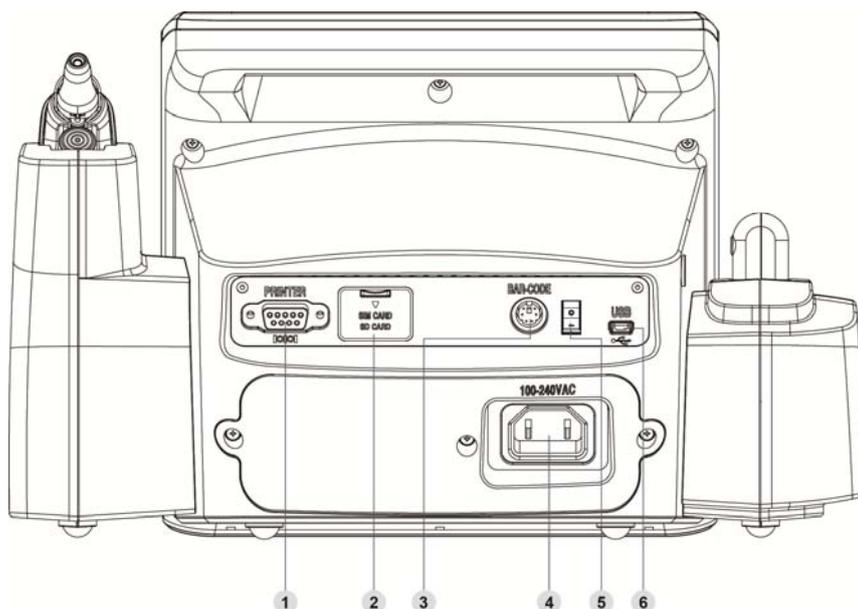
Accessory ports on the front panel

1. SpO₂ sensor connection port
2. ECG cable connection port
3. NIBP pressure hose connection port



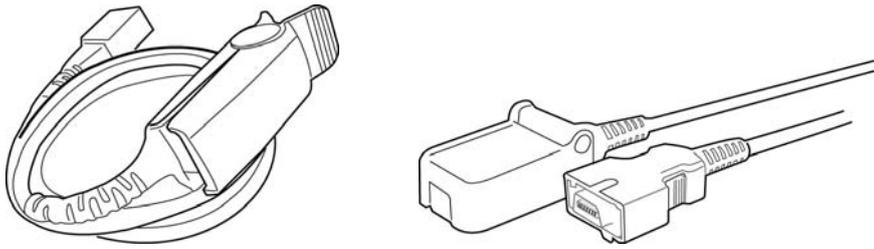
Accessory ports on the back panel

1. Printer port
2. SIM/SD memory card slot
3. Barcode
4. Power switch
5. USB connector
6. AC power cord



Accessories of **VSM100 Pro** include:

1. SpO₂ finger sensor and extension cable



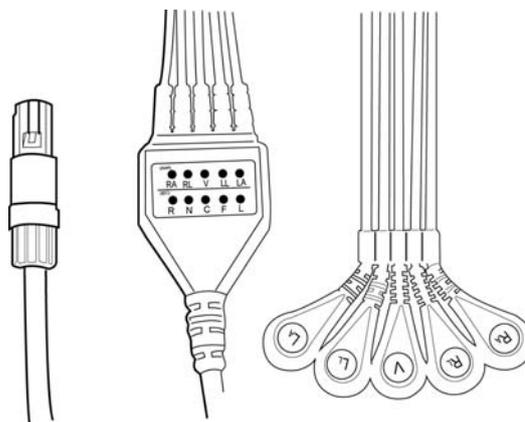
Note:

- If you are going to change the sensor, make sure you choose the corresponding brand to your model.
- In case you have to use a different brand, please consult your agent firstly.

2. NIBP pressure cuff and hose



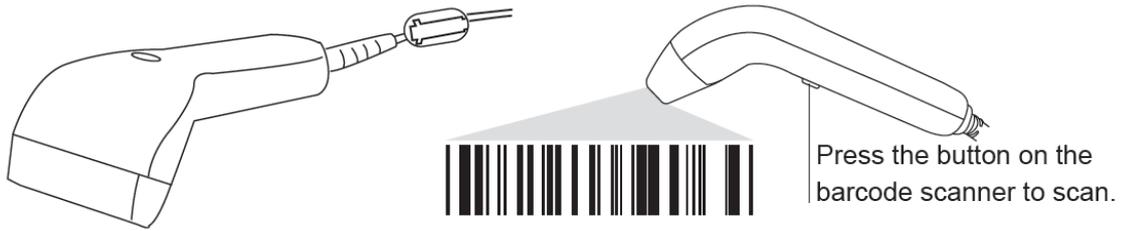
3. ECG cable



Note:

- Color code: the colors shown here are according to IEC requirements.

4. Barcode scanner (Optional)



5. AC power cord



Note:

- Without this item, the monitor can still work until the battery run out.
- Different specifications of AC power cord are for different countries. Make sure you use the correct one in your country.
- Use this AC power cord to recharge the battery. It takes approximately 5 hours for the battery to get fully recharged.

6. Rolling stand (Optional)

This stand is for moving the monitor conveniently. The monitor can work well without this stand. Refer to the rolling stand manual.



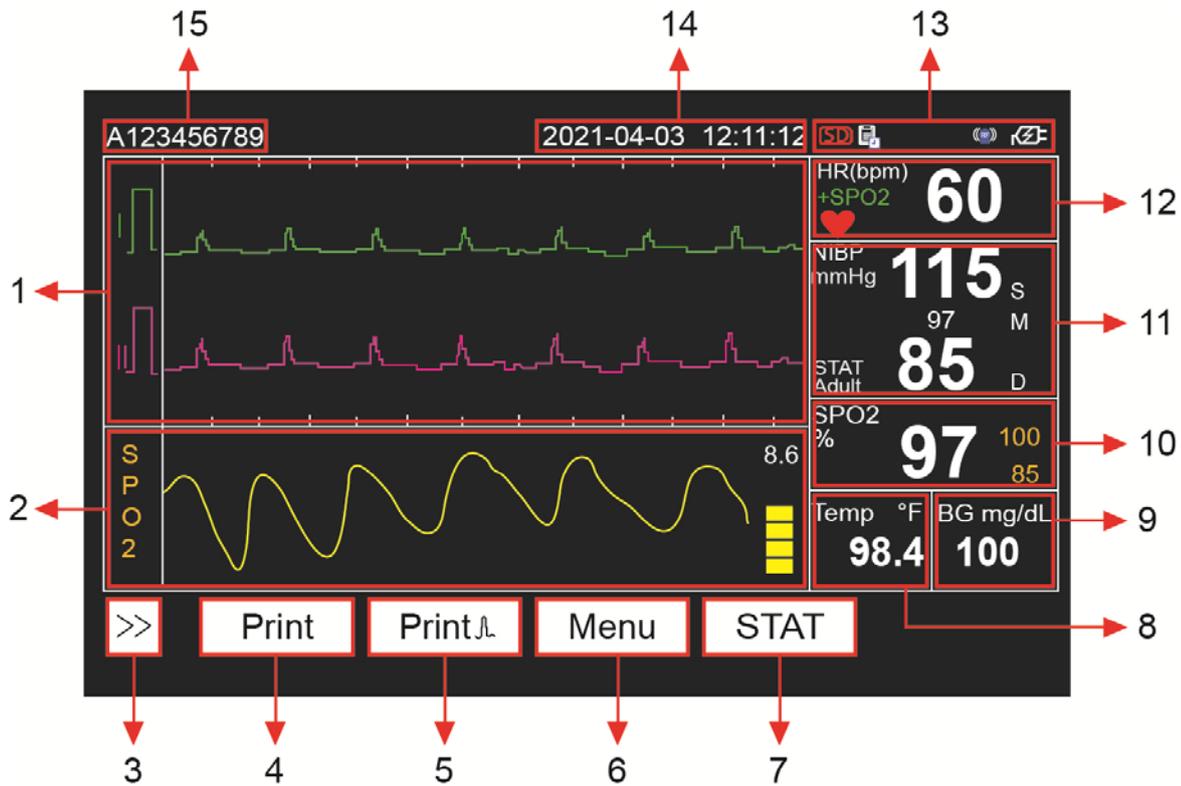
CAUTION!

- Make sure that all accessories are securely connected to monitor before performing any test, or it may cause inaccurate results.

Note:

- Before taking measurements, please **pair up the glucose meter** (please refer to page 32) and **infrared thermometer** (please refer to page 34) with the monitor and **the cuff is completely evacuated**.
- Use only recommended accessories with the monitor.
- The monitor is equipped with a Lithium-ion rechargeable battery. When using the monitor for the first time or the battery is low, connect the monitor to a power source and charge the battery. It takes approximately 5 hours to fully charge the battery.

Monitor Main Display Area



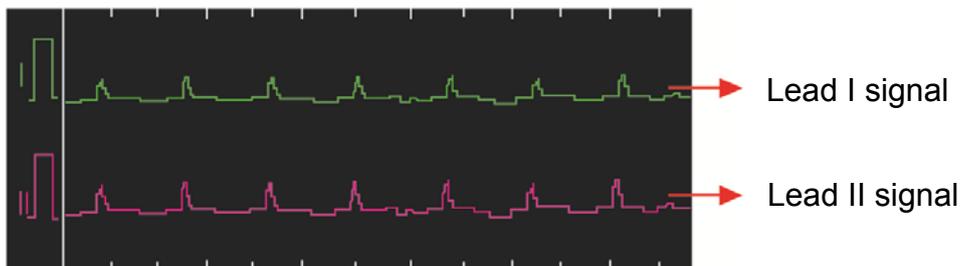
Area	Description
1	ECG display area Display ECG-related info
2	SpO ₂ display area Display SpO ₂ -related info
3	>> button Display ECG- different channel
4	Print button Touch this button to print out the readings
5	Print  button (ECG) Touch this button to save the ECG data and to print out the ECG waveforms
6	Menu button Touch this button to change settings
7	STAT button Touch this button for a 5-min consecutive measurement
8	Temperature display area Display temperature-related info
9	Blood glucose display area Display blood-glucose-related info
10	SpO ₂ display area Display SpO ₂ -related info
11	NIBP display area Display NIBP-related info
12	Heart rate display area Display heart-rate-related info
13	Status indicator display area Display status indicators
14	Date / Time Display date and time You may key in the date and time
15	Patient's info Display the patient's ID

For details, please refer to the following sections.

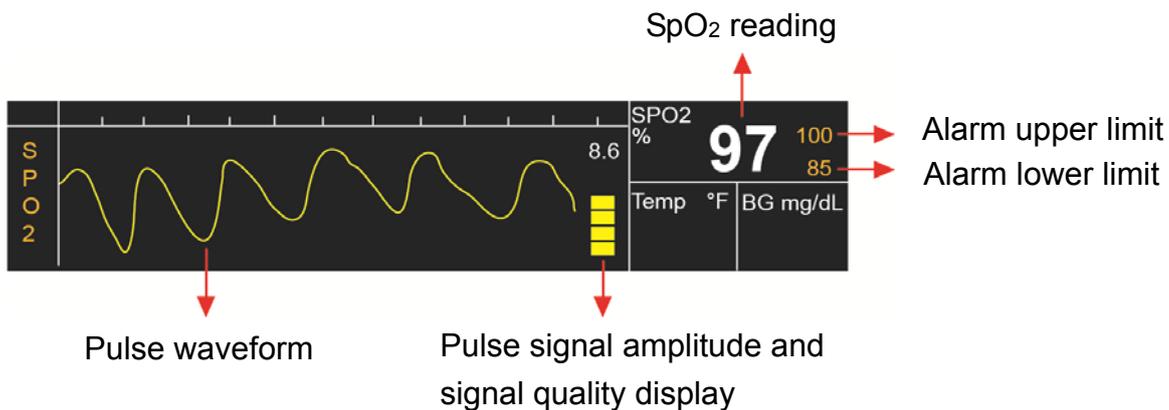
Note:

- To view or change related settings, directly touch SpO₂, BG, Temp, HR, NIBP areas.
- When a reading exceeds the set alarm limit, the reading turns red.
- If the time and date display on the main screen shows red, which indicates an error appeared. Please switch off the power switch in the back of monitor. After waiting for 2 minutes, re-switch it on.

● **ECG Display Area**



● **SpO₂ display area**



Note:

- When the sensor is disconnected, the waveform disappears; the SpO₂ reading remains for 30 seconds and then disappears.

●  **button**

Display ECG-different channel.

● **Print button**

Touch this button to print out the readings. Please refer to page 20.

Note:

- When you touch this button, the monitor beeps. However, the monitor does not detect whether a printer is connected. Please make sure the printer is well connected.

- **Print  button (ECG)**

Touch this button to save the ECG data and to print out the ECG waveforms.

Note:

- When you touch this button, the monitor beeps. However, the monitor does not detect whether a printer is connected. Please make sure the printer is well connected.

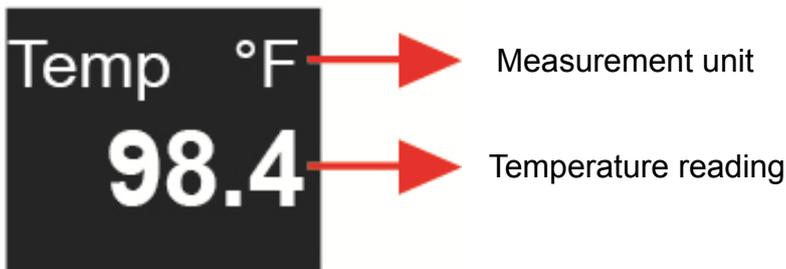
- **Menu button**

Touch this button to enter setup menu. Please refer to page 21.

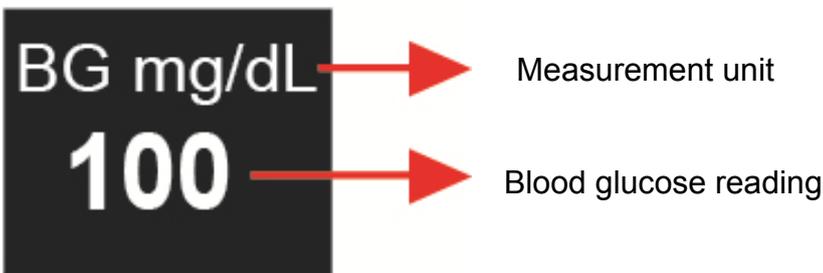
- **STAT**

Touch this button for a 5-min consecutive measurement.

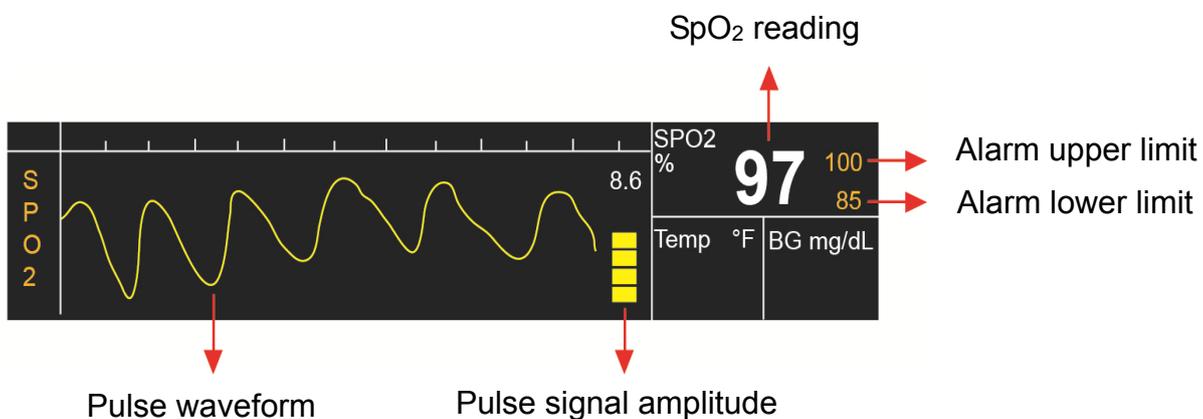
- **Temperature display area**



- **Blood glucose display area**



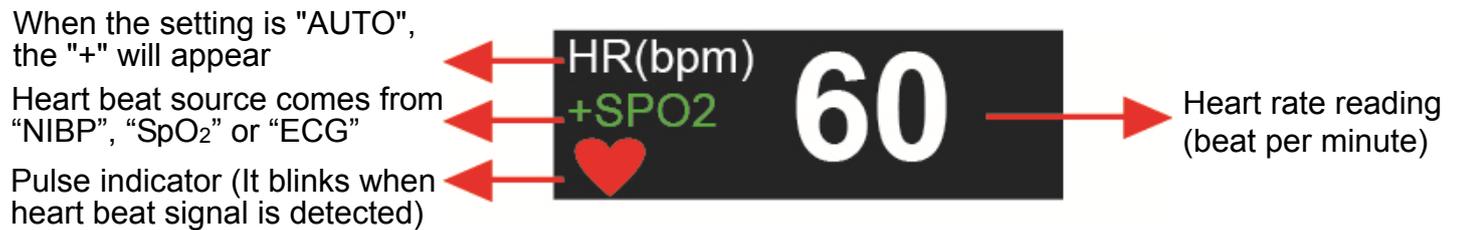
- **SpO₂ display area**



● **NIBP display area**



● **Heart rate display area**



● **Status indicator area**

 This indicator displays when the symbol is blinking, that the SD memory card slot is waiting for plug.

 This indicator displays when Auto Save function is on. Please refer to page 27.

 This indicator displays when Printing function is on. Please refer to page 20.

 This indicator displays when Bluetooth is on. Please refer to page 33.

 This indicator displays with the "Lightning" symbol constantly shown, which means the device is recharging.

 This indicator displays without the "Lightning" symbol, which means that the device has been fully recharged.

Battery indicator: the percentage means the power storage capacity

 **Green:** 41%~100% (normal power)

 **Orange:** 21%~40% (low power)

 **Red:** 0%~20% (very low power)

When the bar turns to red, the information signal makes a long sound every 10 seconds (till the monitor automatically turns off).

Note:

- The stored data will not be deleted, if the monitor automatically turns off.
- Every 10 seconds, **VSM100 Pro** would record the number of Heart rate, SAT value and time. **VSM100 Pro** will overwrite the oldest record instead of creating a new record if the old one was recorded 10 seconds ago. If not, **VSM100 Pro** will append the new record at the end of the latest record. So, the recorded file will show every power-failure time.
- The battery should take approximately 5 hours to be fully recharged, and can be used continuously for 8 hours till the battery is low.

- **Date / Time area**

Please refer to page 32 to change date and time.

- **Patient's info of measurement**

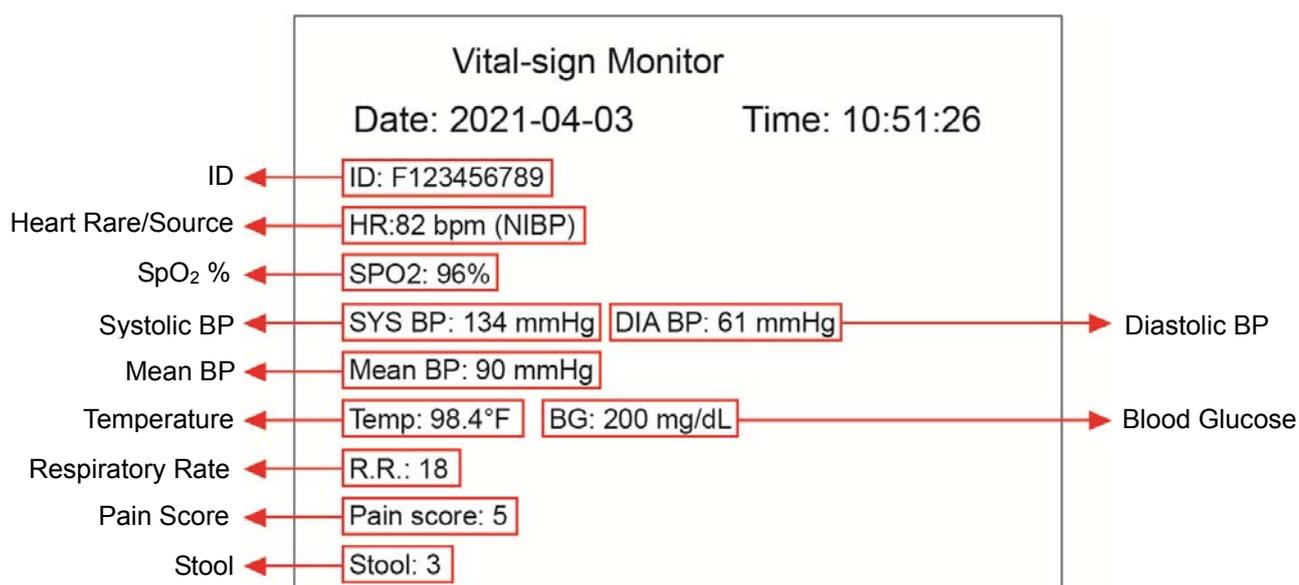
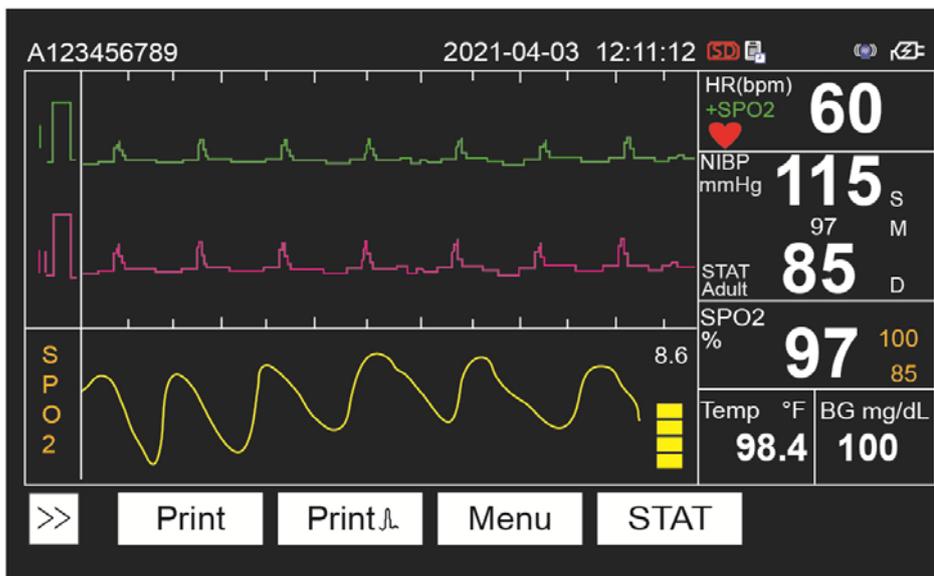
You can name the location when you perform the measurements. Please refer to page 22.

Monitor Functions

After all accessories are well connected, power on the monitor and you can proceed with measurement or enter each mode by touching the screen.

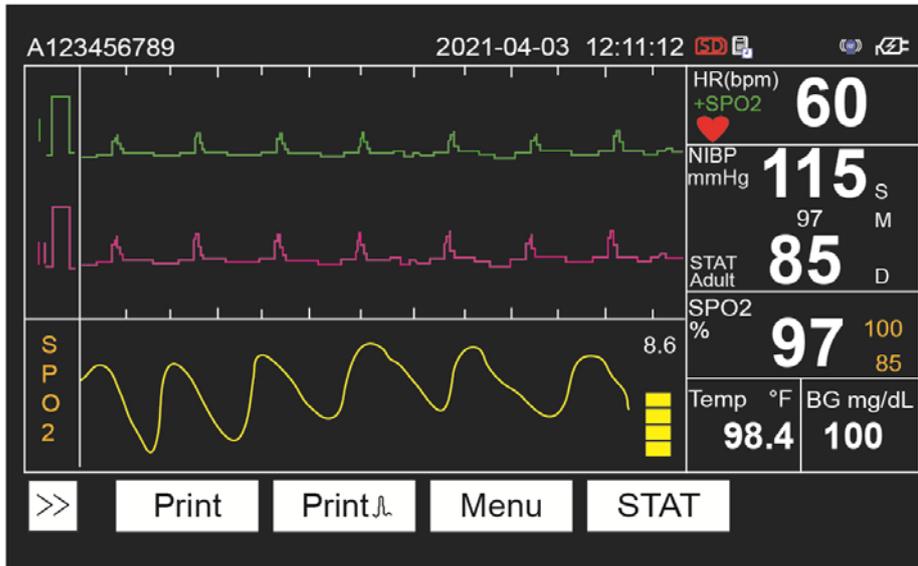
Print

The Print Function provides options for printing out data. Touch the “Print” button and the printer will print out the readings. Please use printers that are designed for **VSM100 Pro**.



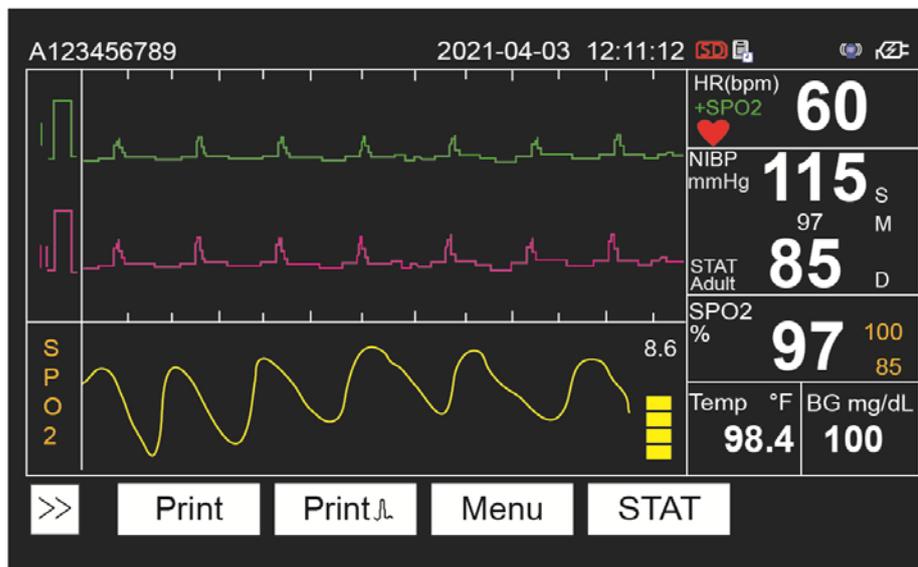
Print

The Print  Function provides options for printing ECG waveform. Touch this button to save the ECG data and to print out the ECG waveforms. Please use printers that are designed for **VSM100 Pro**.



Menu

The Menu function allows system configurations to be adjusted. Touch the Menu button to enter the setting windows. Read the following contents for descriptions.



Note:

During the period from power failure to recovery within 30 seconds, it's no need to reset the monitor.

ID

Input Patient ID, height, weight, and clinician ID. Touch the info areas to enter the key-in windows. **Save**: save the changes. (If no changes, "Save" is in gray and does not function) **Exit**: exit this page without saving.

If you exit without saving the changes, a window pops up:

- **Gender**

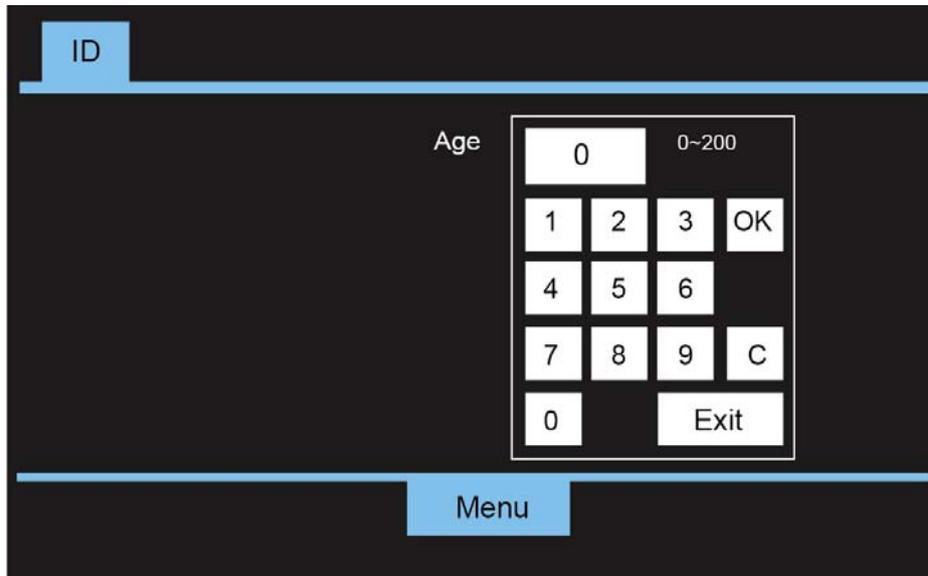
Touch the “Gender” button to select gender: male or female.

- **Patient ID**

Touch the numbers and letters to key in. Touch “Enter” to confirm the ID. You can also use a barcode scanner to input the Patient ID. Touch “Exit” to exit this page without saving. By scanning the patient ID, the patient data saved before can be retrieved and displayed.

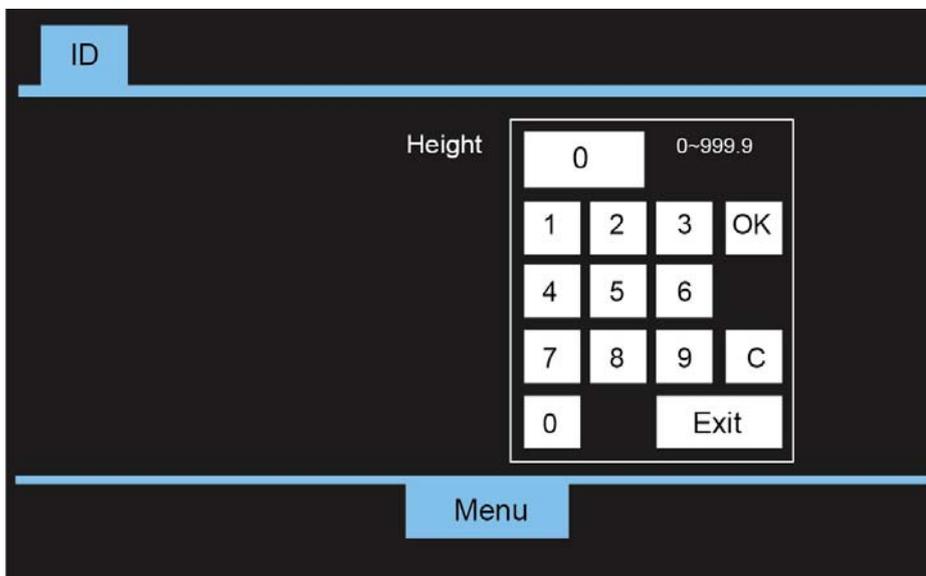
- **Age**

Touch the numbers to key in. **OK**: save the input. **C**: clear the display area to "0".
Exit: exit this page without saving. Input range: 200 ~ 0. (If the input is out of this range, it cannot be saved.)



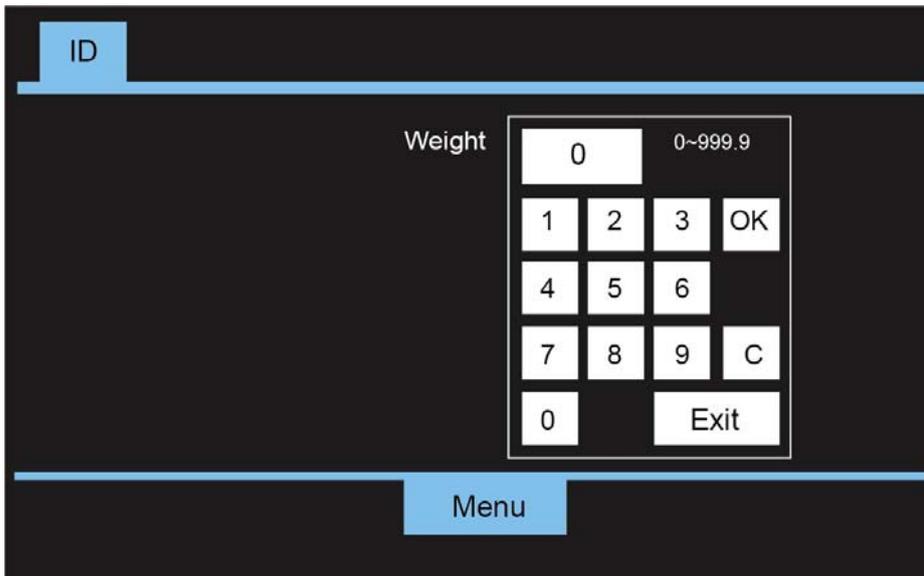
- **Height**

Touch the numbers to key in. **OK**: save the input. **C**: clear the display area to "0".
Exit: exit this page without saving. Input range: 9 ~ 1 (ft), 11 ~ 0 (in), 400 ~ 1 (cm).
(If the input is out of this range, touching "OK" does not function.)



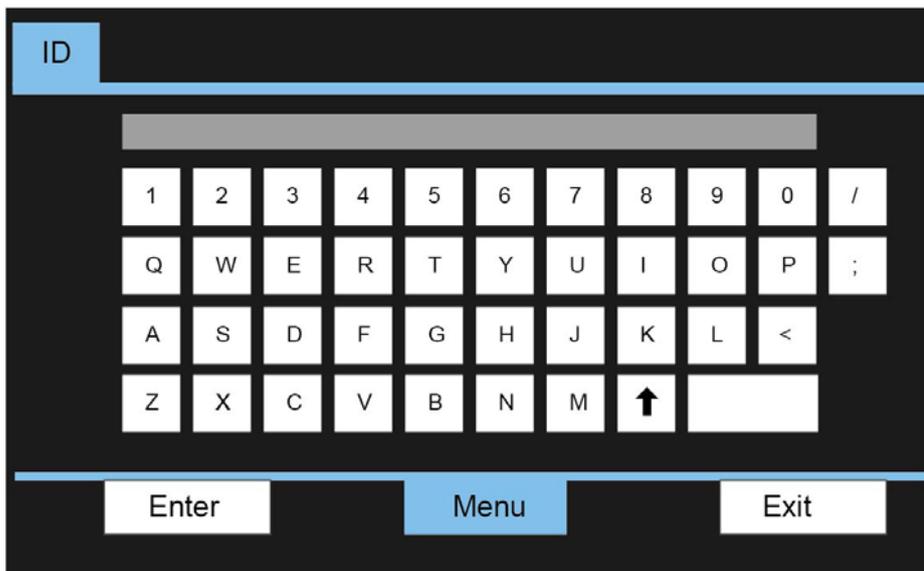
- **Weight**

Touch the numbers to key in. **OK**: save the input. **C**: clear the display area to “0”.
Exit: exit this page without saving. Input range: 999 ~ 1 (lb) / 400 ~ 1 (kg). (If the input is out of this range, touching “OK” does not function.)



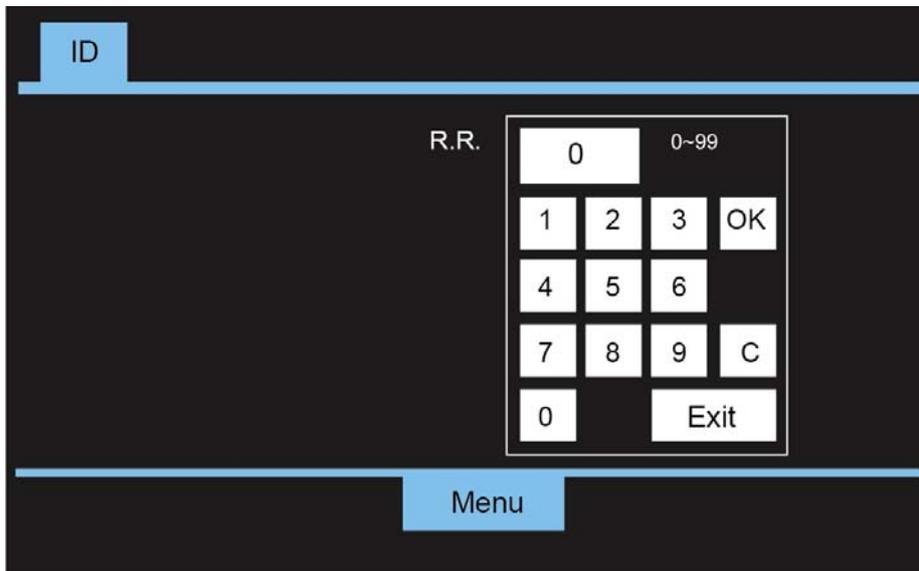
- **Clinician ID**

Touch the numbers and letters to key in.
You can also use a barcode scanner to input Clinician ID. **Enter**: save the input.
Exit: exit this page without saving.



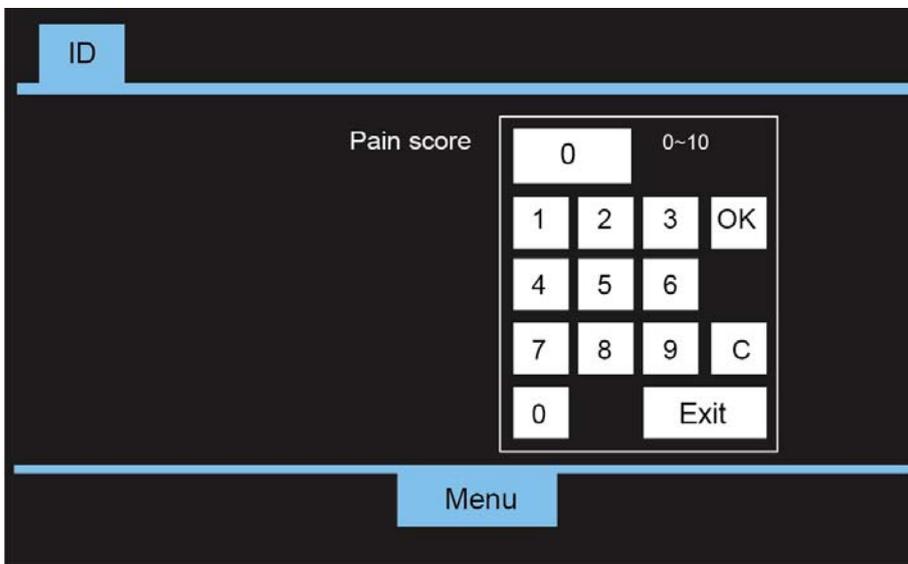
- **R.R.**

Touch the numbers to key in. Touch “OK” to confirm the R.R. number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving.
Input range: 0~99 (min) (If out of this range, touching “OK” does not function.)



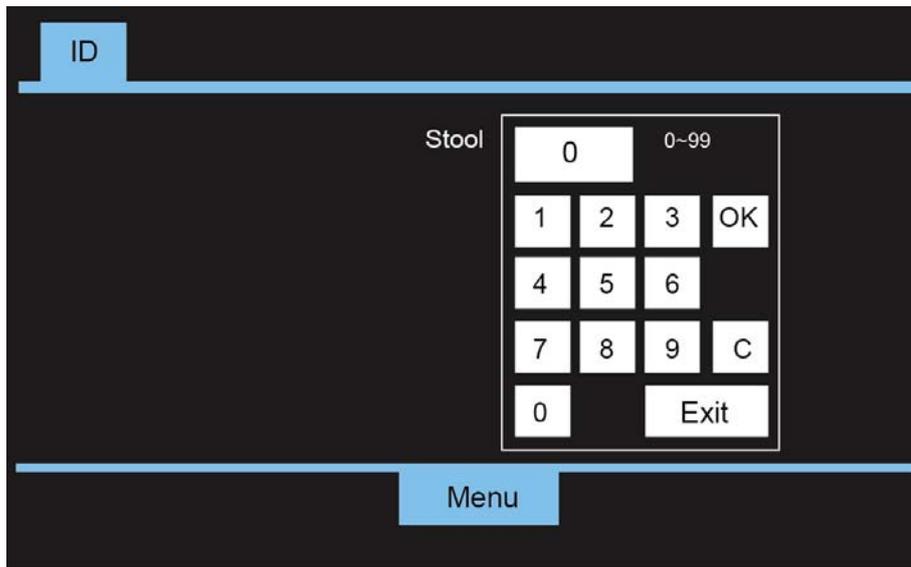
- **Pain score**

Touch the numbers to key in. Touch “OK” to confirm the pain score number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving.
Input range: 0~10 (If out of this range, touching “OK” does not function.)



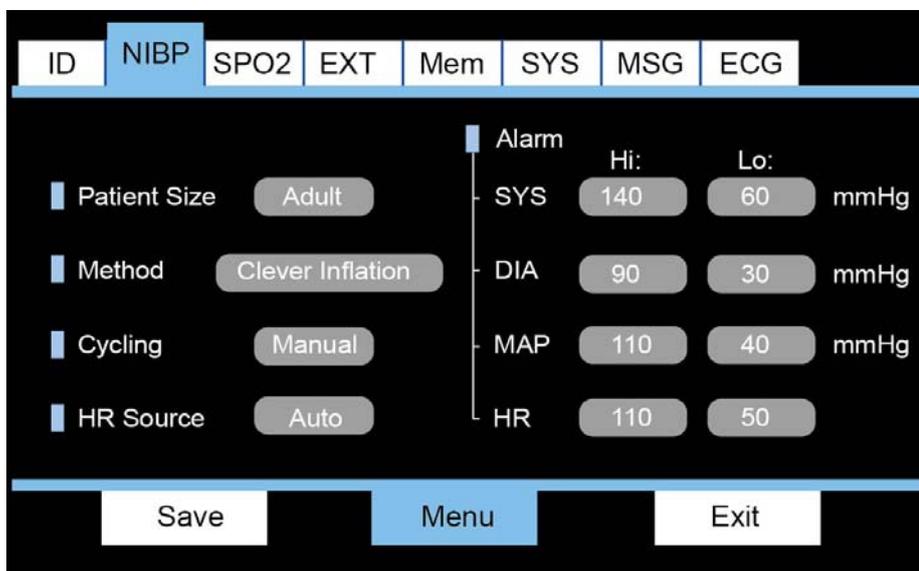
- **Stool**

Touch the numbers to key in. Touch “OK” to confirm the stool number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving. Input range: 0~99 (If out of this range, touching “OK” does not function.)



NIBP

Set up the non-invasive blood pressure function. **Save**: save the changes. **Exit**: exit this page without saving.



NIBP settings are described in the following table:

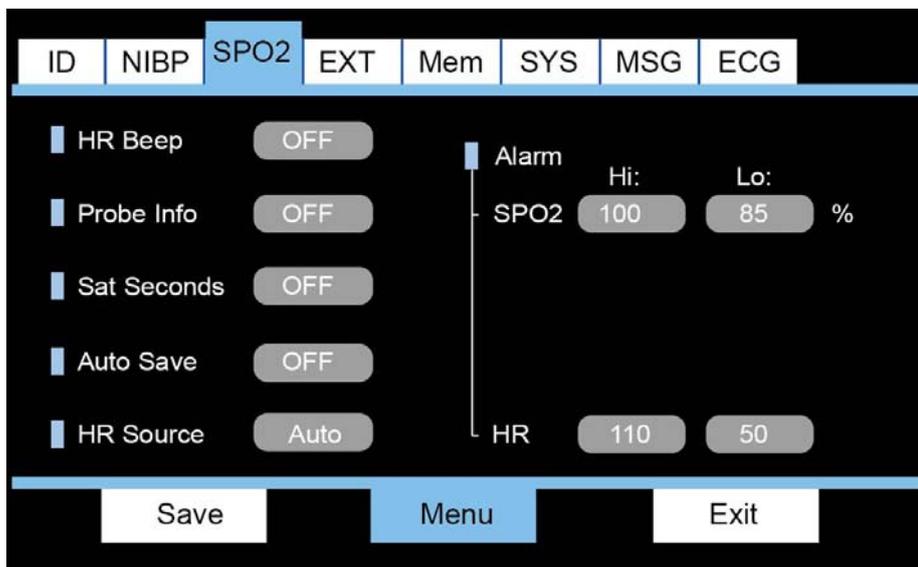
	NIBP Setting	Description
Patient	Adult	
Method	Clever Inflation (default)	If interfered during the first measurement, the monitor will then take a measurement again.
	Deflation Only	
Cycling	Manual (default)	Take a measurement only when press PUMP button.

	OFF	The monitor takes a measurement in the specified interval.
	3 min	
	5 min	
	10 min	
	15 min	
	30 min	
	1 Hr	
	1.5 Hr	
	2 Hr	
	4 Hr	
HR Source	Auto(default)	The monitor automatically switches to a stable heart rate.
	SpO ₂	Take the pulse rate from SpO ₂ measurement.
	NIBP	Take the pulse rate from blood pressure measurement.
	ECG	Take the pulse rate from ECG pressure measurement.

Alarm type	Hi:	Lo:	Description
SYS	275 ~ 61	139 ~ 50	When any reading exceeds its limit, the alarm sounds.
DIA	200 ~ 31	89 ~ 20	
MAP	225 ~ 41	109 ~ 30	
HR	250 ~ 51	109 ~ 20	

SpO₂

Set up the SpO₂ function. **Save**: save the changes. **Exit**: exit this page without saving.



SpO₂ settings are described in the following table:

	SpO ₂ Setting	Description
HR Beep	On	The monitor beeps as the pulse goes.
	Off (default)	The monitor does not beep along with the pulse.

Probe Info	On	The monitor beeps when: 1. The probe is disconnected. 2. The sensor cannot receive signals while taking a measurement.
	Off (default)	The monitor does not beep with the probe conditions.
Auto Save	Off (default)	The monitor will save each reading according to the selected interval setting.
	1 min	
	5 min	
	10 min	
HR Source	SpO ₂	Take the pulse rate from SpO ₂ measurement
	NIBP	Take the pulse rate from blood pressure measurement
	ECG	Take the pulse rate from ECG pressure measurement
	Auto (default)	The monitor automatically switches to a stable heart rate

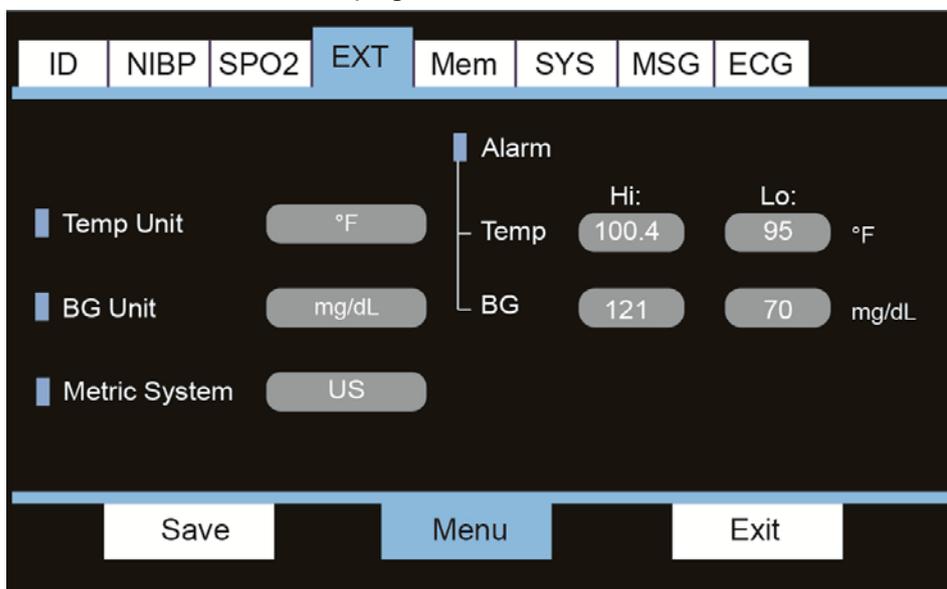
Alarm type	Hi:	Lo:	Description
SpO ₂	100 ~ 86	99 ~ 20	When any reading exceeds its limit, the alarm sounds and the reading turns red.
HR (Heart rate)	250 ~ 51	109 ~ 20	

EXT

Set up the EXT function.

Save: Touch “Save” to save the changes. (If no changes, “Save” is in gray and does not function)

Exit: Touch “Exit” to exit this page.



The settings are described as below.

	Unit setting	Description
Temp	°C	Setting for Celsius unit
	°F	Setting for Fahrenheit unit
BG	mg/dL	Setting for mg/dL unit

(Blood Glucose)	mmol/L	Setting for mmol/L unit
Metric System	US	Setting for US unit
	Int'l	Setting for Int'l unit

Alarm Type	Hi	Lo	Description
Temp	109.4~95.1 (°F)	100.3~89.6 (°F)	When any reading exceeds its limit, the reading turns yellow.
BG (Blood Glucose)	600~71	120~10	When any reading exceeds its limit, the reading turns yellow.

Mem

The Mem function allows users to retrieve all the readings.

Press SN or ID to enter each data for details

SN	ID	Date/Time	Del
00002	A123456789	2000-01-01 00:06:13	00005/00005
00001	A123456789	2000-01-01 00:06:39	

Delete the selected data

Which page you are on

Change to other pages

Enter the selected data

ECG file list

Exit this page

Below is an example of data record:

2021-04-03 00:17:05 00001/00001

ID	A123456789	Height	5 ft 7 in
Clinic ID	Clinic	Weight	132 lb
Gender	Female	Age	40

NIBP		Temp	°F
SYS	134 mmHg	BG	mg/dL
DIA	61 mmHg	R.R.	
MAP	90 mmHg	Pain score	
HR	82 bpm	Stool	
SPO2			
SPO2	%		
HR	bpm		

Print

Del

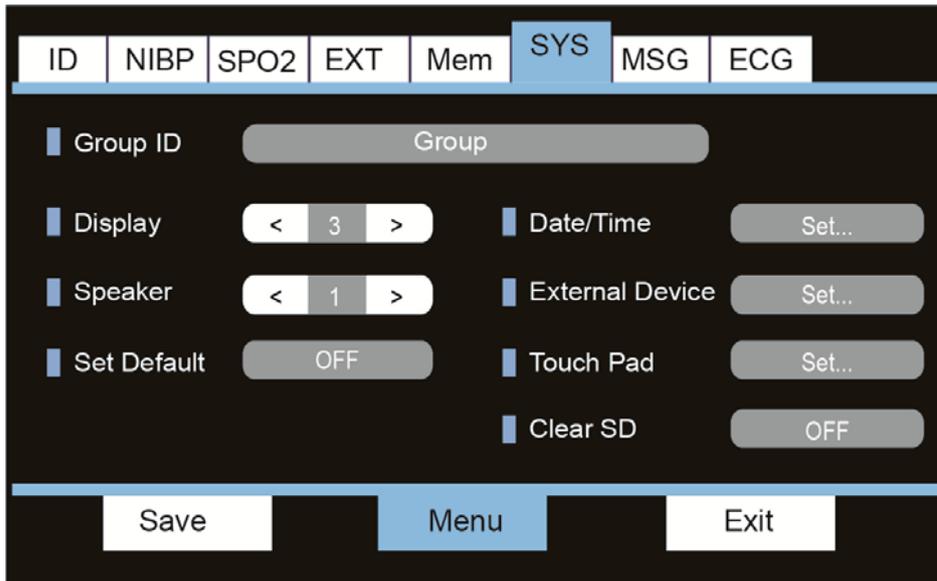
Exit

Note:

- When storage space is less than 20 records, **VSM100 Pro** will display the reminder information.
- While storage space is full, the new reading will not be stored.

SYS

Configure the system settings.

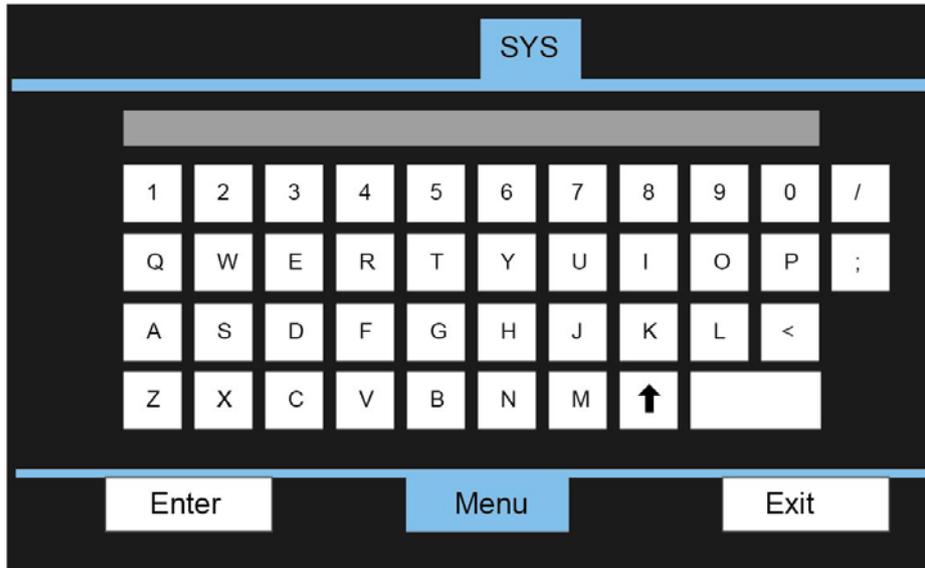


The auto upload selection can be chosen on 5, 10, 20, 30 and 60 minutes.

The settings are described as below.

● Group ID

Touch the numbers and letters to key in. You can also use a barcode scanner to input the Group ID. **Enter**: save the input. **Exit**: exit this page without saving.



The settings are described as below.

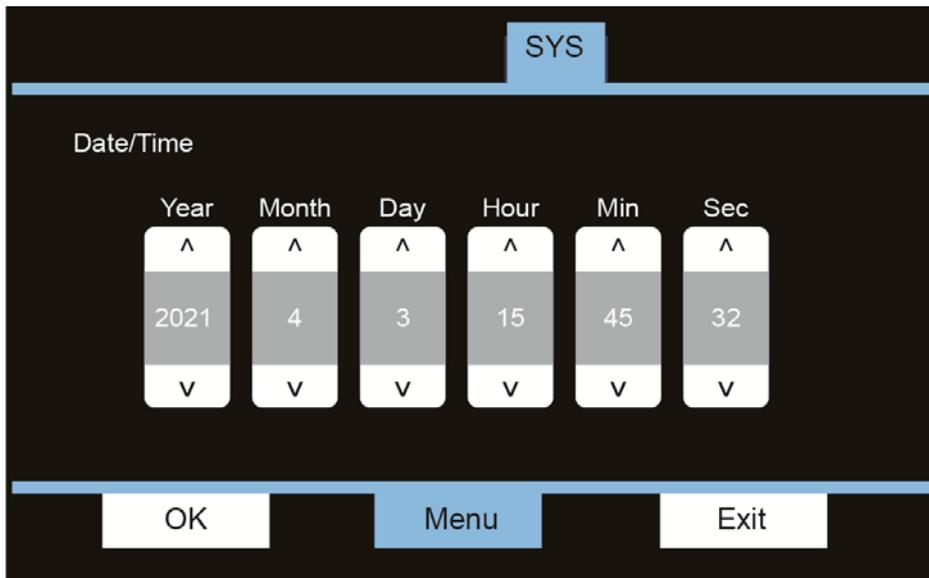
	Setting	Description
Display	1(default)	Touch the icon “>” to increase or “<” to decrease the brightness. 1 is the darkest. 7 is the brightest.
	2	
	3	
	4	
	5	

	6	Touch the icon “>” to increase or “<” to decrease the volume. 1 is the lowest, 3 is the loudest. (Only for Information tone).
	7	
Speaker	1 (default)	
	2	
	3	
	ON	

● **Date/Time**

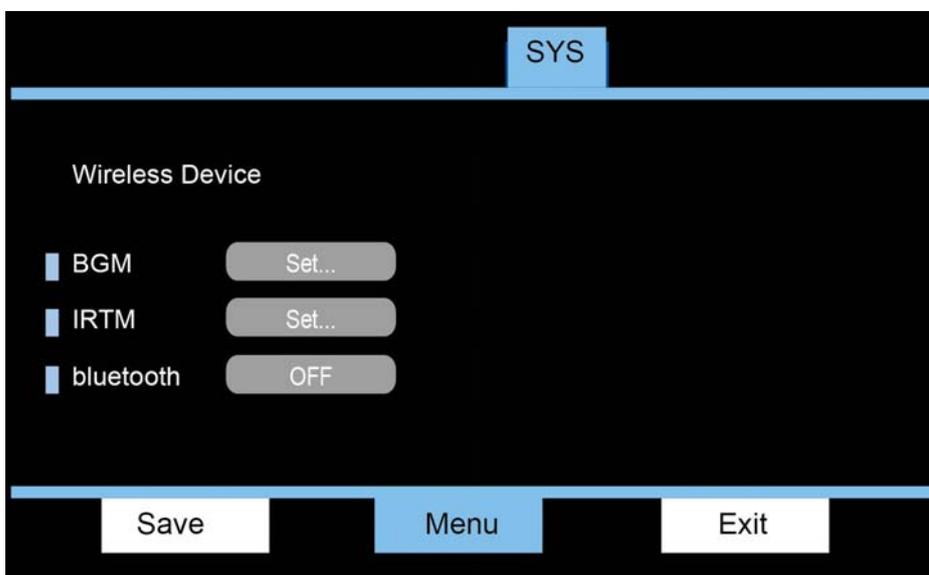
Touch “^” and “v” to adjust the Date and Time. **OK**: save the settings.

Exit: exit this page without saving.



● **Wireless Device**

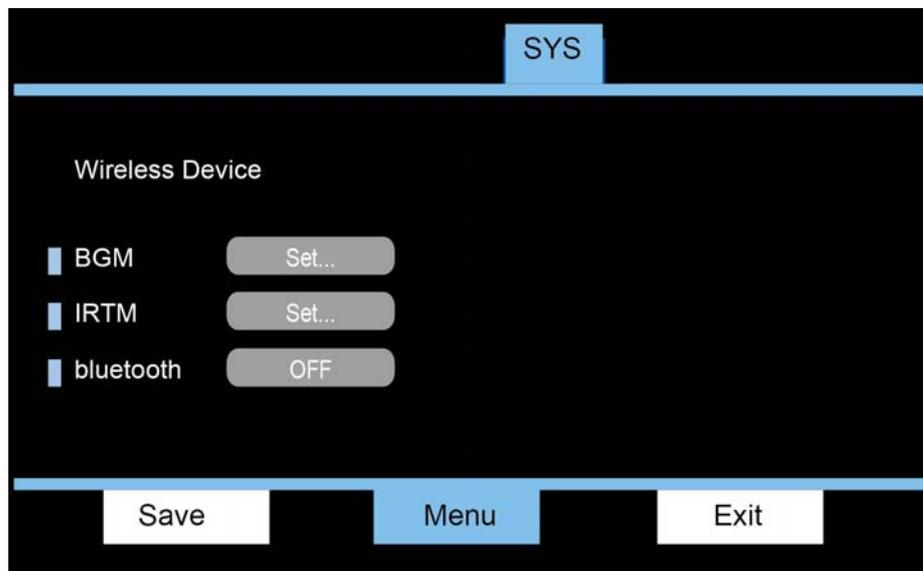
Pair up BGM (Blood Glucose Meter), IRTM (Infrared Thermometer) or Bluetooth device. Touch “Exit” to leave this page.



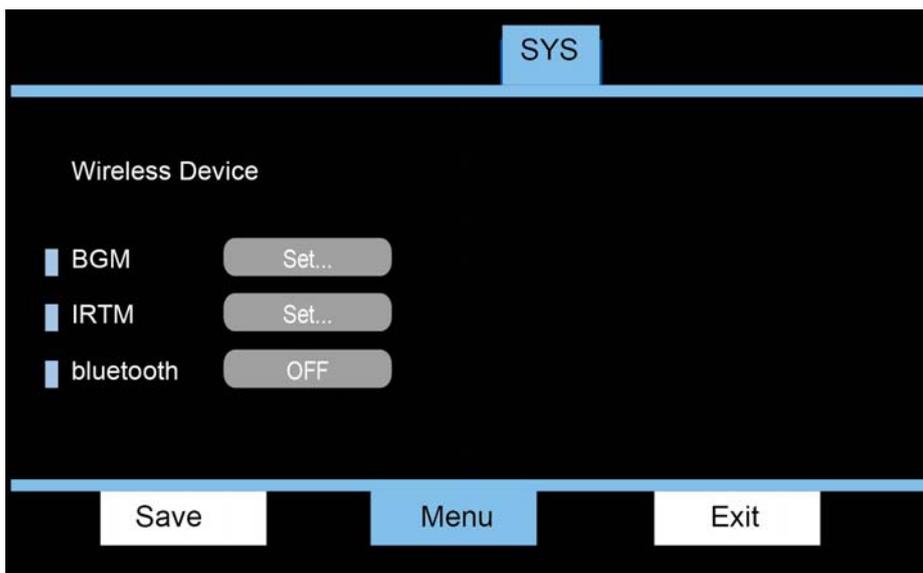
BGM (Blood Glucose Meter)

Before using the blood glucose meter for the first time, be sure to perform Wireless Device setup below.

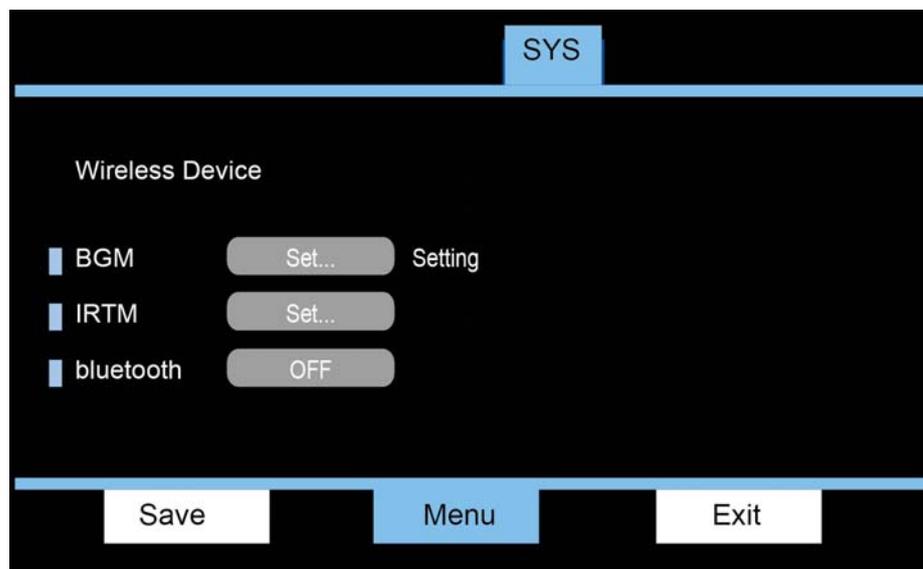
1. Enter Menu ► SYS ► Wireless Device



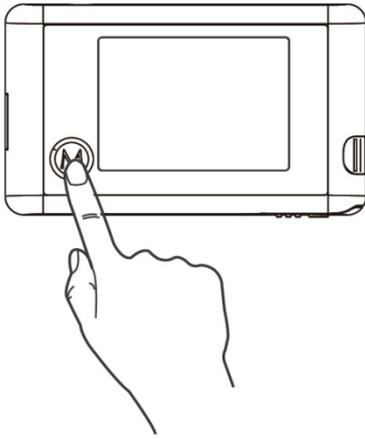
2. Touch "Set" for BGM.



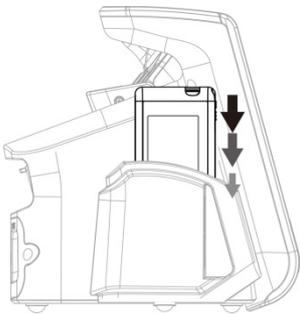
3. "Set..." is displayed. The monitor is ready for pairing up.



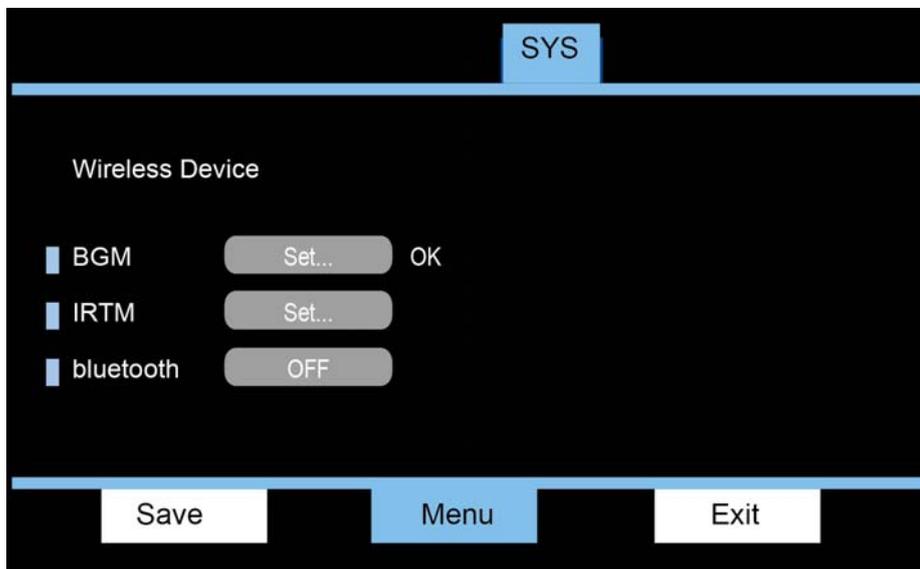
4. Turn on the blood glucose meter.



5. Put blood glucose meter into the meter holder on the blood glucose meter.



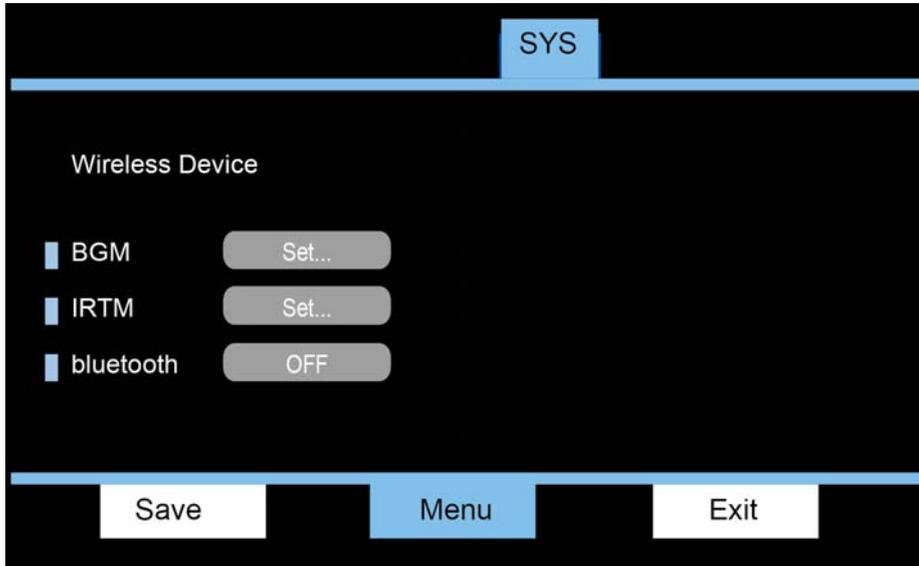
6. "OK" is displayed when the meter is identified.



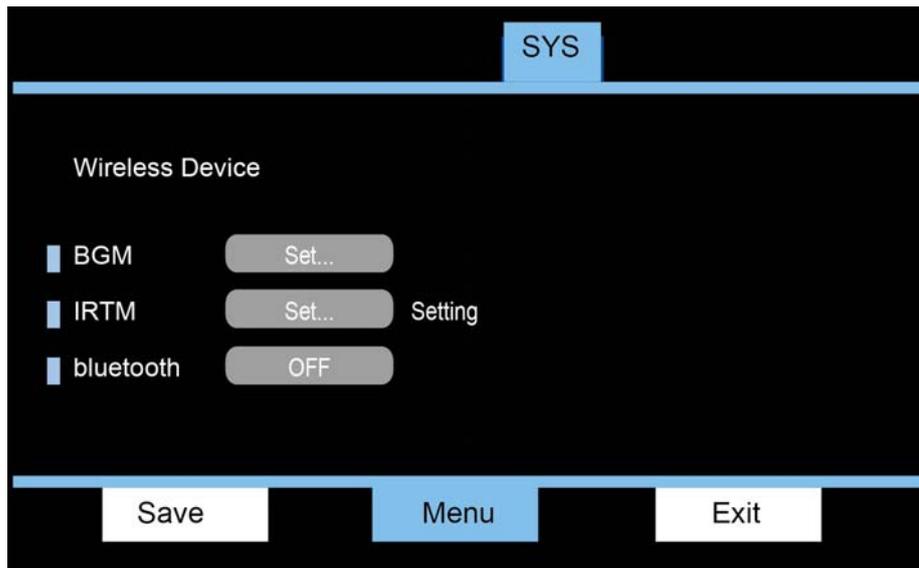
Infrared Thermometer

Before using the thermometer for the first time, be sure to perform Wireless Device setup below.

1. Touch “Set” for IRTM.



2. “Setting...” is displayed. The monitor is ready for identification.



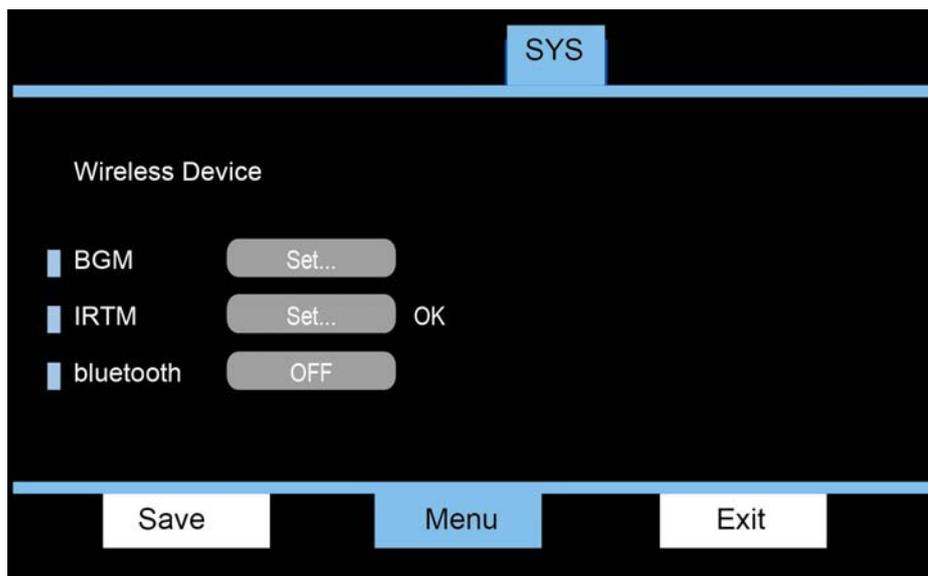
- Turn on the thermometer.



- Put the IR thermometer into the thermometer holder.



- “OK” is displayed when the meter is identified.



- Bluetooth**

PC	Turn on Bluetooth for data transmission in PC mode
Print	Turn on Bluetooth for data transmission in Print mode
OFF	Turn off Bluetooth. (default)

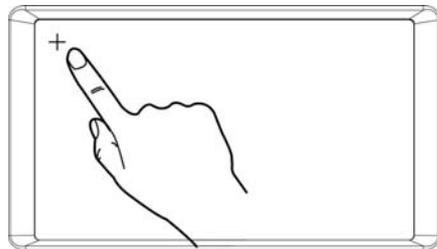
Note:

Make sure the distance between the monitor and the wireless device is less than 10 m without any barrier in between. If you still cannot pair or connect the monitor, try to change the position.

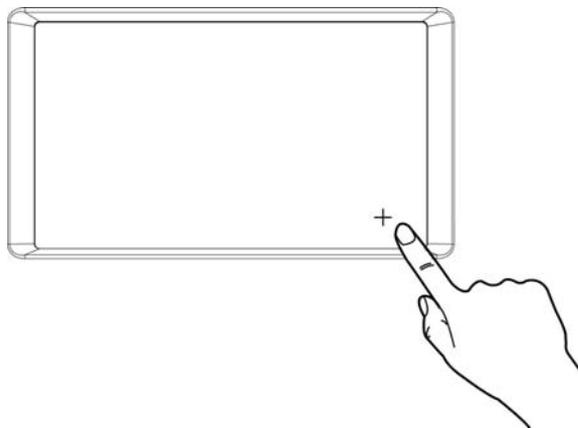
- **Touch pad**

If the monitor does not correctly respond to touch input, please perform the following steps to do touchpad calibration.

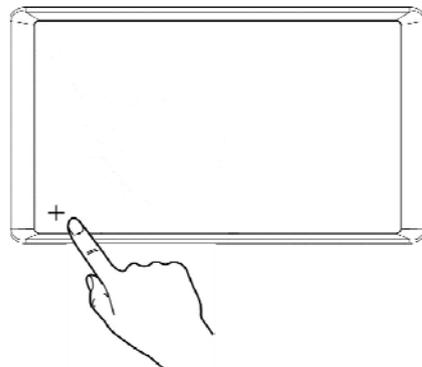
STEP 1: Touch “+” icon on the upper-left corner.



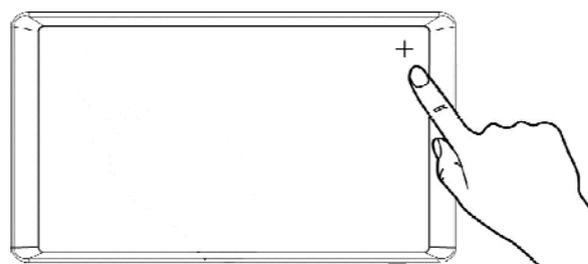
STEP 2: Touch the lower-right corner.



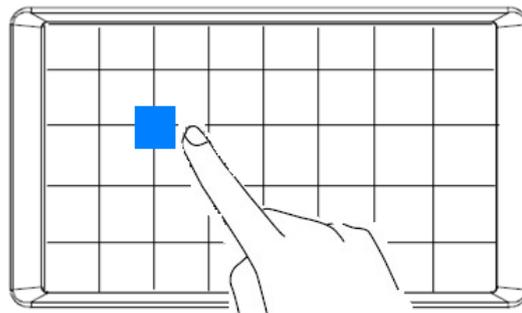
STEP 3: Touch “+” on the lower-left corner.



STEP 4: Touch “+” on the upper-right corner.

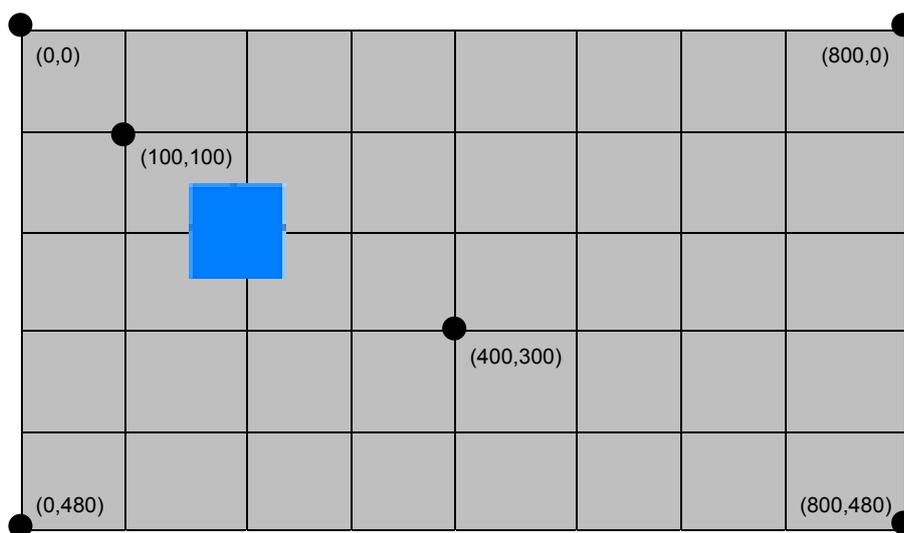


STEP 5: Touch the blue area and the calibration is done.



Note:

In STEP 3, before you touch the blue area (200 ± 30 , 200 ± 30); you can touch to test the touch screen accuracy. The coordinate of the touched point will be displayed on the upper-left corner of the blue area.

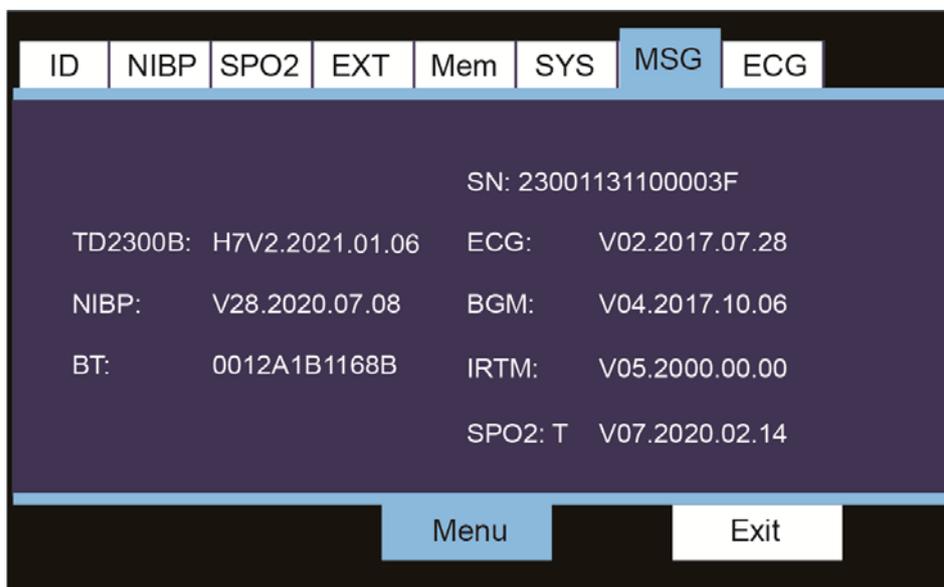


Note:

When the calibration is done, you will see the monitor main display area as above. After calibration, in case of the monitor still cannot respond correctly after calibration, please contact customer service.

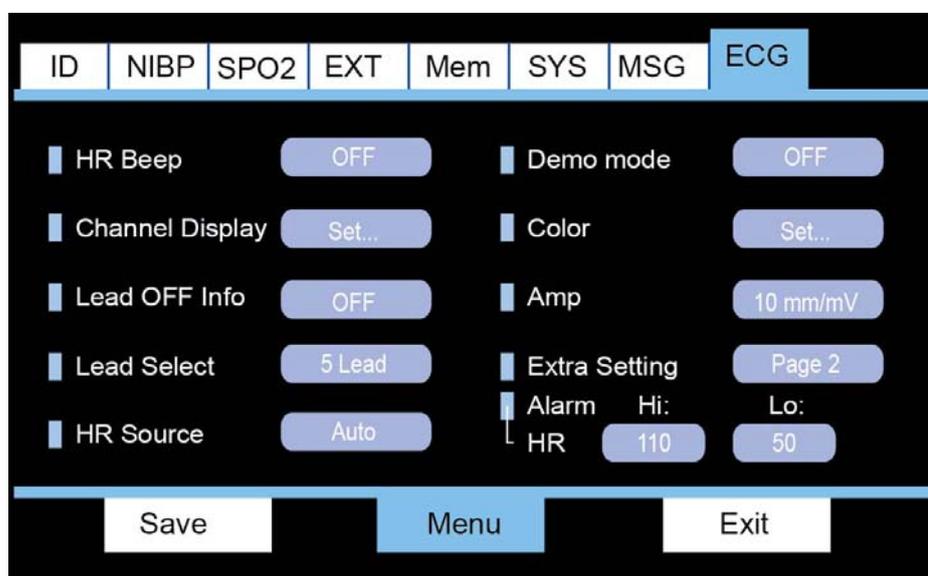
MSG

You can see the Vital Signs Monitor firmware version, ECG firmware version, BGM firmware version, IRTM firmware version, BPM firmware version and SpO₂ firmware version and LOG (history of configuration changes) here.



ECG

Set up the ECG function.



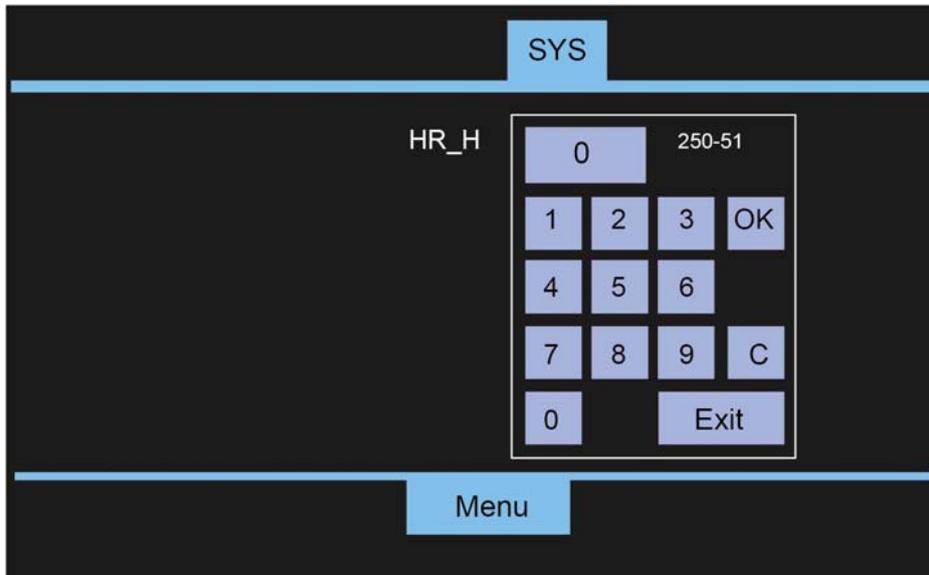
The settings are described as below.

	ECG setting	Description
HR Beep	On	The monitor beeps as the pulse goes.
	Off (default)	The monitor does not beep along with the pulse.
Lead off Info	Off (default)	Setting for Lead off Alarm
	On	
Lead Select	5 Lead (default)	Setting for Lead wires
	Off	
HR source	SpO ₂	Take the pulse rate from SpO ₂ measurement
	NIBP	Take the pulse rate from blood pressure measurement
	ECG	Take the pulse rate from ECG pressure measurement

	Auto (default)	The monitor automatically switches
Demo mode	OFF (default)	Setting view the demo waveform
	ON	
Amp	5 mm/mv	Setting vertical scales (Selectable for Print out only)
	10 mm/mv(default)	

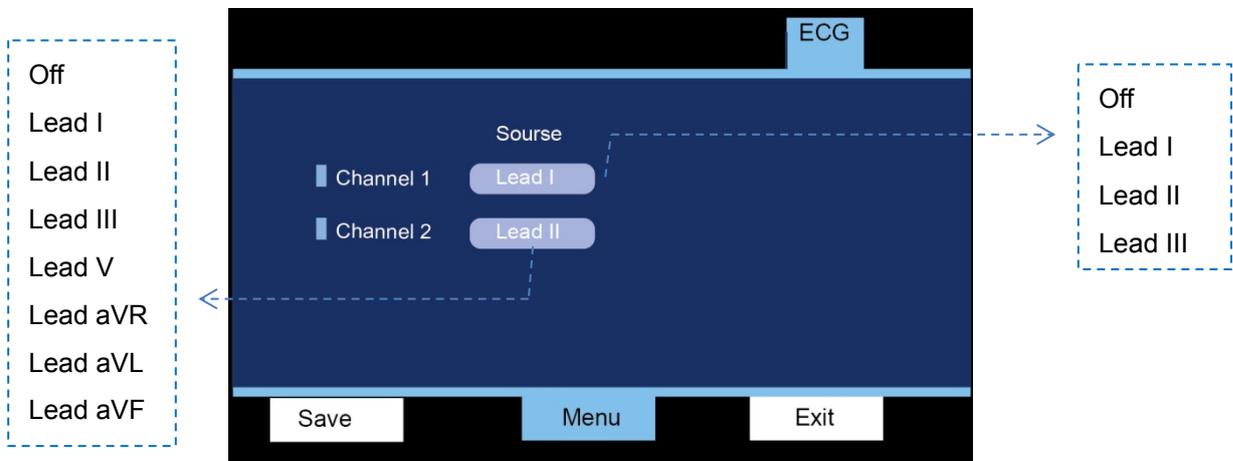
- **Alarm HR**

Touch the numbers to key in. Touch “OK” to input the weight number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving. Input range: 250-51 (If out of this range, touching “OK” does not function)



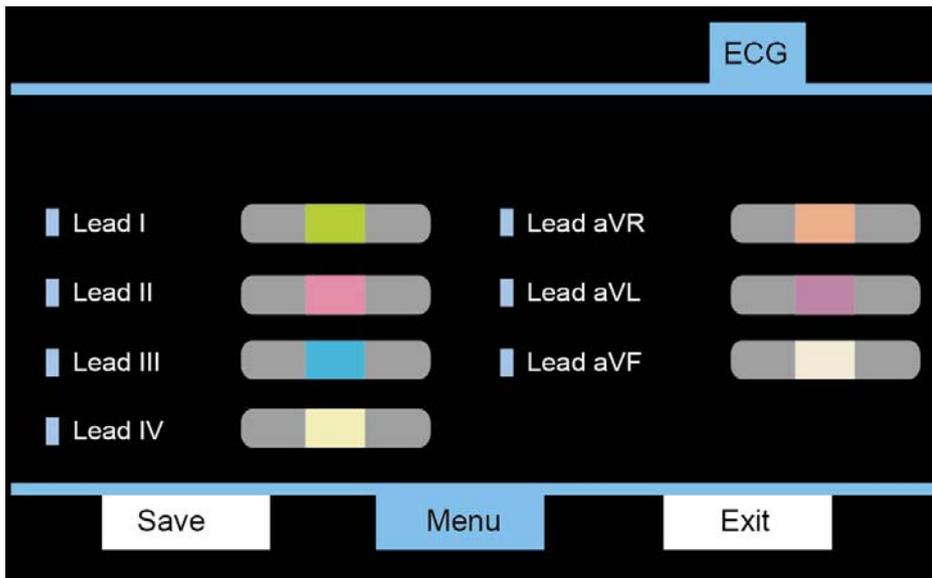
- **Channel Display**

ECG channel display settings are described below. When selecting 5-lead cable option, the device will display two channel output



- **Color**

ECG waveforms color settings are described below. Based on ambient light, adjust the colors feasible for graphic display



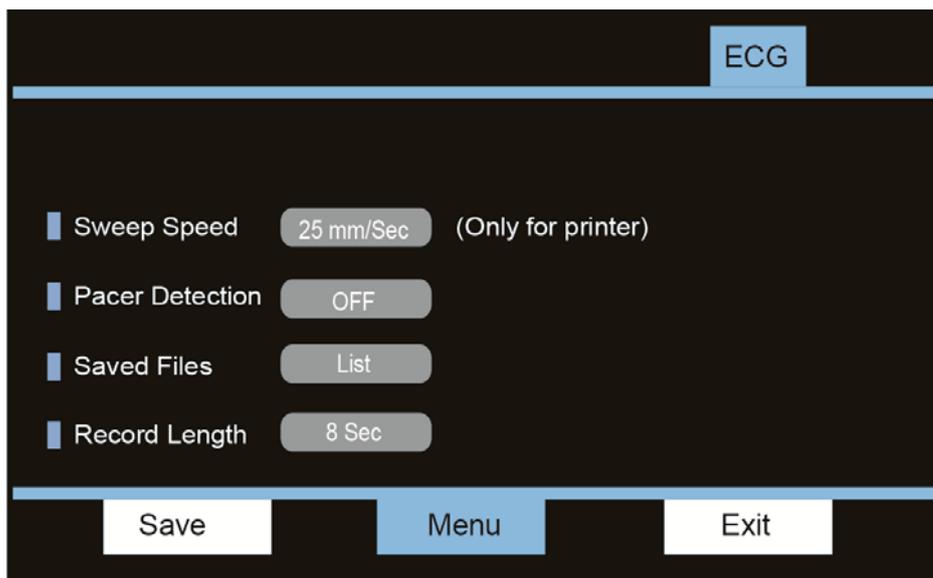
- **Amp**

For setting up amplitude, please touch Amp selection field to change the setting.

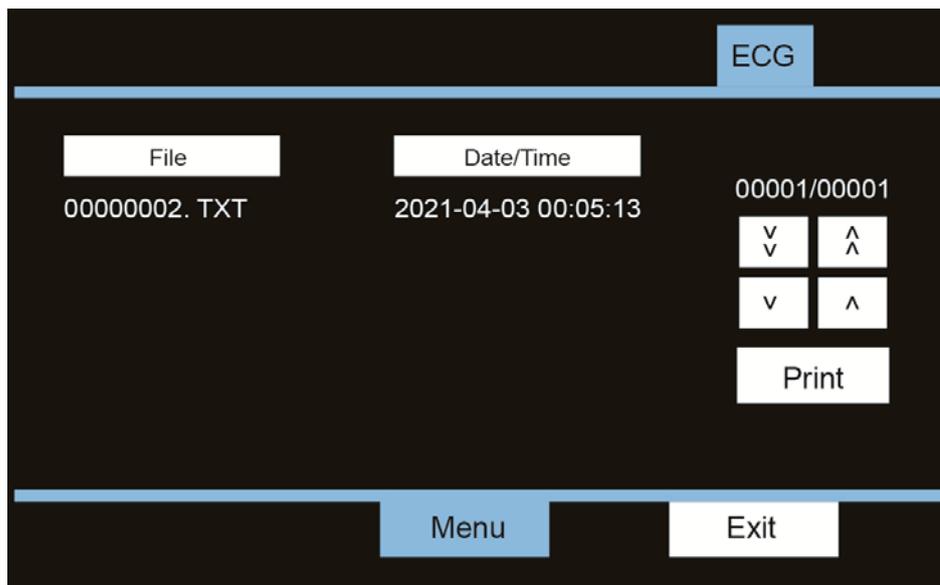
- **Extra Setting**

For setting up sweep speed, please select extra setting to bring up page 2 and tap Sweep Speed field to change the setting.

For ECG saving function, the record length for data saving can be selected as 8, 20, 30 and 60 Sec.



Saved Files shows the recorded lists as follow.



PERFORM MEASUREMENTS

Before taking measurements, make sure all accessories are firmly connected into the instrument.

SpO₂ Measurement

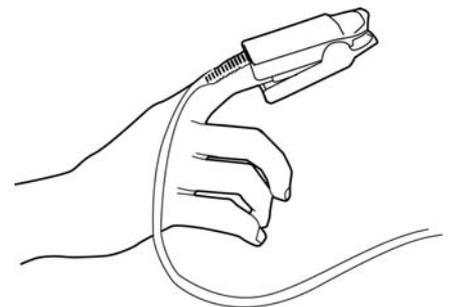
Affecting Factors

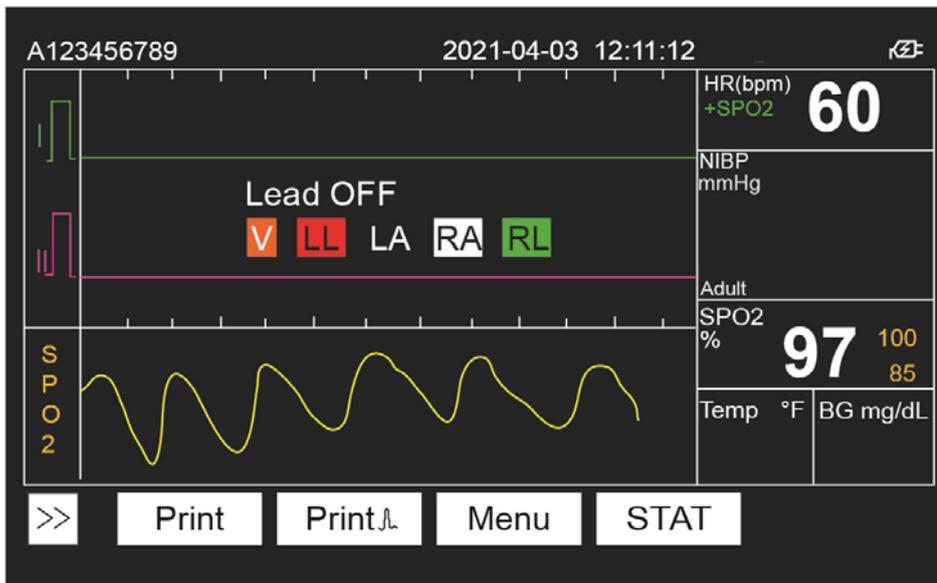
The following factors may lead to inaccurate results:

- Excessive ambient light
- Excessive motion
- Anemia or low hemoglobin concentrations
- Fingernail polish
- Arterial catheters, blood and infusion lines, etc.
- Cardiovascular dyes
- Improper sensor use
- Incorrect sensor
- Electrosurgical interference
- Patient with poor perfusion
- Venous pulsations

Taking measurement

1. Clip on patient's finger as shown in figure. Please make sure that the patient's finger is inserted to touch the inner bottom of the probe. Once the probe is inserted, the monitor will display "Please check the probe!"
2. Wait for 6 to 10 seconds and the monitor will continuously show the waveforms and the result of SpO₂ and pulse rate until the probe is removed.





3. Check and relocate the sensor frequently (every 2 hours) to prevent skin deterioration.
4. Remove the sensor, the monitor will display the last SpO₂ reading for 30 seconds.

NOTE:

- The monitor will display “Probe disconnect!” if the sensor is not connected properly.
- If the result is out of range, the alert alarm will keep beeping, and the SpO₂ result will turn into red and start blinking.
- When the oximeter is turned on for normal operation, the unit will check if the oximeter is ready for use. If probe does not connect to oximeter, the SpO₂ indicator will appear orange light. If probe does not touch the subject’s measurement site or the signal is unstable, the SpO₂ indicator will turn orange light.
- The waveforms of SpO₂ and pulse rate are normalized.
- Adjusting alarm settings is only possible when the monitor is in setting mode. For every power on in which alarm settings have not been recalled or adjusted in Setup mode, the default alarm settings remain in effect.

Item	Default Increments	Adjustment Options	Increments
SpO ₂ High	Off	Off, 91-100	1%
SpO ₂ Low	Off	Off, 85-95	1%

- Check the probe application site frequently to determine circulation, positioning and skin sensitivity. The recommended maximum application time at a single site is 4 hours.
- The data average for minute heart rate is 8 seconds; the data update period is 1 sec.
- The accuracy for heart rate meter is ±1% and there is no response to irregular rhythm detected.
- The response time of heart rate meter to change in heart rate is 8 seconds.
- The time to alarm for tachycardia waveforms is immediate.

WARNING:

- Do **NOT** use with the instruments which are not specified by the manufacturer, as this may lead to inaccurate results.

- Skin irritation or ulceration may occur if applying the sensor to the same location continuously for a long period of time. To prevent this condition, it is recommended moving the sensor application site every 2 hours, or more often if the patient is uncomfortable.

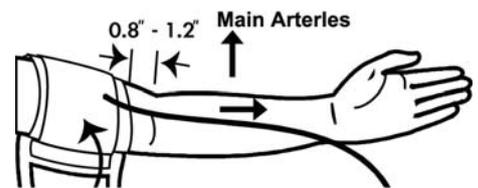
NOTE:

- Misapplication of the SpO₂ probes with excessive pressure for prolonged periods can induce pressure injury.
- A functional tester cannot be used to assess the accuracy of the SpO₂ probe or the SpO₂ monitor.

Blood Pressure Measurement

Before Measurement

1. Sit down for at least 10 minutes before taking a measurement.
2. Place your elbow on a flat surface. Relax your hand with the palm facing up.
3. Wrap and tighten the cuff above your elbow. The red line on the edge of the cuff should be approximately 0.8" to 1.2" (2 cm to 3 cm) above your elbow. Align the tube over the main arteries on the inside.
4. Make sure the cuff is about the same height as the location of your heart.



NOTE:

The suggested cuff size is longer than 9.8" (25 cm).

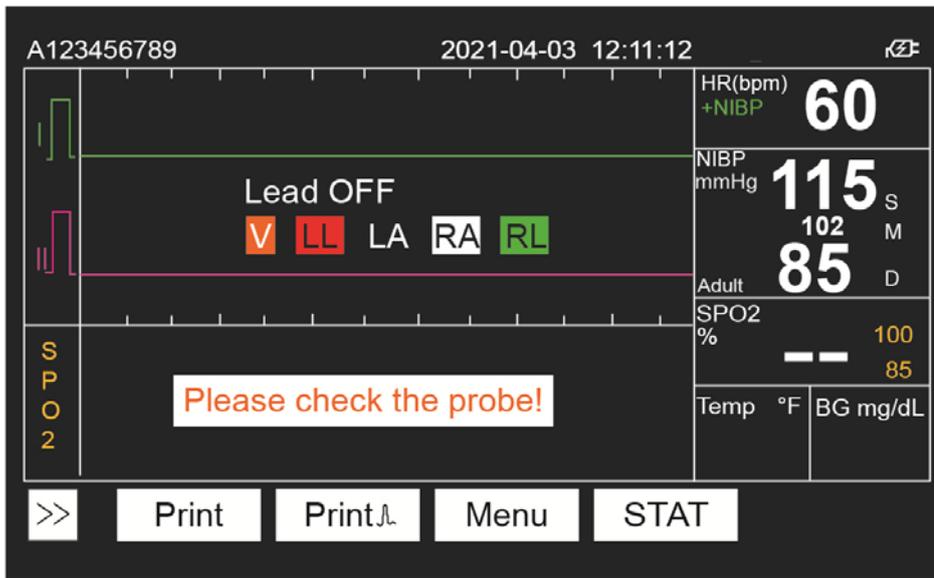
WARNING:

- Excessive tightness may cause venous congestion and discoloration of the limb.
- If the cuff is wrapped too loose or the hose is twisted, inaccurate results may occur.

Taking Measurement

Always apply the pressure cuff before turning on the meter.

1. Press **PUMP**, the cuff will begin to inflate automatically with indicator light up during the measurement.
2. After the measurement, the monitor displays the systolic pressure, diastolic pressure, mean arterial pressure (MAP) and pulse rate.

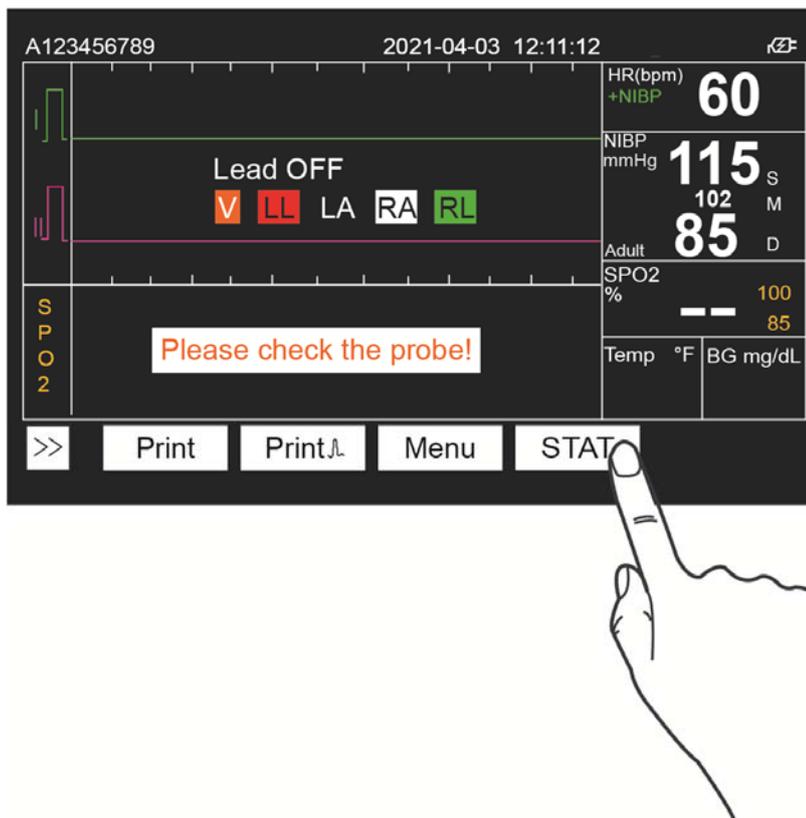


NOTE:

- If you press **PUMP** during measurement, the measure will be stopped.
- If the result is out of range, the alert alarm will keep beeping, and the result will turn into red.
- If the meter has detected a big movement or great vibration(s) of the arm during the measurement and cannot produce results, the meter will then re-pumps automatically and take another measurement. Please remain still while taking the measurement.

STAT

Under STAT mode, the NIBP measurement will be taken consecutively in 5 minutes.



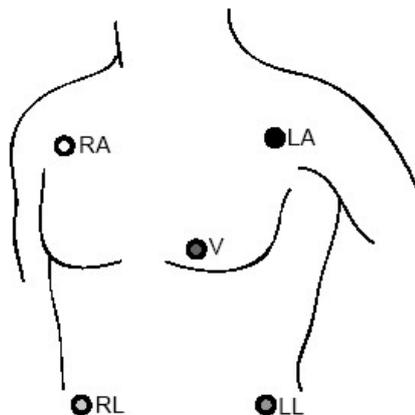
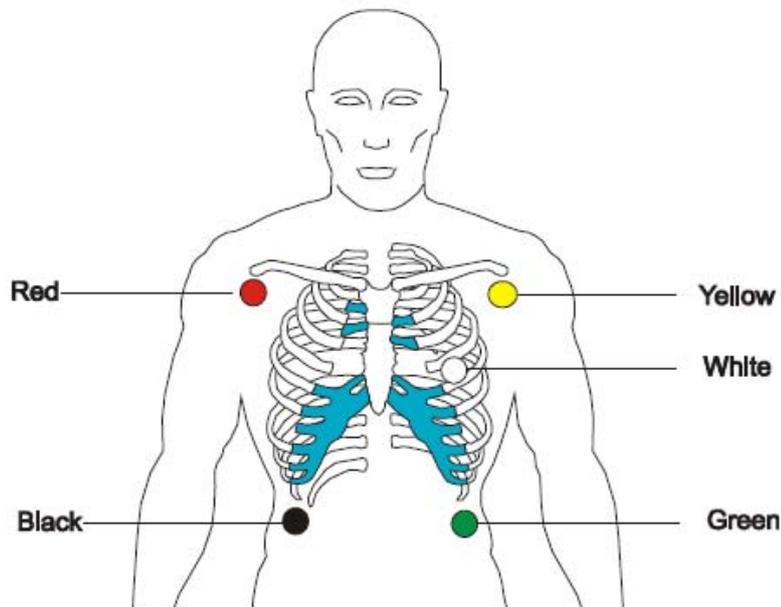
ECG Measurement

IMPORTANT SAFETY PRECAUTIONS - READ BEFORE USE

- Our electrode is color-coded according to International Electrotechnical Commission (IEC) to eliminate the confusion.
- **VSM100 Pro** Vital Signs Monitoring system provides 5-lead for user's selection, please follow the guidelines below.

1. Placement of electrodes for the patient without artificial pacemaker

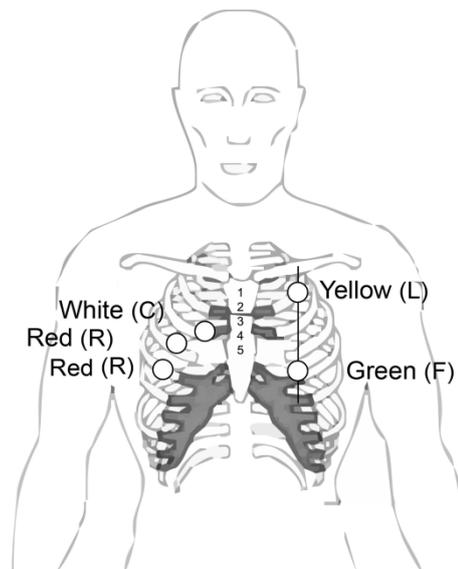
5-lead electrodes placement:



2. Placement of electrodes for the patient with artificial pacemaker

An artificial pacemaker is a medical device that uses electrical impulses to regulate the heartbeat. If the patient is implanted with an artificial pacemaker, the placement of electrodes is different. Please follow the guidelines below.

5-lead electrodes placement:



The following table shows IEC (International Electrotechnical Commission) and AHA (American Heart Association) regulations of color-coded electrodes.

System	IEC (Europe)		AHA (U.S.)	
	Electrode identifier	Color	Electrode identifier	Color
Limb	R	Red	RA (right arm)	White
	L	Yellow	LA (left arm)	Black
	F	Green	LL (left leg)	Red
Chest	C1	White/Red	V1	Brown/Red
	C2	White/Yellow	V2	Brown/Yellow
	C3	White/Green	V3	Brown/Green
	C4	White/Brown	V4	Brown/Blue
	C5	White/Black	V5	Brown/Orange
	C6	White/Violet	V6	Brown/Violet
Neutral	N	Black	RL (right leg)	Green

Before Measurement

1. Shave the hair where the electrodes will be placed.
2. Using cotton moistened with 70% alcohol to clean the area where the electrodes will be placed and let it air dry.
3. Make sure the electrodes are sticky enough to attach on the patient's skin. Please do not reuse the electrodes.

Taking Measurement

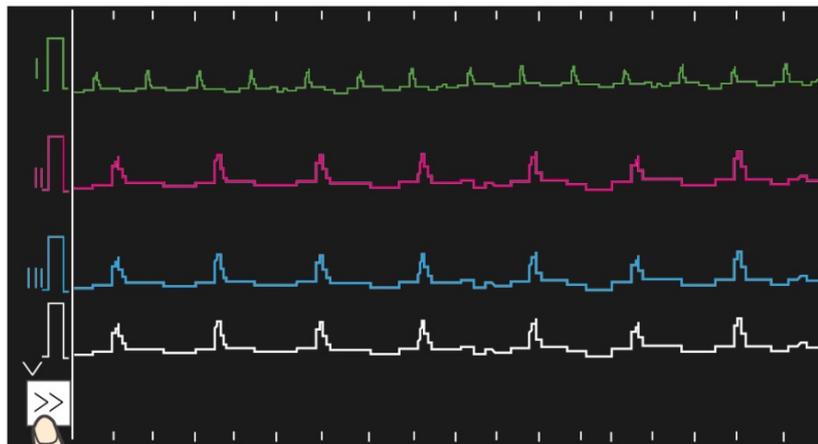
You must enter ECG setting page to confirm your settings every time before taking a measurement.

1. Attach the electrodes to the appropriate locations according to our guideline.
2. Wait for few seconds and the monitor will continuously show the ECG waveforms.

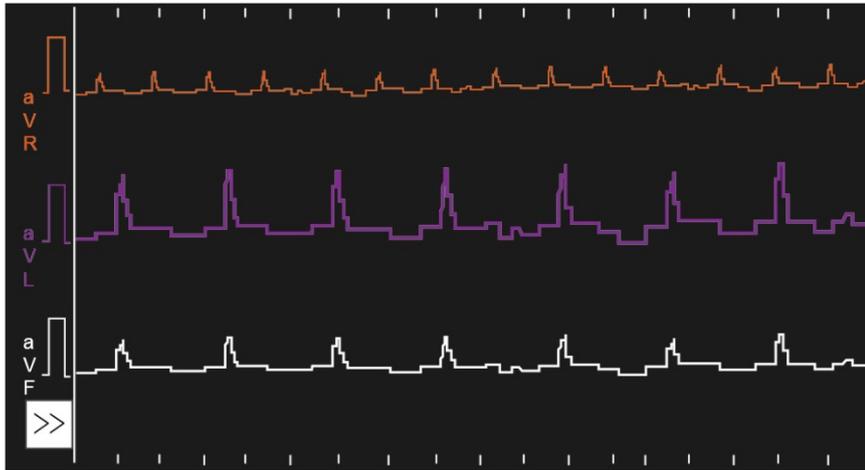
- For 5-lead, the monitor will display “Lead I” and “Lead II” signals.



- Press “>>” once to see “Lead I”, “Lead II”, “Lead III”, and “Lead V” signals.

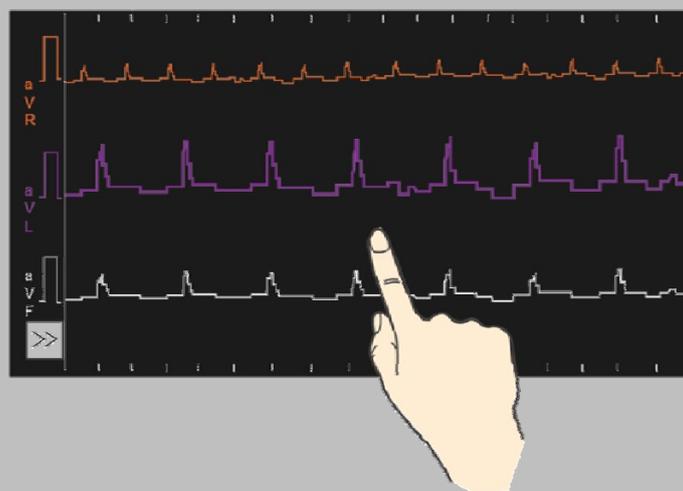


- Press “>>” again to see “aVR”, “aVL” and “aVF” signals.



NOTE:

- If you would like to pause and look into details, simply touch the screen to pause for 10 seconds.
- The monitor will display “Lead-off” and the alert alarm will keep beeping if the electrode is not attached properly.
- The capability for rejecting the interferential wave is that the amplitude and pulse width of pacemaker pulses is 10mV and 1ms.
- The alarm cannot be turned off, but can be temporarily silenced by pressing the SILENCE key. The recovery time is 2 minutes. Only audible alarms can be disable.
- While applying a current to the patient, one method of voltage comparison is set up for “Lead-off” sensing.
- The maximum T-wave amplitude rejection capability can be 1Mv (100%).
- The ECG heart rate measurement is functioning well even the pacemaker pulse is below +10mV.
- ECG can detect QRS amplitude even if the tall T-wave amplitude is same as QRS amplitude (100%), which ECG measurement is functioning well.



WARNING:

- Skin irritation and the electrode gel dry-out may occur if you apply the electrodes to the same location continuously for a long period of time. It is recommended replacing the electrodes at least every 48 hours.

Glucose Measurement

IMPORTANT SAFETY PRECAUTIONS - READ BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.
4. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
5. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
6. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
7. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
8. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
9. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Before You Begin

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values.
- Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to incorrect results.
- We do not recommend using this product on severely hypotensive individuals or patients in shock.
- The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L).

The approximate calculation rule for conversion of mg/dL in mmol/L is:

mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example;

1) $120 \text{ mg/dL} \div 18 = 6.6 \text{ mmol/L}$

2) $7.2 \text{ mmol/L} \times 18 = 129 \text{ mg/dL}$ approximately.

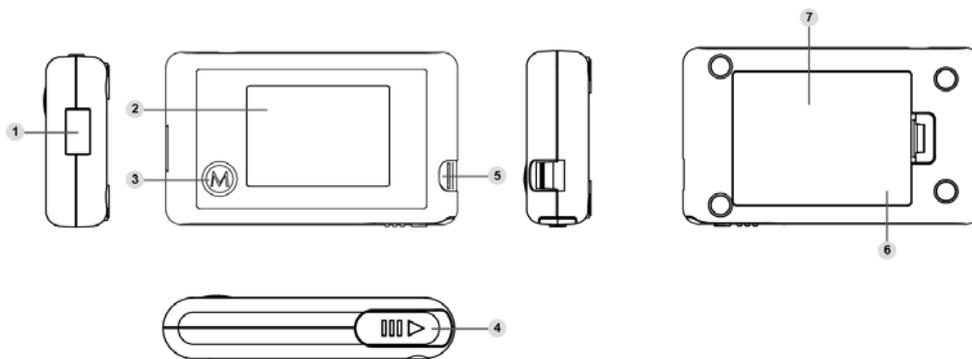
Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by health care professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples from the finger. It should not be used for the diagnosis or screening of diabetes. Professionals may test with capillary and venous blood sample. The system is only used with single-use, auto-disabling lancing device.

Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. The system uses enzyme of FDA-dependent glucose dehydrogenase (FAD-GDH) from *E.coli*.

Meter Overview



1. Data Port

2. Display Screen

3. M Button

Enter the meter memory and mute the reminder alarm.

4. Test Strip Ejector

Eject the used strip by pushing up this button.

5. Test Strip Slot

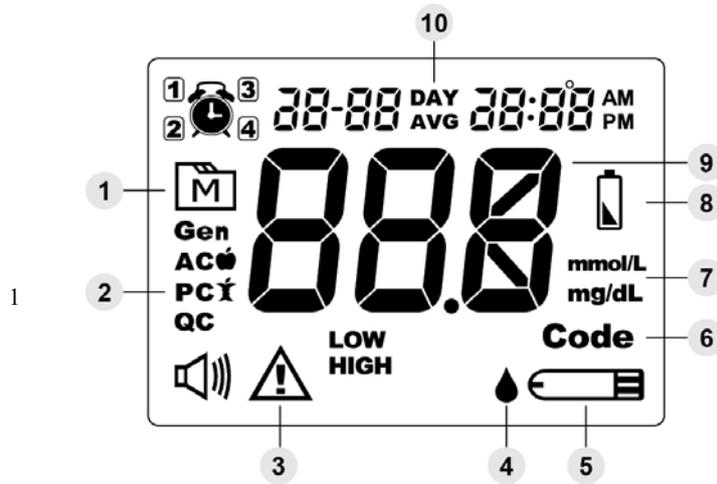
Insert a test strip here to turn the meter on for testing.

6. Set Button

Enter and confirm the meter settings.

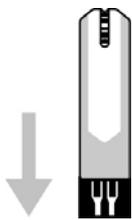
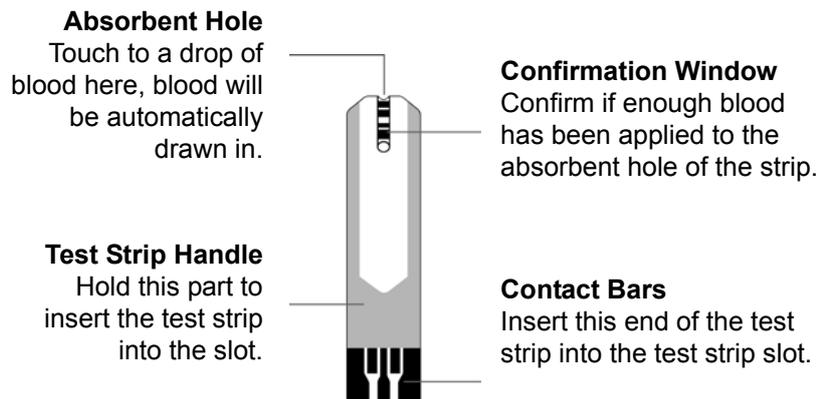
7. Battery Compartment

Display Screen



- | | |
|-----------------------|-----------------------|
| 1. Memory Mode Symbol | 6. Code |
| 2. Measuring Mode | 7. Measurement Unit |
| 3. Error Warning | 8. Low Battery Symbol |
| 4. Blood Drop Symbol | 9. Test Result |
| 5. Test Strip Symbol | 10. Day Average |

Test Strip



ATTENTION:

The front side of test strip should face up when inserting test strip.

Test results might be wrong if the contact bar is not fully inserted into the test slot.

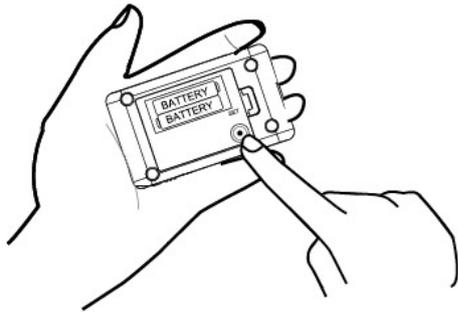
NOTE:

The **VSM100 Pro** monitor should only be used with **VSM100 Pro** Test Strips. Using other test strips with this meter may produce inaccurate results.

Setting the Meter

Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete the steps below

and have your desired settings saved.



Entering the Setting Mode

Start with the meter off (no test strip inserted).

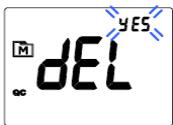
Press **SET**.

Warning: healthcare professionals must wear gloves



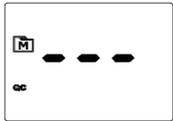
1. Setting the unit of measurement

Press M to switch between mg/dL and mmol/L. Press **SET**.



2. Deleting the QC memory

With “dEL”, “QC” and a flashing “no” on the display, press M and select “no” to keep the QC results in memory then press SET to skip.



To delete all the QC results, press M and select “yes” to delete all the QC memory records.

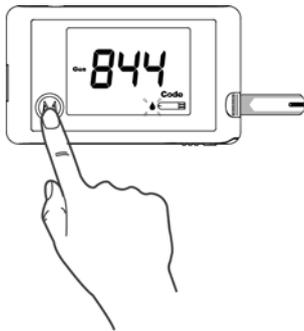
Congratulations! You have completed all settings!

The Four Measuring Modes

The meter provides you with four modes for measuring, General, AC, PC and QC.

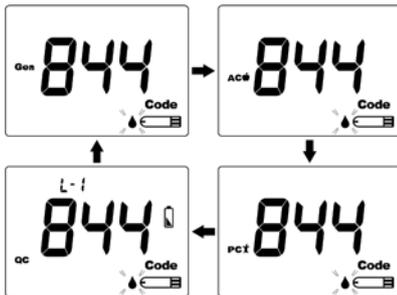
MODES	USE WHEN
General (displayed as "Gen")	any time of day without regard to time since last meal
AC	no food intake for at least 8 hours
PC	2 hours after a meal
QC	testing with the control solution

You can switch between each mode by:



1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing "8", "4", "4" and Gen.

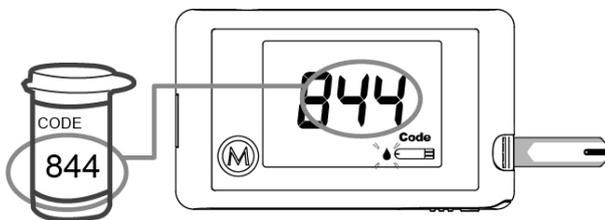
Warning: healthcare professionals must wear gloves



2. Press **M** to switch between General, AC, PC and QC mode.

Before Testing

Checking the Code Number



You need to make sure that the code number displayed on the meter matches the number on the test strip vial before you proceed. If it matches, you can proceed with your test. If the codes do not match, please stop testing and repeat the calibration procedure. If the problem persists contact Customer Service for help.

NOTE:

- The code number on the display is only for your reference, it may not be actual code for this meter.

Warning:

- It is important to make sure that the LCD displayed code is the same as the code on the test strip vial before testing. Failure to do so will get inaccurate results.
- If the displayed code on LCD is not the same as the one on the test strip vial, and the code number cannot be updated, please contact customer service for assistance.

Control Solution Testing

Our Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

Do a control solution test when:

- you first receive the meter,
- at least once a week to routinely check the meter and test strips,
- you begin using a new vial of test strips,
- you suspect the meter or test strips are not working properly,
- your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate,
- practicing the testing process, or
- you have dropped or think you may have damaged the meter.

Test strips, control solutions, or sterile lancets may not be included in the kit (please check the contents on your product box). They can be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

Performing a Control Solution Test



1. Insert the test strip to turn on the meter

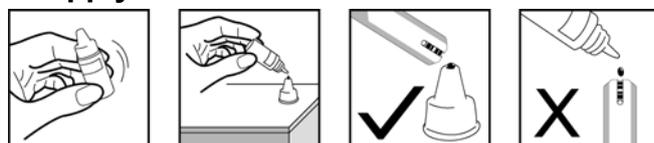
Insert the test strip into the meter. Wait for the meter to display “CHK” and “” and “”.



2. Press M to mark this test as a control solution test

With “QC” displayed, the meter will store your test result in memory under “QC”. If you press **M** again, the “QC” will disappear and this test is no longer a control solution test.

3. Apply Control Solution



Warning: healthcare professionals must wear gloves

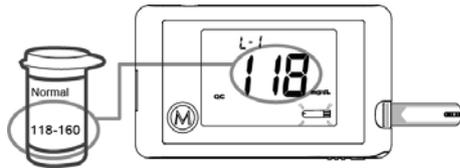
Shake the control solution vial thoroughly before use. Squeeze out the first drop and

wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.

NOTICE:

- To avoid contaminating the control solution, do not directly apply control solution onto a strip.

4. Read and Compare the Result



After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, the meter will ask you to repeat the control solution test until it falls within this range and then you can go to next level.

Out-of-range results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do **NOT** test your blood. Contact the local customer service or place of purchase for help.

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the **MAINTENANCE** section for important information about your control solutions.

Testing With Blood Sample

Warning:

To reduce the chance of infection:

- Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples.
- Wear a new pair of clean gloves before testing each patient. Change gloves between patients.
- Never share a safety lancet.
- Only auto-disabling, single use safety lancet may be used with this device.
- Avoid getting hand lotion, oils, dirt, or debris in or on the safety lancet.

We recommend you perform disinfection procedures between each patient. Please refer to the section Cleaning and Disinfection Procedures for complete instructions. After disinfection, used gloves should be removed and hands washed before proceeding to

the next patient.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the glucose value obtained.

Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- **Wash and dry your hands before starting. Put on a new pair of gloves.**
- Select the puncture site at fingertips.
- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

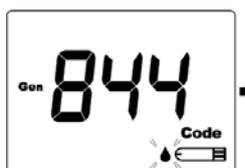
Fingertip testing

Press the safety lancet firmly against the lower side of patient's fingertip.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

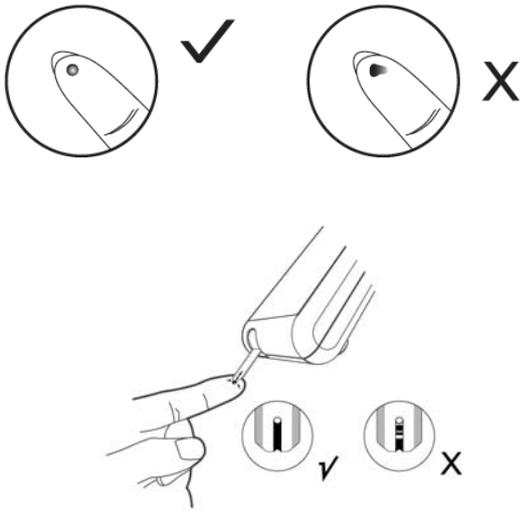
Performing a Blood Glucose Test



1. Insert the test strip to turn on the meter

Wait for the meter to display “CHK” and “”.

2. Select the appropriate measuring mode by pressing M.



3. Obtaining a blood sample

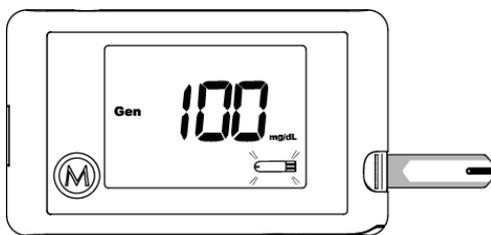
Use the pre-set lancet to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab. The size of the drop should be at least as big as • (actual size), which is 1.1 microliter (μL) of volume. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.

4. Apply the sample

Gently apply the drop of blood to the absorbent hole of the test strip at a titled angle. Confirmation window should be completely filled if enough blood sample has been applied. Do **NOT** remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.



5. Read Your Result

The result of the blood glucose test will appear after the meter counts down to 0.

6. Eject the used test strip

Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.



Warning: healthcare professionals must wear gloves

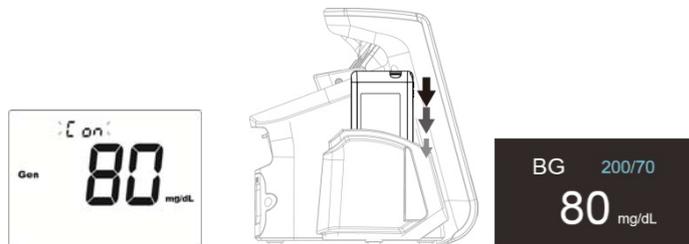
Always follow the instructions in the safety lancet.

WARNING:

- The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

7. Data transmission

After removing the test strip, the flashing “Con” will appear along with the blood glucose test result, indicating that you need to put the meter into the holder in order to transmit the result.



Maintenance

Battery

Your meter comes with two 1.5V AAA size alkaline batteries.

● **Low Battery Signal**

The meter will display one of the messages below to alert you when the meter power is getting low.



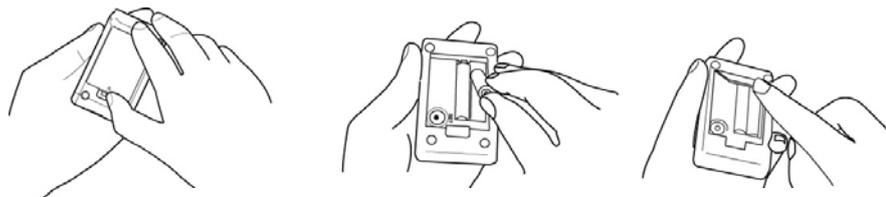
1. The “” symbol appears along with display messages: The meter is functional and the result remains accurate, but it is time to change the battery.



2. The “” symbol appears with E-b,  and low: The power is not enough to do a test. Please change the battery immediately.

● **Replacing the Battery**

To replace the battery, make sure that the meter is turned off.



Warning: healthcare professionals must wear gloves

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old battery and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover. If the battery is inserted correctly, you will hear a

"beep" afterwards.

NOTE:

- Replacing the battery does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

Caring for Your Meter

To prevent the meter and test strips from dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

When to clean and disinfect the meter

All surface of meter if visibly soiled must be physically cleaned to remove gross soil. Disinfect the meter between each patient to prevent infection.

How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt, blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure below. Do **NOT** use organic solvents to clean the meter.

We recommend for meter cleaning and disinfection you should use the disinfecting wipe/towelette from below.

✓ Micro-Kill+™ (Micro-Kill Plus™) by Medline (EPA Reg. No. 59894-10-37549)
To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit www.medline.com. You can also purchase at www.amazon.com.

● **Disinfecting Procedures**

1. Put on non-sterile gloves.
2. Take out one disinfecting wipe from the package and squeeze out any excess liquid in order to prevent damage to the meter.
3. Wipe all meter's exterior surface display and buttons. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. Follow the instructions on the package label of disinfecting wipe.



Warning: healthcare professionals must wear gloves

4. Remove the wipe. Allow the meter surface to dry completely.
5. Discard the used wipes and never reuse them.
6. Remove and discard gloves in appropriate receptacles and wash hands.

After disinfection, remove the used gloves and wash hands before proceeding to the next patient.

Each cleaning and disinfection cycle includes a pre-cleaning step with one wipe and a disinfection step with a second wipe.

This device has been validated to withstand up to 10,000 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 9 cleaning and disinfection cycles per day over 3 years, the expected life of the device. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Improper system cleaning and disinfection may result in meter malfunction. Stop using the meter if you see any signs of deterioration, for example, LCD display cracks or becomes cloudy, buttons no longer function, or outer casing cracks. If you have any question. Please contact customer services for a replacement meter if any of the signs of deterioration are noticed.

NOTE:

- Do NOT clean and disinfect the meter while performing tests.
- Please follow the instructions on the package label of Micro-Kill+™ disinfecting wipes for safe use of the wipes
- Do NOT allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry

For more information on the risk of blood-borne pathogen transmission from blood glucose meter and safety lancet, please refer to:

“FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

“CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)
<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

● **Meter Storage**

- Storage condition: -4°F to 140°F (-20°C to 60°C), 10% to 85% R.H., non-condensing.
- Always store or transport the meter in its original storage case.
- Avoid dropping and strong impact.
- Avoid direct sunlight and high humidity.

● **Meter Disposal**

The used meter should be treated as contaminated that may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

Caring for Your Test Strips

- Storage conditions: 35.6 °F to 89.6 °F (2°C to 32°C), 10% to 85% R.H., non-condensing.
- Do **NOT** freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Write the opening date on the vial label when you first opened it. Discard remaining test strips after 3 months.
- Do not use test strips beyond the expiry date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiry date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 68°F to 77°F (20°C to 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 35.6°F to 86°F (2°C to 30°C). Do **NOT** freeze.

System Troubleshooting

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

Result Readings

MESSAGE	WHAT IT MEANS
Lo	< 10 mg/dL (1.1 mmol/L).
Hi	> 600 mg/dL (33.3 mmol/L).

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please contact customer services.

3. If the control solution testing result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 68°F to 77°F (20°C to 25°C) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.

Detailed Information

The meter provides you with plasma equivalent results.

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%^{*1}. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes (mmol/L)
Fasting ^{*2} and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

^{*1} American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020 Jan; 43(Supplement 1): S14-S31.
<https://doi.org/10.2337/dc20-S002>

^{*2} Fasting is defined as no caloric intake for at least 8 hours.

Temperature Measurement

Before You Begin

IMPORTANT SAFETY PRECAUTIONS - READ BEFORE USE

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the thermometer is used by, on, or near children, handicapped persons or invalids.
2. Use the thermometer only for the intended use described in this manual.
3. Do not use the thermometer if it is not working properly, or if it has suffered any damage.
4. Do not use accessories which are not supplied or recommended by the manufacturer.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Cautions and Warnings

- As with any thermometer, proper technique is crucial to getting accurate temperature readings. Please read this manual thoroughly and carefully before using.
- Always operate the thermometer in an operating temperature range 50°F to 104°F (10°C to 40°C), and relative humidity 10% to 85%, non-condensing.
- Always store the thermometer in a cool and dry place: temperatures between -4°F to 140°F (-20°C to 60°C) relative humidity 10% to 85%, non-condensing. Avoid direct sunlight.
- Avoid dropping the thermometer from a height or strongly hitting it with a hard object.
- For proper hygiene, do not re-use probe cover. Damaged probe cover may result in error display.
- Do not disassemble the thermometer.
- Basic safety precautions should always be observed, especially when the thermometer is used on or near children and disabled persons.
- This thermometer is not intended to be a substitution for consultation with your physician.
- The skin/surface scan temperature serves as a reference only. It cannot be a judgment on fever.
- Temperature of left and right ear may differ. Always measure by using same ear.

Restrictions of Use

This thermometer is clinically proven to produce accurate temperature measurements. However, please be advised if you have the following situations:

- The accuracy cannot be ensured for a person who has deformity in the ear such that the thermometer probe cannot be properly inserted into the ear canal.
- The accuracy cannot be ensured when blood or drainage is found in the ear canal.
- Take temperature from the other ear if ear drops or medications have been placed in an ear.
- For a person who wears ear plug or hearing aid, remove the device and wait for 15 minutes before taking temperature.

NOTE:

- Never try to clean inside the ears. You may accidentally damage the eardrum or its surrounding tissues. Remove excess earwax only when you can reach it with a clean cloth. Consult a physician if you suspect the presence of excess earwax.

Intended Use

This innovative medical device relies on advanced infrared (IR) technology to measure temperature instantly and accurately through two convenient sites: the ear canal and the surface of the skin over the temple.

Our ear thermometer is intended for the intermittent measurement and monitoring of human body temperature from ear canal.

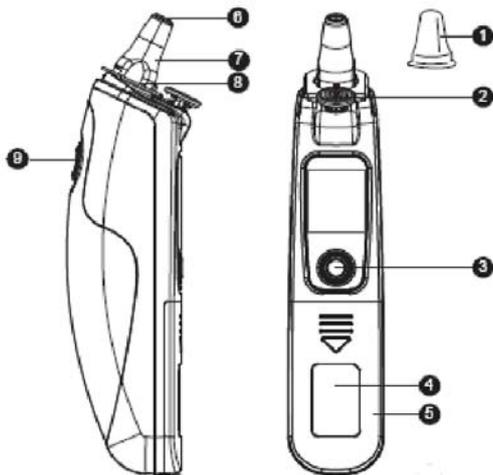
How does it work

The thermometer measures the infrared heat generated by the eardrum and its surrounding tissue or by the surface of the skin over the temporal artery. The thermometer then converts it into a temperature value shown on LCD.

NOTE:

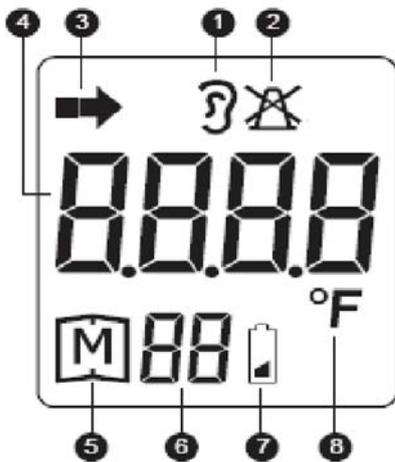
- The thermometer does not emit any infrared signal.

Thermometer Parts



1. Probe lens
2. Probe cover ejection button
3. On/Memory button
4. Manufacturing label
5. Battery cover
6. Probe lens
7. Probe
8. Probe cover detector
9. Scan button

LCD Screen

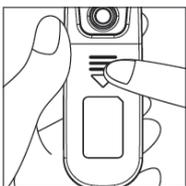


1. Ear temperature indicator
2. Probe cover missing
3. Temperature scanning in progress
4. Temperature display
5. Memory mode
6. Record numbers
7. Low battery indicator
8. Temperature unit

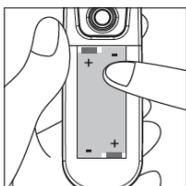
Replacing the Battery

The thermometer comes with two 1.5V AAA alkaline batteries. Replace it

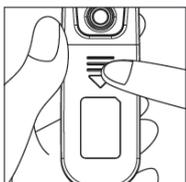
when “” appears. Please follow the steps to replace new batteries.



Step 1: Remove the battery cover.



Step 2: Place the new battery in the battery compartment and press it in until the battery is firmly secured.

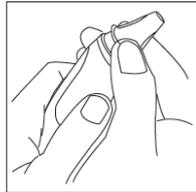


Step 3: Reattach the battery cover.

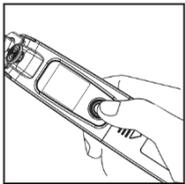
NOTE:

- Although the thermometer works when “” appears, we still recommend that you change the battery to obtain an accurate result.
- Remove the battery if stored for a long period of time.
- The battery should be kept out of reach of children. If they are swallowed, promptly see a doctor for help.

Using the Device



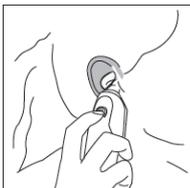
Step 1: Apply a new probe cover.



Step 2: Turn on the thermometer.
Press and release the On / Memory button. When ready, the thermometer displays the last measurement.



Step 3: Gently fit the probe into the ear canal.



Step 4: Press and release the Scan button.
Do not remove the thermometer until it beeps.



Step 5: Read the result.
“” is shown together with a temperature value.

Step 6: Eject the used probe cover.
Eject the used probe cover into trashcan by pushing the lens filter ejection button.



Step 7: Data transmission
After removing the used probe cover, you need to put the meter into the holder in order to transmit the result.

NOTE:

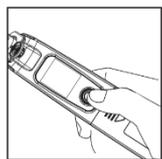
- Turn off the thermometer by pressing On / Memory button twice. It will automatically turn off if left idle for 3 minutes. If you need to take another reading, wait “” flashing before taking another measurement.
- The thermometer does not send out any infrared signal. The thermometer is an adjusted mode clinical thermometer.

Warning:

- Use only recommended probe covers. Using other manufacturers' probe covers may result in inaccurate temperature measurements or monitor errors.

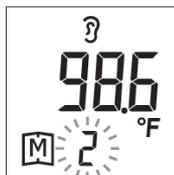
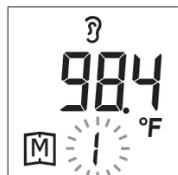
Recalling the Memory

Your thermometer stores 10 recent readings in the memory.



Step 1: Be sure the thermometer is OFF before recalling this memory.

Step 2: Press the On / Memory button to turn on the thermometer.



Step 3: Press the On / Memory button for 3 seconds to enter memory mode.

Each time you press the On / Memory button, a result will be displayed in the order of dates (latest result shown first), together with “” and number (from 1 to 10).

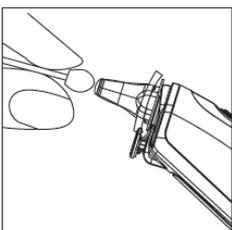
When the memory is full, the oldest result is deleted as the new one added. When the last record is displayed in the LCD, press On / Memory button again to return the first record.

Step 4:

Exit the memory.

Press the Scan button and LCD will show latest results with flashing “”. Then press On / Memory button twice to exit the memory.

Care & Cleaning



If you would like to clean the probe lens, wipe it gently with an 70% alcohol swab or soft cloth moistened with 70% alcohol. Do not attach a new lens filter within 30 minutes.

The probe is not waterproof. Please wipe with a clean and dry cotton swab to clean the probe on the inside.

The body of the thermometer is not water-resistant. Never put the

thermometer under a running tap or submerge it into water. Use a soft and dry cloth to clean it. Do not use abrasive cleaners.

Store the thermometer in a cool and dry location. Free from dust and away from direct sunlight.

ALARM AND MESSAGE

The monitor provides both audible and visible alarm indicators to alert the operator of system status changes and physiological parameter alarms.

Alarms are provided for all monitored parameters. Each parameter limit alarm condition triggers both audible and visible alarms until one of the following events occurs:

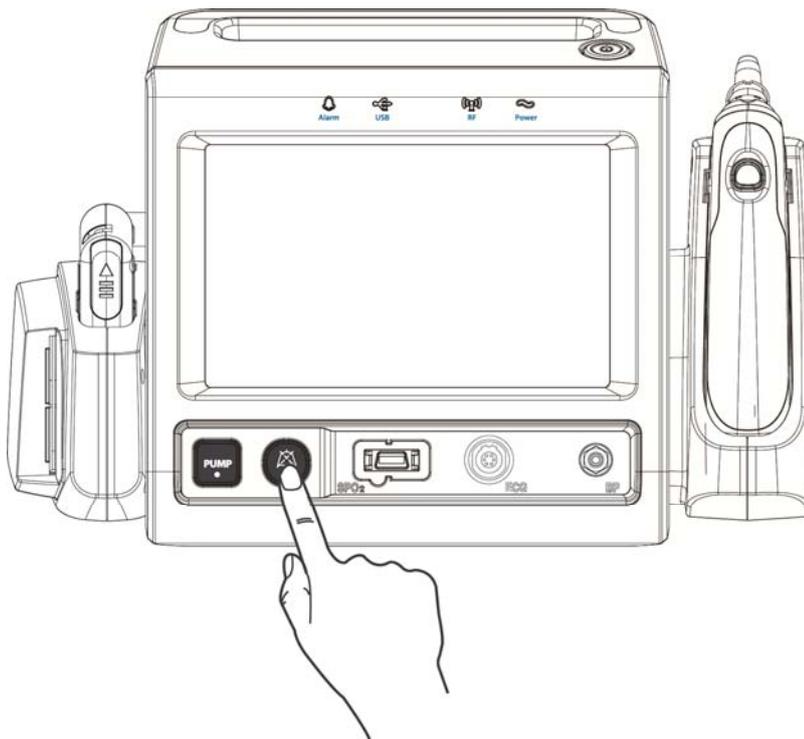
- The parameter value returns to within the alarm limit.
- The alarm limit is set beyond the present parameter value.
- The SILENCE key is pressed. (Audible alarms only)

Audible Alarms

The high priority alarm consists of a pair of bursts. Each burst consists of five tone pulses. The pair of bursts repeats every 5 seconds and sound 57 dB. The alarm indicator will light in red if presses the Alarm button.

Visible Alarms

The monitor displays visible text alarms on the screen. If a physiological parameter exceeds the high limit or falls below a low limit value, the numerical value will flash in red.



Alarm silence key

The alarm volume cannot be turned off, but can be temporarily silenced by pressing the SILENCE key. The silence interval is 2 minutes.

Response for the operator after the alarm is triggered

High priority alarm signal: The operator should stop his/her task at hand immediately

and investigate the cause of the alarm.

Low priority alarm signal: The operator may not be interrupted, but the operator is able to investigate the cause of the alarm later.

Alarm Message List

Alarms and messages for heart rate may be generated by the ECG, SpO₂ or NIBP module.

Only visual alarm: NIBP.

Both visual and audible alarm: Heart Rate, SpO₂ and ECG.

	Alarm	Priority	Description
HEART RATE	LOW (audible and visual alarm)	High	The heart rate value has dropped below the value set in the menu.
	HIGH (audible and visual alarm)	High	The heart rate value has exceeded the value set in the menu.
SpO₂	LOW SpO ₂ (audible and visual alarm)	High	The SpO ₂ value has dropped below the value set in the menu.
	HIGH SpO ₂ (audible and visual alarm)	High	The SpO ₂ value has exceeded the value set in the menu.
NIBP	HIGH SYS (Visual alarm)	Low	The systolic value has exceeded the value set in the menu.
	LOW SYS (Visual alarm)	Low	The systolic value has dropped below the value set in the menu.
	HIGH DIA (Visual alarm)	Low	The diastolic value has exceeded the value set in the menu.
	LOW DIA (Visual alarm)	Low	The diastolic value has dropped below the value set in the menu.
	HIGH MAP (Visual alarm)	Low	The mean arterial pressure value has exceeded the value set in the menu.
	LOW MAP (Visual alarm)	Low	The mean arterial pressure value has dropped below the value set in the menu.
Temperature	HIGH TEMP (Visual alarm)	Low	The temperature value has dropped below the value set in the menu
	LOW TEMP (Visual alarm)	Low	The temperature value has dropped below the value set in the menu

BG (Blood Glucose)	HIGH (Visual alarm)	Low	The BG value has dropped below the value set in the menu
	LOW (Visual alarm)	Low	The BG value has dropped below the value set in the menu

	Information signal	Description
SpO2 Probe OFF	Warning Tone	The SpO ₂ sensor is missing or defective. Connect or replace the sensor.
ECG Lead OFF	Warning Tone	The ECG lead is off. Check electrodes, lead wires, and cables. If necessary, change to a different lead.
Battery Low	Warning Tone	Battery Low Warning

NOTE:

- The warning tone will be displayed for all pages (Ex. Lead Off, Probe Off or Battery Low).

TAKING CARE OF THE MONITOR

Note:

- Before performing any maintenance or service to the monitor, disconnect the AC power line from the electrical outlet.
- Store the monitor at -4 °F to 140 °F (-20 °C ~ to 60 °C), 10% to 85% R.H., non-condensing.
- Avoid dropping, direct sunlight and humidity.
- The operator shall follow the daily maintenance procedure as wipe off the dirt on the monitor, check the monitor display and visual/auditory alarm signals if it works well after turning on the power switch, also the relevant cables are well-connected.

Cleaning/ Disinfection

Vital-sign Monitor

When necessary, clean the monitor with a cloth slightly dampened with 70% isopropyl alcohol / mild detergent / water (Do not use corrosive liquids). Never immerse the monitor and accessories in any type of liquid.

Blood Pressure Cuff

Clean the blood pressure cuff with a damp cloth, or wash in water with soap or detergent. Before washing the blood pressure cuff, remove the tube. After washing, allow the blood pressure cuff to air dry.

Cables and Pressure Hose

Wipe the cabling and pressure hose with a damp cloth moistened in a mild detergent solution. Do not immerse.

Temperature Sensor

Periodically wipe the temperature sensor clean with an alcohol-dampened cloth, warm water, or properly diluted, non-staining disinfectant. Do not immerse the sensor.

SpO₂ Sensor

Clean the reusable SpO₂ sensor with a 70% isopropyl alcohol solution and allow to air dry. Do not immerse the sensor or cable.

Every 3 months, inspect the temperature sensor, SpO₂ sensor, and accessories for fraying or other damage. Replace as necessary.

Battery Removal and Replacement

As necessary, replace the internal battery after heavy use or the battery no longer charges. Use a battery with the same part number.

- Turn the monitor off and disconnect the AC power cord.
- Remove the screws holding the battery door using a Phillips-head screwdriver and then remove the battery door to expose the battery.
- Disconnect and discard the old battery per local regulations. Reconnect the new battery as soon as possible to prevent loss of power to the unit and subsequent loss of clock time.
- Slide the new battery completely into the compartment. Lay the connector on the battery.
- Replace the battery door and tighten each of the screws.

SpO₂ Accessory Disposal

Dispose of all finger sensors and cables in accordance with facility, local, and government regulations.

ECG Accessory Disposal

Dispose of all ECG electrode pads in accordance with facility, local, and government regulations.

Technical Assistance

If you have an equipment problem that you cannot resolve, call the representative who you purchased the monitor from.

Note:

- Both the monitor and the battery can be recycled. When you wish to dispose of the monitor or are replacing the battery, please recycle according to your local regulations.

ERROR MESSAGES

Blood Pressure Measurement Error Messages

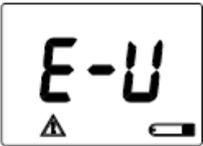
	ERROR MESSAGE DEFINITIONS	RECOMMENDS CORRECTION
Error 01	Cuff serious leakage or inflation too slow.	Check Cuff and connector
Error 02	Amplitude is enlarged over 4x than the previous 2 Amplitudes.	Pump again
Error 03	Cuff pressure is too high.(> 300mmHg)	Check tube and pump again
Error 04	No pulse or Detected pulse count less than 3	Pump again
Error 05	There is no pulse detected before/after lmax.	Check cuff and connector
Error 06	Pulse Amplitude is too large & Saturated.	Pump again
Error 07	Pressure Sensor is failed for 0 or 4095 zero AD	Check cuff and connector. If still occur, please call service
Error 08	system keeps repumping over 2 times	Pump again
Error 09	Cuff cannot deflation or deflation is too slow	Pump again

SpO₂ Measurement Error Messages

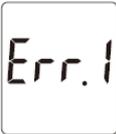
MESSAGE	CAUSE	WHAT TO DO
Please check the probe!	The probe is sensing any object.	Re-click the patient's finger or try the other fingers
Probe disconnect!	Oximeter probe is not connected.	Check the probe connection
Initial SpO ₂ !	When booting up, the SpO ₂ module is in initiation process.	Wait for the initiation process to finish.

Blood Glucose Measurement Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
	Low battery notification	Replace the batteries immediately

	A used test strip is detected	Replace with a new test strip
	Incorrect strip code or other coding errors	Review the instructions and repeat the test with a new test strip. If the problem persists, contact the customer service.
	Ambient temperature is above system operation range	System operation range is 50°F to 104°F (10°C to 40°C). Repeat the test after the meter and test strip are in the above temperature range.
	Ambient temperature is below system operation range	
  	Meter errors	Repeat the test with a new test strip. If the problem persists, please contact the customer service for assistance.
	The test strip is removed while counting down, or insufficient blood volume.	Review the instructions and repeat test with a new strip. If the problem persists, please contact the local customer service for help.

Ear Temperature Measurement Error Messages

MESSAGE	CAUSE	WHAT TO DO
	Ambient temperature is below 50°F (10°C).	Put the thermometer under operating temperature range of 50°F to 104°F (10°C to 40).
	Ambient temperature is below 104°F (40°C).	Put the thermometer under operating temperature range of 50°F to 104°F (10°C to 40°C).

	<p>No probe cover is detected while measuring ear temperature.</p>	<p>Please put on probe cover again.</p>
	<p>Thermometer errors</p>	<p>Review the instructions and re-start the measurement procedure. If the problem persists, please contact the agent.</p>
	<p>Low battery with “” shown on LCD</p>	<p>Please replace batteries as soon as possible.</p>
	<p>Batteries cannot provide enough power for a test.</p>	<p>Please replace new batteries.</p>
	<p>Temperature measurement fails outside the displayed temperature range: (ear temperature range from 89.6°F to 109.4°F (32°C to 43°C)).</p>	<p>Please follow this manual to take a measurement again.</p>

SPECIFICATIONS

BLOOD PRESSURE																
Measurement Method	Oscillometric															
Cuff Pressure Range	0 - 300 mmHg															
Maximum inflation pressure	300 mmHg															
Systolic range	60 - 250 mmHg															
Diastolic range	30 -180 mmHg															
MAP range	40 - 210 mmHg															
Resolution	1 mmHg															
Pressure Accuracy	±3mmHg or ±2% of reading															
Automatic Cycles	OFF, 3min, 5 min, 10 min, 15 min, 30 min, 1 hr, 1.5 hr ,2 hr, 4hr															
Heart Rate Range	40 - 199 bpm															
Heart Rate Accuracy	±4% of reading when HR < 70 bpm															
STAT mode function	Continuous measurements in 5 minutes															
SpO ₂																
Measuring Range	35-99%															
Accuracy	70% - 99%: within ±3%															
Measured SpO ₂ accuracy	<table border="1"> <thead> <tr> <th>Pooled</th> <th>70% - 80% SaO₂</th> <th>80% - 90% SaO₂</th> <th>90% - 100% SaO₂</th> <th>70% - 100% SaO₂</th> </tr> </thead> <tbody> <tr> <td>Mean Bias</td> <td>-0.17</td> <td>0.18</td> <td>0.19</td> <td>0.08</td> </tr> <tr> <td>Arms</td> <td>2.37</td> <td>2.38</td> <td>1.82</td> <td>2.64</td> </tr> </tbody> </table> 	Pooled	70% - 80% SaO ₂	80% - 90% SaO ₂	90% - 100% SaO ₂	70% - 100% SaO ₂	Mean Bias	-0.17	0.18	0.19	0.08	Arms	2.37	2.38	1.82	2.64
Pooled	70% - 80% SaO ₂	80% - 90% SaO ₂	90% - 100% SaO ₂	70% - 100% SaO ₂												
Mean Bias	-0.17	0.18	0.19	0.08												
Arms	2.37	2.38	1.82	2.64												
Heart Rate range	30 - 250 bpm															
Heart Rate Accuracy	±1 bpm or ±1% of HR															
Probe Type	Finger type with dual wavelength LED															
Dimensions	25 H x 66 W x 25 L (mm)															
Length	900mm															
Operating Temperature	50°F to 104°F and Humidity 10% to 85% R.H., Non-condensing															

Storage Temperature	-4°F to 140°F and Humidity 10% to 85% R.H., Non-condensing
ECG	
Input Dynamic Range	Maximum input DC offset voltage range = ±300mV
Gain Setting and Accuracy	Selectable 250 (5mm/mV) or 500 (10mm/mV)
Input Impedance	2.5MΩ
Heart Rate Range	30 - 250 bpm
Heart Rate Accuracy	±4%
Lead / Electrode	5 leads
BLOOD GLUCOSE	
Measurement Range	10-600 mg/dL
Enzyme	Glucose dehydrogenase (FAD-GDH)
Blood Volume	1.1 µl
Reaction time	5 seconds
Operating Condition	50 °F to 104 °F
Storage & Transportation Condition	-4 °F to 140 °F
Power source	2 x 1.5V AAA alkaline batteries
Data transmission	IrDA communication with main unit
TEMPERATURE	
Detection method	Infrared sensor
Measurement Range	89.6°F to 109.4°F
Accuracy	±0.4°F, for the range of 96.8°F-102.2°F ±0.5°F, for the range of <96.8°F or >102.2°F
Display resolution	0.1 °F
Operating condition	50°F to 104°F
Storage condition	-4°F to 140°F
Power source	2 x 1.5V AAA alkaline batteries
Data transmission	IrDA communicate with main unit
Wireless Transmission	
Type	Bluetooth 2.0+EDR
Frequency	2400MHz to 2483.5MHz
Modulation	GFSK
Transmission Power	4dBm Max.
Operating distance	10m indoor without barrier
Alarms	
Indication Method	Audible and Visual
Sound Volume	57dB
Silence Option	Yes; 2 minutes (press once) or permanent (press and hold)
Displays	
Display Type	7" TFT-LCD with touch-screen(resister type)

Parameters	Vital signs: NIBP, SpO ₂ , ECG, BG, Temperature, Pulse Rate, Pulse Bar, Patient data: ID, Weight, Height, Respiration, Patient Size, Reading Number, other comments (from doctor, nurse) System : Date, Time, Battery Status, Location
Status Indication	Alarm Silence; Sensor; Low Battery, Charging state, External Power
Patient Data Management	Allow to recall the patient data and record the patient conditions, such as patient name, ID, height, weight, and respiration condition.
Languages(U.I.)	English
Barcode Reader	
Illumination	630 nm LED
Receiving	3648 element linear
Reading distance	1" ~ 7.9" (2.5 ~ 20 cm)
Reading width	5 in. code width at 7 in.
Skew Angle	±55°
Resolution	3 mi. at 3.5" distance
Decode rate	270 decodes/sec.
Interface	Serial PS/2 connector with main unit
Mechanical (main unit)	
Dimensions	12.2 H x 7.5 W x 7.5 D (inch) / 309 H x 190 W x 190 D (mm)
Weight	5.5 lb (2.5 kg), including accessory and battery
Mounting Option	Mobile Stand and Wall Mount
Portability	Hand-carried by the top handle
Power Requirements (main unit)	
Input source:	AC 100~240V, 47~63Hz
Main Unit Battery	7.4V 4600 mAh-----Rechargeable Li-ion Battery; Operation time: 8 hours (with backlight DIM=4) , Fully charged time: 5 hours
Environmental	
Operating Temperature	50 °F to 104 °F
Storage & Transportation Temperature	-4 °F to 140 °F
Operating, Storage & Transportation Humidity	10% to 85% R.H., non-condensing
Classification	
Type of Protection	Class I equipment
Degree of Protection	Type CF defibrillator-proof equipment
Protection against Ingress	IPX2 rating, Drip-Proof Equipment IPX2 (effective against bigger solid bodies; protected against dripping water)

Harmonized Standard	
	IEC 60601-1
	IEC 60601-1-2
	IEC 60601-1-8
	IEC 60601-2-27
	IEC 60601-2-49
	IEC 80601-2-30
	ISO 80601-2-61

IMPORTANT INFORMATION REGARDING

ELECTRO MAGNETIC COMPATIBILITY (EMC)

Medical devices manufactured by **VSM100 Pro** vital signs monitor conform to this IEC60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by **VSM100 Pro**, with the exception of cables sold by **VSM100 Pro** vital signs monitor as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the unit and create a potentially unsafe situation.
Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter.

The **VSM100 Pro** is intended for use in the electromagnetic environment specified below. The customer or the user of the **VSM100 Pro** should assure that it is used in such environment.

ELECTROMAGNETIC EMISSIONS IEC60601-1-2		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The vital sign monitor is not suitable for use in residential and domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	None	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	None	

ELECTROMAGNETIC IMMUNITY IEC60601-1-2

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines*1)	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1KV line to line ±2KV line to earth	±1KV line to line ±2KV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0.5 cycle	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the vital sign monitor requires continued operation during power mains interruption, it is recommended that the vital sign monitor be powered from an uninterruptible power supply or battery.
	40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles	40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles	
	70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles	70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles	
	<5 % <i>UT</i> (95 % dip in <i>UT</i>) for 5 sec.	<5 % <i>UT</i> (95 % dip in <i>UT</i>) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: *UT* is the A.C. mains voltage prior to application of the test level.

*1) The test of input/output lines is not applicable since they are shorter than 3.0m.

Recommend separation distance

The following list where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,*2) should be less than the compliance level in each frequency range.*3)

Interference may occur in the vicinity of equipment marked following symbol: 

Electromagnetic Immunity IEC60601-1-2			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz ~ 80 MHz	3 V rms	Recommend separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	Recommend separation distance $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

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

Recommended separation distance between portable and mobile RF communications equipment and the vital signs monitor

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

	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER IN METER		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 kHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
Output Power of Transmitter in Watt	separation distance in meters (m)	separation distance in meters (m)	separation distance in meters (m)
0.01	0.1 (0.4)	0.1 (0.4)	0.2 (0.7)
0.1	1.4 (1.1)	1.4 (1.1)	0.7 (2.2)
1	1.3 (3.5)	1.3 (3.5)	2.3 (7.0)
10	3.8 (11.1)	3.8 (11.1)	7.3 (22.1)
100	12.0 (35.0)	12.0 (35.0)	23.0 (70.0)

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

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

NOTE:

- If you need USB / Bluetooth protocol information, please contact customer services for assistance.

FEDERAL COMMUNICATIONS COMMISSION STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement

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.

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 of the device.

FCC RF Radiation Exposure Statement:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator radiation source and your body.

FORA[®] VSM100 Pro

Distributed by ForaCare, Inc.

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Products made in Taiwan

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