UT100 Handheld Pulse Oximeter

Operation Manual

— English

Version 1.0, January 2010

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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.

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

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.

1.2 Definition of Symbols

SYMBOLS	DEFINITION
	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)
	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 SpO_2 sensors supplied with, or specifically intended for use with, this device.

WARNING! Do not plug the monitor into an outlet controlled by a wall switch.

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 tomograph (CT) equipment.

WARNING! Use only SpO_2 sensors supplied with, or specifically intended for use with, this device.

WARNING! SpO_2 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 SpO_2 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 SpO_2 readings.

WARNING! Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO_2 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! Disconnect the AC power supply from the outlet before disconnecting it from the monitor. Leaving the AC power supply connected to an AC power outlet without being connected to the monitor may result in a safety hazard.

WARNING! Do not allow any moisture to touch the AC power supply connectors or a safety hazard may result. Ensure that hands are thoroughly dry before handling the AC power supply.

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! If there is a risk of the AC power supply becoming disconnected from the monitor during use, secure the cord to the monitor several inches from the connection.

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.

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! Ensure the device's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the UTECH Co., Ltd after-service department, or your local distributor, for help.

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! When using AC power, the Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

NOTE! It is recommended that batteries be used with the monitor when operating with AC power to prevent monitor shutdown with loss of AC power.

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 (SpO_2), pulse rate and pulse strength. The monitor is a battery or AC adapter 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 SpO_2 and pulse rate on all patients from neonatal to 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 SpO_2, 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 500 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 SpO_2 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 SpO_2 or pulse rate alarm. Adjustable high and low alarm limits for SpO_2 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.
- Data can be transferred to PC through a data line for storage, review and analysis.

2.3 Theory of Operation

The pulse oximeter determines %SpO_2 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 *SpO_2 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.

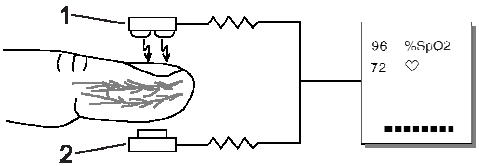

Figure 2.1: Theory of Operation

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

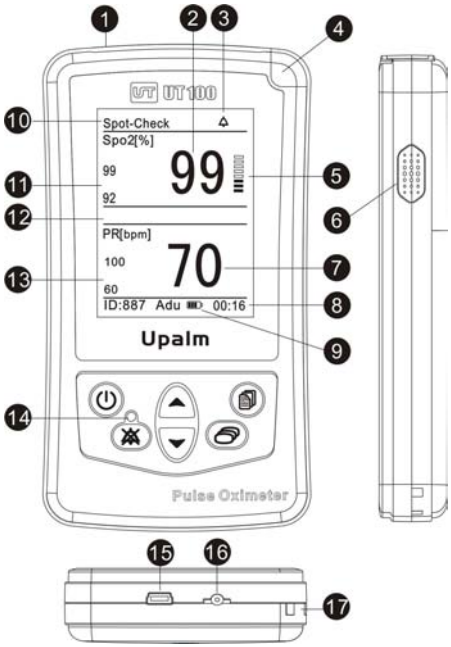


Figure 3.1: Monitor Controls, and Features

1. Sensor Connector

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

2. SpO_2 Numeric Display

A number shows the patient's SpO_2 value in percent. Dashes (- - -) mean the monitor is not able to calculate the SpO_2 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 there measuring modes, sensor off/finger off/pulse search/low perfusion icon and volume icon.

11. Current Alarm Limits of SpO_2
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 indictor lights steadily during permanent/indefinite alarm silence.

15. USB Interface
The USB interface is used to connect the monitor with PC for trend data output.

16. AC Power Jack
An optional AC power supply connects here.

17. Slot for hanging strap

3.2 Monitor Operating keys

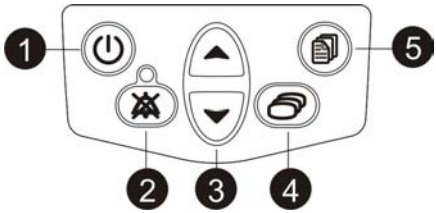


Figure 3.2: Monitor Operating Keys

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.

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

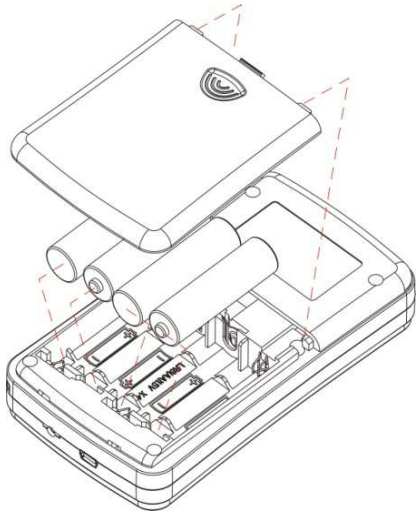


Figure 4.1: Installing the Batteries

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 AC Power Adapter

The AC power adapter can be used as the monitor's power supplier and Ni-MH cells' charger.

NOTE! Do not plug the monitor into an outlet controlled by a wall switch.

NOTE! When using AC power, the Digital Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

NOTE! Do not use the AC adapter to charge alkaline batteries.

4.3.1 Charging Ni-MH batteries

The battery may discharge during prolonged storage or shipment. If the monitor have been in storage for more than 2 months, it is important to plug the AC power adapter into an AC outlet and allow the batteries to charge for approximately 30 minutes before attempting to operate the instrument.

To charge a low battery, connect the monitor to an AC power through the AC power adapter. A full charge of a completely discharged battery takes 20 hours

while the monitor is turned off.

4.4 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.

4.4.1 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 15-45Kg	Finger Finger or toe Ear	Sensor, Adult (reusable) Sensor, Disposable, Ped. Finger Sensor, Ear (reusable)
Neonate ＜3Kg (for spot-check only)	Hand or Foot Foot	Sensor, Disposable, Neonate Sensor, Wrap. Neonate(reusable)

4.4.2 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.

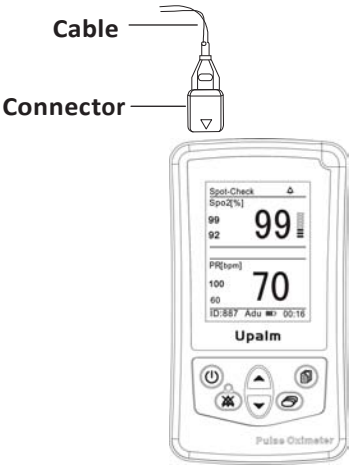


Figure 4.2: Disconnecting or connect the sensor

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

Place an adult/pediatric SpO_2 sensor:

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

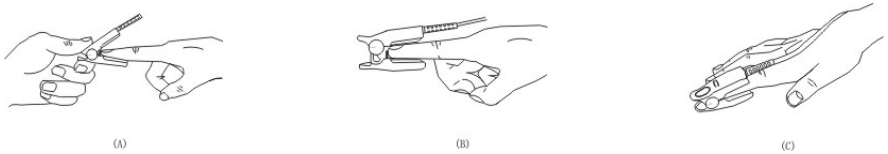


Figure 4.3: Positioning the cable of the finger sensor

Place a neonatal SpO_2 sensor:

Neonatal SpO_2 sensors are Y-type with a rubber wrap. First insert the Y into the slots of the wrap as shown in Figure 4-4. After placed, the Neonatal SpO_2 sensors look like Figure 4-5.

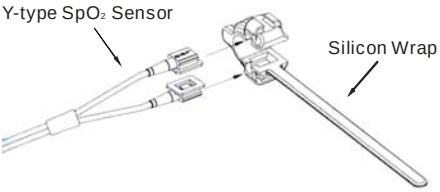


Figure 4.4 Placing Neonatal SpO_2 Sensor

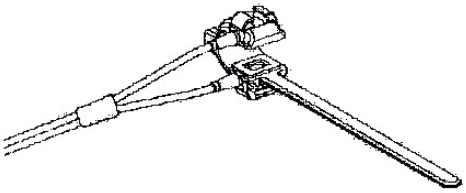


Figure 4.5 Placing Neonatal SpO_2 Sensor

Place the sensor onto the foot or hand. Secure the wrap (about 20mm long) to ensure the correct position of the sensor as shown in Figure 4-6. Do not secure the wrap too tight as it may affect the blood flow.

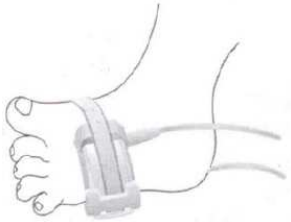


Figure 4.6 Placing Neonatal SpO_2 Sensor

4.4.3 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:

   a. 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.

4.4.4 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.

4.5 Performance Considerations

WARNING! Pulse oximetery 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 SpO_2 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 SpO_2 sensor. To prevent interference form 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

4.6 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 nrmeric display until the SpO_2 and pulse rate reading have satbilized. 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.

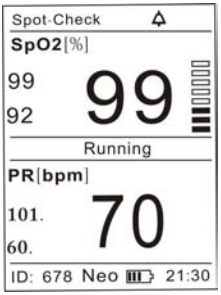
WARNING! Verify that the power indicator lights up and you can hear the POST pass tone upon startup of the device. If not, do

not use the monitor.

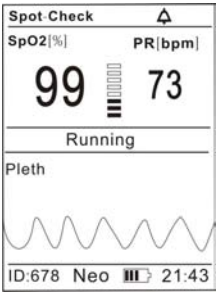
WARNING! The oximeter will automatically be powered off when no finger is in the device and no operation for longer than five minutes in the Spot-check and Monitoring measuring modes. The screen brightness will be decreased when no finger is in the device and no operation for longer than three minutes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

4.6.1 Four Display Modes

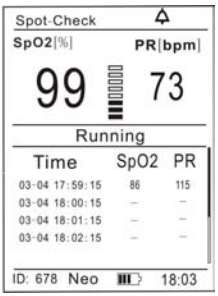
There are four Display Modes of the monitor, you can switch between them by pressing the Mode Key. The modes are shown as below:



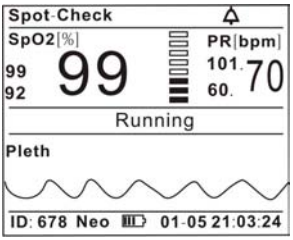
(A)Big Display Mode



(B) Waveform Display Mode



(C)Trend-table Display Mode



(D) Horizontal Display Mode

Figure 4.7 Four Display Modes

4.6.2 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:

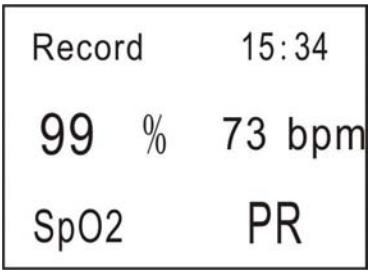


Figure 4.8 Interface of Record Measuring Mode

4.7 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.

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 /neonatal) and Mode (Spot-Check/Record/Monitor).

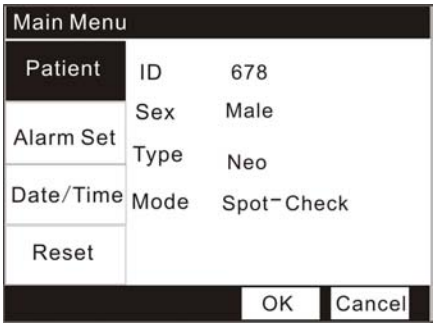


Figure 5.3 Managing the patient's information

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-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-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-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

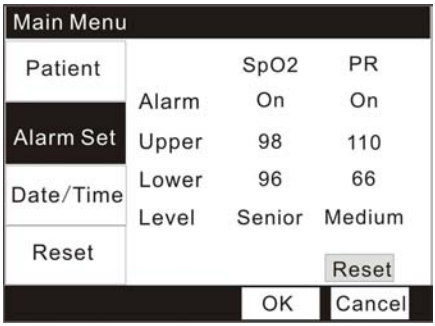


Figure 5.4 Changing the alarm settings

Each measurement, SpO_2 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 SpO_2 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

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

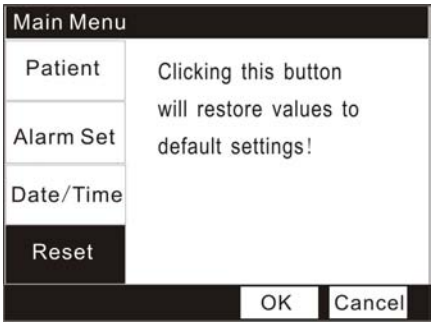


Figure 5.6 Restoring default settings

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: Trend Data Output and Analysis

6.1 Connecting the Oximeter to PC

The UT100 can store 120 hours of SpO_2, Pulse Rate, Trend Data captured at 1 second intervals. This trend data can be transferred to a PC for evaluation.

Trend data is stored in non-volatile memory, so it is not erased when the unit is shut off or when the batteries are replaced.

The device will send out trend data through USB interface so that the data can be stored, analyzed and printed. An additional USB Data Cable is required to connect the device to a PC.

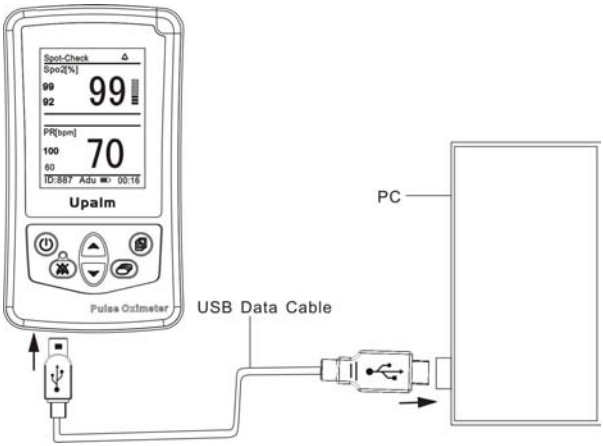


Figure 6.1: PC Communication Setup

6.2 Installing the Oximetry Data Management System

The Oximetry Data Management System (ODMS) is a management and analysis system for oximetry data. It supplies functions like data download, data review, case information edit, data analysis and result print etc. To install the ODMS, Please conduct the following steps:

1. Insert the CD into CD-ROM.
2. Copy to the Setup file from the CD to your computer.
3. Open the Setup file and dblclick to install it. It will take about 1 minute.

4. You are now ready to use the ODMS.

6.3 Function of Main Menu

Figure 6-2: The main menu

1. ***Open Data Base:*** Allows user to create, delete, search, and view patient files and study records.

2. ***Case Information:*** Allows user to immediately refer back to patient information while viewing study data.

3. ***Down Load All:*** Allows user to access to the patient database and transfer all trend data from the oximeter to ODMS for analysis.

4. ***Print Report:*** Allows user to print statistical, desaturation, SpO_2, or full reports.

5. ***Option:*** Allows user to setup serial communication, Baud Rate and auto or manual etc.

6. ***Help:*** Displays user sheet and operate method when problems occur.

7. ***Exit:*** Allows user to exit the ODMS.

6.4 Trend Data Download

To download trend data to PC, please conduct the following steps:

1. Connect the UT100 with the PC through an USB data cable.
2. Turn on the UT100.
3. Start the ODMS.
4. Select the appropriate COM port number, if necessary.
5. There are two way to download trend data：

A. Click the icon “ ”or “Case Info” at the main menu, the following interface will pop up:

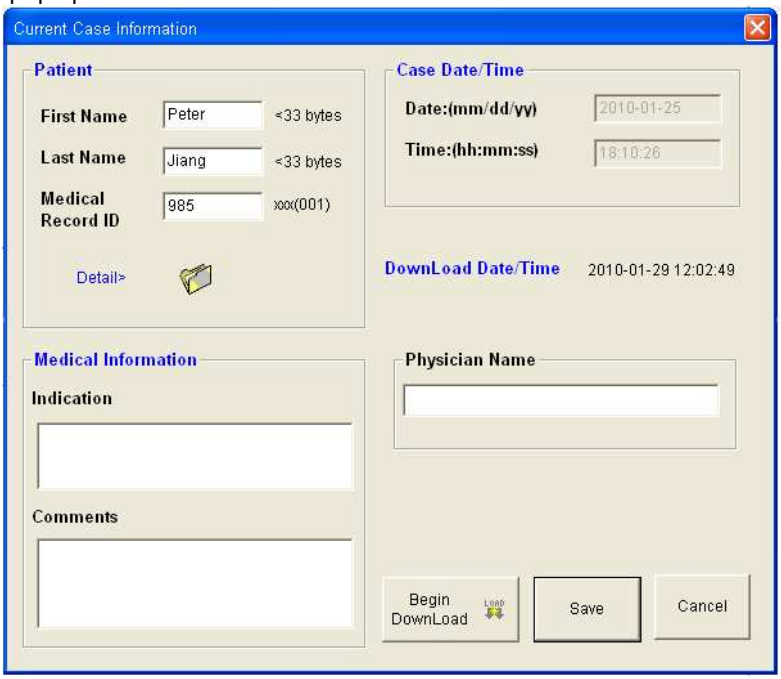


Figure 6.3: Case Information

Patient: Fill in the basic and detail information of the patient.

Case Date/Time: Means the time to collect the patient’s data.

DownLoad Date/Time: Means the time to stop collecting the patient’s data.

Medical Information: Fill in the name of physician, indication of the patient and comments on the patient.

After writing down the current case information, click this button to begin download the trend data of this ID.

NOTE! The patient's ID and information should be corresponded with each other.

If you want to change the case information of the patient whose trend data have already been download, follow the same steps and click this button to save your changes.

B. Click the icon "" or "DownLoad All" to download all trend data from the oximeter.

6.5 Open the Data Base

Click the icon" " or "Open DataBase" to open the data base, the following window will pop up:

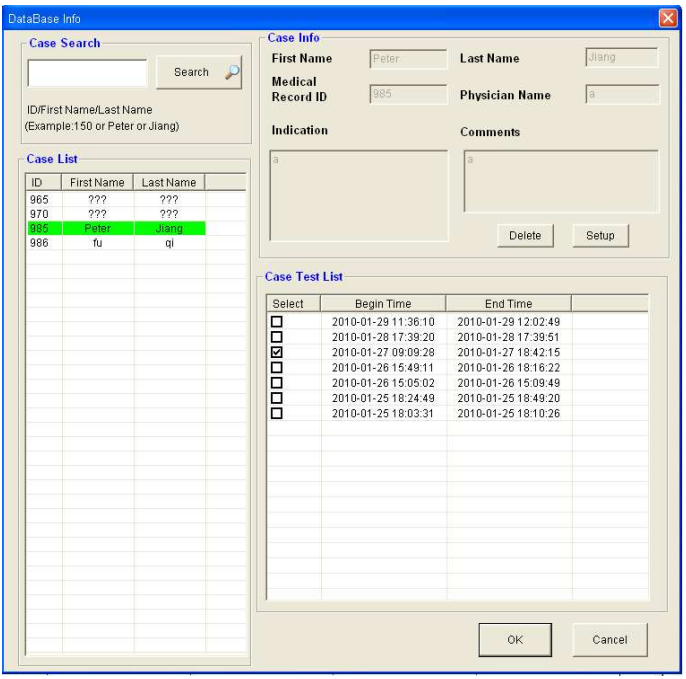


Figure 6.4: Data Base

Case Search: Put ID/Frist Name/Last Name to search patient files you want to review.

Case List: List all the downloaded cases. "???" means the information of this patient hasn't been edited. Click the Setup button to add the information.

Case Test List: Dblclick the patient file, the case test list of this patient will be displayed at the right side.

Delete: Select patient file you want to delete and then click the Delete button to delete it.

6.6 Data Analysis and Reports

Select one period from the case test list to analyze trend data. Press the OK button to enter the main analysis interface, as shown below:

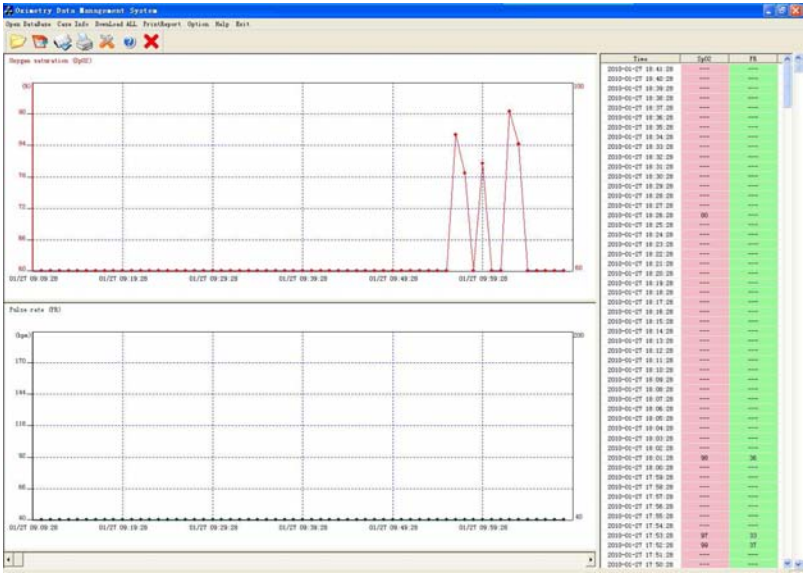
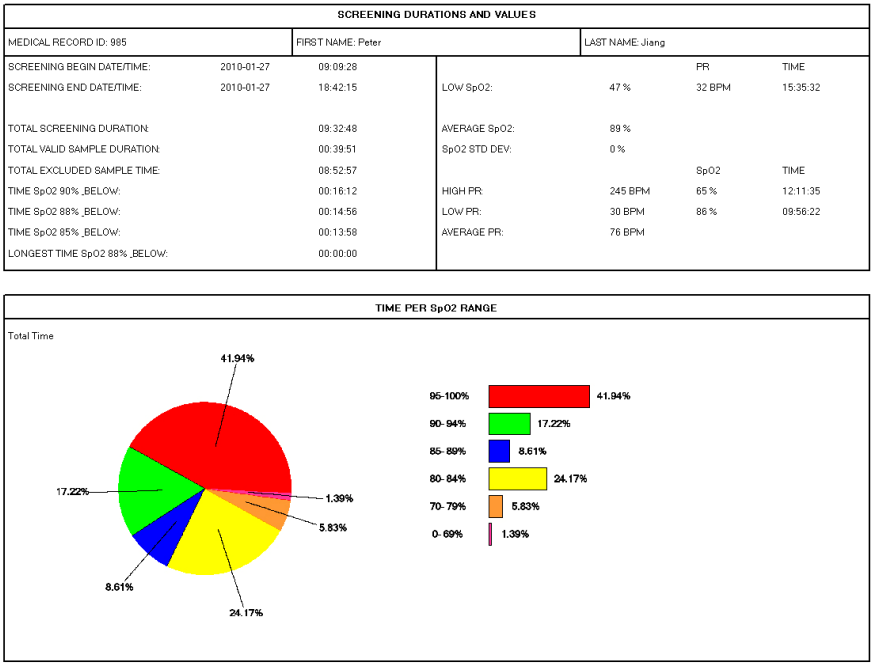


Figure 6.5: The Main Analysis Interface

The main analysis interface displays two bar charts and one list of SpO_2 and PR.

The Full Report consists of 3 reports: Statistical Report, Desaturation Report and Graphic Report.

1. ***Statistical Report:*** The software will analyze, calculate, and print statistical parameters for downloaded data.



SCREENING DURATIONS AND VALUES

MEDICAL RECORD ID: 985		FIRST NAME: Peter		LAST NAME: Jiang		
SCREENING BEGIN DATE/TIME:	2010-01-27	09:09:28			PR	TIME
SCREENING END DATE/TIME:	2010-01-27	18:42:15	LOW SpO2:	47 %	32 BPM	15:35:32
TOTAL SCREENING DURATION:		09:32:48	AVERAGE SpO2:	89 %		
TOTAL VALID SAMPLE DURATION:		00:39:51	SpO2 STD DEV:	0 %		
TOTAL EXCLUDED SAMPLE TIME:		08:52:57			SpO2	TIME
TIME SpO2 90% _BELOW:		00:16:12	HIGH PR:	245 BPM	65 %	12:11:35
TIME SpO2 88% _BELOW:		00:14:56	LOW PR:	30 BPM	86 %	09:56:22
TIME SpO2 85% _BELOW:		00:13:58	AVERAGE PR:	76 BPM		
LONGEST TIME SpO2 88% _BELOW:		00:00:00				

Figure 6.6: The Statistical Report

Screening Start Date/Time: represents when the monitor began collecting data.

Screening End Date/Time: Time when monitor stopped collecting data, either because of power off or memory full, and is calculated by the software based on the amount of data downloaded.

Total Screening Duration: calculated by software.

Total Valid Sample Duration: Total Screening duration minus the excluded sample time.

Total Excluded Sample Time: Total time the monitor registered invalid data.

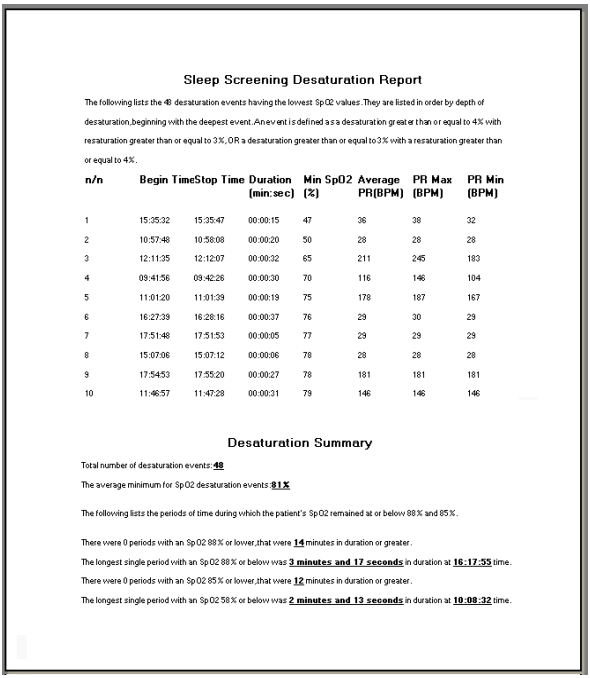
Low SpO_2: The lowest SpO_2 value taken from the valid sample with the pulse rate and time at which the lowest SpO_2 value occurred.

SpO_2 Standard Deviation: The measure of the variability of the sample. A higher standard deviation indicates greater variability in the samples.

High PR: The highest pulse rate value taken from the valid sample and the SpO_2 value& time the highest pulse rate occurred.

Low PR: The lowest pulse rate taken from the valid sample and the SpO_2 value & time the lowest pulse rate occurred.

2. ***Desaturation Report:*** Lists up to 50 of the deepest (lowest SpO_2 values) desaturation events. The events are listed in order of depth, beginning with the deepest event.



Sleep Screening Desaturation Report

The following lists the 48 desaturation events having the lowest SpO2 values.They are listed in order by depth of desaturation,beginning with the deepest event.An event is defined as a desaturation greater than or equal to 4% with resaturation greater than or equal to 3%,OR a desaturation greater than or equal to 3% with a resaturation greater than or equal to 4%.

n/n	Begin Time	Stop Time	Duration (min:sec)	Min SpO2 (%)	Average PR(BPM)	PR Max (BPM)	PR Min (BPM)
1	15:35:32	15:35:47	00:00:15	47	36	38	32
2	10:57:48	10:58:08	00:00:20	50	28	28	28
3	12:11:35	12:12:07	00:00:32	65	211	245	183
4	09:41:56	09:42:26	00:00:30	70	116	146	104
5	11:01:20	11:01:39	00:00:19	75	178	187	167
6	16:27:39	16:28:16	00:00:37	76	29	30	29
7	17:51:48	17:51:53	00:00:05	77	29	29	29
8	15:07:06	15:07:12	00:00:06	78	28	28	28
9	17:54:53	17:55:20	00:00:27	78	181	181	181
10	11:46:57	11:47:28	00:00:31	79	146	146	146

Desaturation Summary

Total number of desaturation events:**48**

The average minimum for SpO2 desaturation events:**81%**

The following lists the periods of time during which the patient's SpO2 remained at or below 88% and 85%.

There were 0 periods with an SpO2 88% or lower,that were **14** minutes in duration or greater.

The longest single period with an SpO2 88% or below was **3 minutes and 17 seconds** in duration at **16:17:55** time.

There were 0 periods with an SpO2 85% or lower,that were **12** minutes in duration or greater.

The longest single period with an SpO2 58% or below was **2 minutes and 13 seconds** in duration at **10:08:32** time.

Figure 6.7: The Desaturation Report

Reference for the event: A unique number between 1-50, which identifies each desaturation event.

Duration of the event: calculated by the software.

Desaturation Summary:

- •Total number of desaturation events detected
- •Average minimum for SpO_2 desaturation events
- •Number of events with 88% SpO_2 or below 5 minutes or longer
- •Duration of longest single event with 88% SpO_2 or below & time it occurred
- •Number of events with 85% SpO_2 or below 5 minutes or longer
- •Duration of longest single event with 85% SpO_2 or below & time it occurred

3. ***Graphic Report:*** it contains three trend graphs of SpO_2 and PR per page.

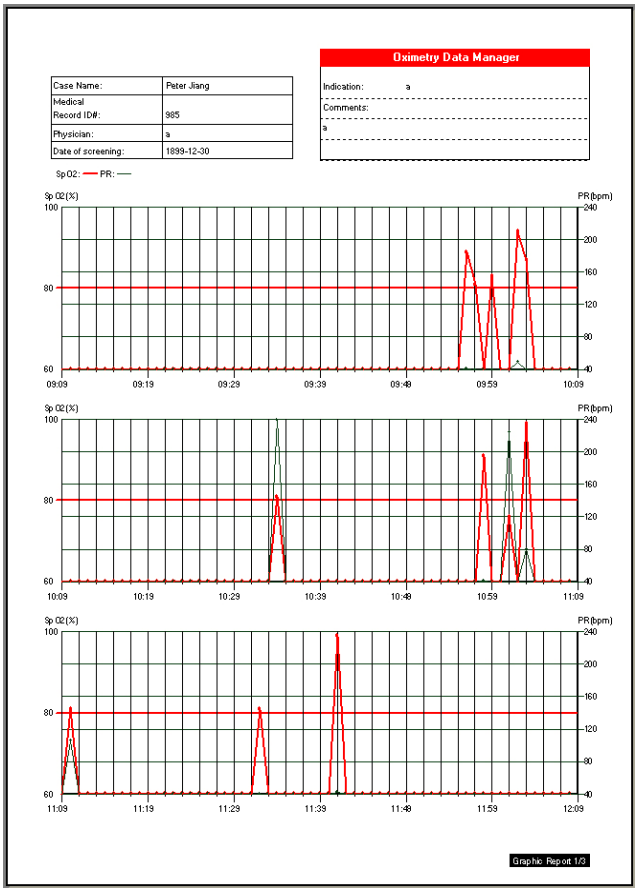


Figure 6.8: The Graphic Report

Chapter 7: Accessories

7.1 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

7.2 Optional Accessories

CAT.NO	DESCRIPTION	QTY
UTPW0920	AC Adapter	Each
DAS3000	Data Analysis Software CD	Each
1616	AA size Ni-MH Batteries	Four
4210	Reusable sensor, Adult, Finger	Each
4211	Reusable sensor, Pediatric, Finger	Each
4212	Reusable sensor, Neonatal/infant, Foot	Each
4213	Single patient use sensor, Adult>30kg	Each
4214	Single patient use sensor, Ped 3-50kg	Each
4215	Single patient use sensor, neonatal <3kg	Each
3425	SpO_2 extension cable	Each

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Chapter 8: Maintenance and Troubleshooting

8.1 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.

8.2 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)

8.3 Troubleshooting

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
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.
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	•Charging alkaline batteries. •Batteries incorrectly installed. •There are no batteries.	•Install Ni-MH cells in stead of alkaline ones. • 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.	•Check sensor connections to the patient cable and to the oximeter.
	•Sensor is incorrectly positioned on the patient.	•Reposition the sensor.
	•Poor patient perfusion.	•Reposition the sensor.
	•Defective sensor or patient cable	•Try a new sensor or contact UTECH Co., Ltd After Service Department for help.

8.4 EMI Interference

CAUTION! This device has been tested and found to comply within the limits for medical devices to IEC 601-1-2:1993, EN 60601-1-2:1994, 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 heath-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 9: Specification

9.1 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:	Portable
Degree of Protection Against Electric Shock:	Type BF
Safety Requirements:	EN60601-1:1990

9.2 SpO_2

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.

9.3 Pulse Rate

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

9.4 Default Settings of Alarms Limits

	High Alarm Limits			Low Alarm Limits		
	Adult	Pediatric	Neonatal	Adult	Pediatric	Neonatal
SpO_2	99	99	99	92	92	92
PR	100	110	120	60	70	80

9.5 Power Requirements

AC power supply 100-240VAC, 47-63Hz
Or four standard “AA” alkaline or Ni-MH cells (IEC Type LR6)

9.6 Battery Life

Alkaline Cells: 20 hours

9.7 Dimensions

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

9.8 Environmental Specification

Operating Temp.:	0 to 45℃
Storage Temp.:	-20 to +55℃
Relative Humidity:	-40 to +55℃
	30 to 95% (operating)
	10 to 95% (storage)
	0 to 95% (shipping)

Appendix A: Revision History

Revision	Date	Comment
Rev1.0	2010-3	•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.

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