FORA® VSM100 Pro

Vital Signs Monitor

Operator's Manual

FORA® VSM100 Pro

About the Manual

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

Version 2.0 2020/08

TABLE OF CONTENTS

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 **FORA 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 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, SpO_2 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 entering 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 the AC adapter cable into an AC outlet (or unplug it) with wet hands.

CAUTION!
- Every three months, inspect the blood pressure cuff, SpO_2 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 **FORA VSM100 Pro** will display message to remind the user.

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 0 mmHg. 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.

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.

Infrared Thermometer Warnings

CAUTION!

- Always store the thermometer in a cool and dry place: temperatures between -4°F to 158°F (-20°C to 70°C), relative humidity less than 95%. 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” *https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.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://wayback.archive-it.org/7993/20170111013014/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

INTRODUCTION

Intended Use

The monitor is intended to be used to monitor non-invasive blood pressure (systolic, diastolic and mean arterial pressure), pulse rate, body temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO_2) for adult, pediatric, and neonatal patients. The monitor is intended to be used by clinicians and medically qualified personnel and trained users.

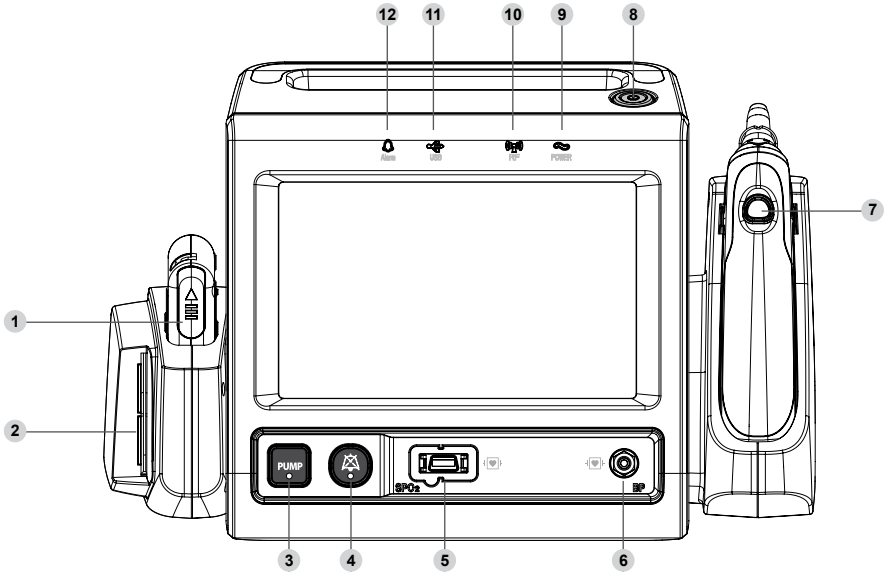
Main Measurement Function

- NIBP (Non-Invasive Blood Pressure)
- SpO_2
- Infrared Thermometer
- Blood Glucose Meter

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. Blood Glucose Code Card
7. Safety Lancet (10 pieces)
8. SpO_2 Sensor and Extension Cable
9. NIBP Upper Arm Cuff and Extension Hose
10. AC Power Cord
11. Warranty Card
12. SD Mmemory Card

Monitor Overview



1. **Blood Glucose Meter**
2. **Smart Card Reader**
3. **Non-Invasive Blood Pressure (NIBP) Measurement Button**
   (When PUMP LED lights up, you can press the button to start a NIBP measurement. You can also press this button for emergency stop during the measurement.)
4. **Silence Button**
   (When the alarm is sounding, press this button to temporarily mute it, audio paused. Refer to page 70 for related settings.)
5. **SpO2 Sensor Connection Port**
6. **NIBP Pressure Hose Connection Port**
7. **Infrared Thermometer**
8. **Power On/Off Button**
9. **Power Display LED**
10. **RF LED**
11. **USB LED**
12. **Alarm LED**

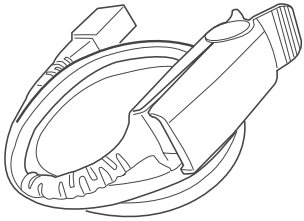
Before Measurement - Connecting Accessories

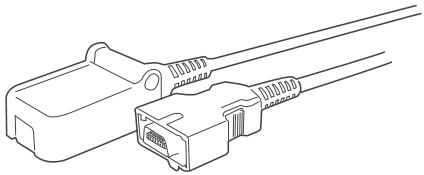
Start with the monitor off, and connect all accessories to the monitor. Please find the connection ports from page 15.

NOTE:
The figures are just for reference. Actual accessories may differ.

Accessories of **FORA VSM100 Pro** include:

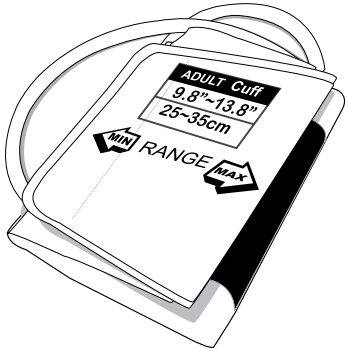
1. SpO₂ Finger Sensor And Extension Cable

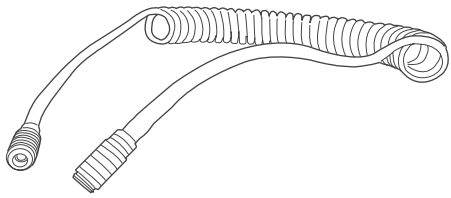




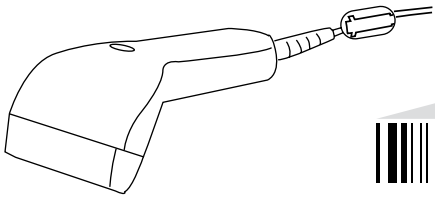
NOTE:
- Sensors of adults / pediatric patients / and neonates are different. Be sure to read the package printings and use a correct sensor.
- If you are going to change the sensor, make sure you choose the corresponding brand to your model.
- In case you have to use a different brand, please consult your agent first.

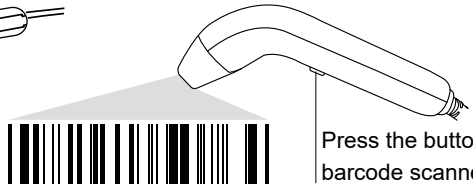
2. NIBP Pressure Cuff and Hose





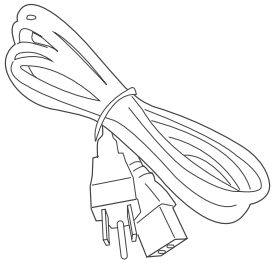
3. Barcode Scanner (Optional)





Press the button on the barcode scanner to scan.

4. AC Power Cord

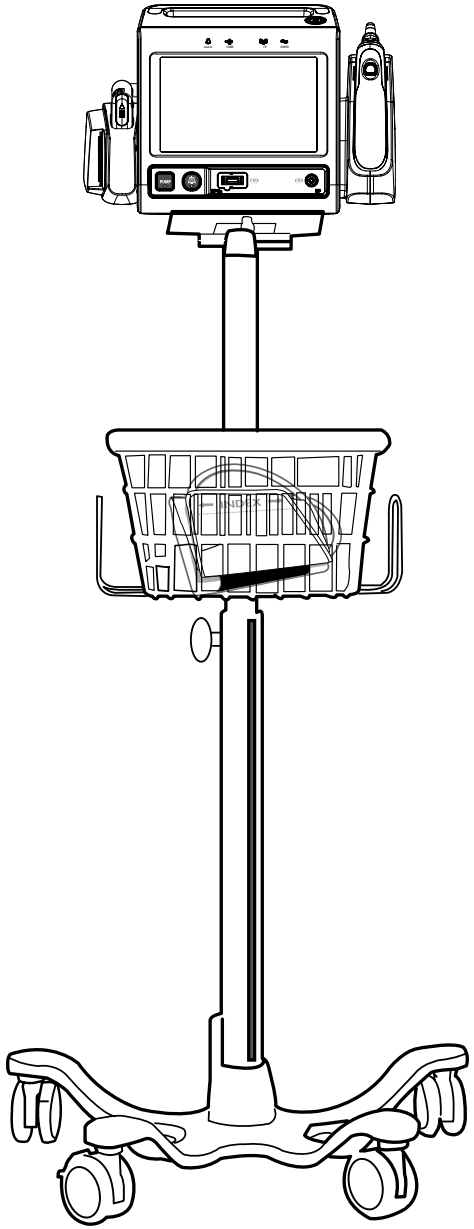


NOTE:

- Without this item, the monitor can still work until the battery is out of electricity.
- There are different specifications of AC power cord for different countries. Make sure you use the correct one for your country.
- This AC power cord can recharge the battery. It takes approximately 5 hours for the battery to get fully recharged.
- Make sure to use the American specification cord or European specification cord accordingly to the voltage of the country.

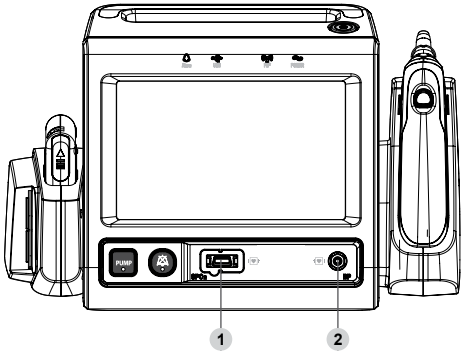
5. Rolling Stand (Optional)

(This stand is for moving the monitor conveniently. The monitor still works well without this stand.)
Refer to rolling stand manual.



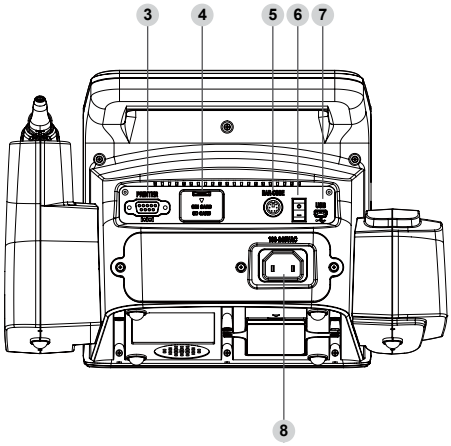
Connection Ports in the Front Panel

1. **SpO2 Sensor Connection Port**
2. **NIBP Pressure Hose Connection Port**



Connection Ports in the Back

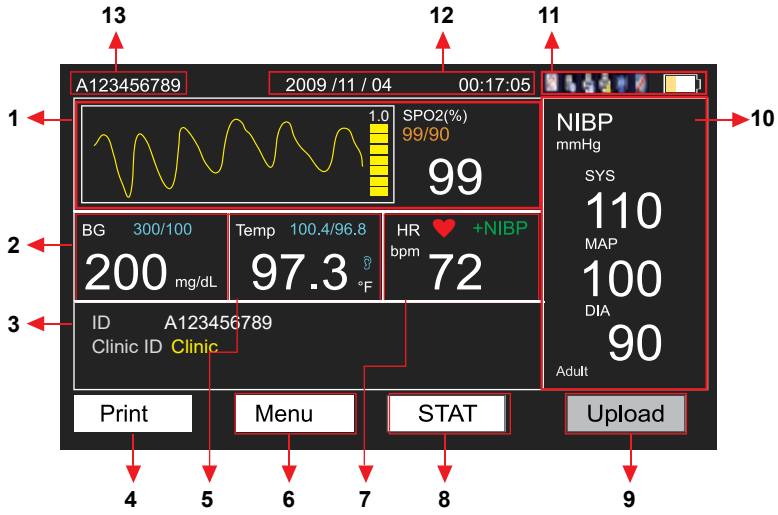
3. **Printer Port**
4. **SD Memory Card Slot**
5. **Barcode Scanner Port**
6. **Power Switch**
7. **USB Connector**
8. **AC Power Ccord**



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 34) and **infrared thermometer** (please refer to page 36) with the monitor and make sure **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 be full charged.

Monitor Main Display Area



Main Display Description

	AREA	DESCRIPTION
1	SpO2 display area	Display SpO2-related info.
2	Blood glucose display area	Display blood-glucose-related info.
3	Patient's info	Display patient's info. You may key in the info.
4	Print button	Touch this button to print out the readings.
5	Temperature display area	Display temperature-related info.
6	Menu button	Touch this button to change settings.
7	Heart rate display area	Display heart rate related info.
8	STAT button	Touch this button for a 5-min consecutive measurement.
9	Upload button	Touch this button to upload the recorded data.
10	NIBP display area	Display NIBP-related info.
11	Status indicator display area	Display status indicators.
12	Date / Time	Display date and time. You may key in the date and time.
13	Patient's ID	Display the patien's ID.

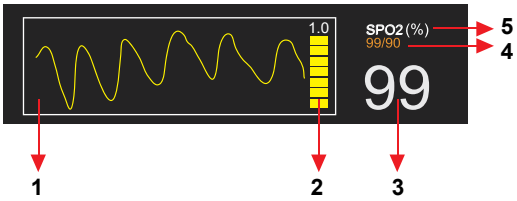
For details, please refer to the following sections.

NOTE:

- To view or change related parameter settings, you can directly touch the SpO2, BG, Temp, HR, ID, 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.

● SpO2 Display Area

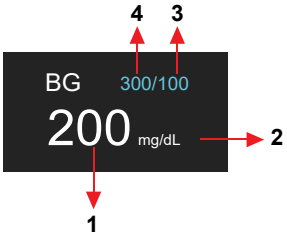
1. Pulse waveform
2. Pulse signal amplitude (PI)
3. SpO2 reading
4. Alarm lower limit
5. Alarm upper limit



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

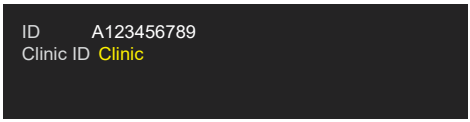
● Blood Glucose Display Area

1. Blood glucose reading
2. Measurement unit
3. Alarm lower limit
4. Alarm upper limit



● Patient's Information Display Area

You can change the ID, weight, height in Menu. Please refer to page 22.



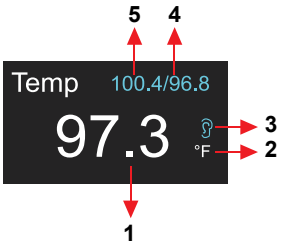
● Print Button

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.

● Temperature Display Area

1. Temperature reading
2. Measurement unit
3. Temperature source
4. Alarm lower limit
5. Alarm upper limit

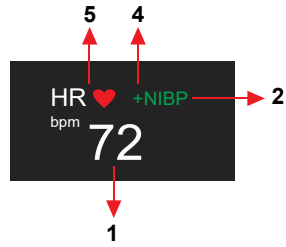


● **Menu Button**

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

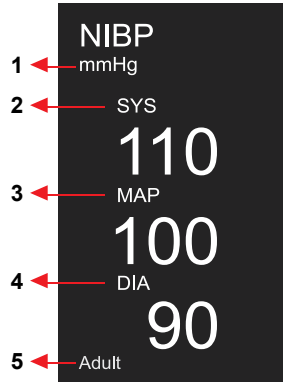
● **Heart Rate Display Area**

1. Heart rate reading (beat per minute)
2. Heart beat source comes from “NIBP” or “SpO2”
3. When the setting is “AUTO”, the “+” will appear.
4. Pulse indicator
(It blinks when heart beat signal is detected)



● **NIBP Display Area**

1. Measurement unit
2. Systolic pressure reading
3. Mean arterial pressure reading
4. Diastolic pressure reading
5. Patient population



● **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 you turn on Auto Save function. Please refer to page 28.

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

This indicator displays when you turn on Bluetooth. Please refer to page 37.

This indicator displays when the “Lighting” symbol is constantly shown, the device has been recharging.

This indicator displays when the “Lighting” symbol disappears, that the device has been recharged completely.

Battery indicator: the percentage means the power storage capacity.

Green: 41% ~ 100% (power normal)

Orange: 21% ~ 40% (power low)

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

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, **FORA VSM100 Pro** would record the number of Heart rate and SAT value and the time. **FORA VSM100 Pro** will overwrite the old record instead of the new record if the old was recorded 10 seconds ago. If not, **FORA VSM100 Pro** will append the new record at the end of the last old record. So the recorded file will show every power-failure time.

● Date / Time Area

Please refer to page 33 to change date and time.

● Patient's Info of Measurement

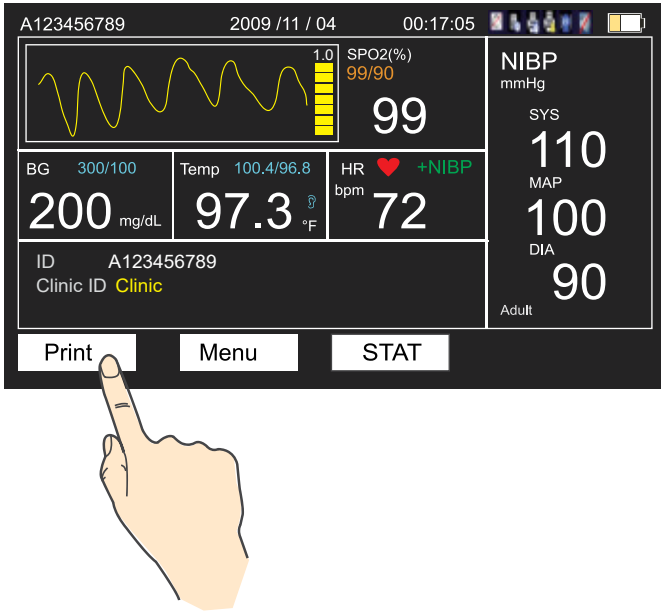
You can name the Patient's ID where you perform the measurements. Please refer to page 22.

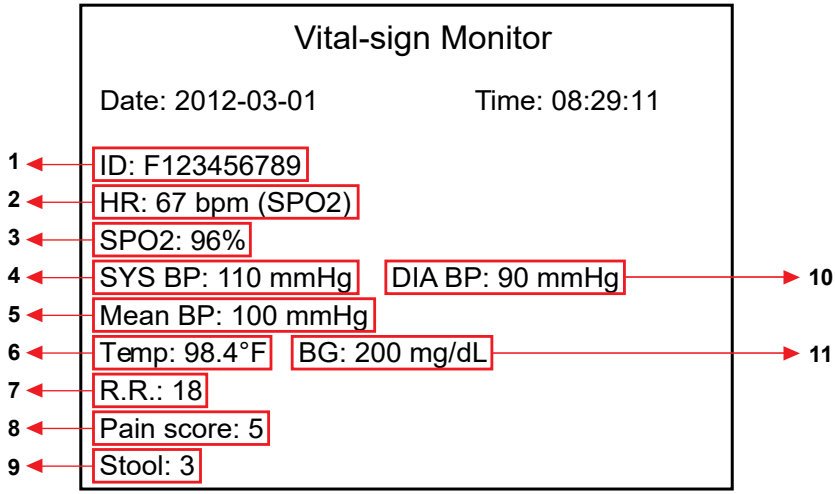
Monitor Functions

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 only printers that **FORA** provides.

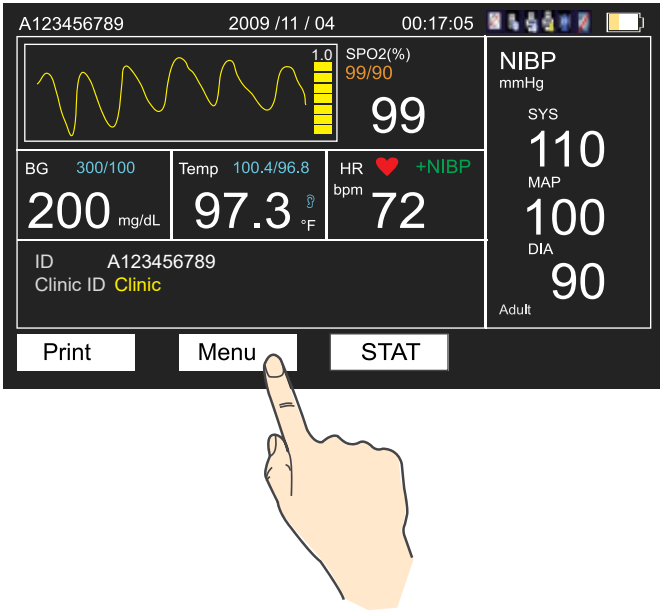




1. ID
2. Heart Rare / Source
3. SpO2 %
4. Systolic BP
5. Mean BP
6. Temperature
7. Respiratory Rate
8. Pain score
9. Stool
10. Diastolic BP
11. Blood Glucose

Menu

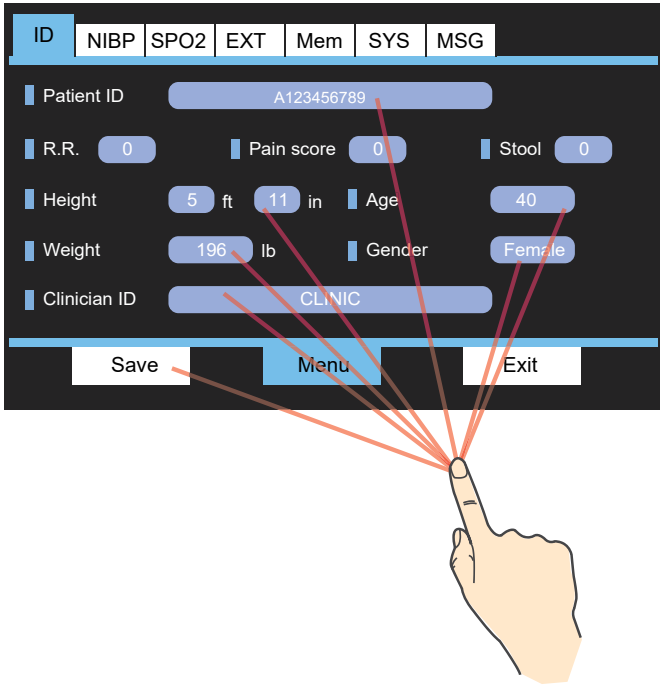
The Menu function allows system configurations to be adjusted. Touch the Menu button to enter the setting windows. Read the following contents for descriptions.



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



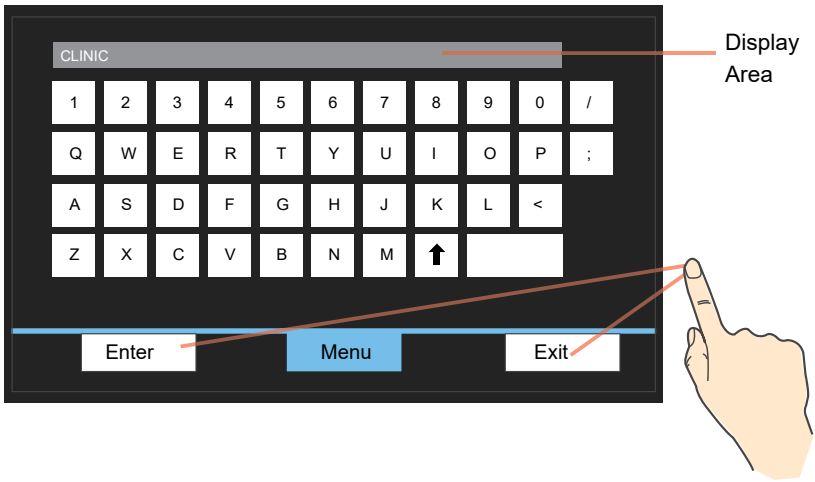
Gender

Touch the “Gender” button and Select the 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.

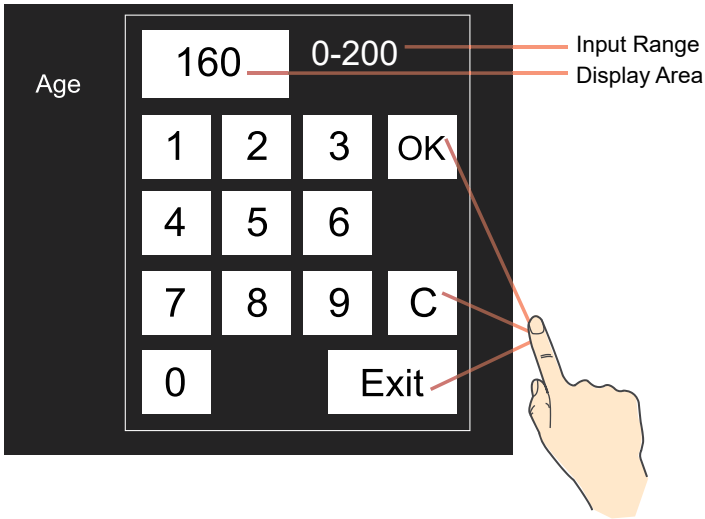


Age

Touch the numbers to key in. Touch “OK” to confirm the height number. Touch “C” to clear the display area to “0”.Touch “Exit” to exit this page without saving.

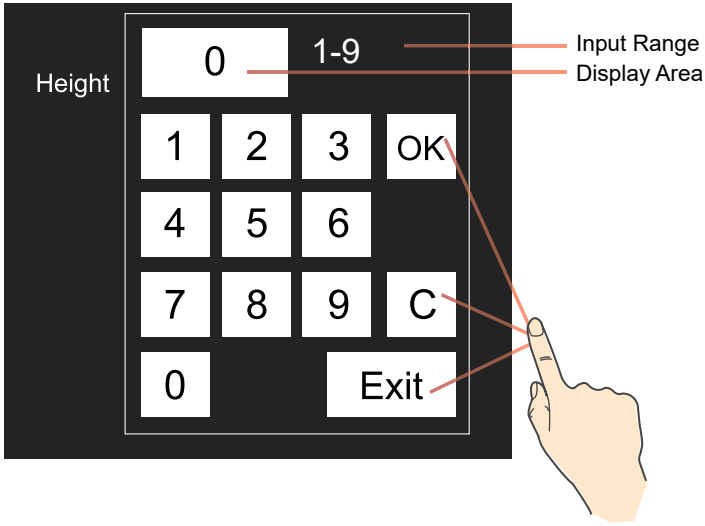
Input range: 0 ~ 200

(If out of this range, touching “OK” does not function.)



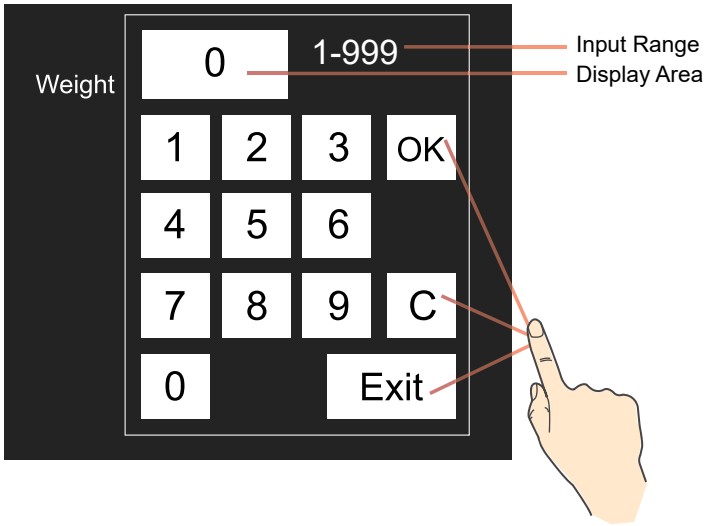
Height

Touch the numbers to key in. Touch “OK” to confirm the height number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving.
Input range: 1 ~ 9 (ft), 0 ~ 11 (in) / 0 ~ 999.9 (cm)
(If out of this range, touching “OK” does not function.)



Weight

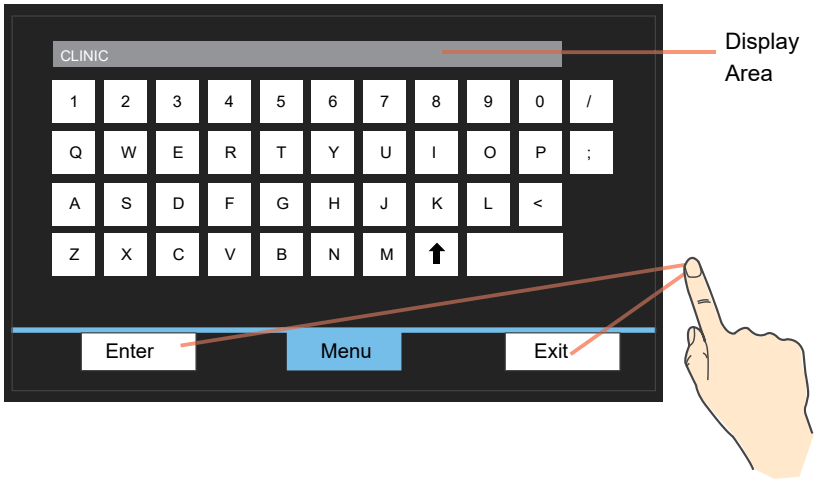
Touch the numbers to key in. Touch “OK” to input the weight number. Touch “C” to clear the display area to “0”. Touch “Exit” to exit this page without saving.
Input range: 1 ~ 999 (lb) / 0 ~ 999.9 (kg)
(If out of this range, touching “OK” does not function.)



Clinician ID

Touch the numbers and letters to key in.

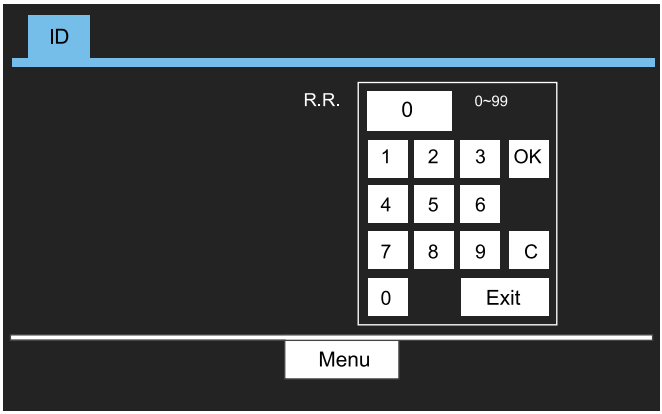
Touch “Enter” to confirm the Clinician ID. You can also use a barcode scanner to input the Clinician ID. Touch “Exit” to exit this page without saving.



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.

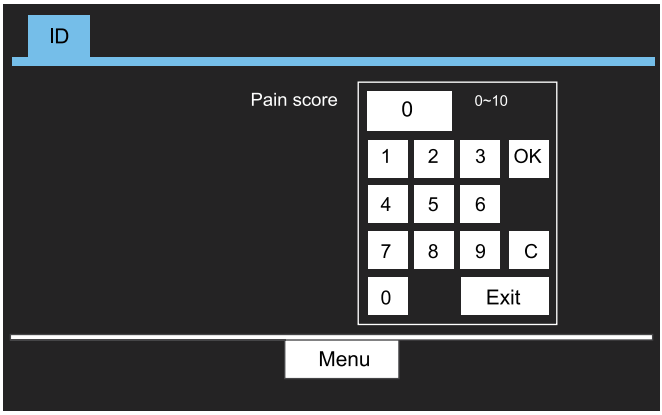
Input range: 0~99 (min) (If out of this range, touching “OK” does not function.)



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.)

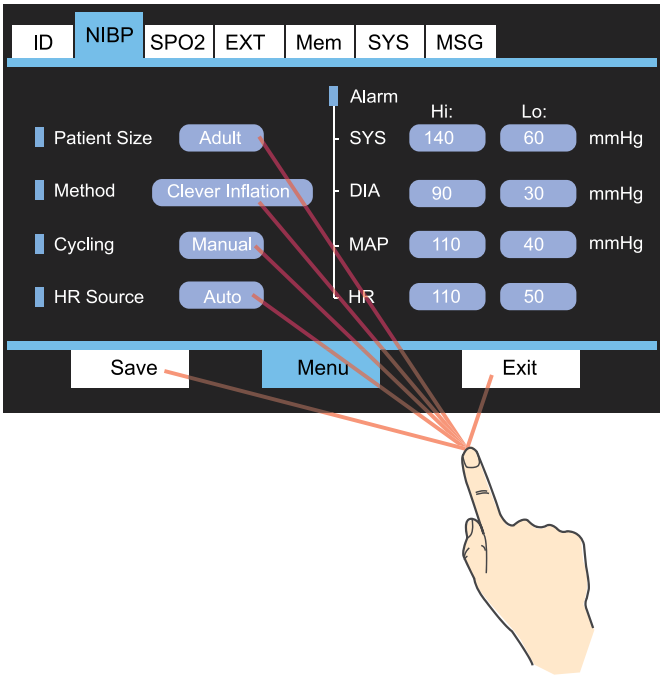


NIBP

Set up the non-invasive blood pressure 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.

NIBP Settings

	NIBP SETTING	DESCRIPTION
Patient	Neonate	Select the patient population accordingly.
	Pediatric	
	Adult (default)	
Method	Clever Inflation (default)	If interfered during the first measurement, the monitor will then take a measurement again.Touch this button to print out the readings.
	Deflation Only (for neonate)	Take a measurement only during inflation.
Cycling	Manual (default)	Take a measurement only when you press " PUMP " button.
	3 min	The monitor takes a measurement in the specified interval.
	5 min	
	10 min	
	15 min	
	30 min	
	1 Hr	
	1.5 Hr	
	2 Hr	
	4 Hr	
HR Ssource	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.

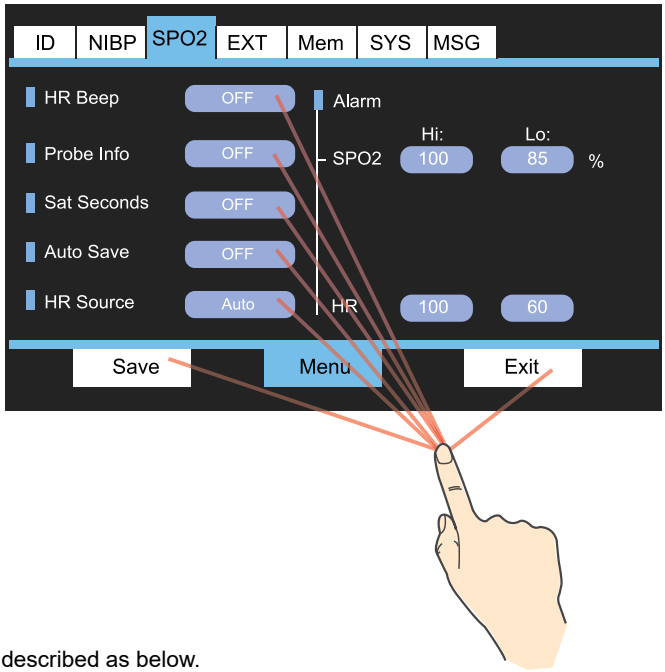
ALARM TYPE	Hi:	Lo:	DESCRIPTION
SYS	275 ~ 61	139 ~ 50	When any reading exceeds its limit, the alarm sounds.
DIA	200 ~ 31	89 ~ 20	
MAP	225 ~ 41	109 ~ 30	
HR	250 ~ 51	109 ~ 20	

SpO2

Set up the SpO2 function.

Save: 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.

SpO2 Settings

	SpO2 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 can not receive signals while taking a measurment.
	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.
	10 sec	
	20 sec	
	30 sec	
	1 min	
	5 min	
	10 min	

	SpO_2 SETTING	DESCRIPTION
Sat Seconds	Off (default)	Setting for Sat Seconds Alarm. (Only for Nellcor SpO_2)
	10	
	25	
	50	
	100	
HR Asource	SpO_2	Take the pulse rate from SpO_2 measurement
	NIBP	Take the pulse rate from blood pressure measurement.
	Auto (default)	The monitor automatically switches to a stable heart rate.

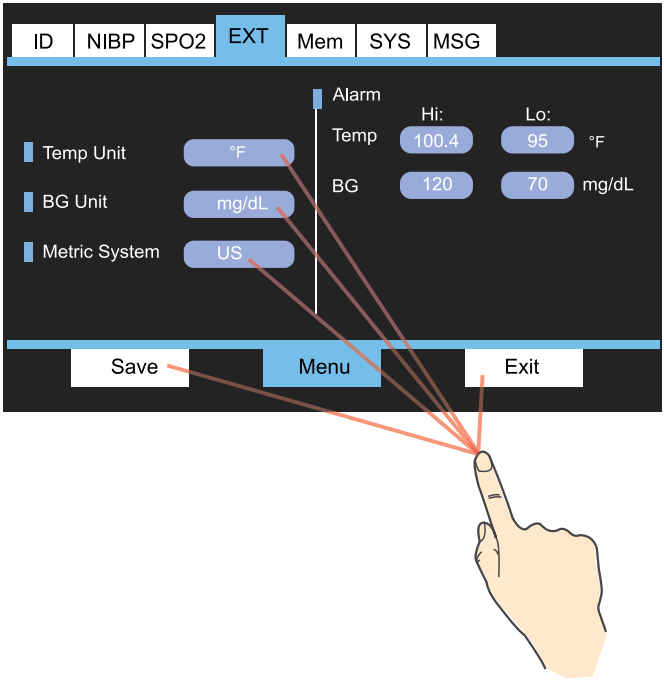
ALARM TYPE	Hi:	Lo:	DESCRIPTION
SpO_2	100 ~ 86	99 ~ 20	When any reading exceeds its limit, the alarm sounds.
HR (Heart rate)	250 ~ 51	109 ~ 20	

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.

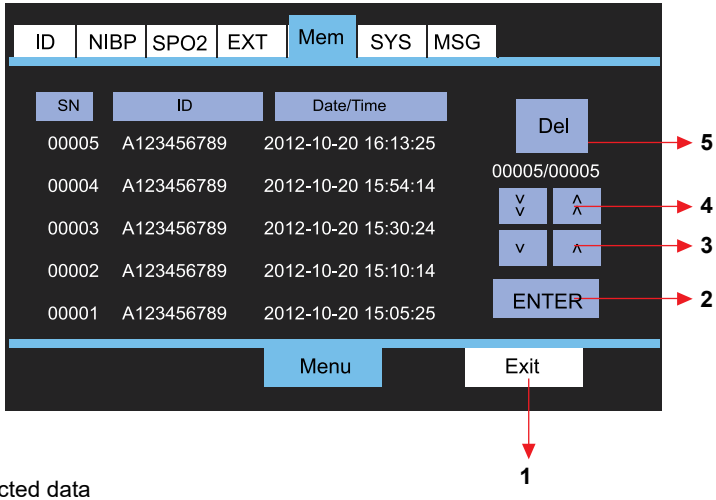
EXT Settings

	UNIT SETTING	DESCRIPTION
Temp	°C	Setting for Celsius unit
	°F	Setting for Fahrenheit unit
BG (Blood Glucose)	mg/dL	Setting for mg/dL unit
	mmol/L	Setting for mmol/L unit
Metric System	US	Setting for US unit
	Int'l	Setting for International unit

ALARM TYPE	Hi:	Lo:	DESCRIPTION
Temp	109.4°F ~ 95.1°F	95.7°F ~ 68°F	When any reading exceeds its limit, the alarm sounds.
BG (Blood Glucose)	600 ~ 71	119 ~ 10	

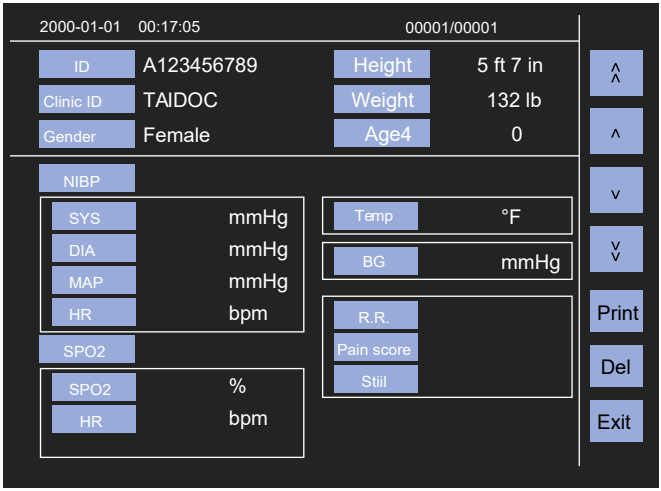
Mem

The Mem function allows users to retrieve all the readings.



1. Exit this page.
2. Enter the selected data
3. Change to other pages
4. Which page you are on
5. Delete the selected data

See a data example as below.

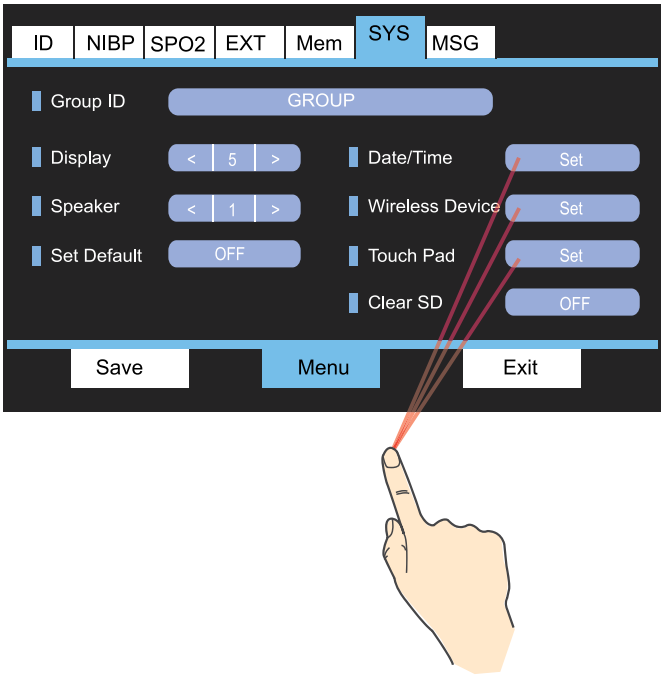


NOTE:

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

SYS

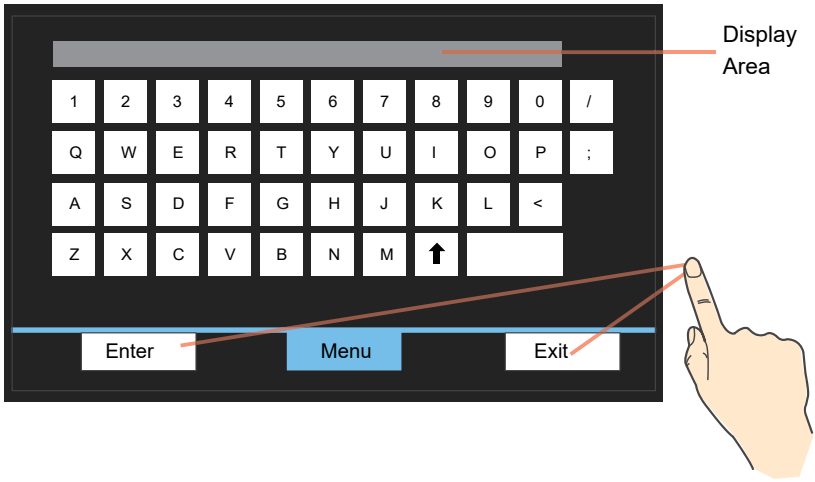
System setup.



The settings are described as below.

Group ID

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



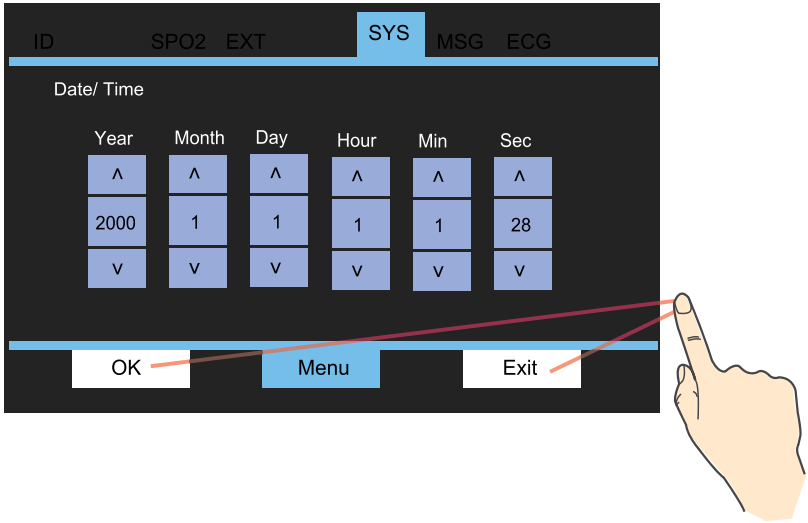
The settings are described as below.

System Settings

	SETTING	DESCRIPTION
Display	0	Touch the icon “ > ” to increase or “ < ” to decrease the brightness. 0 is the darkest. 7 is the brightest.
	1	
	2	
	3 (default)	
	4	
	5	
	6	
	7	
Speaker	1(default)	Touch the icon “ > ” to increase or “ < ” to decrease the volume. 1 is the lowest, 3 is the loudest. (only for Information tone).
	2	
	3	

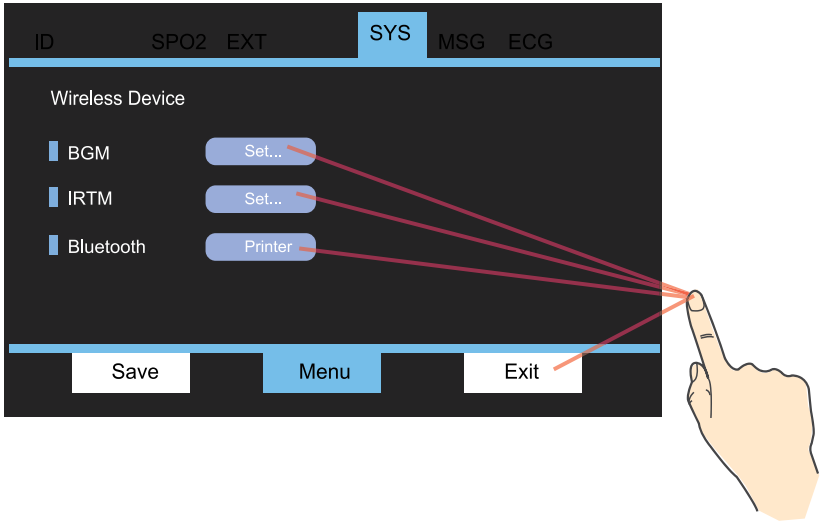
Date/Time

Touch " ∧ " and " ∨ " to adjust the Date and Time. Touch "OK" to confirm the setup. Touch "Exit" to exit this page without saving.



Wireless Device

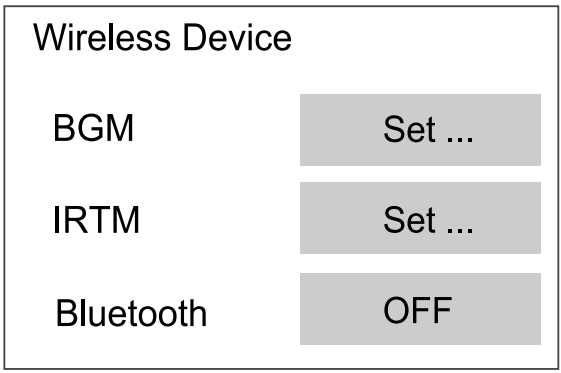
Pair up BGM (Blood Glucose Meter) or IRTM (Infrared Thermometer). Touch "Exit" to leave this page.



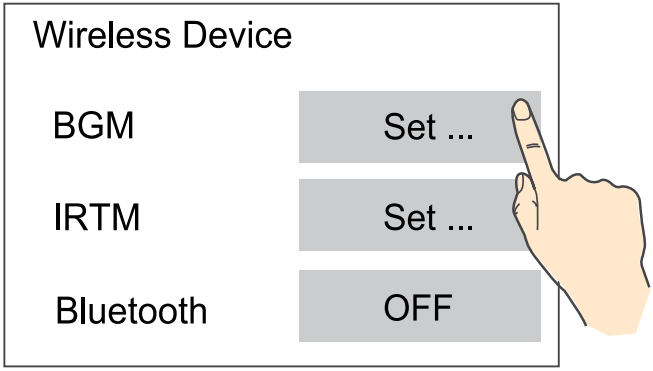
● BGM (Blood Glucose Meter)

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

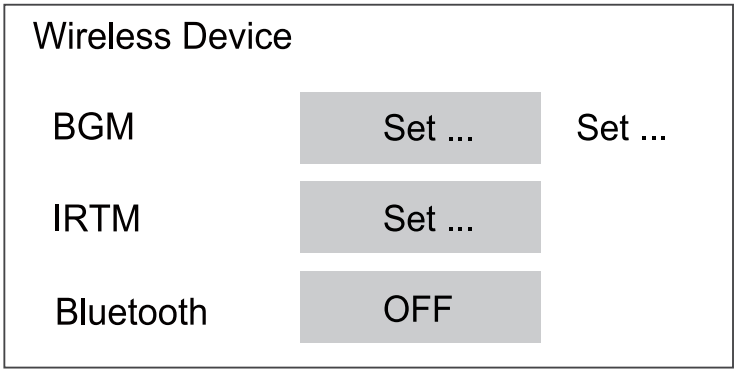
1. Enter Menu ► SYS ► Wireless Device.



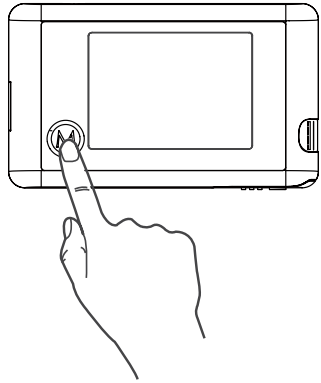
2. Touch “Set” for BGM.



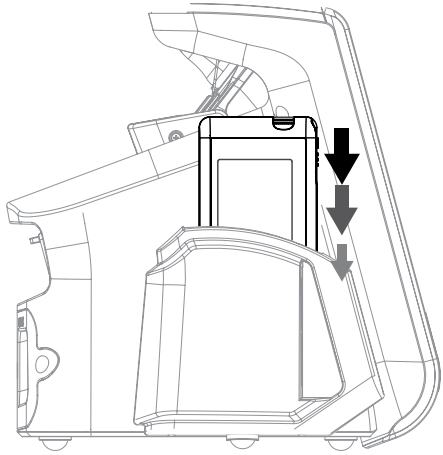
3. “Set…” is displayed. The monitor is ready for pairing up.



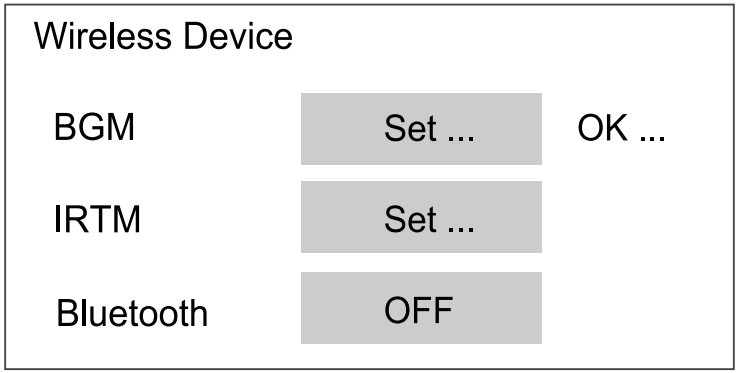
4.Turn on the blood glucose meter.



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

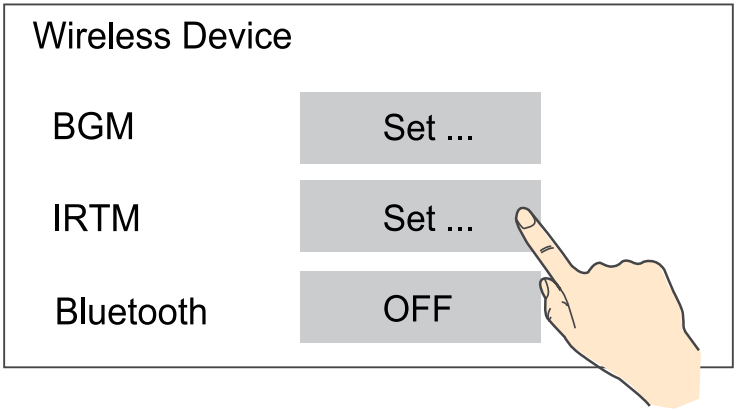


6. “OK” is displayed when the meter is identified.

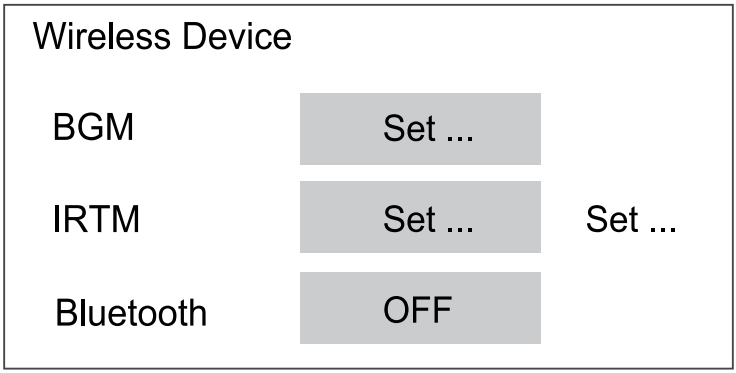


● **Infrared Thermometer**

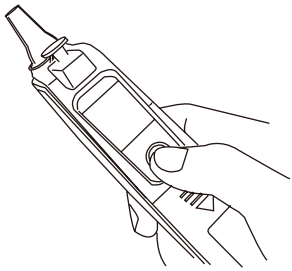
1. Touch “Set” for IRTM.



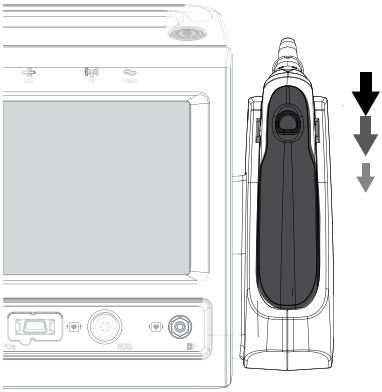
2. “Set…” is displayed. The monitor is ready for identification.



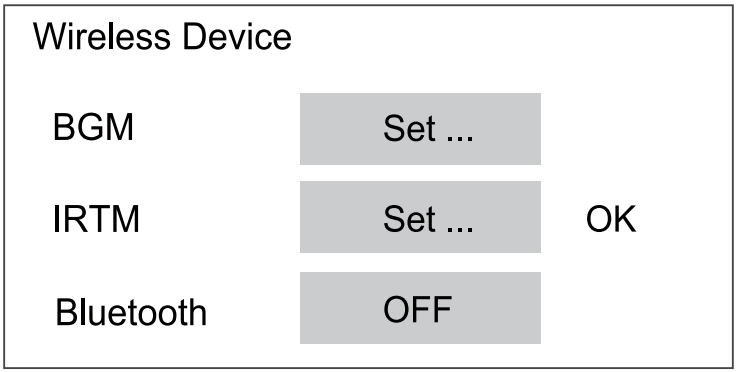
3. Turn on the thermometer.



4. Put the IR thermometer into the thermometer holder.



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



Bluetooth Settings

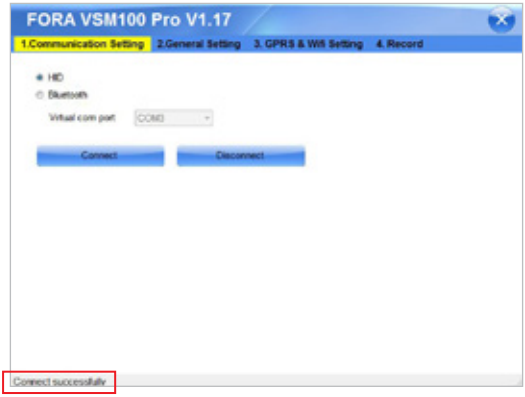
PC	Turn on Bluetooth for data transmission in PC mode
Print	Turn on Bluetooth for data transmission in Print mode
OFF	Turn off Bluetooth. (default)

FORA VSM100 Pro Setting Tool

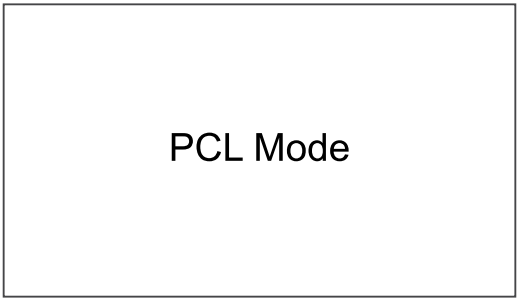
1. Use the USB cable to connect the **FORA VSM100 Pro** with PC. On the PC, enter the “FORA VSM100 Pro Setting Tool”. The green USB LED lights up.

2. In the “1. Communication Setting” tab, select “HID” and press "Connect" button. Please make sure the USB cable is connected.

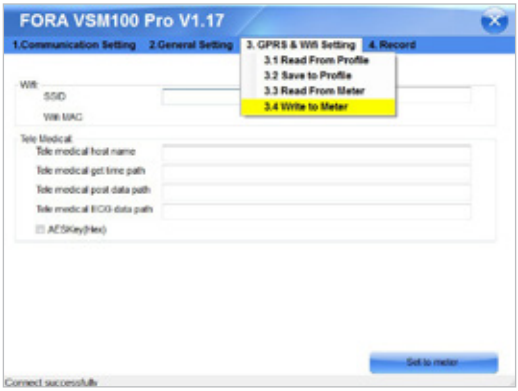
3. After successfully connected, the message will be displayed at the bottom of the screen.



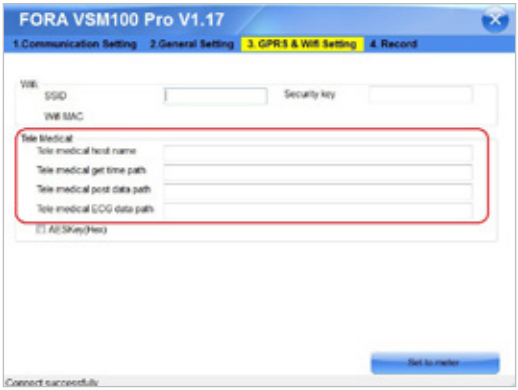
The display screen on **FORA VSM100 Pro** should be as the follows.



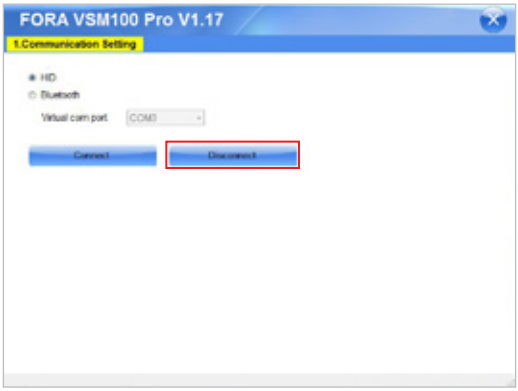
4. In the “3. GPRS & WiFi Setting” tab, select “3.4 Write to Meter”.



5. Input the required information. For information in the red box, please contact your representative. Press “Set to meter” to complete.



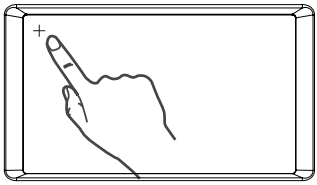
6. Return to “1.Communication Setting” and press “Disconnect”. Remove the USB cable to complete the setting process.



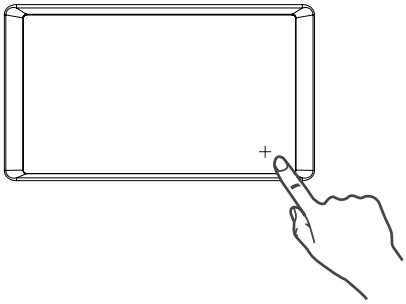
Touchpad

If the monitor is not responding to your touch, please follow the steps below to calibrate the touchpad.

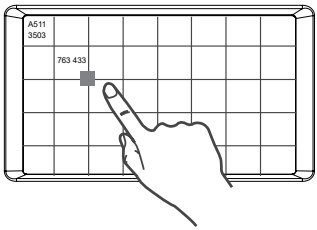
1. Touch the “+” icon in the upper-left corner.



2. Touch the lower-right corner.

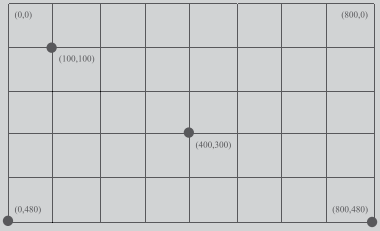


3. Touch the blue area and the calibration is done.



NOTE:

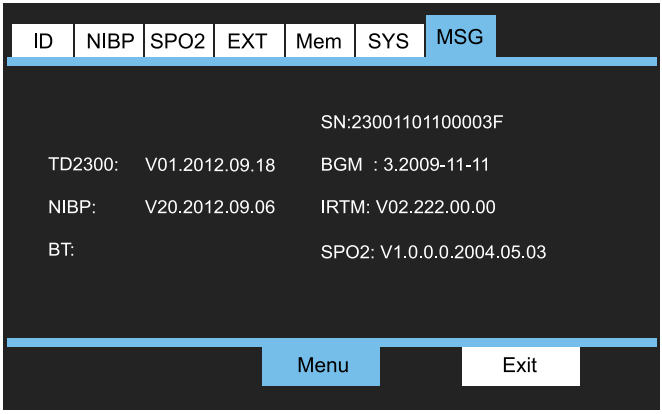
- In **3**, before you touch the blue area (200±30 , 200±30); you can touch to test the touch screen accuracy. The coordinate of the touched point will be displayed on the upper-left corner of the blue area.



- When the calibration is done, you will see the monitor main display area as above.
- After calibration, in case the monitor still does not respond correctly, call your representative.

MSG

You can see the Vital Signs Monitor firmware version, BPM firmware version and SpO_2 firmware version and LOG (history of configuration changes) here.



PERFORM MEASUREMENTS

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

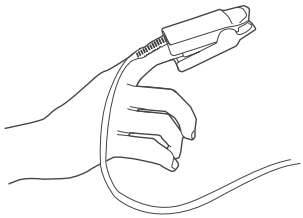
SpO_2 Measurement

The Following Factors May Lead to Inaccurate Results:

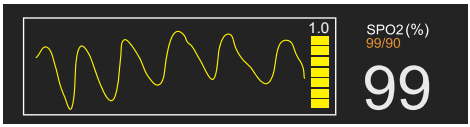
- Excessive ambient light
- Excessive motion
- Anemia or low hemoglobin Concentrations
- Fingernail polish
- Arterial catheters, blood and infusion lines, etc.
- Cardiovascular dyes
- Improper sensor use
- Incorrect sensor
- Electrosurgical interference
- Patient with poor perfusion
- Venous pulsations

Taking Measurement

1. Clip on patient's finger as below. 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 SpO_2 and pulse rate until the probe is removed.



3. Inspect and reposition the sensor frequently (every 2 hours) to prevent skin deterioration.

4. When the sensor is removed, the monitor will display the last SpO_2 reading up to 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 SpO_2 result will turn red and start blinking.

WARNING:

- Do **NOT** use with the instruments which are not specified by the manufacturer. Use of other instruments than we mentioned above may lead to inaccurate results.
- Skin irritation or ulceration may occur if you apply 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.

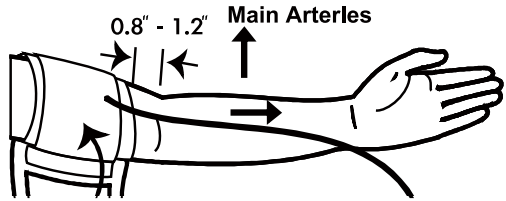
Blood Pressure Measurement

Before Measurement

1. Sit down for at least 10 minutes before measuring.

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 sizes are classified as below:

- for Adult - longer than 9.8” (25 cm)
- for Pediatric - 6.3” to 9.8” (16 to 25 cm)
- for Neonate - shorter than 6.3” (16 cm)

WARNING:

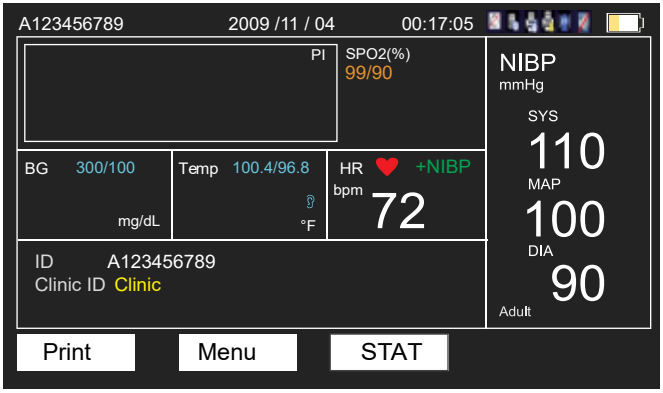
- Excessive tightness may cause venous congestion and discoloration of the limb.
- If the cuff is wrapped too loose or the hose is twisted may cause the inaccurate results.

Taking Measurement

Always apply the pressure cuff before turning on the meter.

1. Press “ PUMP ”. The cuff will begin to inflate automatically. The LED lights up during the measurement.

2. After the measurement, the monitor displays the systolic pressure, diastolic pressure, mean arterial pressure (MAP) and pulse rate.

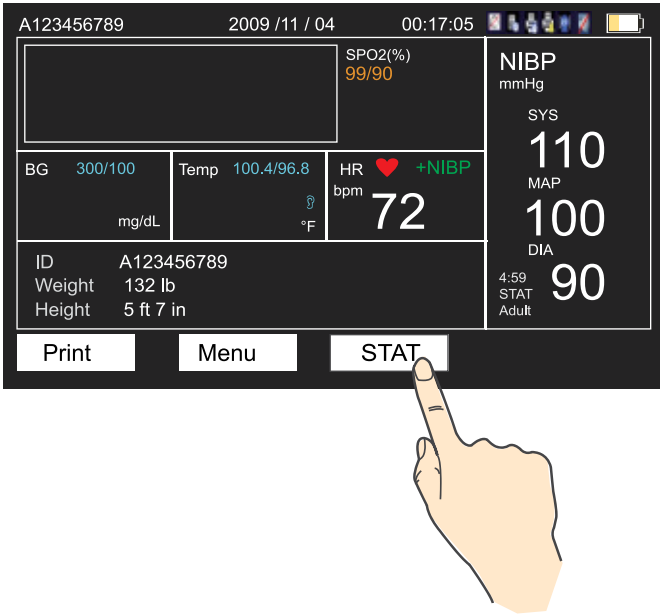


NOTE:

- If you press PUMP during measurement, the meter will turn off.
- If the result is out of range, the alert alarm will keep beeping, and the result will turn red.
- If the meter has detected a big movement or great vibration(s) of the arm during the measurement and cannot produce a value. The meter will then re-pump 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.



Blood 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. Do **NOT** use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
5. 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.
6. 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.
7. 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.
8. 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.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. 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 mg/dL ÷ 18 = 6.6 mmol/L

2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

Intended Use

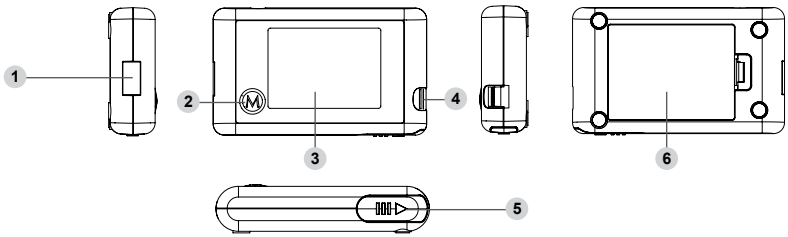
This system is intended for use outside the body (*in vitro* diagnostic use) by healthcare professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples from the finger.

It should not be used for the diagnosis or screening of diabetes. Professionals may test with capillary, venous, arterial and neonatal blood sample.

Test Principle

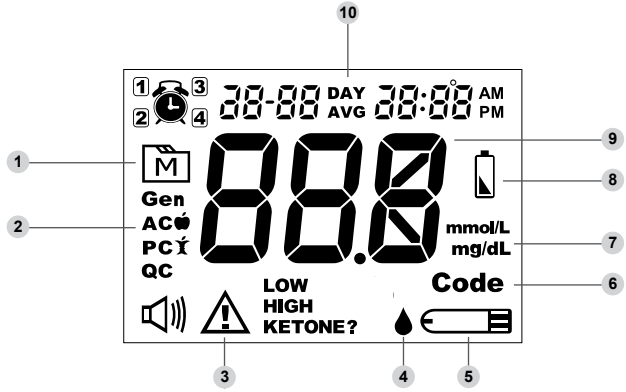
Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Meter Overview



1. **Data Port**
2. **M Button**
   Enter the meter memory and silence a reminder alarm.
3. **Display Screen**
4. **Test Strip Slot**
   Insert test strip here to turn the meter on for testing.
5. **Test Strip Ejector**
   Eject the used strip by pushing up this button.
6. **Battery Compartment**

Display Screen



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

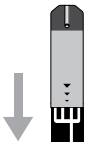
Test Strip

Absorbent Hole
Apply a drop of blood here. The blood will be automatically absorbed.

Confirmation Window
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.

Test Strip Handle
Hold this part to insert the test strip into the slot.

Contact Bars
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

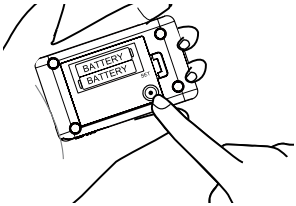


ATTENTION:
The front side of test strip should face up when inserting test strip.
Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:
The **FORA VSM100 Pro** blood glucose monitor should only be used with **FORA VSM100 Pro** blood glucose Test Strips. Using other test strips with this meter can produce inaccurate results.

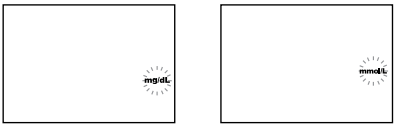
Setting The Meter

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.



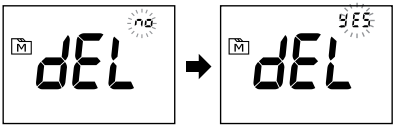
Entering the Setting Mode

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



1. Setting the unit of measurement

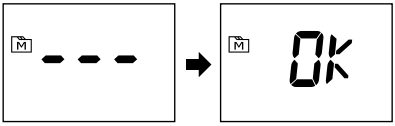
Press Ⓜ to switch between mg/dL and mmol/L. Press **SET**.



2. Deleting the memory

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

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



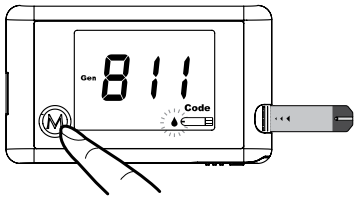
Congratulations! You have completed all settings!

The Four Measuring Modes

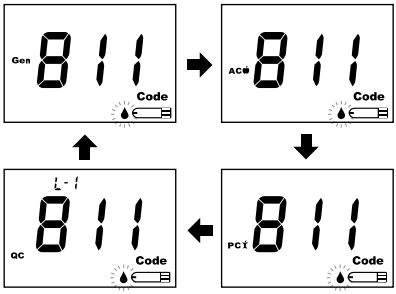
The meter provides you with four modes for measuring, General, AC, PC and QC.

MODES	USE WHEN
General (displays 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 “ ” and “Gen”.



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

Before Testing

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:

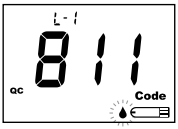
- you first receive the meter,
- at least once a week to routinely check the meter and test strips,
- you begin using a new vial of test strips,
- you suspect the meter or test strips are not working properly,
- your blood glucose test results are not consistent with how you feel, or if you think the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



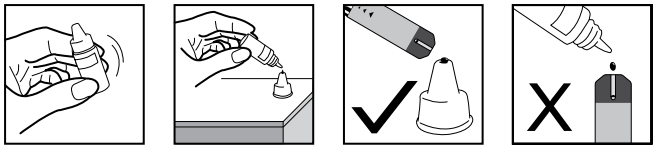
2. Press Ⓜ to mark this test as a control solution test

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

WARNING:

When doing the control solution test, you have to mark it so that the test result will **NOT** mix with the blood glucose **TEST RESULTS** stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.

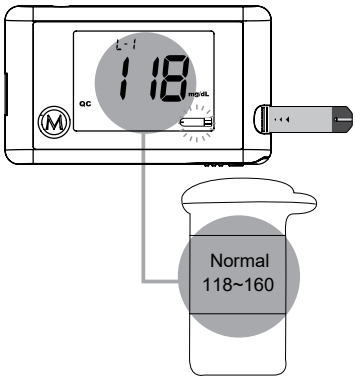
3. Apply control solution



Shake the control solution vial thoroughly before use. Squeeze out 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.

(118 mg/dL = 6.5 mmol/L; 118−160 mg/dL = 6.5−8.8 mmol/L)

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.

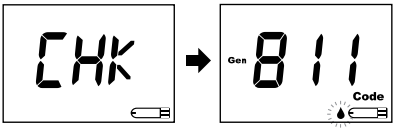
- **Fingertip Testing**

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

NOTE:

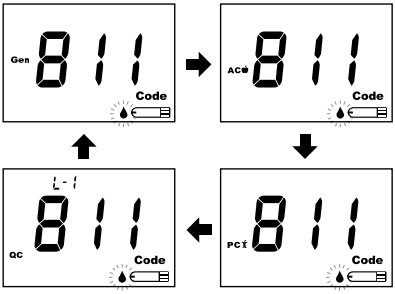
- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

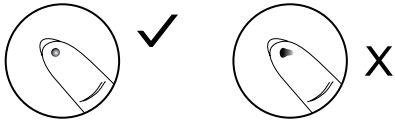


1. Insert the test strip to turn on the meter

Wait for the meter to display " ▭ " and " 🩸 ".



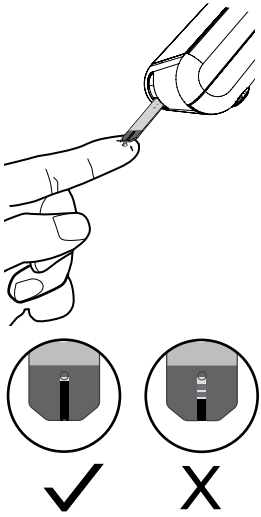
2. Select the appropriate measuring mode by pressing Ⓜ



3. Obtaining a blood sample

Use the pre-set lancing device 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.

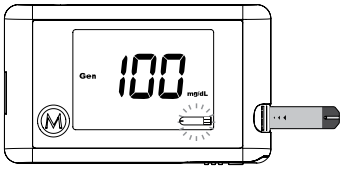


4. Apply the sample

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.

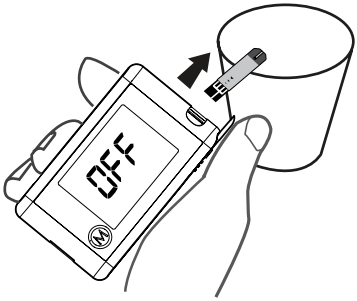
NOTE:

- 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 healthcare 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. The blood glucose result will be stored in the meter memory and transmit to the vital sign monitoring system automatically.
(100 mg/dL = 5.5 mmol/L)



6. Eject the used test strip

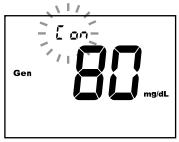
Eject the test strip by pushing the eject button on the side. Use a sharp bin to dispose of used test strips. The meter will switch itself off automatically.

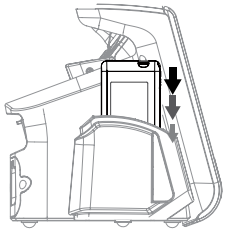
Always follow the instructions in the safety lancet.

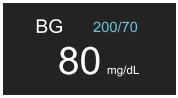
NOTE:
The used lancet and test strip may be biohazardous. Please discard them carefully according to your local regulations.

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

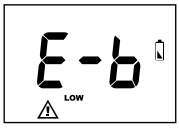
Battery

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

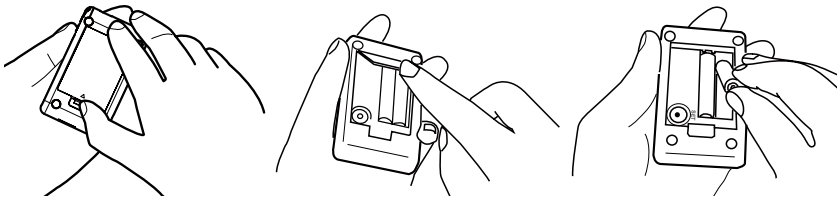
Low Battery Signal

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 batteries.



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



Replacing the Battery

To replace the batteries, make sure the meter is turned off.

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with two 1.5V AAA size alkaline batteries.
3. Close the battery cover. If the batteries are 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 avoid the meter and test strips attracting 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 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)

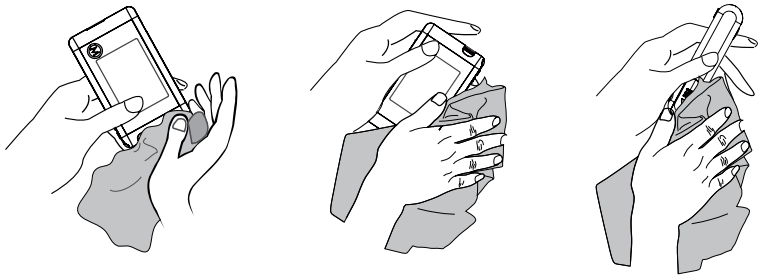
To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit www.medline.com. You can also purchase at www.amazon.com.

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.



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 service 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 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://wayback.archive-it.org/7993/20170111013014/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), below 95% relative humidity.
- 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.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 35.6°F to 89.6°F (2°C to 32°C), below 85% relative humidity. 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 expiration 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.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only our control solutions with your meter.
- Do not use the control solution beyond the expiration 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
	< 10 mg/dL (1.1 mmol/L).
	> 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 service.

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 service.

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

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 expiration 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 service.

Detailed Information

The meter provides you with plasma equivalent results.

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

Source: American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020 Jan; 43(Supplement 1): S14-S31.

Temperature Measurement

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 less than 95%.
- Always store the thermometer in a cool and dry place: temperatures between -4°F to 140°F (-20°C to 60°C), relative humidity less than 95%. 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.

Before You Begin

Intended Use

This innovative medical device relies on advanced infrared (IR) technology to measure temperature instantly and accurately from the ear canal.

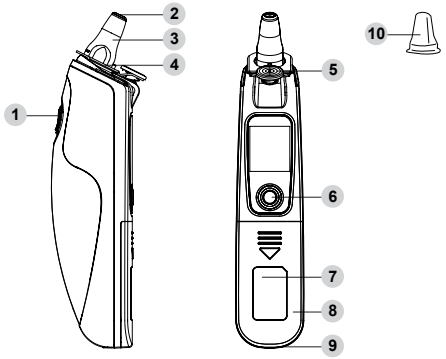
Our ear thermometer is intended for the intermittent measurement and monitoring of human body temperature from ear canal.

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.

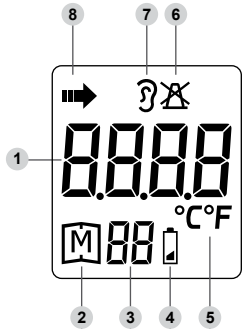
NOTE:
The thermometer does not emit any infrared signal.

Thermometer Parts



1. **Scan Button**
2. **Probe Lens**
3. **Probe**
4. **Probe Cover Detector**
5. **Probe Cover Ejection Button**
6. **On/Memory Button**
7. **Manufacturing Label**
8. **Battery Cover**
9. **Data Port**
10. **Probe Cover**

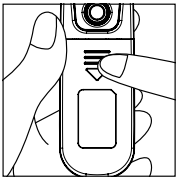
LCD Screen



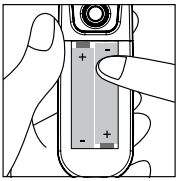
1. **Temperature Display**
2. **Memory Mode**
3. **Record Numbers**
4. **Low Battery Indicator**
5. **Temperature Unit**
6. **Probe Cover Missing**
7. **Ear Temperature Indicator**
8. **Temperature Scanning in Progress**

Replacing the Battery

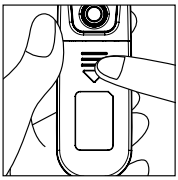
The thermometer comes with two 1.5 V AAA alkaline batteries. Replace it when " " appears. Please follow the steps to replace new batteries.



1. Remove the battery cover.



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

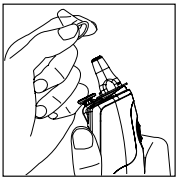


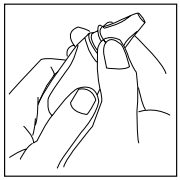
3. Reattach the battery cover.

NOTE:

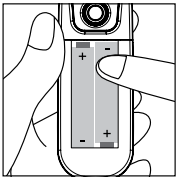
- Although the thermometer works when " " appears, we still recommend that you change the battery to obtain an accurate result.
- Remove the battery if stored for a long period of time.
- The battery should be kept out of reach of children. If they are swallowed, promptly see a doctor for help.

Using the Device





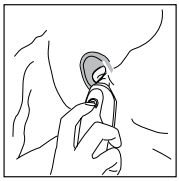
1. Apply a new probe cover



2. Turn on the thermometer

Press and release the On / Memory button. When ready, the thermometer displays the last measurement.

3. Gently fit the probe into the ear canal

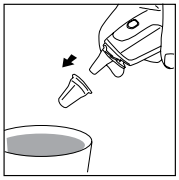


4. Press and release the Scan button

Do not remove the thermometer until it beeps.

5. Read the result

" " is shown together with a temperature value.



6. Eject the used probe cover

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

NOTE:

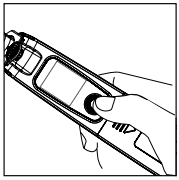
Turn off the thermometer by pressing On / Memory button twice. It will automatically turn off if left idle for 3 minutes. If you need to take another reading, wait " " flashing before taking another measurement.

WARNING:

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

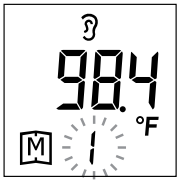
Recalling the Memory

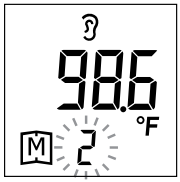
Your thermometer stores 10 recent readings in the memory.



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

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





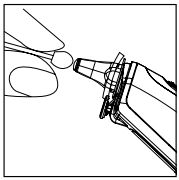
3. Press the On / Memory button for 3 seconds to enter memory mode.

Each time you press the On / Memory button, a result will be displayed in the order of dates (latest result shown first), together with " M " 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.

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.

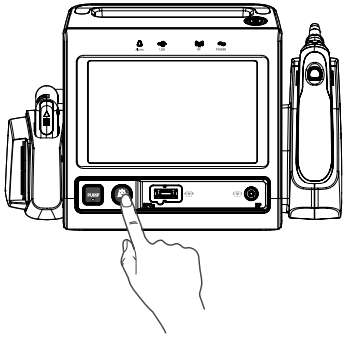
Store the thermometer in a cool and dry location. Free from dust and away from direct sunlight.

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 repeat every 5 seconds and sound 57 dB. The alarm indicator will light up red, if the alarm button is pressed.

Visible Alarms
The monitor provides visible text alarms on the interface display screen. If a physiological parameter exceeds the high limit or falls below a low limit value, the numerical value will flash red.



Alarm Silence Key

The alarm cannot be turned off, but can be temporarily silenced by pressing the **SILENCE** key. The recovery time 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, however the operator is able to investigate the cause of the alarm at later time.

Alarm Message List
Alarms and messages for heart rate may be generated by the SpO2 or the NIBP module.
For visual alarm only: NIBP, Temperature and Blood Glucose.
For both visual and audible alarm: Heart Rate and SpO2.

	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.
SpO_2	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
SpO_2 Probe OFF	Warning Tone	The SpO_2 sensor is missing or defective. Connect or replace the sensor.
Battery Low	Warning Tone	Low battery warning.

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 to 60°C), below 95% relative humidity.
- Avoid dropping and direct sunlight and humidity.

Cleaning / Disinfection

Vital-Signs 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.

SpO_2 Accessory Disposal

Dispose of all finger sensors and cables 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

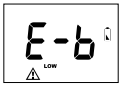
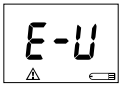
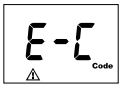
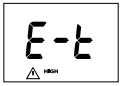
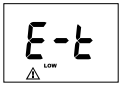
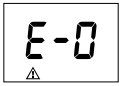
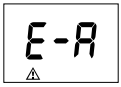
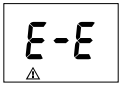
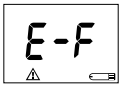
Blood Pressure Measurement Error Messages

	ERROR MESSAGE DEFINITIONS	RECOMMENDS CORRECTION
Error 01	Cuff serious leakage or Inflation too slow.	The SpO2 sensor is missing or defective. Connect or replace the sensor.
Error 02	Amplitude is enlarged over 4x than the previous 2 Amplitudes.	Pump again
Error 03	Cuff pressure is too high.(> 300 mmHg)	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 Imax.	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 re-pumping over 2 times	Pump again
Error 09	Cuff cannot deflation or deflation is too slow	Pump again

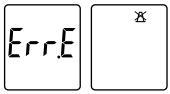
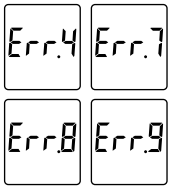
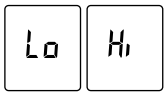
SpO2 Measurement Error Messages

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 SpO2!	When booting up, the SpO2 module is in initiation process.	Wait for the initiation process to finish.

Blood Glucose Measurement Error Messages

MESSAGE	CAUSE	WHAT TO DO
	Appears when the batteries are too low.	Replace the batteries immediately.
	Appears when a used test strip is inserted.	Repeat with a new test strip.
	Appears when the wrong code strip is inserted or other coding errors.	Review the instructions and repeat the test with a new test strip. If the problem persists, please contact the local customer service for help.
	Appears when ambient temperature is above system operation range.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip are in the above temperature range.
	Appears when ambient temperature is below system operation range.	
  	Problem with the meter.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
	Appears when 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
	Room temperature is below 50°F (10°C).	Put the thermometer under operating temperature range of 50°F to 104°F (10°C to 40).
	Room 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).
	You don't use probe cover while measuring ear temperature.	Please place probe cover into probe again.
	Problem with the thermometer.	Review the instructions and re-start the measurement procedure. If the above step do not work. Please contact the agent.
	Battery is low and " " appears on LCD.	Please replace batteries as soon as possible.
	Appears when the batteries can not provide enough power for a test.	Please replace new batteries.
	Temperature measurement fails outside the displayed temperature range: (ear temperature range from 89.6°F to 109.4°F (32°C to 43°C)).	Please follow this manual to take a reading again.

NOTE:
The error messages are displayed on the infrared thermometer.

SPECIFICATIONS

BLOOD PRESSURE	
Cuff Pressure Range	0 mmHg to 300 mmHg
Measurement Method	Adult and Pediatric mode (Clever Inflation or Deflation) Neonate mode (Deflation Only)
Systolic Range	60 ~ 250 mmHg (Adult & Pediatric) 50 ~ 125 mmHg (Neonate)
Diastolic Range	30 ~ 180 mmHg (Adult & Pediatric) 20 ~ 85 mmHg (Neonate)
MAP Range	40 ~ 210 mmHg (Adult & Pediatric) 30 ~ 100 mmHg (Neonate)
Max. Pressure	300 mmHg (Adult & Pediatric) 150 mmHg (Neonate)
Resolution	1 mmHg
Static Pressure Accuracy	±3 mmHg over full range
Automatic Cycles	5 min, 10 min, 15 min, 30 min, 1 hr, 1.5 hr, 2 hr, 4Hr
Heart Rate Range	30 ~ 240 beats/min
Heart Rate Accuracy	±2% or ± 1 beat/min when HR < 70 beats/min
STAT Mode Function	Continuous measurements in 5 minutes
Suggested Cuff Size	1. Adult - longer than 9.8” (25 cm) 2. Pediatric - 6.3” to 9.8” (16 to 25 cm) 3. Neonate - shorter than 6.3” (16 cm)
SpO_2	
Display Update Interval	1 second
Measuring Range	35% ~ 100%
Accuracy	70% to 79% ±3%, 80% to 100% ±2%, others are undefined.
Heart Rate Range	30 ~ 250 beats/min
Heart Rate Accuracy	±1% or ±1 beat/min when HR < 100 beats/min.
Measuring Principles	Dual wavelength LED
Audio	Tone with each detected pulse; pitch varies with saturation
HEART (PULSE) RATE	
Method	Select measuring the pulse rate by BPM, SpO_2 in Menu
Measuring Range	30 to 250 bpm
Update Time	Every second (for SpO_2 measuring)
Resolution	1 bpm

BLOOD GLUCOSE	
QC Function	Built in BG meter
Interface	IrDA communication with main unit
Power Source	Battery AAA x 2
Temperature	
Measurement Type	Infrared thermometer
Measurement Range	89.6°F to 109.4°F (32°C to 43°C)
Accuracy & Reliability	Better than ±0.2°C (0.2°C)
Interface	IrDA communicate with main unit
Power Source	Individual battery (“AAA” type)
Alarms	
Indication Method	Audible and Visual
Sound Volume	57 dB
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, BG, Temperature, Pulse Rate, Pulse Bar, Patient data: ID, Weight, High, 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
Printer	
Method	Thermal line dot printing
Resolution	384 dots/line , 8 dots/mm
Paper width, Type	58 mm, rolling type
Paper Loading	Easy paper operation
Power Source	1. Build-in Li battery (7.2 V), charge from main unit 2. DC-9V adapter
Interface	Serial RS-232 with main unit and charging

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	
Dimensions	12.2 H x 7.5 W x 7.5 W (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	
Input Source	100 to 240 VAC, 50 to 60 Hz input
Main Unit Battery	Li-ion Battery (DC 7.4 V, 4600 mAH); Operation time: 4 hours, Charging time: 5 hours
Environmental	
Operating Temperature	50°F ~ 104°F (10°C ~ 40°C)
Storage Temperature	-4°F ~ 140°F (-20°C ~ 60°C)
Operating Humidity	15% to 90%, 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
Harmonized Standard	
	IEC 60601-1; IEC 60601-1-2; IEC 60601-2-49; IEC 61010-2-101; IEC 61326, EN 60601-1:2006 , ISO 80601-2-61:2011 EN 1060-1; EN1060-3; EN1060-4; IEC 80601-2-30 , IEC 81060-2 American Advancement of ANSI/AAMI SP10; EN 12470; ISO 15197; ASTM E 1965-98

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

Medical devices manufactured by **FORA VSM100 Pro** vital sign monitor conform to this IEC 60601-1-2 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by **FORA VSM100 Pro**, with the exception of cables sold by **FORA 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 **FORA VSM100 Pro** is intended for use in the electromagnetic environment specified below. The customer or the user of the **FORA VSM100 Pro** should assure that it is used in such environment.

ELECTROMAGNETIC EMISSIONS IEC 60601-1-2		
Emission Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF emissions CISPR 11	Group 1	The vital sign monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The 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.
Harmonic emissions IEC 61000-3-2	None	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	None	

ELECTROMAGNETIC IMMUNITY IEC 60601-1-2			
Emission 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 % U_T (> 95 % dip in U_T) for 0.5 cycle	< 5 % U_T (> 95 % dip in U_T) 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 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	< 5 % U_T (95 % dip in U_T) for 5 sec	< 5 % U_T (95 % dip in U_T) 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: U_T 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 3.0 m.

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 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 to 80 MHz	3 V rms	Recommend separation distance d = 1.2 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommend separation distance d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √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 sign monitor

The vital sign monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of the vital sign monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the vital sign 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 2.5 GHz** $d = 2.3\sqrt{P}$
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 80 MHz and 800 MHz, 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 your agent for details.

FEDERAL COMMUNICATIONS COMMISSION (FCC) 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 in¬stalled and operated with a minimum distance of 20 centimeters between the radiator radiation source and your body.

FORA® VSM100 Pro

Distributed by ForaCare, Inc.
893 Patriot Drive Suite D, Moorpark, CA 93021 USA
Products made in Taiwan

Read instructions before use.

If you have questions, please call ForaCare Customer Care Service Center at **1-888-307-8188** (8:30 am - 5:00 pm PST, Mon. - Fri.).

For assistance outside of these hours, please visit www.foracare.com for additional information.