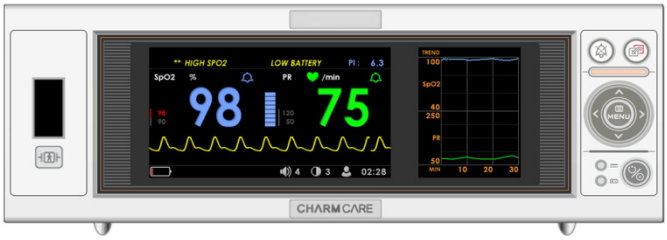
Pulse Oximeter

User Guide

ACCURO



Charmcare Co., Ltd.

CE
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Part 1 Before You Begin

1.1 Overview

This manual contains information for collecting patient oxygen saturation data while operating the ACCURO.

1.2 Intended Audience

This manual provides information to health-care professionals acting as caregivers for operation and user of the monitoring system. Before use, carefully read this manual, accessory Directions for Use, and all precautionary information and specifications.

1.3 Safety Information, Warning, Caution and Note

This is contains safety information requiring users to exercise appropriate caution while using the monitoring system.

1.3.1 Safety Symbol Definitions

Warning

"Warning" is used to refer to factors, which, when ignored, may result in severe and/or fatal injuries and property damage.

Caution

"Caution" is used to refer to factors, which, when ignored, may result in moderate, but non-life-threatening, injuries.

Note

"Note" is used to highlight factors that are not dangerous, but should be paid close attention to during installation, use, and maintenance.

1.3.2 ⚠ Warning

- Do not use the battery with other manufacturer's batteries.
- Do not use any monitoring system or pulse oximeter cables, sensors, or connectors that appear damaged.
- Do not use any monitoring system, sensor, cable, or connector that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.
- No modification of this equipment is allowed.
  Do not lift by the sensor or interface cable. The cable may disconnect, potentially dropping the monitoring system on a patient or damaging surface.
- When installing the AC power cord, ensure the cord is carefully positioned to prevent tripping and entanglement.
- Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis, since this may cause damage to the monitoring system.
- To ensure accurate performance and prevent device failure, do not subject to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.
- Use only when connected to a grounded outlet to avoid electric shock.
- Do not pause or disable audible alarms or decrease the volume of the audible alarm if patient safety could be compromised. Do not dim or disable visual alarms if patient safety could be compromised.
- Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
- Operator shall not touch the battery compartment and the patient simultaneously.
- The measured values of the monitoring system can be affected by patient conditions, excessive patient movement, sensors, environmental conditions, and nearby electromagnetic external conditions.
- Ensure the monitoring system is clear of any obstructions that prevent awareness of visual or audible alarms. Failure to do so may result in inadvertently missing a visual alarm or an inaudible alarm tone.
- The use of accessories, transducers and cable other than those specified may result in increased emissions or decreased immunity performance of the equipment.
- The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

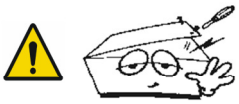
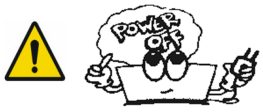
1.3.3 ⚠ Caution

- Accessory equipment connected to the monitoring system's data interface must be certified according to IEC Standard 60950-1 for data-processing equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1:2012 Requirements for Medical Electrical Systems. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible for ensuring the system complies with the requirements of IEC Standard 60601-1:2012 and IEC Standard 60601-1-2:2007.
- When connecting the monitoring system to any instrument, verify proper operation before clinical use.
- Both the monitoring system and the instrument connected to it must utilize a grounded outlet.
- Any equipment connected to the data interface must be certified according to the latest IEC/EN 60950-1 standard for data-processing equipment, the latest IEC/EN 60601-1 standard for electro-medical equipment, or the latest IEC/EN safety standards relevant to that equipment.
- All combinations of equipment must be in compliance with Requirements for Medical Electrical Systems IEC Standard 60601-1:2012.
- Anyone who connects equipment to the data interface is configuring a medical system and, therefore, is responsible for ensuring the system complies with the Requirements for Medical Electrical Systems IEC/EN Standard 60601-1 and the electromagnetic compatibility IEC/EN Standard 60601-1-2:2007.
- Accuracy may degrade if it is connected to secondary I/O devices when the equipment is not connected to earth reference.
- Use only approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.
- The top of the monitoring system screen indicates the sensor type when connecting a recommended sensor to the monitoring system or when the monitoring system completes POST with an attached sensor.
- If the pulse beep tone does not sound with each pulse, the pulse beep volume is set to zero, the speaker is malfunctioning, or the signal is corrupt. Reset the device.
- Perform the following checks every 12 months.
- Inspect the monitoring system for mechanical and functional damage or deterioration.
- Inspect the internal fuses for proper value and rating.
- Ensure all user interface items, cables, and accessories function normally.
- Have a qualified service technician replace the battery at least every 6 months.
- The battery is recyclable. Do not dispose of the battery by placing it in the regular trash.

- Dispose of the battery in accordance with local guidelines and regulations or contact Charmcare to arrange for disposal.
- Inspect the safety relevant labels for legibility. Contact Charmcare or a local representative, if labels are damaged or illegible.
- Instructions provided on preventive inspection, calibration, maintenance and its frequency
- Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT
- Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL
- Magnetic and electrical fields are capable of interfering with the proper performance of the device.
- X-ray equipment or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.

1.3.4 Proper Environments For The Product

- Do not use or store the product in the following conditions:

 **Exposure to Humidity and/or Moisture** Do not use the product with wet hands.	 **Do not store or place the product in direct sunlight.**
 **Do not store or place the product in areas where temperature changes are drastic.** Use the product between temperatures of 5°C and 35°C and at a humidity between 30% and 85%.	 **Do not place the product near heat sources.**
 **Do not store or place the product in very humid areas or areas where air circulation is a problem.**	 **Do not subject product to severe shock and or vibrations.**
 **Do not store or place the product in places where product is exposed to chemicals or flammable gas.**	 **Keep product free of dust and debris, particularly metallic objects.**
 **Do not attempt to disassemble the product yourself. Charmcare is not liable for any problems that may occur should you attempt to do so.**	 **Do not connect the power during installation. This may damage the product.**
 **Grip the plug when unplugging the product from a power source.**	

1.3.5 Warranty Period

- To obtain information about a warranty, if any, for this product, contact your local Charm-care representatives.
- This product has been manufactured and inspected following the strict quality assurance guidelines of Charmcare.
- Refer to the Economic Planning Board's "Regulations Regarding Consumer Compensation" for more information on conditions for product repairs and exchanges.
- Product malfunctions occurring from regular use shall be repaired for free at the Charmcare service center during the term of the warranty period.
- During the term of the warranty period, report all problems with the product to Charmcare by including the model no., the device no., date of purchase and a detailed description of the error.
- Manufacturer and/or the store where the product was purchased do not assume any responsibility for any and/or all problems resulting from improper use or improper storage of the product.

1.3.6 Battery Replacement

- If the monitor has not been used for a long period of time, the batter will need charging.
  To charge the battery, contact your local Charmcare representatives.
- Charmcare recommends that the Li-ion rechargeable battery be replaced at 6 months intervals.
  Refer to the monitor service manual for batter replacement and general service instruction.
  Follow local governing ordinances and recycling plans regarding disposal or recycling of the battery and other device components.
- Remove the battery if the equipment is not likely to be used for some time.
- When incorrect battery replacement by inadequately trained personnel would result in an unacceptable risk(e.g. excessive temperatures, fire or explosion)

1.3.7 Contact Us

- Please contact us for better service and products.
- Charmcare service is always open.

Need to purchase products or parts?	Charmcare Co., Ltd. (Gasan-dong, Woolim Lions2-cha)714, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Korea Tel : +82-2-862-5052 Fax : +82-2-862-5065
Need service or repairs?	
Need technical advice?	
Website	http://www.charmcare.com

1.3. 8 Electrical Safety

Please check the following conditions before attempting to use the product.

- Are you using the proper power source line? (100-240VAC)
- Are all parts (power cord and optional parts) connected properly to the product?

Warning

The AC power plug is a means to isolate its circuits electrically from the supply mains on all poles simultaneously. Do not place the device in an area when there is difficult to disconnect from the supply mains.

Warning

To avoid risk of electric this equipment must only be connected to a supply mains with protective earth.

Warning

The ACCURO pulse oximeter is a prescription device and is to be operated by qualified personnel only.

Caution

To prevent noise, install the product away from generators, X-ray machines, speakers and power cords. Proximity of the product to such equipment may result in improper functioning of the product and lead to undesirable results. A separate power circuit and secure grounding of the product are very important. Sharing of a power source with other equipment(s) may lead to undesirable results.

1.3. 9 Maintenance And Cleaning

- Using various methods can clean pulse oximeter and its accessories. Please follow the methods mentioned below to avoid unnecessary damage or contamination to the Equipment.
- In the event that harmful (unauthorized) materials are used for cleaning, the damaged or contaminated Equipment shall not be serviced without charges regardless of warranty period.

⚠ Caution
Please check carefully both frame and sensor, after cleaning the Equipment, Do not use the Equipment that is worn out or damaged.

- At least once a month, clean and wipe off the frame by using the soft cloth after wetting it with lukewarm water and alcohol. Do not use lacquer, thinner, ethylene, or oxides, which could be harmful to the Equipment.
- For surface cleaning and disinfection of the monitoring system, follow institutional procedures or the recommended actions below.
- Surface cleaning – Use a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, lightly wiping the surfaces of the monitoring system.
- Disinfection – Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the monitoring system.
- Before attempting to clean a Charmcare sensor, read the Instructions for Use enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor. Follow the sensor cleaning and disinfecting procedures in the particular sensor's Instructions for Use.
- Make sure both cables and accessories are free of dust or contaminants, and wipe them off with soft cloth wetted with lukewarm water (40℃/104°F), and at least once a week, clean them by using the clinical alcohol.
- Do not submerge the accessories under any liquid or detergent. Also, make sure any liquid not to penetrate into the Equipment or probe.

⚠ Caution
Do not dispose single use probe to any hazard place, Always think about environmental contamination

Perform the following checks every 12 months.

- Inspect the monitoring system for mechanical and functional damage or deterioration.
- Inspect the internal fuses for proper value and rating.
- Ensure all user interface items, cables, and accessories function normally.
- At least once a month, clean and wipe off the frame by using the soft cloth after wetting it with lukewarm water and alcohol. Do not use lacquer, thinner, ethylene, or oxides, which could be harmful to the Equipment.

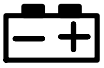
Warning
A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor

1.3. 10 Classifications

The ACCURO patient monitor is classified, according to IEC 60601-1 as:

Equipment Classification	ISO 80601-2-61 : 2012 EN 60601-1 : 2012
Type of protection	Class II
Degree of protection	BF-Type applied part
Electromagnetic Compatibility	EN 60601-1-2:2007
Liquid Ingress	IPX1
Degree of Safety	Not suitable for use in the presence of flammable anesthetics

1.3. 11 Description Of Product & Label Symbols

Icon	Comments	Icon	Comments
	System power On/Off		Alarm pause
	Pulse Volume		Screen change
	AC Input Indicator	**100-240VAC 50/60Hz**	Connect AC power cord
	Battery Input Indicator	**RS-232 10101**	Use for program upgrade
	Type BF applied part complying with IEC 60601-1	**%SPO2**	Oxygen Saturation
	Manufacturer	**IPX 1**	Conforms to IEC60601-1 sub-clause 44.6 and IEC60529 standard.
	Reference number		Date of manufacture
SN	Serial number		Crossed-out wheeled bin
	CE Mark		EU representative
	Do not use hand hooks		Keep away from water
	Fragile, handle with care		This side up
	Caution		Warning
	Refer to instruction manual / booklet		Prohibition
	Note	**LOT**	Lot number
MENU	Menu		Alarm

Part 2 Product Summary

2.1 Intended use

The intended use of Pulse oximeter ACCURO is detecting and measurement as below parameters to provide and help doctors for making figure out the patient's vital condition.

- Exact and stable Oxygen saturation of arterial blood
- Accurate Pulse Rate

Especially, Pulse oximeter ACCURO has AGC (Auto Gain Controller) function for weak pulsatile patients.
The device is to detect and control its gain automatically in accordance with patient's pulse rate strength.
Designed for hospital , transport and home use .

Note

Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital and in hospital-type facilities. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Note

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

▣ Frequently used functions

- Connect the SpO2 probe
- Patient mode setting
- Alarm system (according to IEC 60601-1-8:2006)
- Measure SpO2, Pulse rate
- Battery (Internally powered)

▣ Essential performance

- SpO2 accuracy
- Heart rate accuracy
- Alarm limit
- Battery condition alarm

▣ Patient population

a) Age: newborn, infant, adult

b) Weight: not relevant

c) Health: not relevant

d) Nationality: multiple

e) Patient state: patient is not user – not relevant, unless patient is agitated

▣ Part of the body or type of tissue applied to

a) Measurement site: finger, the back of hand, arm, toe, top of the foot.

b) Condition: the area which wish to place the probe is wiped down with alcohol.

▣ User profile

Intended conditions of use

Considerations	Requirement description
Education	• Nurse who had gotten a specialized education • Physician who have the national license and can treat a patient
Knowledge	• Read and understand ‘westernized Arabic' numerals when written in Arial font • Can perceive alarm conditions and distinguish alarm priority • Understand means of the parameter used on the equipment • Can distinguish spo2 and Pulse rate • Understands hygiene
Language understanding	• Understand how the equipment functions in the IFU • Understand abbreviations used in the IFU
Experience	• A training related to how the equipment functions • Be enough familiar with the IFU • Can use spo2 probe correctly • Can diagnose patient states through measured parameters

▣ Intended conditions of use

Considerations		Requirement description
Environment	General	• Professional use, not intended for home use • Indoor use only • When it is functioning it shall keep its calibration / precision • Use environment away from x-ray equipment, any mobile device • Battery charging and replace for maintaining normal operation
	Conditions of visibility	• Operation distance: within 1m
	Physical	• Operating environment Temperature: 5℃ to 35℃ Humidity: 30% to 85% non-condensing • Storage environment Temperature: -20℃ to 70℃ Humidity: 10% ~ 100% • background sound pressure level: <55db in the range of 100Hz – 8khz
Frequency of use	• Measure patient state continuously	
Mobility	• Portable medical device to be used on a resting patient	

2.2 List of Parts

▣ Basic Parts

Type	Quantity
ACCURO Unit	1

▣ Basic Accessories

Type	Quantity
SpO2 Sensor(ACCY-0A0PRB Reusable type)	1
Power cord	1
User Manual	1

▣ Optional Parts

	Type
1	SpO2 Sensor(Pediatric, Neonate)
2	SpO2 Sensor(Pediatric, Neonate Y-type)
3	SpO2 extension cable(9pin)
4	IV Pole Clamp
5	Carrying Bag

▣ Sensor and Cable Length

Type	Length
SpO2 adult Sensor	1m, 3m
SpO2 pediatric Sensor	1m, 3m
SpO2 neonate Sensor	1.5m, 3m
SpO2 neonate Sensor	1m, 3m
SpO2 extension cable	2.5m
Power Cord	1.8m

Warning

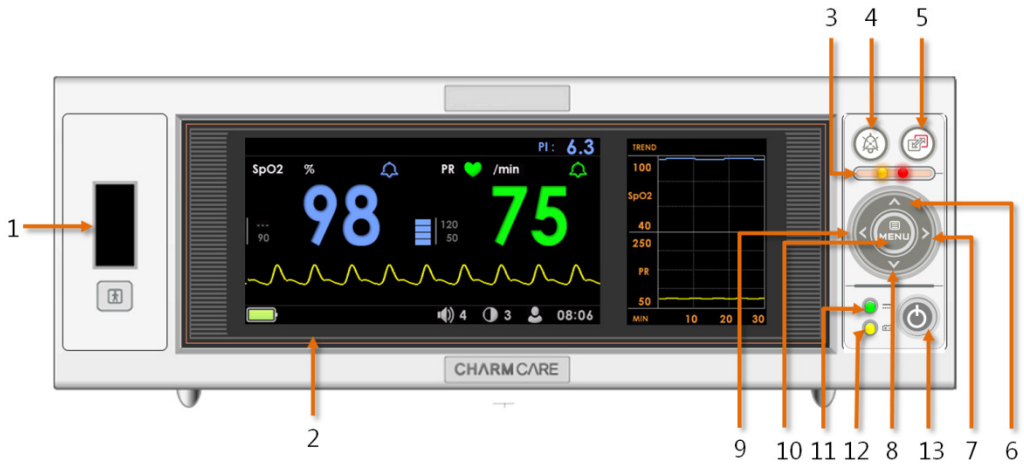
The use of accessories, pulse oximetry sensors, and cables other than those specified may result in inaccurate readings of the monitoring system and increased emission of the monitoring system.

2.3 Nomenclature of the Parts

This section identifies the symbols, controls, displays, and indicators on the ACCURO

Unit

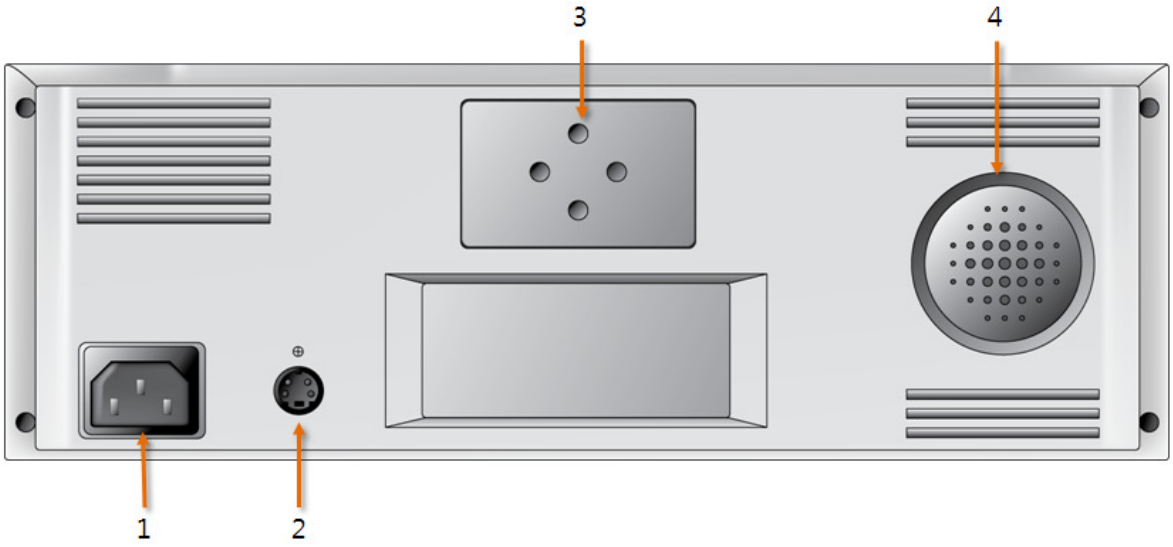
▣ Front Panel



No	Name	Description
1	SpO2 probe port	Connect the patient cable to the ACCURO by patient cable plugging the cable into the patient cable connector. Use only connector charmcare compatible sensors and cables with this oximeter. See part5, sensors and patient cables for more details.
2	Screen	Measured SpO2 & Pulse rate values are displayed on the LCD screen. Additional information such as waveform, alarm messages and short trend records are displayed.
3	Alarm lamp	The alarm lamp is illuminated when an alarm condition is active and the Alarm Status Indicator is shown.
4	Alarm pause button	Press the alarm pause button to temporarily silence patient and low battery alarms. Press the alarm pause button when the "SENSOR OFF" or "FINGER OFF" messages are flashing (i.e. The sensor is removed from the patient) to acknowledge the end of monitoring. In these states, all further alarms are suspended until the pulse oximeter starts measuring SpO2 and pulse rate again. Note: System failure alarms can be paused by pressing the power/standby or alarm pause button. If the power/standby

		button does not pause the system fault alarm, press the alarm pause button.
5	Screen Button	This button switches from one main screen mode to another. Main screen modes can be found in this user manual at Part 6.
6	∧ button (up)	Used to move upward from one menu category to another or to alter available preset values of each menu category.
7	> button (right)	Change the screen contrast ◑ at the top menu Used to move rightwards from one menu category to another or to alter available preset values of each menu category.
8	∨ button(down)	Used to move downward from one menu category to another or to alter available preset values of each menu category.
9	< button(left)	Change the pulse volume 🔊 at the top menu Used to move leftwards from one menu category to another or to alter available preset values of each menu category.
10	MENU selection button	Used to move up and down on the main menu tree and to select each menu category.
11	AC power usage indicator	Indicates connection to alternating current power source.
12	Battery status indicator	The Battery Status Indicators show the capacity.
13	Power button	Press the Power On/Off Button to turn the instrument on. Press, hold the button for more than 2 seconds and then release the button to turn the instrument off.

▣ Rear Panel



No	Name	Description
1	AC Power port	It can directly supply AC power via this AC power port for supplying constant power and recharging the handheld while docked.
2	Serial port Connector	This ports are software upgrade port
3	Attaching clamp holes	Holes for attachment to the IV pole clamp
4	Speaker	The speaker indicates audio alarms. Care should be taken not to cover the speaker and muffle the audible alarm volume.

Warning
To prevent electric shock, keep the top cover closed and do not attempt to disassemble the product on your own. Product should only be disabled by authorized service personnel.

Part 3 Product Installation

First-time users: Read the installation instructions thoroughly and install the product in a safe place to ensure product longevity.

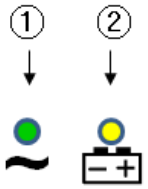
Caution When Installing

- Use the product in a place where the temperature is between 5~35℃ and the humidity is 30~85%.
- Make sure that the power cord is plugged in properly.
- Do not plug in more than one device into one outlet.
- Ground the product if noise develops.
- Do not use a power cord that causes noise.
- The product is very sensitive to shock. Caution is advised.
- Keep the product dust-free and install away from flammable materials.

Connecting The AC Power

- Connecting the Power – Connect the power to the power port.
- Grounding the Product – Connect the grounding line to the grounding port in the back of the product if needed.

  AC power cord is connected in AC power port, a green light appears in the AC power usage indicator. Product usage is possible without AC power via the embedded battery. In such cases, a red light appears in the Battery Usage Indicator.



① AC Power Usage Indicator

② Battery Usage Indicator

Caution

When the charge level of the embedded battery is running low, the battery usage indicator blinks and an information alarm is emitted. Depending on usage parameters, power may be cut instantly, and thus the AC power should be connected for use.

Caution

Both the monitoring system and the instrument connected to it must utilize a grounded outlet.

Warning

The battery usage warranty period is six months. Following this period, battery life can diminish significantly.

Warning

Use the power supply device supplied by the manufacturer. Failure to do so may result in electric shock and damage to the product. Edge or points of the Product can hurt to patient and user.

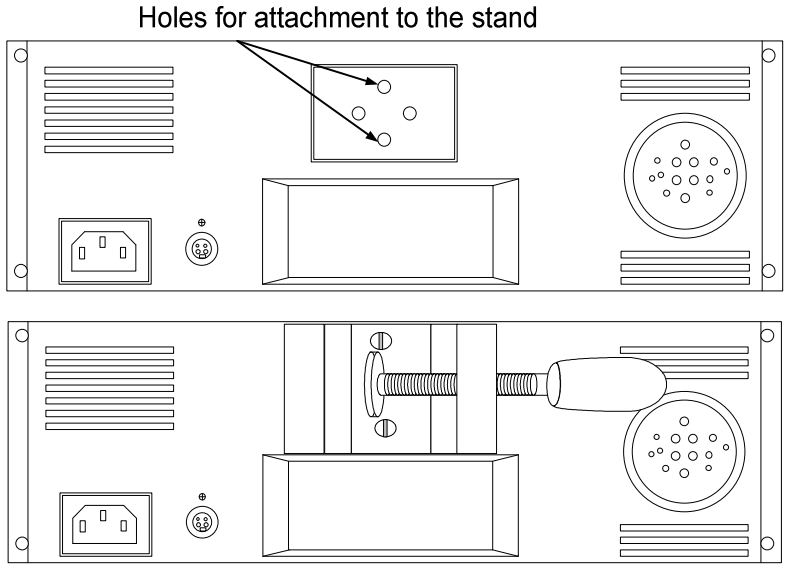
Warning

Accuracy may degrade if it is connected to secondary I/O devices when the equipment is not connected to earth reference.

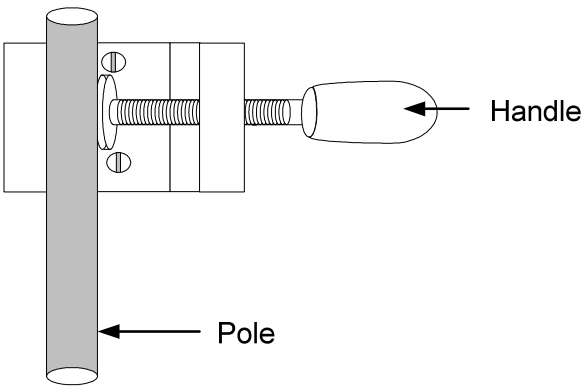
Installing the IV Pole

The product may also be mounted on a clamp, which can then be attached to an IV Pole. This makes the product more portable. (*IV Pole is optional.)

(1) The product may be used horizontally or vertically. First, decide how you want the product to be mounted. Then, insert two bolts into the holes on the clamp and tighten.



(2) Mount the clamp to the pole by sliding the clamp onto the pole and then, turn the handle to tighten.



⚠ Caution

The pole on which the stand is mounted should be less than 30mm in diameter. Do not use poles that are any thicker than this.

Part 4 Using The Product

This section contains information on the basic nomenclature and directions for using the product.

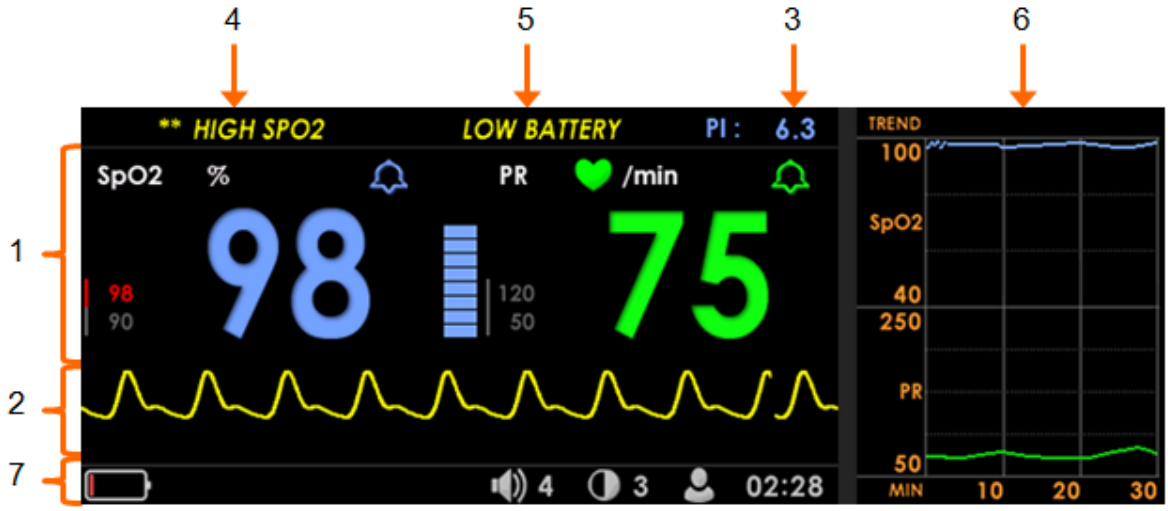
Preparations before Use

- Check for defects on the exterior of the SpO2 sensor(Oxygen sensor).
- Check for defects on the exterior of the AC power cord, oximetry use cable.
- Connect the power, oximeter use cable to the SpO2 sensor and product. (If the oximetry use cable is not utilized, SpO2 sensor is directly connected to the product.)
- Check the connection status of the cable and status of SpO2 sensor before turning the product on and connecting the product to the patient.
- Since this product uses the principle of a spectrophotometer, check if a surgery light is located where the product is placed, and if the ray blocks the usability cover the SpO2 sensor with a opaque cloth.
- Check the attachment region of the SpO2 sensor and the compatibility, and avoid certain locations according to the status and use a SpO2 sensor that can be attached on to the bridge of the nose or forehead.
- When attaching the SpO2 sensor on to the finger, no manicure should be on the finger nails.
- For sterilization or antiseptic. cleaning is necessary for the SpO2, select the methods shown below according to the environment conditions of the medical institution equipment, and use the usage and application of the professional prefers.

*How to use antiseptic .cleaning solution

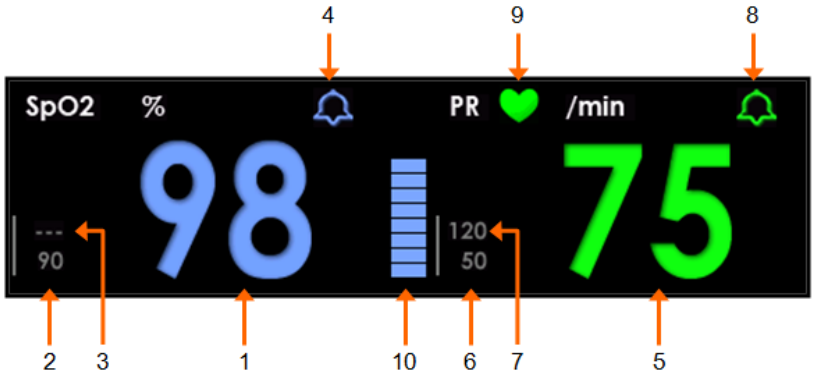
Chemical Product		Method
Alcohol	Isopropyl alcohol	Use soaked gauze.
Liquid Soap	Benzalkonium Chloride	0.05 W/V%(x200 diluted) Use soaked gauze.
Iodine	Povidone-iodine	0.02 W/V%(x50 diluted) Use soaked gauze.
Glutaral	C5H8O2	2 W/V %(test solution) Use soaked gauze.

The Screen



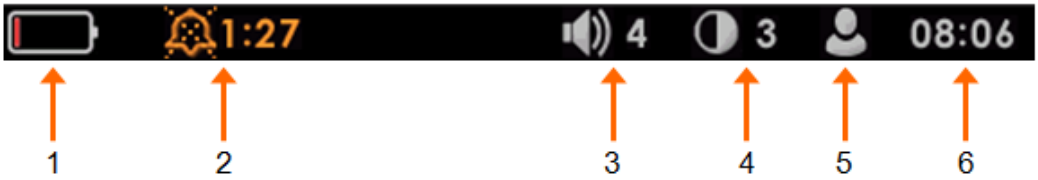
No	Name	Description
1	SpO2/PR data area	Displays the measured SpO2, PR and related values.
2	Waveform area	Displays SpO2 waveform.
3	PI data area	Displays measured perfusion Index. The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal (Pulse strength).
4	Patient Alarm area	Displays the alarm message from the measured value. When multiple alarms occur, it shows according to higher priority.
5	Technical Alarm area	Displays the alarm message related to the system.
6	Short Trend area	Displays the SpO2, PR value saved during the previous 30 minutes or 15 minutes on a graph.
7	System status area	Displays status of battery, alarm and current time.

SpO2/PR Data Area



No	Name	Description
1	Oxygen saturation (SpO2) reading	Displays the measured value of SpO2. When the value exceeds the SpO2 alarm limit, the SpO2 value will turn red and flash.
2,3	SpO2 alarm limit	The Saturation Alarm Limits Display shows the upper and lower saturation alarm limits. When the value above or below limits if it turns red.
4	SpO2 alarm status	Displays the alarm watch state of SpO2. (refer to alarm status)
5	Pulse rate (PR) reading	Displays the measured PR value. When the value exceeds the PR alarm limit, the PR value will turn red and flash.
6,7	PR alarm limit	The pulse rate Alarm Limits Display shows the upper and lower saturation alarm limits. When the value above or below limits if it turns red.
8	PR alarm status	Displays the alarm watch state of PR. (refer to alarm status)
9	Heart beat icon	Blinks when a heart beat occurs. If the PR value derails from PR alarm limit it will be blinking in red.
10	Level bar	Indicates pulse beat and the relative (non-normalized) pulse amplitude in numbers only view. As the detected pulse becomes stronger, more bars light with each pulse.

System Status



NO	Name	Description
1	Power status	Displays the battery status. Uses a battery and capacity is low(about10min) Uses a battery and capacity is low (about30min) Uses a battery and capacity is 1/4 Uses a battery and capacity is 1/2 Uses a battery and capacity is 3/4 Uses a battery and capacity is FULL Uses AC power and battery is being charged Uses AC power only but battery is fully charged
2	Alarm sound status	Displays the alarm sound off state. 0:48 Displays the alarm sound paused state and left time 0 Displays the Alarm sound off state
3	Pulse volume	Display pulse volume level and state
4	LCD brightness	Display brightness level
5	Patient type	Display patient type ADULT PEDIATRIC NEONATE
8	Current-time clock	Displays the current time(hour: minute)

Post-Use Storage And Management

- After use, store the product in an area that does not exceed 85% humidity, and maintain the temperature in the range of 5℃~ 35℃.
- Do not store the product together with chemical products and/or in an area subject to gas exposure.
- Avoid exposing the product directly or indirectly to heat.
- Make sure to review the product usage instructions prior to use.
- Store the product in an area where it will not come in contact with water.
- Store the product in an area free of dust and/or other foreign substances.
- Store the product away from direct sunlight.

- Maintain the product in a safe and stable condition away from vibration and/or other sources of shock.
- If the product and/or sensor area becomes dirty, wipe it clean with rubbing alcohol and cotton swabs, and then allow it to dry at room temperature for 30 minutes.

Power off

- Press power button during 3seconds to power off. When display is off, separate the power cord by pulling off the cords connector from device rear .

Part 5 Measuring the SpO2

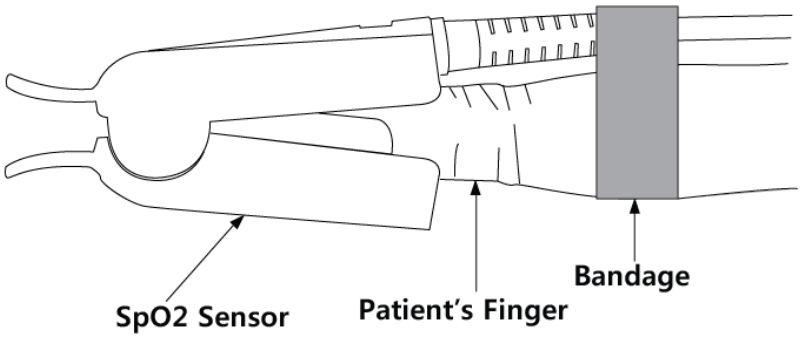
Attaching The SpO2 Probe

(1) Wipe down the area where you wish to place the probe with alcohol.

(2) Attach the probe to the patient's finger.

(3) To get an accurate reading, make sure the patient minimizes all movement and Please attach the probe wire to patient's finger firmly. Attach the bandage loosely so as to not cut of circulation to the finger.

(4) Check the patient's finger and the probe every two to three hours to make sure that the sensor is properly placed over the finger. If there is a change in the appearance of the patient's finger due to the prolonged exposure to the probe, switch the probe to another finger.



Warning

-Measuring SpO2 on a patient undergoing an MRI may result in severe burns for the patient. To minimize risk for burns, use a non-inductive wire. In the event that this does occur, immediately remove the probe from the patient.

-The area around the Sp02 sensor shall not exceed 37℃. The sensor will not work in temperatures above 37℃.

-Do not attach the probe near arterial or venous catheters.

-Make sure that the sensor emits a light and that the sensor is properly placed over the patient's finger.

-Excessive pressure for prolonged periods from the sensor may cause necrosis of the skin.

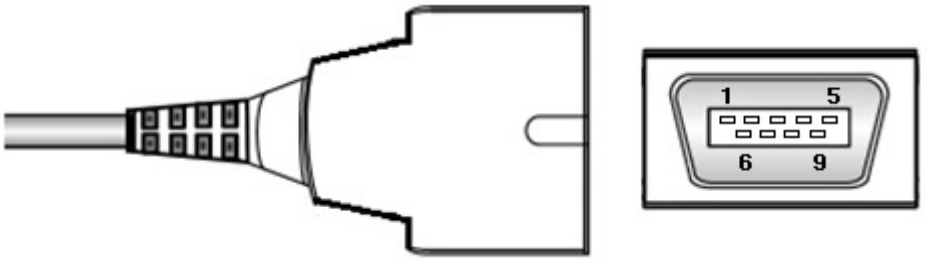
-Sensor sites should be changed at least every 8 hours

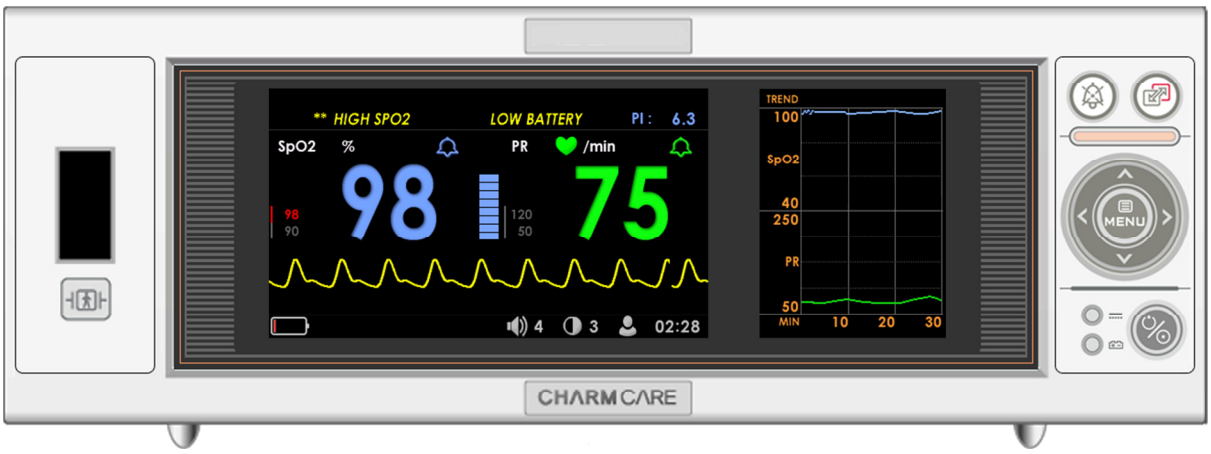
SpO2 Sensor Port

Use only approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

If the pulse beep tone does not sound with each pulse, the pulse beep volume is set to zero, the speaker is malfunctioning, or the signal is corrupt. Reset the device.

- Wire connection





Warning

-Before use the probe sensor, operator needs to verify that the SpO2 sensor type match

Caution

-Handle the probe sensor and wire with caution. Careless handling may damage the sensitive sensor. Protect the wire from sharp objects.

-The skin of patients who have high fevers or have problems with distal circulation will be 2-3 degrees higher than normal.

-Patients with abnormally high oxyhemoglobin or methemoglobin levels will not give a proper SpO2 reading.

Note

-Taking the NIBP can affect the SpO2 reading. When taking NIBP, place the SpO2 probe on the other arm.

-Avoid using the probe with other medical equipment that affects blood flow. Avoid placing the probe near an area that requires medical attention.

Measuring The SpO2

(1) Connect AC power to AC power port on the back side.

(2) Connect SpO2 sensor to upper side.

(3) Press the power button.

(4) After initialed ACCURO, the measurements are ready.

(5) Attach the SpO2 sensor to finger.

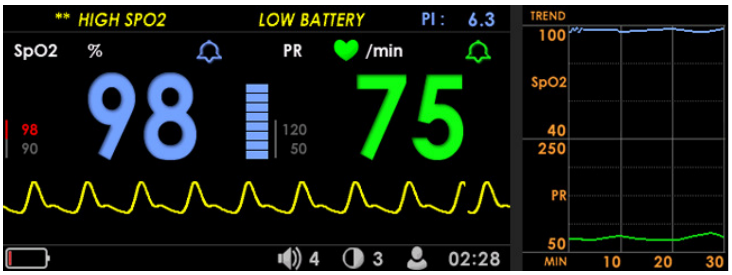
(6) When the display reads "Learning," this means that SpO2 measurement has begun. Minimize patient movement until the screen no longer reads "Learning" to ensure a proper SpO2 reading.

(7) After receiving data for 3 seconds, SpO2 results will be indicated.

Part 6 Switch Screen Mode

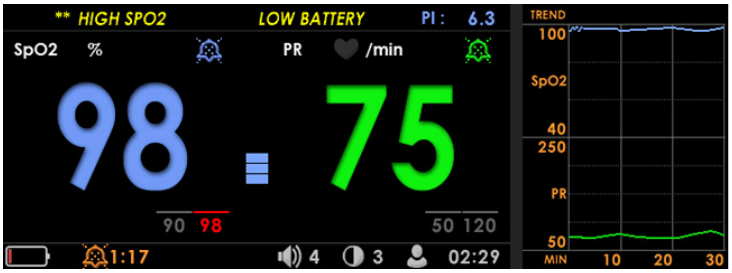
Switch Screen Mode

ACCURO consists of 4 types of screens and the can be switch to the screen the user designates. Press button to switch the screen. Switching the screen is as follows.



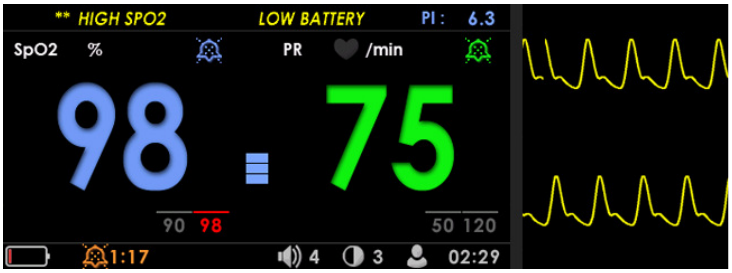
SpO2, PR, Wave, Short trend

<screen 1>



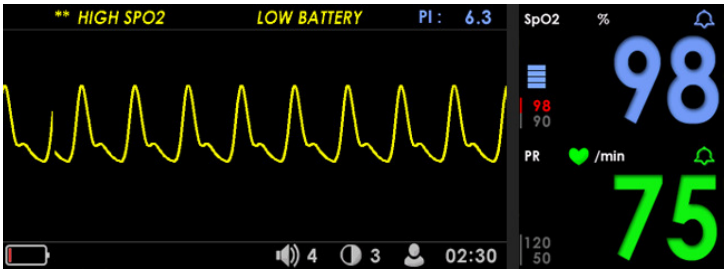
SpO2, PR, Short trend

<screen 2>



SpO2, PR, Wave

<screen 3>



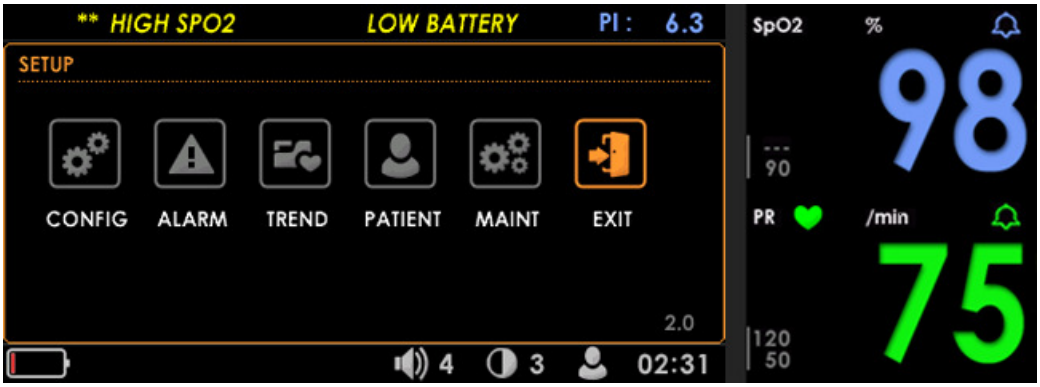
Wave, SpO2, PR

<screen 4>

Part 7 How to Use Menu

The SETUP menu allows for the adjustment of various settings including current time, patient mode, alarm volume, pulse volume, alarm settings, etc.

Entering Main Menu



(1) Press the menu button to enter the SETUP menu. Screen will change to the right of the <screen 4> to display the parameter data is the right of the menu screen.

(2) Move the icon to enter the sub-menu <(left) button or > (right) button, press the menu button.

(3) Press the menu button on the "EXIT" item will leave the SETUP menu.

Setup Configuration

(1) Press the ∧ (up) button or ∨ (down) button to move to the item set.

(2) You can adjust the settings in the item set press < (left) button or > (right) button.

(3) Press the menu button on the "EXIT" item will leave the SETUP menu.

The contents of each item are as shown as below.

Item	Description	Range
PULSE VOLUME	Set the level of the pulse volume.	OFF, 1~7
BUTTON VOLUME	Set the level of the button volume.	OFF, 1~7
BRIGHTNESS	Set the brightness of the screen.	1~5
SCREEN TYPE	Set the main screen mode.	1~4
SPO2 AVERAGE	Set the calculation time for SpO2 measurement.	4, 8, 12, 2 (sec) (Neonate 8,12)
WAVE FILL	Set whether to fill in the wave at display.	OFF, ON
PLETH BAR	Set the display status of the level bar.	OFF, ON
SWEEP SPEED	Set display speed for ECG wave.	6.25, 12.5, 25mm/s
TIME	Go to submenu to set time	

Setup Current Time

(1) From the setup menu using menu buttons move to time submenu.

(2) Press the ∧ (up) button or ∨ (down) button to move to the item set.

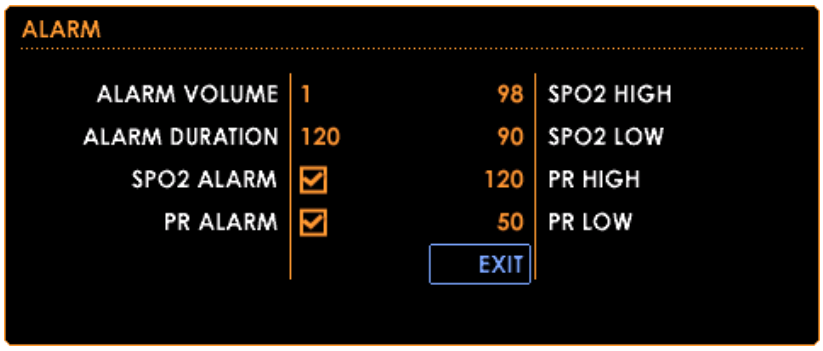
(3) You can adjust the settings in the item set press < (left) button or > (right) button.

(4) Press the menu button on the "EXIT" item will leave the SETUP menu.

The contents of each item are as shown as below.

Set	Year	Month	Day	Hour	Minute
Range	2000~2099	1~12	1~31	0~23	0~59

Setup Alarm



(1) Press the ∧ (up) button or ∨ (down) button to move to the item set.

(2) You can adjust the settings in the item set press < (left) button or > (right) button.

(3) Press the menu button on the "EXIT" item will leave the SETUP menu.

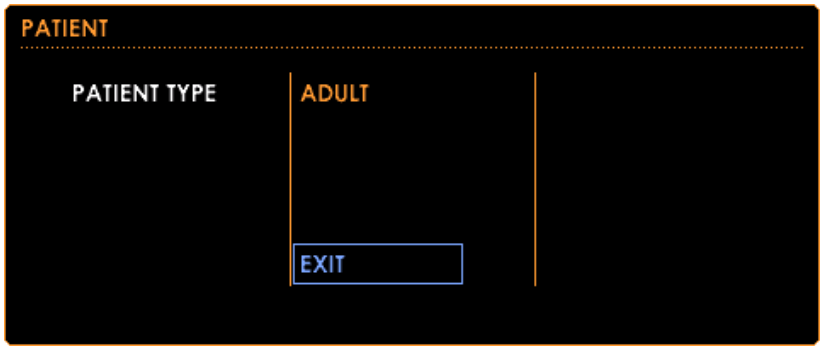
The contents of each item are as shown as below.

Item	Description	Range
ALARM VOLUME	Set the level of the alarm volume. If you want to set the alarm volume at "0" you can only do this by executing "Alarm 0 USE" command at the MAINT menu.	(OFF), 1~7
ALARM DURATION	Set the duration (second) when in alarm sound pause and alarm sound	30, 60, 90, 120 seconds
SPO2 ALARM	Checks if the SPO2 measurement value is out of the range of the setup range during alarm watch. SpO2 alarm watch status displays when setting is 'OFF'.	OFF, ON
PR ALARM	Checks if the PR measurement value is out of the range of the setup range during alarm watch. PR alarm watch status displays when setting is 'OFF'.	OFF, ON
SpO2 HIGH	Sets the alarm upper limit for the SPO2 value. When the value is larger or the same, the alarm beeps.	20~100, OFF
SpO2 LOW	Sets the alarm lower limit for the SPO2 value. When the value is smaller or the same, the alarm beeps.	OFF, 20~100
PR HIGH	Sets the alarm upper limit for the PR value. When the value is larger or the same, the alarm beeps.	15~300, OFF
PR LOW	Sets the alarm upper limit for the PR value. When the value is smaller or the same, the alarm beeps.	OFF, 15~300

Caution

Cautiously setup value when the user cannot recognize the patient status when the alarm occurs and alarm sound is OFF. Frequently check the patient status when OFF.

Setup Patient



(1) Press the ∧ (up) button or ∨ (down) button to move to the item set.

(2) You can adjust the settings in the item set press < (left) button or > (right) button.

(3) Press the menu button on the "EXIT" item will leave the SETUP menu.

The contents of each item are as shown as below.

Item	Description	Range
PATIENT TYPE	Sets up the patient mode.	ADULT,PEDIATRIC,NEONATE

When the Patient Mode changes, the alarm limit value and SPO2 average switches to the USER CONFIG value or FACTORY SET value.

Entering Maintenance Menu

(1) From the SYSTEM menu using <, > arrow buttons move to MAINT, press menu button MAINT PASSWORD submenu to pop up as above.

(2) You can press the Menu button to go to each place and change the gray background to change the number. Press the Menu button again to enter Password 4 of the value, you move from the '<' button to move to "MAINT" menu.

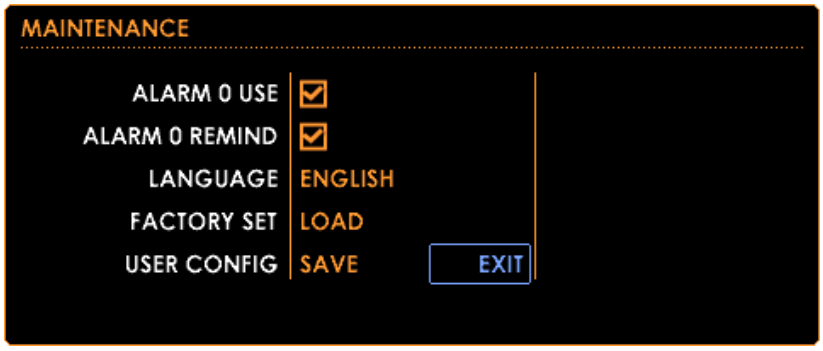
(3) Incorrect PASSWORD is displayed at the bottom of the input "Please enter the correct password" message.

(4) Press the menu button on the "EXIT" item will leave the SETUP menu.

⚠ Caution

MAINT setting can be manipulated by authorized personnel only. Be aware that the contents of MAINTENANCE are of nature that is not to be altered by normal users.

Setup Maintenance



(1) Press the ∧ (up) button or ∨ (down) button to move to the item set.

(2) You can adjust the settings in the item set press < (left) button or > (right) button.

(3) Press the menu button on the factory set load items displayed "factory set loaded" message and press the menu button on the user config save items displayed "user configuration saved." message.

(4) Press the menu button on the "EXIT" item will leave the SETUP menu.

The contents of each item are as shown as below.

Item	Description	Range
ALARM 0 USE	From SOUND menu it enables to turn ALARM Volume 0.	ON, OFF
ALARM 0 REMIND	When the alarm volume is 0 and the alarm occurs, sets if the alarm should beep in 3 minutes duration.	ON, OFF
LANGUAGE	Changes language setting, as altered once with newly desired language it will display it immediately.	ENGLISH
FACTORY SET	Press the Menu button to change the factory default settings, all settings.	LOAD
USER CONFIG	The user-defined value is stored in memory, brings to the default settings when you reboot.	SAVE

Part 8 Save and View TREND Data

Saving Measured Data

The value of the measured SpO2, PR value is saved as below.

1. The SpO2, PR value is saved in a 2, 4, or 10 second unit span.
2. Saves the limit alarm state.
3. When data exceeds the capacity, old data is deleted and new data is saved.
4. When the SpO2 sensor is not connected to the device, data is not saved.

Setup Trend

(1) Press the ∧ (up) button or ∨ (down) button to move to the item set.

(2) You can adjust the settings in the item set press < (left) button or > (right) button.

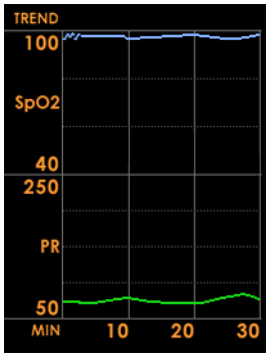
(3) Press the menu button on the "EXIT" item will leave the SETUP menu.

The contents of each item are as shown as below.

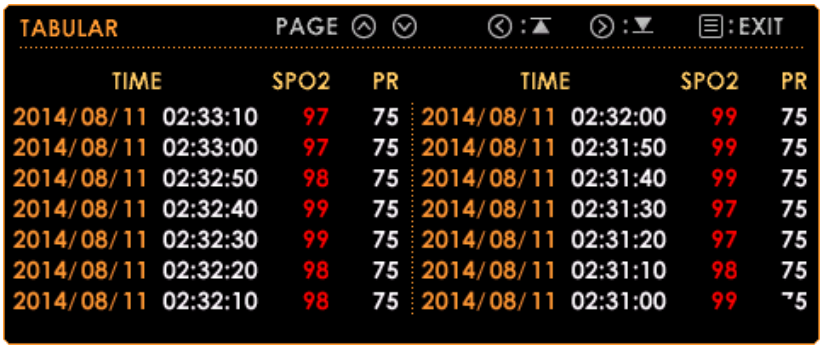
Item	Description	Range
SAVE INTERVAL	Sets the interval of saving time.	2, 4, 10 sec.
SHORT TREND	Sets total duration of short trend until present time from the set value ago. (For some available main screens)	15, 30 min
ERASE DATA	Erase trend data.	

Short Trend View

The recently recorded SpO2 and PR value can be shown in a graph as shown below on the Available on main screen type 1 and 2 shows SHORT TREND up till present time from the preset value (SETUP>TREND>SETUP>SHORT TREND)



Tabular Trend View



(1) Press menu button on the SETUP>TREND>TABULAR.

(2) TABULAR trend table pops up like below. It show the most recent data.

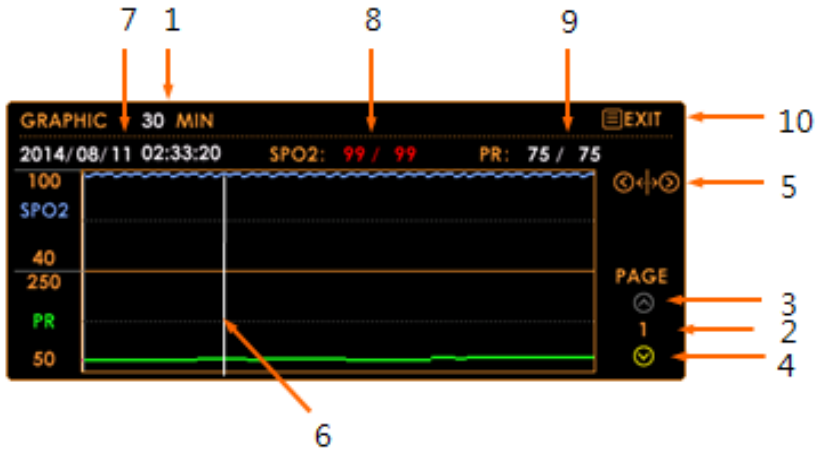
Item	Description
∧ (up) button	Go to the previous page. Moves quickly to the page after pressing more than 2 seconds
∨ (down) button	Go to the next page. Moves quickly to the page after pressing more than 2 seconds < (left) button Displays the page of the newest saved data.
< (left) button	Go to the first page.
> (right) button	Go to the last page.
MENU button	Exit tabular trend menu. Moves to the upper menu (TREND) screen.

When saving a pair of parameter values (SpO2 and PR), it saves any alarm events as well. (If any alarm ever goes off at any given saving time – display red color)

Graphic Trend View

(1) Using <, > arrow button move to items (30min~72hr) and press MENU button.

(2) GRAPHIC trend pops up like below.



No	Item	Description
1	Time interval	Displays the size of time of the Graphic trend screen.
2	Current page	Moves to the latest data saved.
3,4	Move pages	Using ARROW(∧, ∨) buttons you can move along pages.
5	Move trend bars	Using ARROW(<, >) buttons you can move along trend bars.
6	Trend bar	Displays current trend bare on present page.
7	Date/time	Date and time of trend data saved on the timeline.
8	SpO2 value	Displays the measured SpO2 value in the trend bar. The value color changes to red when the limit alarm occurs.
9	PR value	Displays the measured PR value in the trend bar. The value color changes to red when the limit alarm occurs.
10	EXIT	Moves to the upper menu (TREND) screen using the 'MENU' button.

Part 9 Alarm

The screen, sound and lamp alerts according to the alarm sensed alarm signaled from the patient during measurement and alarm occurred from the system

Alarm Categories

Alarm consists and is managed in two types, Patient alarm and Technical alarm.

- Patient Alarm
  This alarm occurs from the patient data. Occurs when the measured physiological signal value initiate the limit alarm or alerts through the patient status.
- Technical Alarm
  This alarm occurs from the system. Occurs for product related actions or system errors.
- General Message
  The alarm does not occur and shows a related message to the user. This is information such as "LEARNING..." and "PATIENT MOVING" that starts the measurement after sensing a signal.

Alarm Levels

Single alarm is classified and managed in high, medium and low priority level.

- High Priority
  Occurs when the danger is detected in life of the patient.
- Medium Priority
  Occurs when the physiological signal is abnormal or requires treatment.
- Low Priority
  Occurs when the user has to be notified or the system confronts an error during measurement.

Patient alarm and Technical alarm are prioritized according to the content, and some parts can be set by the user from alarm settings.

Note . Refer to Attachment2 for alarm message and alarm level content.

Alarm Indicators

The alarm is displayed as below when alarm occurs.

- Alarm message

  In the upper portion of the screen the alarm message field shows as below.

1. Patient alarm message area : Displays the Patient alarm message.
2. Technical alarm message area : Displays the Technical alarm message.

Displays the message according to high priority, and shows the message with same priority in a sequence.

High Priority : Red color font , and displays patient alarm attaches ***.
Medium Priority : Yellow color font, and displays patient alarm attaches **.
Low Priority : Yellow color font, and displays patient alarm attaches *.

- Alarm Tone

  When multiple alarms occur, alarms will beep according to the order of top priority.
  When the state is on alarm sound pause or alarm sound off, alarm sound will not occur.

Tone Category	Description
***High priority alarm signal	
Pulse Frequency	523Hz
Pulse width	150ms
Number of pulse in burst	10, interburst interval of 4 seconds
Repetitions	continually
Sound level range	70~76dB
**Medium priority alarm signal	
Pulse Frequency	523Hz
Pulse width	150ms
Number of pulse in burst	3, interburst interval of 8 seconds
Repetitions	continually
Sound level range	60~67dB
*Low priority alarm signal	
Pulse Frequency	659Hz
Pulse width	250ms

Number of pulse in burst	2, interburst interval of 16 seconds
Repetitions	continually
Sound level range	57~62dB

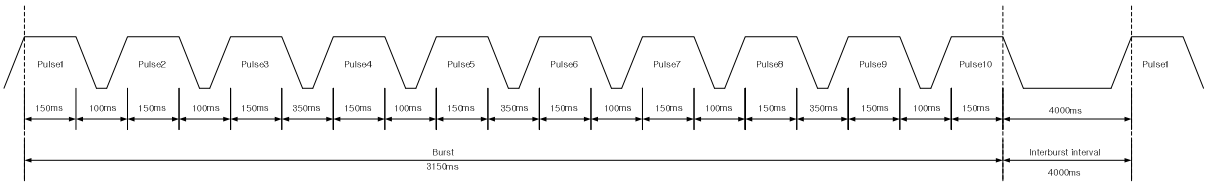
- Alarm lamp

  When multiple alarms occur, lamps will turn on according to the order of top priority.

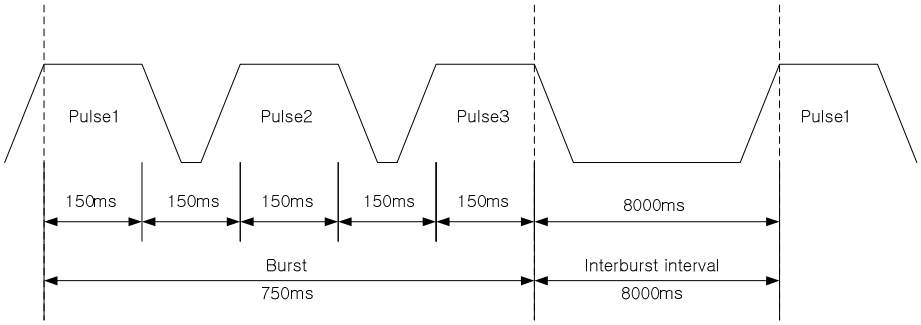
  High Priority : Red lamp blinks 2 times for 1 second.
  Medium Priority : Yellow lamp blinks for each second.
  Low Priority : Yellow lamp is turned on and maintains its state.

Priority Signal Timing

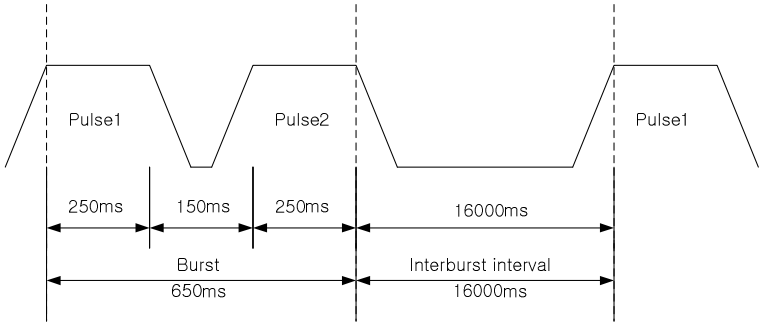
1) High priority



2) Medium priority



3) Low priority



Alarm Conditions

Alarm condition	Auditory alarm	Alarm signal	Messages
High heart rate limits violated	Medium	Visual alarm Auditory alarm	HIGH PR
Low heart rate limits violated	Medium	Visual alarm Auditory alarm	LOW PR
High SpO2 limits violated	Medium	Visual alarm Auditory alarm	HIGH SPO2
Low SpO2 limits violated	Medium	Visual alarm Auditory alarm	LOW SPO2
Unable to determine pulse rate or SpO2.	Low	Visual alarm Auditory alarm	CHECK PROBE
Communication Error	High	Visual alarm Auditory alarm	SPO2 FAULT
SpO2 cable/sensor disconnect	Low	Visual alarm Auditory alarm	SENSOR OFF
Finger off form SpO2 sensor	Low	Visual alarm Auditory alarm	FINGER OFF
Low battery	Medium	Visual alarm Auditory alarm	LOW BATTERY
Low Internal Coin Battery	Low	Visual alarm Auditory alarm	BATT ERROR
Clock settings lost (Invalid date and time value detected during start up)	Low	Visual alarm Auditory alarm	CLOCK ERROR

Alarm Conditions Delay

- Average Time

  Average time 2 - Responds to changes in blood oxygen saturation in 2 to 4 seconds.

  Average time 4 - Responds to changes in blood oxygen saturation in 4 to 8 seconds.

  Average time 8 - Responds to changes in blood oxygen saturation in 8 to 16 seconds.

  Average time 12 - Responds to changes in blood oxygen saturation in 12 to 24 seconds.

Alarm Status

- Alarm Status Symbol

  Displays the alarm watch state as shown below.

No.	Status
	Alarm watch on
	Alarm sound paused
	Alarm sound off
	Alarm watch off

- Alarm sound paused

Press the  button when the alarm occurs and the alarm sound is paused. The alarm does not sound when it is paused. During the audible alarm pause period, you can press Alarm button again to re-enable the audible alarm tone. Alarm pause time is set to SETUP > ALARM > ALARM DURATION.

There are operations according to the alarm when alarm sound is paused.

- Patient Alarm : Stops the alarm sound during ALARM DURATION
- Technical Alarm : When SENSOR OFF, FINGER OFF, LOW BATTERY occurs,

Alarm sound stops and is maintained before each state is canceled.

Warning

Do not pause button the audible alarm or decrease its volume if patient safety could be compromised.

Warning

Each time the monitor is used, check alarm limits to make sure that they are appropriate for the patient being monitored.

- Alarm off

This turns the SpO2 or PR limit alarm watch off. It is excluded in alarm messages and alarm sound operations for limit alarms.

To stop the limit alarm watch of SpO2, uncheck the SETUP > ALARM > SPO2 ALARM. And the alarm watch status switches to  in the SpO2 screen window.

To stop the limit alarm watch of PR, uncheck the SETUP > ALARM > PR ALARM. And the alarm watch status switches to  in the PR screen window

- Alarm sound off

  This turns the alarm souund off. It operates the alarm message and alarm lamp when an alarm occurs.

  When the value is set to '0' in SETUP > ALARM > ALARM VOLUME, the alarm souund stops, and the alarm watch status of SpO2 and PR switches to 0.

  When the alarm souund is off, an alarm sounds every 3 minutes to alert the current alarm status. This can be set when the alarm occurs and when SETUP > MAINT > ALARM 0 REMIND is checked.

Warning

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

Warning

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area

Warning

Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions

Note

As the alarm sounds emitted are difficult to describe in words, it is recommended that the user listen directly to the sounds of the high priority and medium priority alarms prior to product use

Caution

When turning alarm sound OFF, you should take extra caution because there is a chance that you can not recognize the status of patient. If you have to turn it OFF, check on patient frequently.

Caution

If alarm limits set to extreme values, that can render the alarm system useless.

Verifying Visual and Audible Alarm Indication

If the monitor fails to perform as specified in this test, contact qualified service personnel or your local supplier for assistance.

You can verify the alarm operation for all parameters SpO2 by following the below procedures.

(1) Connect the monitor to an AC power source.

(2) Press Power button to turn on the monitor.

(3) Connect the simulator to sensor input cable and connect cable to monitor.

(4) Set the simulator to smaller value than the lower alarm limit on the monitor.

(5) Verify following the monitor reaction:

a. The monitor begins to track the physiological signal from the simulator.

b. After about 10 to 20 seconds, the monitor displays the value measured as specified by simulator. Verify values are within the tolerances specified in Specification section for each parameter.

c. Audible alarm sounds.

d. The numerical area flashes, indicating the parameter has violated default alarm limits.

Note

It is recommended that you listen to the high and mid alarms beforehand in order to be cognizant of the sounds when the alarms do go off.

Part 10 Basic Troubleshooting

Here are some basic troubleshooting hints. There may be times when the product does not work as it is supposed to and you may not know how to proceed. Try the following steps to work through the problems.

▣ General

Situation	Cause
The power will not come on.	- Make sure the product is plugged in. - Make sure the battery is fully charged.
I can't hear the alarm or the pulse sounds	- Make sure the alarm is not turned off.
Coin battery image ( ) is shown in the lower portion of the screen.	- Make sure the coin battery is not lacking capacity.
The saved value is initialized.	- Make sure the coin battery is not lacking capacity. - Make sure the memory has no problems

▣ Measuring the SpO2

Situation	Cause
The red sensor light does not come on.	- The probe is not connected properly. - The probe is broken.
I can't see the waves.	- The probe is not connected properly.

▣ Error Message

Message	Cause
HIGH PR	SpO2 is above the alarm limit. Check patient immediately.
LOW PR	SpO2 is below the alarm limit. Check patient immediately.
HIGH SPO2	SpO2 is above the alarm limit. Check patient immediately.
LOW SPO2	SpO2 is below the alarm limit. Check patient immediately.
CHECK PROBE	Sensor not attached to patient. Reposition or replace sensor.
SPO2 FAULT	Analog board resulted in unstable contact with the IC Communication. Return to a qualified service technician.
SENSOR OFF	Sensor not attached to patient. Reposition or replace sensor.
FINGER OFF	Sensor not attached to patient finger. Reposition or replace sensor.
LOW BATTERY	Connect to AC power. Continue charging on AC
BATT ERROR	Low Internal Coin Battery. Return to a qualified service technician.
CLOCK ERROR	Date and time setting lost. Set the date and time. Return to a qualified service technician.

Part 11 Product Specification

Product Specification

- **PERFORMANCE**

Saturation (SpO2)			
Range	0~100%		
Resolution	1%		
Accuracy	Adult, Pediatric	70%~100%	±2 Digits
		50%~69%	±3 Digits
		0%~49%	unspecified
	Neonate	70%~100%,	±3 Digits
		50%~69%	±4 Digits
		0%~49%	unspecified
Average	Adult, Pediatric	2, 4, 8, 12,	
	Neonate	8, 12	
Pulse rate			
Range	30~250bpm		
Resolution	1bpm		
Accuracy	30~250bpm	±3 Digits	
Perfusion index			
Range	0.05 ~ 20%		

- **Electrical**

Instrument	
Power Input	100-240 Vac, 50/60Hz
Fuse rating	5A, 32VAC/DC
Battery	
Type	7.2V Li-ion rechargeable battery
Charge time	6 hours
Battery Capacity	Typically 6hours using new, fully charged battery
Warranty	6 months

- **Environmental**

Storage Temperature	-20℃ ~ 70℃
Storage Humidity	10% ~ 100%
Operating Temperature	5℃ ~ 35℃
Operating Humidity	30% ~ 85%, R.H. non-condensing
Operating Pressure	80kPa ~ 106kPa
Operating Attitude	0 – 2,000m

- **Physical Characteristics**

Weight	1000g
Dimensions	85(H) x 84(W) x 245(D) mm
Package unit	1ea

- **Accessories**

Basic	SpO2 Sensor(ACCY-0A0PRB Reusable type)	1EA
	Power Cord	1EA
	User Manual	1EA
Optional	SpO2 Sensor(pediatric, neonate)	
	SpO2 Sensor(pediatric, neonate Y-type)	
	SpO2 extension cable(9pin)	
	IV Pole Clamp	
	Carrying Bag	

- Sensor and Cable Length

Type	Patient Size
SpO2 adult Sensor	1m, 3m
SpO2 pediatric Sensor	1m, 3m
SpO2 neonate Sensor	1.5m, 3m
SpO2 neonate Sensor	1m, 3m
SpO2 extension cable	2.5m
Power Cord	1.8m

- **General**

Display	
Display	Color TFT Dual LCD
Size	4.3inch(480 x 272 dots), 2.4inch(240 x 320 dots)

Brightness	1~5
LED Lamp	
Display power status	AC Power Status Lamp Battery Power Status Lamp
ALARM	
Alarm indicators	Alarm message, Alarm sound, Alarm lamp
Alarm level	High Priority, Medium Priority, Low Priority
Alarm volume	0~7
Alarm duration	30, 60, 90, 120 seconds
Trends	
Memory	Save continuously for 15 days (for 10 seconds saving period)
Display	Tabular, Graphic
External Communication	
Serial RS-232	Software Upgrade

Manufacturer's Declaration

- Electromagnetic Compatibility (EMC)

Caution

This monitoring system is intended for use by healthcare professionals only. This monitoring system may cause radio interference or may disrupt the operation of nearby equipment, regardless of whether it is CISPR compliant or not. It may be necessary to take mitigation measures, such as re-orienting or relocating the monitoring system or shielding the location.

Caution

The use of accessories, Sensors, and cables other than those specified may result in inaccurate reading s of the monitoring system and increased emission and/ or decreased electromagnetic immunity of the monitoring system.

- Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1 Class A	Not intended for use in a residential environment. If used in a domestic environment, may not offer adequate protection to radio-frequency communication services. The user may be required to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

- Electromagnetic Immunity

Immunity test	EN/IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during

on power supply input lines IEC 61000-4-11	70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 .0A/m	3 .0A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

- . Electromagnetic Immunity Compliance

Immunity test	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic Environment-Guidance**
	Frequency of Transmitter		Equation for Separation Distance (d)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	d = 1.2√P 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m 80 MHz to 800 MHz	d = 1.2√P 80 MHz to 800 MHz
	3 V/m 800 MHz to 2,5 GHz	3 V/m 800 MHz to 2,5 GHz	d = 2.3√P 800 MHz to 2,5 GHz

- Recommended Separation Distance

Rated maximum output power (P) of transmitter in watts	**Separation Distance in Meters**		
	d = 1.2√P 150 kHz to 80 MHz	**d = 1.2√P 80 MHz to 800 MHz**	**d = 2.3√P 800 MHz to 2,5 GHz**
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, estimate the separation distance (d) using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note

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

Note

Portable and mobile RF communications equipment can affect medical electrical equipment.
Such RF equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Clinical Studies

Overview

This contains data from clinical studies conducted for Neonate Sensor Adult Sensor, Disposable Sensor and Pediatric Sensor used with the ACCURO oximeter.

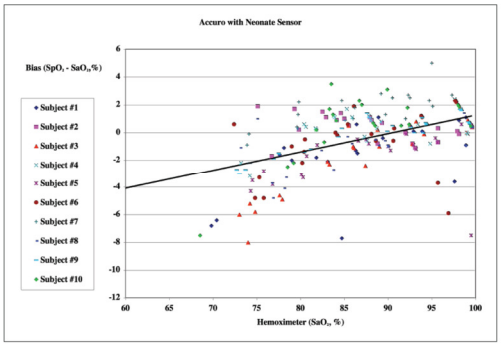
Methods

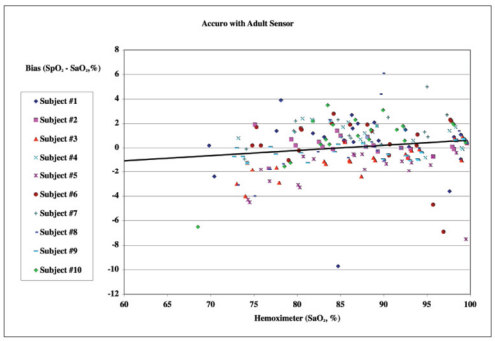
The current study for Charmcare, Inc. performed 3/18/10 included 10subjects- 7 women and 3 men. The ACCURO oximeter was studied with three different sensors: adult, disposable and neonate. A radial arterial cannula was placed in either the left or right wrist of each subject. Blood gas analysis to determine oxyhemoglobin saturation was performed on an OSM 3® multi- wavelength oximeter (Hemoximeter, Radiometer, Copenhagen, serial 89R0243 N010). This instrument underwent a full factory technician calibration and reference standards check on June 8, 2009. The instrument was also verified to read within specifications with the use of Radiometer Qualicheck standards within 48 hours of the study dates. No subject was anemic (Hemoglobin ≤ 10 gm•dl-1) and only healthy non-smoking individuals of age 21-49 were included in the study.

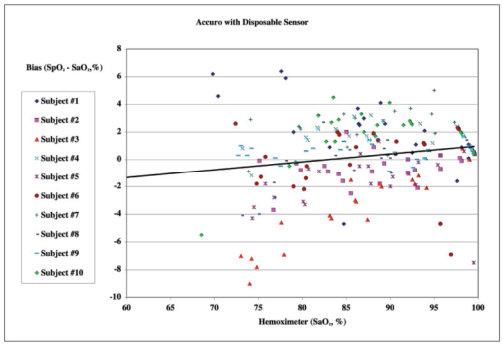
The study was reviewed and approved by the University of California at San Francisco Committee on Human Research. The approval date was 3/21/09, expiration April 21, 2010. The Approval number is H6301-01706-24. The approval letter is on file at UCSF. Each subject had control data taken at the beginning of each experiment, with two control blood samples drawn while breathing room air. Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Each plateau level

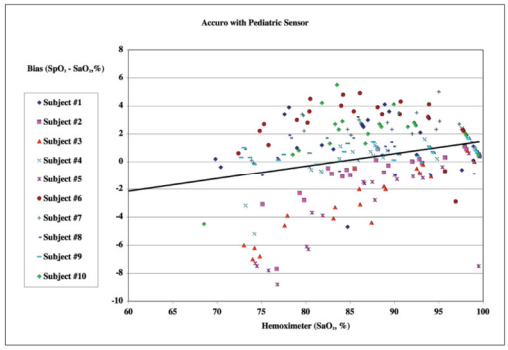
of oxyhemoglobin saturation was maintained for at least 30 seconds and until pulse oximeters readings had stabilized. Two arterial blood samples were then obtained, approximately 30 seconds apart. Each stable plateau therefore was maintained for at least 60 seconds with SpO2 fluctuating by less than 3%. The plateaus were nominally at 100%, room air saturation, 93%, 90%, 87%, 85%, 82%, 80%, 77%, 75% and 70%. A total of 22-24 samples were obtained that the plateaus across this span. Data were recorded by computer. At least 200 data points were collected for each type of oximeter and probe combination studied.

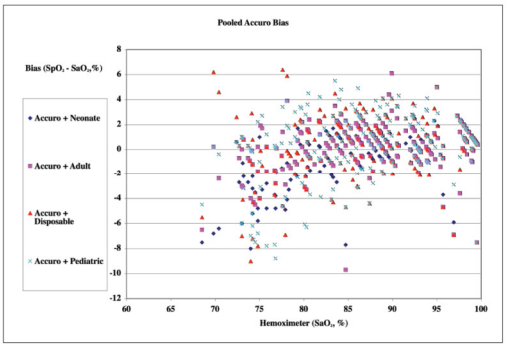
Study Results











Conclusion

The pooled results indicate that for a saturation range of 60-80% for SpO2, the acceptance criterion was met for the monitoring system when tested with Neonate Sensor Adult Sensor, Disposable Sensor and Pediatric Sensor. The pooled results indicate that for a saturation range of 70-100% for SpO2, the acceptance criterion was met.

Attachment 1 Factory Set

The default value of the product is as shown below.

Factory Set

* Timing to save

- **When altering parameter values** : When a user changes each parameter value at her/his discretion it will be saved in memory that after a quick restarting the last saved values will be applied.

- **USER CONFIG**: Even if the user changes parameter values at his/her discretion validity of this change will be preserved for only 30 seconds after powering off the device before restarting it. Authorized maintenance personnel can only change USER CONFIG setting(MAINT>USER CONFIG>SAVE) that will be always retrieved if restarted more than 30 seconds after any other normal users manipulations.

Below shows the parameters that users can changes.

Menu	Item	Factory set	* Timing to save
CONFIGURATION	PULSE VOLUME	4	When changing parameter value.
	BUTTON VOLUME	4	When changing parameter value.
	BRIGHTNESS	3	When changing parameter value.
	SCREEN TYPE	3	When changing parameter value.
	SPO2 AVERAGE(s)	8 (neonate :12)	USER CONFIG
	WAVE FILL	OFF	When changing parameter value.
	PLETH BAR	ON	When changing parameter value.
	SWEEP SPEED(mm/s)	12.5	When changing parameter value.
ALARM	Alarm volume	4	USER CONFIG
	Alarm duration	120	USER CONFIG
	SpO2 Alarm	ON	USER CONFIG

	PR Alarm	ON	USER CONFIG
	SpO2 High limit	OFF	USER CONFIG
	SpO2 Low Limit	90(neonate:85)	USER CONFIG
	PR High Limit	Adult : 120 Pediatric :160 Neonate : 200	USER CONFIG
	PR Low Limit	Adult : 50 Pediatric : 75 Neonate : 100	USER CONFIG
PATIENT	PATIENT	ADULT	When changing parameter value.
TREND	SAVE INTERVAL(s)	10	When changing parameter value.
	SHORT TREND(min)	30	When changing parameter value.

Maintenance Set

Below shows the parameters that authorized personnel with password can change.

Category	Name	Factory Default	* Timing to save
MAINTENANCE	ALARM 0 USE	OFF	When changing parameter value. (Authorized maintenance personnel)
	ALARM 0 REMIND	OFF	When changing parameter value. (Authorized maintenance personnel)
	LANGUAGE	ENGLISH	When changing parameter value. (Authorized maintenance personnel)

Factory Set By Patient Type

* When transferred to Patient mode, the alarm limit value and SPO2 Average value automatically changes to the USER CONFIG set.

Item	Factory Default
SPO2 HIGH (%)	ADULT : OFF PEDIATRIC : OFF NEONATE : OFF
SPO2 LOW (%)	ADULT : 90 PEDIATRIC: : 90 NEONATE : 85
PR HIGH (bpm)	ADULT : 120 PEDIATRIC: : 160 NEONATE : 200
PR LOW (bpm)	ADULT : 50 PEDIATRIC : 75 NEONATE :100
SpO2 Average (s)	ADULT : 8 PEDIATRIC : 8 NONATE :12

Attachment 2 Alarm Message

The level and cause of a single alarm is presented. '*' mark can be changed according to the value, and when the value does not need to be changed it is set to a fixed value.

- **Patient Alarm Message**

Alarm Message	Level	Cause
HIGH SPO2	Medium	Occurs when the measured value is greater than the high limit or greater than the low limit. Check the status of the patient. Also, check if the limit set value is valid.
LOW SPO2	Medium	
HIGH PR	Medium	
LOW PR	Medium	

- **Technical Alarm Message**

Alarm Message	Level	Cause
SPO2 FAULT	High	Not connected with the oxygen saturation measuring part.
SENSOR OFF	Low	The sensor is not connected to the product. Occurs when the sensor is not correctly connected or a problem is detected in the sensor.
FINGER OFF	Low	The sensor is not attached to the patient.
CHECK PROBE	Low	Checking the sensor status is required. The light of the sensor may be exposed to an external light.
LOW BATTERY	Medium	Battery is low. Connect AC power and charging is necessary.
BATT. ERROR	Low	Coin battery is low.
CLOCK ERROR	Low	An error for time value occurs. reset is necessary.

CE 0120

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