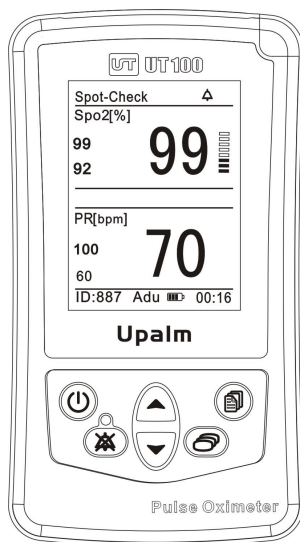


UT100 Handheld Pulse Oximeter

Operation Manual



— English
Version 1.5, November 2020
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Warranty and Service Information

Proprietary Notice

Information contained in this document is copyrighted by UTECH Co., Ltd. And may not be duplicated in full or part by any person without prior written approval of UTECH Co., Ltd. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

Limited Warranty

UTECH Co., Ltd. (“Seller”) warrants each new device to be free from defects in workmanship and materials under normal use and service for a period of one (1) years from the date of shipment. The sole obligation of UTECH company under this warranty will be repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provide if the products are modified without the express written consent of UTECH company and seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Warranties are subject to change. Please contact UTECH company for current warranty information.

Service Support

Repairs for devices manufactured by UTECH company under warranty must be made at authorized repair centers. If the device needs repair, contact your local distributor or the UTECH company after-service department. When calling, have the device’s model and serial number ready.

If you need to ship the device, pack the device and accessories carefully to prevent shipping damage. All accessories should accompany the device.

NOTE! Shipments received without a return number will be returned to

sender.

CE Notice

Marking by the symbol **CE** indicates compliance of this device to the Medical Device Directive 93/42/EEC.

EC REP Authorized Representative (as defined by the Medical Device Directive):

CMC Medical Devices & Drugs S.L.
C / Horacio Lengo No. 18, CP 29006, Malaga, Spain.

Phone: +34 951387714
Email: info@cmcmmedicaldevices.com.

Chapter 1: Introduction

1.1 About this Manual

The Operation Manual provides installation, operation, and maintenance instructions for health-care professionals and other users, trained in monitoring respiratory and cardiovascular activity.

These instructions contain important information for the safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, UTECH reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

1.2 Definition of Symbols

SYMBOL	DEFINITION
LS	
	Attention, see in instructions for use
	Type BF Defibrillation
	Power on/off
	Alarm silence
	Up and Down Arrows
	Mode Change Key
	Menu Key
	Date of Manufacturing
IPX1	Drip Proof (monitor only)
	CE Mark
	Indicates separate collection for electrical and electronic equipment.

1.3 Warning Information

KEYWORD	DEFINITION
WARNING	Tells you something that could hurt the patient or hurt the operator.
CAUTION	Tells you something that could damage the device.
NOTE	Tells you other important information.

Warnings

WARNING! Do not use this device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

WARNING! Use only SpO₂ sensors supplied with, or specifically intended for use with, this device.

WARNING! This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

WARNING! It is the operator's responsibility to set alarm limits appropriately for each individual patient.

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

WARNING! ELECTRICAL SHOCK HAZARD when cover is removed. Do not remove covers. Refer servicing to qualified personnel.

WARNING! Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a monitor with a broken display panel.

WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.

WARNING! Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure proper operation.

WARNING! If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

WARNING! Remove device batteries prior to long term storage.

WARNING! Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

WARNING! Operation of this device may be adversely affected in the presence of computed tomography (CT) equipment.

WARNING! Use only SpO₂ sensors supplied with, or specifically intended for use with, this device.

WARNING! SpO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

WARNING! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO₂ reading.

WARNING! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO₂ readings.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO₂ measurement.

WARNING! The monitor was not designed or tested to be an apnea monitor.

WARNING! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

WARNING! Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.

WARNING! Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored.

WARNING! Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in a way that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO₂ and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

WARNING! Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

Cautions

CAUTION! Do not autoclave, ethylene oxide sterilize, or immerse the monitor or sensors in liquid. Always disconnect the power source and remove all batteries before cleaning or disinfecting the monitor.

CAUTION! Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

CAUTION! The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.

CAUTION! Pressing front panel keys with sharp or pointed instruments may permanently damage the keypad. Press front panel keys only with your finger.

CAUTION! Do not allow water or any other liquid to spill onto the monitor. Unplug the external power supply from the monitor before cleaning or disinfecting the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

CAUTION! Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

Notes

NOTE! Batteries are user replaceable. Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

NOTE! All user and patient accessible materials are non-toxic.

NOTE! Each input and output connection of the monitor is electrically isolated.

Chapter 2: Intended Use and General Information

2.1 Intended Use

The UT100 Handheld Pulse Oximeter is a low cost monitor for spot checking, continuous, noninvasive monitoring or recording of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate and pulse strength. The monitor is a battery powered pulse oximeter. It may be used in the hospital, clinical environment, homecare, and during emergency land transportation. The oximeter works with given sensors providing SpO₂ and pulse rate on pediatric and adult.

This device is intended for continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

NOTE! The monitor was not designed or tested to be an apnea monitor.

2.2 Monitor Features

- Provides fast, reliable SpO₂, pulse rate, and pulse strength measurements.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, and during emergency land transport.
- Portable and lightweight. It weighs only 258 grams, with batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses four (4) standard “AA” alkaline or Ni-MH batteries.
- Battery life is approximately twenty (20) hours.
- Bright, easy-to-read LCD displays indicate SpO₂ and pulse rate measurements, Plethysmogram and trend table.
- Screen rotation provides upright display for vertical or horizontal monitoring positioning.
- Perfusion Index indicates arterial pulse signal strength.

- Three measuring modes:
Spot-Check mode: Measure data intermittently.
Monitor mode: Measure and store data continuously.
Record mode: Measure and store data in energy-save mode.
- Adjustable volume (including silence) “beep” sounds with each pulse beat.
- Positive identification of SpO₂ or pulse rate alarm. Adjustable high and low alarm limits for SpO₂ and pulse rate measurements.
- Adjustable volume for alarm and alert tones (including silence).
- Low battery icon flashes when about 15 minutes of battery use remains. A red high priority alarm information turns on the alarm bar and an audible two groups of 5-beep burst notifies the user low battery life.
- Patient information management. Patient’s information such as ID, Sex, Type can be managed.

2.3 Theory of Operation

The pulse oximeter determines %SpO₂ and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photodetector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the *SpO₂ Specifications* section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

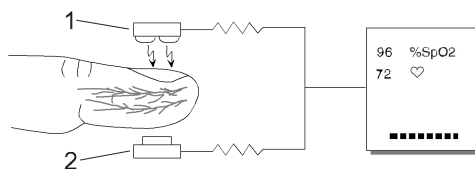


Figure 2.1: Theory of Operation

1. Low intensity Red and Infrared LED light sources

2. Detector

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO_2) to identify the pulses and calculate functional oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

WARNING! Since measurement of SpO_2 depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO_2 and pulse rate readings.

WARNING! Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO_2 and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

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Chapter 3: Controls and Features

3.1 Monitor Front Panel

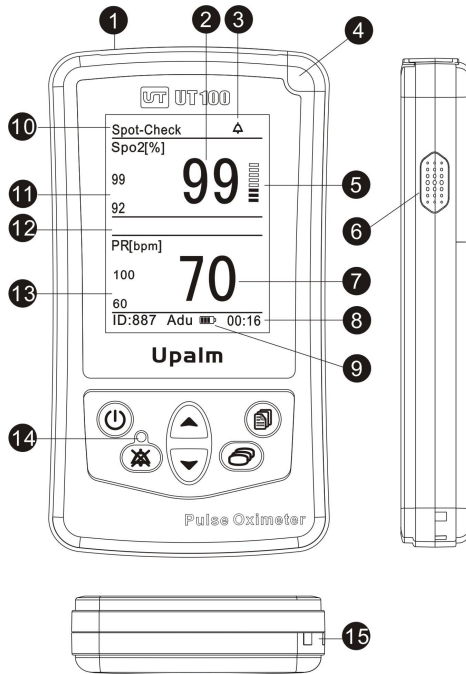


Figure 3.1: Monitor Controls, and Features

1. Sensor Connector

The sensor connects here, or an oximetry extension cable can be connected between the monitor and the sensor.

2. SpO₂ Numeric Display

A number shows the patient's SpO₂ value in percent. Dashes (- -) mean the monitor is not able to calculate the SpO₂ value.

3. Mute icon

The mute icon is displayed at the status bar and it has three statuses:

“” this icon means the normal status of alarm sound.

“” this icon is displayed during temporary 30sec, 60sec, 90sec, 120sec alarm silence.

“” this icon is displayed steadily during permanent alarm silence.

4. Power Indicator

This indicator lights steadily to inform the working status of the monitor. Green means the monitor working normally and red means alarm occurred.

5. Pulse Strength Bar Graph

The pulse strength bar graph “sweeps” with the patient’s pulse beat. The height of the bar graph shows the patient’s pulse strength.

6. Speaker

It provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered.

7. Pulse Rate Numeric Display

A number shows the patient’s pulse rate value in beats per minute. Dashes (- - -) mean the monitor is not able to calculate the pulse rate value

8. Information Bar

The information bar displays patient’s ID/ type, battery level icon, date/time.

9. Battery level Icon

This icon is displayed at the information bar and has four levels. It flashes when there is only 15 minutes left for the monitor shut down it self.

10. Status Bar

The status bar displays the three measuring modes, sensor off/finger off/pulse search/low perfusion icon and volume icon.

11. Current Alarm Limits of SpO₂

If the high/low alarm limit has been changed from the default settings, there will be a decimal point displayed after it.

12. Alarm bar

The alarm bar displays high and medium alarm events to alert users.

13. Current Alarm Limits of Pulse Rate

If the high/low alarm limit has been changed from the default settings, there will be a decimal point displayed after it.

14. Silence Indicator

This indicator flashes during temporary two-minute alarm silence. The indicator lights steadily during permanent/indefinite alarm silence.

15. Slot for hanging strap

3.2 Monitor Operating keys

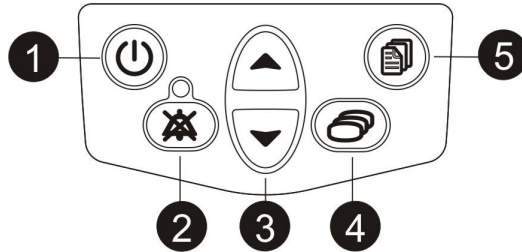


Figure 3.2: Monitor Operating Keys

1.ON/OFF key

Pressing this key for 5 seconds turns the monitor ON and OFF.

2. Silence key

Pressing the Silence key once in turn can disable the alarm tone for 30sec, 60sec, 90sec, 120sec and disable it indefinitely (until canceled or the monitor is turned off). Note: each pressing should be within 3 seconds.

To cancel the temporary alarm and alert tone silenced condition, press the Silence key twice. To cancel the indefinite silenced alarm, press the Silence key once. The Silence indicator will turn off.

3. Up and Down Arrows

The Up and Down arrow keys are used to adjust the following settings:

- Alarm/ Pulse Volume
- Move the cursor circularly.
- Increase/decrease numbers
- Choose options.

4. Mode Key

Press this key to switch between the four display modes that are big display mode, waveform mode, trend table mode and horizontal display mode.

5. Menu Key

Press this key to change the settings like: patient's information, high/low alarm limits, time and date.

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Chapter 4: Operating Instructions

WARNING! Do not use an UT100 monitor, sensor, cables, or connectors that appear to be damaged.

WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.

4.1 Unpacking the Monitor

1. Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

4.2 Install the Batteries

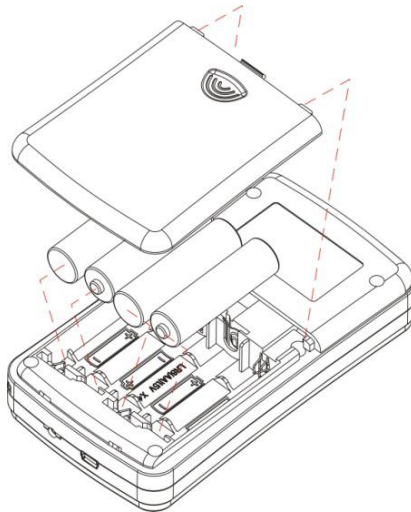


Figure 4.1: Installing the Batteries

The oximeter uses 4 (four) standard “AA” alkaline or Ni-MH cells.

To install/replace the batteries:

1. Depress the battery door and remove it downward.

2. Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive tab. Press the battery down into place.
3. Place battery door into the slots of the monitor back panel, depress the door tab, and press the door into place.

NOTE! If you install disposable batteries, be sure to dispose of them in compliance with your institution's guidelines and local ordinances.

NOTE! The unit will hold data for about one and a half minutes with no battery power. This will insure the safety of trend data during battery replacement.

4.3 Attaching the Sensor to the Patient

WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

Attaching the patient to the monitor requires these steps:

1. Choose the sensor.
2. Check the sensor and oximetry cable.
3. Clean or disinfect the sensor if using the reusable type (Disposable sensors are for single-patient use and do not require cleaning or disinfecting).
4. Attach the sensor to the patient.

4.3.1 Choosing the Sensor

WARNING! Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.

Choose the appropriate sensor from the following chart.

PATIENT	SITE	DESCRIPTION
---------	------	-------------

Adult >45Kg	Finger Finger or toe Ear	Sensor, Adult (reusable) Sensor, Disposable, Adult Finger Sensor, Ear (reusable)
Pediatric 3-45Kg	Finger Finger or toe Ear	Sensor, Adult (reusable) Sensor, Disposable, Ped. Finger Sensor, Ear (reusable)

4.3.2 Care and Handling of the Sensor

WARNING! Misuse or improper handling of the sensor and cable could result in damage to the sensor. This may cause inaccurate readings.

Hold the connector rather than the cable when connecting or disconnecting the sensor to the device as shown in Figure 4.2.

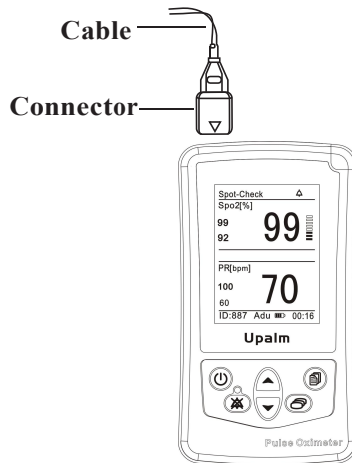


Figure 4.2: Disconnecting or connect the sensor

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor.

Place an adult/pediatric SpO₂ sensor:

When placing the sensor on the patient, allow the cable to lay the back of hand as shown in Figure 4.3.

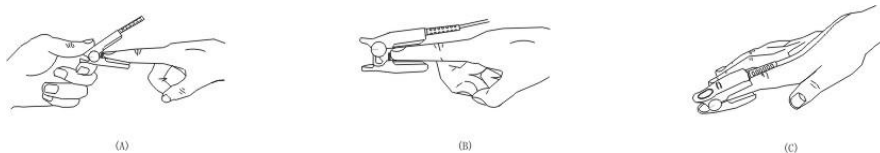


Figure 4.3: Positioning the cable of the finger sensor

4.3.3 Checking the Sensor and Oximetry Cable

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable are working properly.

WARNING! Using a damaged sensor/cable may cause inaccurate readings. Inspect each sensor/cable. If a sensor/cable appears damaged, do not use it. Use another sensor/cable or contact your authorized repair center for help.

1. Carefully inspect the sensor to make sure it does not appear damaged.
2. If using the oximetry cable, carefully inspect the oximetry cable to make sure it does not appear damaged.
3. If using the oximetry cable:
 - a. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable. Push the connectors together firmly and close the latch to secure the connectors.
 - b. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor. Push the connector firmly into the monitor.
4. If not using the oximetry cable, connect the sensor to the monitor. Push the connector firmly into the monitor.
5. If the monitor is not already on, press the On/Off key to turn on the monitor.

WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.

6. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:

7. Make sure the red light in the sensor is illuminated.

NOTE! Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.

7. You are now ready to attach the sensor to the patient.

4.3.4 Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.

WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

4.4 Performance Considerations

WARNING! Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- Incorrect application of the sensor
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Prolonged patient movement

Loss-of-pulse signal can occur for the following reasons:

- The sensor is too tight
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is arterial occlusion proximal to the sensor

Select an appropriate sensor, apply it as directed, and observe all warnings and Cautions presented in the directions for use accompanying the sensor. Clean and remove any substance such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

WARNING! Tissue damage can be caused by incorrect application or duration of use of a SpO₂ sensor. Inspect the sensor site as directed in the sensor directions for use.

High ambient light source such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO₂ sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

NOTE! Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

If patient's movement presents a problem, try one or more of the following remedies to correct the problem:

- Verify that the sensor is properly and securely applied
- Move the sensor to a less active site
- Use an adhesive sensor that tolerates some patient motion
- Use a sensor with fresh adhesive backing

4.5 Turning On the Monitor

WARNING! To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING! As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING! Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

1. To turn on the monitor, press and held the ON/OFF key for about five seconds. When turned ON, the monitor does the following:

- The monitor starts a power-on self test (POST) quickly.

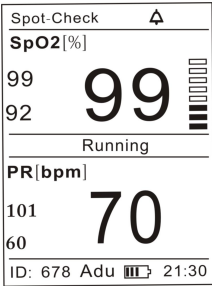
- The monitor's software revision is momentarily displayed.
 - The Power Indicator illuminates green.
2. Upon successful completion of the POST, the UT100 sounds a one-second tone indicating that the monitor has passed the test.
 3. If a sensor is connected to the monitor and the patient, the Pulse Search Icon (♥) is displayed at the Status Bar. "--" will flash on the numeric display until the SpO₂ and pulse rate reading have stabilized. The monitor will search the pulse for 8 seconds.
 4. The monitor will pop up a dialog to remind operator to set the patient's ID. If choose NO or no pressing within 5 seconds, the monitor will use the last ID for the present patient.
 5. Monitor the patient.

WARNING! **Verify that the power indicator lights up and you can hear the POST pass tone upon startup of the device. If not, do not use the monitor.**

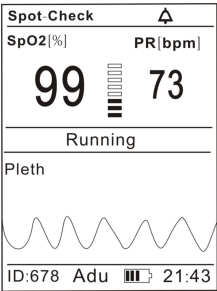
WARNING! **The oximeter will automatically be powered off when no finger is in the device and no operation for longer than five minutes in the Spot-check and Monitoring measuring modes. The screen brightness will be decreased when no finger is in the device and no operation for longer than three minutes in the Recording measuring modes.**

4.5.1 Four Display Modes

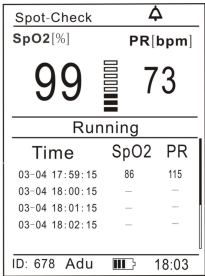
There are four Display Modes of the monitor, you can switch between them by pressing the Mode Key. The modes are shown as below:



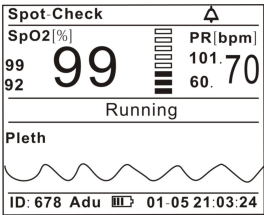
(A)Big Display Mode



(B) Waveform Display Mode



(C)Trend-table Display Mode



(D) Horizontal Display Mode

Figure 4.4 Four Display Modes

4.5.2 Three Measuring Modes

There are three Measuring Modes: Spot-Check, Continuous Monitor, Record. Their differences are compared in to below table:

Modes	Spot-Check	Monitor	Record
Way of Measurement	intermittently	continuously	continuously
Data Saved or not	NO	YES	YES
Energy-save or not	NO	NO	YES
Alarm or not	YES	YES	NO
Volume Adjustable or not	YES	YES	NO

In the Record measuring mode, if you don't press any key for 3 minutes, the monitor will display the following interface in order to save energy:

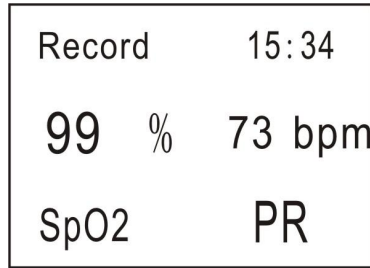


Figure 4.5 Interface of Record Measuring Mode

4.6 Turning Off the Monitor

After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules.

Turn off the monitor when you are not monitoring a patient. To turn off the monitor, press and held the On/Off key for about five seconds.

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Chapter 5: Changing the Monitor's Settings

5.1 Changing the Pulse Volume



Figure 5.1 Pulse Volume Bar

A “beep” tone sounds with each pulse beat. The volume of the “beep” can be adjusted to seven (7) settings. Setting the volume by pressing the Up and Down Arrow, the volume is increased or decreased with each key press.

5.2 Changing the Alarm Volume



Figure 5.2 Alarm Volume Bar

Hold the Silence key for 3 seconds to change the alarm volume. Setting the volume by pressing the Up and Down Arrow, the volume is increased or decreased with each key press.

5.3 Managing the Patient's Information

Please write down the information of the patient who is going to be monitored like: Patient's ID (from 000 to 999), Sex (Male or Female), Type (Adult/pediatric) and Mode (Spot-Check/Record/Monitor).

Main Menu		
Patient	ID	678
Alarm Set	Sex	Male
	Type	Adu
Date/Time	Mode	Spot-Check
Reset		
		OK Cancel

Figure 5.3 Managing the patient's information

1. Press the Menu key to enter into the Main Menu interface.

2. Press the Down key and the Menu key to enter the "Patient" submenu.
3. Press the Up/Down key to choose items you want to change and press the Menu key to active the items.
4. Press the Up/Down key increase/decrease the setting and then use the Menu key again to exit.
5. Press the Up/Down key to OK/ Cancel button to confirm/ cancel your settings.

5.4 Changing the Alarm Limits

Alarms are audio and visual indicators generated by the monitor to alert doctors and nurses. These alarms occur when the vital signs of the patients being monitored become abnormal, or the monitor itself malfunctions and could not perform the monitoring task.

5.4.1 Alarm Summary

Alarm Events	Alarm Level	Alarm adjustable or not	Visual alarm	Audio alarm
SpO ₂ exceed the pre-set limits	High	Yes	1. Numbers of SpO ₂ will flash. 2. Alarm event will be displayed in red at the Alarm Bar. 3. Alarm icon  will flash in the middle of the screen for 5 seconds.	Two groups of "dee-dee-dee-dee" Period: 10 secs
PR exceed the pre-set limits	Medium	Yes	1. Numbers of SpO ₂ will flash. 2. Alarm event will be displayed in yellow at the Alarm Bar.	Two groups of "dee-dee-dee" Period: 18 secs
Sensor off	High	NO	1. The icon  will be displayed at the Status Bar. 2. "Sensor off" will be displayed in red at the Alarm Bar.	Two groups of "dee-dee-dee-dee" Period: 10 secs
Finger off	High	NO	1. The icon  will be displayed at the Status Bar. 2. "Finger off" will be displayed in red at the	Two groups of "dee-dee-dee-dee" Period: 10 secs

			Alarm Bar.	
Low battery	High	NO	1. The Battery Level Icon will flash. 2. "Low battery" will be displayed in red at the Alarm Bar.	Two groups of "dee-dee-dee-dee-dee" Period: 10 secs
Data full	Medium	NO	"Data full" will be displayed in yellow at the Alarm Bar.	Two groups of "dee-dee-dee" Period: 18 secs
Battery abnormal	High	Yes	"Battery abnormal" will be displayed in red at the Alarm Bar.	Two groups of "dee-dee-dee-dee-dee" Period: 10 secs

NOTE! The power indicator will flash in red in all levels of alarm.

WARNING! There is no alarm in the Record Measuring Mode.

5.4.2 Changing the Alarm Settings

Main Menu			
Patient	SpO2	PR	
Alarm	On	On	
Alarm Set	Upper	98	110
Date/Time	Lower	96	66
Level	Senior	Medium	
Reset			Reset
	OK	Cancel	

Figure 5.4 Changing the alarm settings

Each measurement, SpO₂ and Pulse Rate, has a high and low alarm limit setting.

1. Press the Menu key to enter into the Main Menu interface.
2. Press the Down key twice and the Menu key to enter the "Alarm Set" submenu.
3. Press the Up/Down key to choose items you want to change and press the Menu key to active the items.
4. Press the Up/Down key increase/decrease the setting and then use the Menu key again to exit.
5. Press the Up/Down key to OK/ Cancel button to confirm/ cancel your

settings.

You can press the “Reset” button to reset you settings.

WARNING! Be aware of alarm limits of similar units in the same area when adjusting alarm limits of this device to avoid confusion.

NOTE! Alarm limits are non-overlapping. You cannot set the high alarm equal to or lower than the low alarm and you cannot set the low alarm equal to or higher than the high alarm.

NOTE! While setting alarm limits, if no keys are pressed for twenty seconds, the alarm limit setting mode is exited and the SpO₂ and pulse rate measurements are shown. Changes aren't saved.

NOTE! The alarm actions occur for each violated alarm, even if more than one alarm is violated at the same time.

NOTE! Alarms may be tested while the monitor is in use by setting alarm limits such that the measured parameter is outside alarm limits. Return limits to the required settings after testing.

NOTE! If you change the patient's type, the alarm limits will become default limits of this type.

5.5 Changing the date and time

Main Menu			
Patient	YY - MM - DD		
	2010	2	15
Alarm Set	HH mm SS		
	15	30	22
Date/Time			
Reset			
		OK	Cancel

Figure 5.5 Changing the date and time

1. Press the Menu key to enter into the Main Menu interface.
2. Press the Down key thrice and the Menu key to select the “Date/Time”

- submenu.
3. Press the Up/Down key to choose items you want to change and press the Menu key to active the items.
 4. Press the Up/Down key increase/decrease the setting and then use the Menu key again to exit.
 5. Press the Up/Down key to OK/ Cancel button to confirm/ cancel your settings.

5.6 Resetting

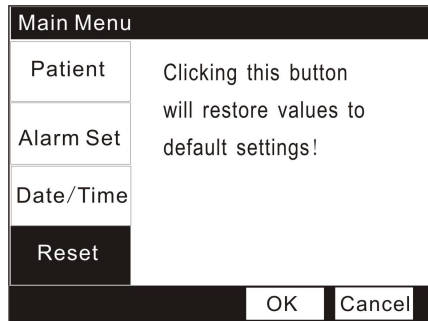


Figure 5.6 Restoring default settings

1. Press the Menu key to enter into the Main Menu interface.
2. Press the Down key for four times and the Menu key to select the “Reset” option.

NOTE! If you choose to reset your settings, all settings will be restored to the Factory Default Settings except the Date and Time.

Factory Default Settings:					SpO ₂	PR
Patient	ID	987	Alarm	Alarm	On	On
	Sex	Male		Upper	99	100
	Type	Adult		Lower	92	60
	Mode	Spot-Check		Level	Senior	Medium

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Chapter 6: Accessories

6.1 Standard Configuration

CAT.NO	DESCRIPTION	QTY
UT100B	UT100 Handheld Pulse Oximeter	Each
US10BS	Adult Finger SpO ₂ Sensor	Each
1615	AA size Alkaline Batteries	Four
5479	Hanging Strap	Each
9230	Operation Manual	Each

6.2 Optional Accessories

CAT.NO	DESCRIPTION	QTY
1616	AA size Ni-MH Batteries	Four
4210	Reusable sensor, Adult, Finger	Each
4211	Reusable sensor, Pediatric, Finger	Each
4213	Single patient use sensor, Adult>30kg	Each
4214	Single patient use sensor, Ped 3-50kg	Each
3425	SpO ₂ extension cable	Each

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Chapter 7: Maintenance and Troubleshooting

7.1 Schedule of Maintenance

MAINTAIN THIS ITEM	HOW OFTEN	BY DOING THIS
Battery	When Battery Level icon is flashing, and/or audible alarm sounds.	Follow the instructions for installing the batteries.
Disinfecting the reusable sensor.	Before attaching the sensor to the patient.	Follow the instructions for cleaning the reusable sensor.
Disinfecting the monitor.	When necessary.	1. Remove the batteries from the unit. 2. Wipe the surfaces of the monitor with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet.

CAUTION! Do not allow isopropyl alcohol or water to enter any of the openings on the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

7.2 Storage

WARNING! To ensure accurate performance and prevent device failure, do not subject the UT100 to extreme moisture such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

Whenever possible, the monitor should be stored at room temperature in a dry environment.

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing.

Storage specifications are as follows:

Temperature: -20°C to +55°C
 Relative Humidity: 10% to 95% (noncondensing)

7.3 Troubleshooting

PROBLEM	POSSIBLE CAUSE	CORRECTIVE
No pulse shown on the bargraph.	• Patient cable or sensor is disconnected from the oximeter. • Sensor is incorrectly positioned on the patient. • Poor patient perfusion. • Defective sensor or patient cable.	• Check sensor connections to the patient cable and to the oximeter. • Reposition the sensor. • Reposition the sensor. • Try a new sensor or contact your authorized repair center for help.
No Pulse	• Pulse signal is too weak	• Check signal source.
Pulse rate is erratic, intermittent, or incorrect.	• Sensor incorrectly positioned. • Patient motion	• Reposition the sensor. • Patient must remain still to obtain an accurate measurement.
SpO ₂ value is erratic, intermittent, or incorrect.	• Poor patient perfusion. • Patient motion.	• Reposition the sensor. • Patient must remain still to obtain an accurate measurement.
No PR and SpO ₂ values.	• Defective sensor or patient cable or monitor.	• Try a new sensor or contact your authorized repair center for help.
Battery Abnormal	• Batteries incorrectly installed. • There are no batteries.	• Reposition batteries correctly. • Equip with oximeter with batteries.
The oximeter doesn't turn on.	• Batteries weak. • Batteries not installed or batteries incorrectly installed.	• Replace the batteries. • Ensure the batteries are installed correctly.
The oximeter turns off unexpectedly.	• Batteries are weak or dead.	• Replace the batteries.

Sensor	•Patient cable or sensor is disconnected from the oximeter. •Sensor is incorrectly positioned on the patient. •Poor patient perfusion. •Defective sensor or patient cable	•Check sensor connections to the patient cable and to the oximeter. •Reposition the sensor. •Reposition the sensor. •Try a new sensor or contact UTECH Co., Ltd After Service Department for help.
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7.4 EMI Interference

CAUTION! This device has been tested and found to comply within the limits for medical devices to EN 60601-1:2006, EN 60601-1-2:2007, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phone, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not operate correctly.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect function. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.

- Increase the separation between the interfering equipment and this equipment.

If assistance is required, contact the UTECH Co., Ltd after-service department or your local representative.

Chapter 8: Specification

8.1 Equipment Classification

Type of Protection Against Electric shock:	Internally Powered
Mode of operation:	Continuous
Degree of Protection Against ingress of Liquids:	IPX1, drip proof
Degree of Mobility:	Handheld
Degree of Protection Against Electric Shock:	Type BF
Safety Requirements:	EN60601-1:2006

8.2 SpO₂

Range:	0-100%
Accuracy:	±2 at 70 - 100% <70%, undefined
Resolution:	1%
Display Response:	The display is to functional saturation. The pulse strength bar graph is not proportional to pulse volume.

8.3 Pulse Rate

Range:	30-250bpm
Accuracy:	±2 at 30 – 250bpm
Resolution:	1bpm

8.4 Default Settings of Alarms Limits

	High Alarm Limits		Low Alarm Limits	
	Adult	Pediatric	Adult	Pediatric
SpO₂	99	99	92	92
PR	100	110	60	70

8.5 Power Requirements

Four standard “AA” alkaline or Ni-MH cells (1.5Vdc, IEC Type LR6)

8.6 Battery Life

Alkaline Cells: 20 hours

8.7 Dimensions

Width:	75mm (2.95 inches)
Height:	135mm (5.31 inches)
Depth:	28mm (1.10 inches)
Weight:	258grams (9.10 ounces) with batteries

8.8 Environmental Specification

Operating Temp.:	0 to 40°C
Storage Temp.:	-20 to +55°C
Shipping Temp.:	-40 to +55°C
Atmospheric Pressure:	70,0KPa to 106,0KPa
Relative Humidity:	30 to 95% (operating)
	10 to 95% (storage)
	0 to 95% (shipping)

Appendix A: Revision History

Revision	Date	Comment
Rev1.0	2010-3	•Added CE Notice and European Representative to Warranty section. •Updated Symbols and their Definition. •Updated product pictures. •Updated the way to change alarm and pulse volumes in chapter 3 and 5. •Added a note about alarm limits changing with patient type in chapter 5. •Add this Revision History.
Rev1.1	2010-9	•Delete all the information about neonatal patients.
Rev1.2	2012-12	•Revise the company address and contact information •Change the operation temperature •Add the atmospheric pressure •Delete the LOGO
Rev1.3	2015-8	•Add “No Pulse” prompt. •Updated the address and phone.
Rev1.4	2019-12	•Updated the address and phone and Fax.
Rev1.5	2020-11	•Update the information on the representative of Europe

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