



EN Handheld Pulse Oximeter

www.rossmax.com

| Manufacturer's declaration-electromagnetic immunity | | | |
|--|---|---|---|
| The SA310 is intended for use in the electromagnetic environment specified below. The customer or the user of the SA310 should assure that is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment-guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | Portable and mobile RF communications equipment should be used no closer to any part of the SA310 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P, d = 1,2 √P 80MHz to 800 MHz, d = 2,3 √P 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: |
| Radiated RF IEC 61000-4-3 | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz | |

NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

More information on EMC compliance of the device may be obtained from Rossmax using the contacts shown in this manual.

Warranty Card
This instrument is covered by a 2 year guarantee from the date of purchase, batteries and accessories are not included. The guarantee is valid only on presentation of the guarantee card completed by the dealer confirming date of purchase or the receipt. Opening or altering the instrument invalidates the guarantee. The guarantee does not cover damage, accidents or non-compliance with the instruction manual. Please contact your local seller/dealer or www.rossmax.com.

Customer Name: _____
Address: _____
Telephone: _____
E-mail address: _____
Product Information: _____
Date of purchase: _____
Store where purchased: _____

The text is subject to change without further notice.

| | | |
|---------------------------------|---|----------------------------|
| The display disappears suddenly | The device will auto power off when it gets no signal | Normal |
| | Low battery | Replace with new batteries |

Note: If the unit does not work, return it to your dealer. Under no circumstance should you disassemble and repair the unit by yourself.

Warning

- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
- This device only for spot-checking, but not medical result evaluation.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
 - Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line (s)
 - Excessive light, such as sunlight or direct home lighting.
 - Not steady at the site of application (e.g. trembling)
 - Moisture in the device
 - Improperly applied device
 - Finger is too large or too small to fit into the device
 - Poor pulse quality
 - Venous pulsations
 - Anemia or low hemoglobin concentrations
 - Cardio green and other intravascular dyes
 - Carboxyhemoglobin
 - Methemoglobin
 - Dysfunctional hemoglobin
 - Artificial nail or fingernail polish
 - On fingers with anatomical changes, oedemas, scars or burns.
 - The conditional of probe. Use only the Rossmax approved pulse oximeter sensor, cable and accessories. These parts are not reprocessed. Use of other sensors, cable and accessories can result in inaccurate readings.
- Using the device for long periods may cause pain for people with circulatory disorders. Reposition the device (probe) at least once every 4 hours to allow the patient's skin to breath and to check patient's condition regularly.
- Do not use the device near flammable or explosive gas mixtures.
- Do not use the device during an MRI or CT scan.
- The device will be affected by electromagnetic interference during operation.
- A warning that other cables and accessories may negatively affect EMC performance.
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- Do not overextend the device's spring.
- A functional tester cannot be used to access the accuracy of a pulse oximeter monitor.
- Do not self-diagnose or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the probe are harmful to your eyes.
- Please be aware that user with susceptible skin.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- The maximum temperature might reach 42.4°C when operating for long time.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle.
- Do not reuse or disinfect disposable SpO2 probe. (only for PD100)
- The product is with a service life of 5 years is the course of regular use.
- If any serious incident (e.g. death) has occurred in relation to the device should be reported to the dealer, manufacturer, and the competent authority of Member State in which the user and/or patient is established.

Cleaning

- Please clean the surface of the device before using. Wipe the device with medical alcohol (70% (w/w) Ethanol) first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to clean the product after use, prevent from cross infection for next time use.
- The best storage environment of the device is -25°C ~ 70°C ambient temperature and not higher than 90% relative humidity.

Note: 1. Do not sterilize, autoclave or immerse this device in liquid. Do not pour or spray any liquids onto the device.
2. Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

Maintenance

Recommends user to return this device to the manufacturer perform the following checks every 24 months.

- Inspect the equipment for mechanical and functional damage or deterioration.
- Ensure all user interface keys and accessories function normally.

Note: Manufacturer use Index2 simulator to verify operation of the pulse oximeter device.

Electromagnetic Compatibility Information

- This device needs to be installed and put into service in accordance with the information provided in the user manual.
 - WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SA310, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- If higher IMMUNITY TEST LEVELS than those specified in Table are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation.

| | | | | | |
|---|-----------------------------|---|--|---|--|
| 4 | Probe failure alarm | | The icon shows on the screen | Beep-beep sounded repeatedly | X |
| 5 | Probe connect failure alarm | | The icon shows on the screen | Beep-beep sounded repeatedly | x |
| 6 | Low battery alarm | | The icon shows on the screen | Beep-beep sounded repeatedly for 1 minute and power off | x |
| 7 | Automatic Off | X | | Beep-beep sounded and then power off | After pulse is undetectable for around 1 minute. |
| 8 | Unable measure | | Blood saturation & pulse rate appears "--" | Beep-beep sounded repeatedly. | x |
| 9 | AC Power | | | | Remove or connect AC power cable to device. |

Note: Description of the effect on displayed and transmitted SpO2 and pulse rate:
 • Data averaging: 4 seconds for SpO2; 8 seconds for pulse rate.
 • Data update delay: Less than 2 seconds.
 • Alarm condition delay: Less than 8 seconds for SpO2; Less than 16 seconds for pulse rate.
 • Alarm signal generation delay: Less than 1 second for SpO2 and pulse rate.

Specification

| | |
|---------------------------------|--|
| SpO2 | |
| Measuring range | 35% – 100% (the resolution is 1%) |
| Accuracy | 70% - 100%: ±2 %, 35% - 69%: unspecified |
| Pulse Rate | |
| Measuring range | 30 – 250 bpm (the resolution is 1 bpm) |
| Accuracy | 30 – 250 ± 3 digits |
| Probe Type | |
| Probe model | Rossmax PA100, PB100, PC100, PD100(Single Use), PF100 |
| Extension cord | Rossmax PE100 |
| Optical Sensor | The wavelength of red LED is 660nm and Infrared LED is 905/880nm with maximum optical output power of 4mW. |
| Electrical Specification | |
| Battery | AA * 4 (Alkaline) |
| Battery Life | Continually for 15 hours with 4 alkaline batteries |
| AC Adaptor | Model: HK-X205-A06, HK-XW05-A06, (W=1,2,3,4), HKKS-13116, HKKS-13117 Input: AC100-240V, 50/60Hz, 0.2A max; Output: DC 6V, 0.8A |
| Environmental conditions | |
| Operation Condition | Temperature: 5°C – 40°C (41°F – 104°F), Relative Humidity: 15% – 95% (non condensing), Atmospheric pressure: 700hPa ~ 1060hPa |
| Storage /Transport Condition | Temperature: -25°C – 70°C (-13°F – 158°F), Relative Humidity: 15% – 90% (non condensing), Atmospheric pressure: 700hPa ~ 1060hPa Note: The condition of -25°C or 70°C back to use should stand for 3 hours at room temperature. |
| Dimension | Size: 14.5(L) x 7.25(W) x 2.25cm(H) |
| Weight | About 150g (without the batteries) |
| Standard | IEC/EN60601-1, IEC/EN60601-1-2, IEC/EN60601-1-11, ISO80601-2-61 |
| Symbol Descriptors | |
| | Manufacturer |
| | Serial number |
| | EU representative |
| | Type BF (Body Floating) |
| | IP22: Protected against foreign objects and moisture |
| | CE Mark |
| | Warning: the symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment. |

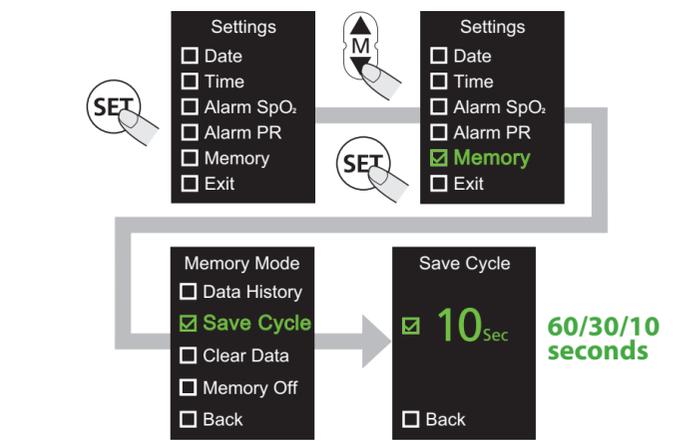
Troubleshooting

| Symptoms | Check points | Corrections |
|---|--|---|
| SpO2 or Pulse rate cannot displayed | The icon "--" shows on the screen | Place the finger properly and try again. |
| | This icon means probe connect failure. | Be sure "Rossmax" probe is connected to the device correctly. |
| SpO2 or Pulse rate are not displayed stably | This icon means probe dysfunction | Replace with new probe. |
| | Applied finger improperly | Place the finger properly and try again |
| No display when the bottom is pressed | Finger is shaking or body is moving | Keep body steady |
| | Batteries run down | Replace with new batteries |
| | Batteries inserted incorrectly | Re-insert batteries |

- Bar Chart**
- Entry "Data History", press the / button to highlight "Bar Chart" option for viewing statistics of SpO2, and then press the button to select the option.
 - Entry "SpO2 Memory Data", press the button to go back to the monitoring screen.
- Memory Transfer to ROSSMAX Software**
- Entry into "Data History", press the / button to highlight "Memory Transfer" option, and then press the button to start data transmission for a few seconds.
- Note: Before entering the data history mode, the icon should collect more than 1 data.

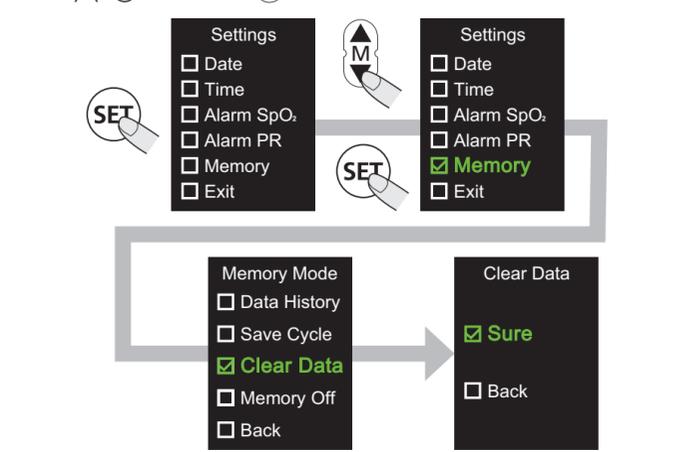
Memories mode- Save Cycle

- Optional of memory interval: 60 / 30 / 10 seconds**
- Press the button and / button to highlight "Memory" option, and then press the button to select the option.
 - Entry "Memory Mode", press the / button to highlight "Save Cycle" option, and then press the button to select the option.
 - Entry "Save Cycle", press the / button to highlight option, and then press the button to select the option.
 - Press the / button to change the value; press the button to save the desired value.
 - Press the / button and the button to select "Back/Exit" to return.



Memories mode- Clear Data

- Press the button and / button to highlight "Clear Data" option, and then press the button to select the option.
- Entry "Clear Data", press the / button to highlight "Sure" option, and then press the button to select the option.
- Press the / button and the button to select "Back/Exit" to return.



Note: After clearing data, the icon will show 0 data.
Caution: The deleted data could not be restored.

Audio Signals

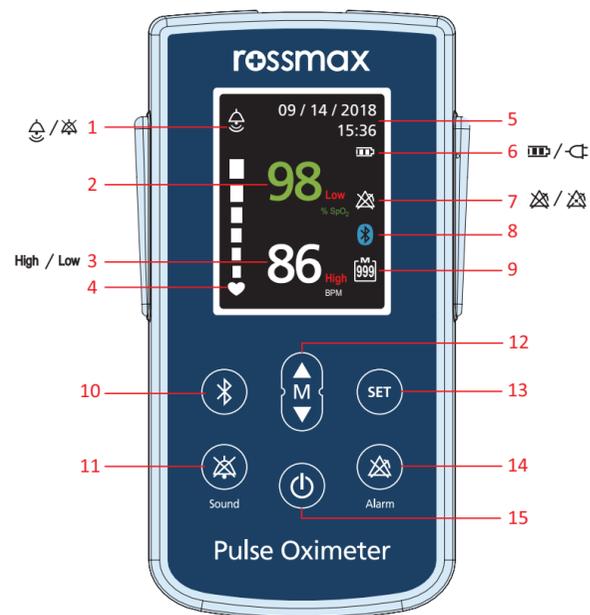
| No. | Name | LCD Display | Sound | Control |
|-----|--------------------------------------|---|--|-------------------------|
| 1 | Power on | | Beep for 2 seconds | Press button |
| 2 | Pulse search | | X | X |
| 3 | Max/ Min SpO2 and Pulse rate warning | Show High or Low in red icon. Reflects upper or lower alarm limits. | Beep-beep sounded repeatedly Mute for temporary, will Beep-beep sounded after two minutes. Mute before power off | Default mode mode |

Introduction

Rossmax Handheld Pulse Oximeter is used to measure oxygen saturation in blood (SpO2) and pulse rate, also to issue warnings immediately. It is a non-invasive device intended for spot-check of adults, child, and infants with corresponding probe applied at home, hospital and clinics.

Attention: Consult the accompanying documents. Please read this manual carefully before use. Please be sure to keep this manual.

Name/ Functions of each part



| No. | Item | Purpose |
|-----|-------------------|--|
| 1 | Sound icon | loud volume / silence |
| 2 | SpO2 icon | 99% SpO2 SpO2 real-time value Low Reflects lower SpO2 warning. |
| 3 | Pulse Rate | 75 BPM Pulse rate real-time value High / Low Reflects upper and lower pulse rate warning. |
| 4 | Pulse strength | |
| 5 | Date/Time | Show the Date (MM/DD/YYYY) / Time |
| 6 | Power status icon | Battery: Full batteries / Critically Low-Battery AC Power: AC power cable connected |
| 7 | Alarm icon | Alarm off / Alarm pause for 2 minutes |
| 8 | Bluetooth icon | For Bluetooth on / off for real-time data transmission |
| 9 | Memory icon | Collection of Memories Up to 999 memories |
| 10 | Bluetooth button | Press to turn on / off the Bluetooth function |
| 11 | Sound button | Press to turn on / off the heartbeat sound |
| 12 | UP/DOWN button | Press to scroll options and change value |
| 13 | SET button | Press to adjust default setting / Press to select the option |
| 14 | Alarm button | Press to pause alarm. To turn off alarm permanently, please entry "Settings" mode to set up. |
| 15 | Power button | Press to power on/off |
| 16 | | it's for AC Adaptor. |

Power installation

Power can be supplied either by batteries or AC power cable.

AC power cable:

Plug AC power cable into AC power source and printout socket. Icon as show on the display. Note: Once AC power is on, the power supply of the device is switched to AC power. Once AC power is off, the power supply of the device is switched to battery power.

Note: Don't regard icon as whether the AC power supply is normal.

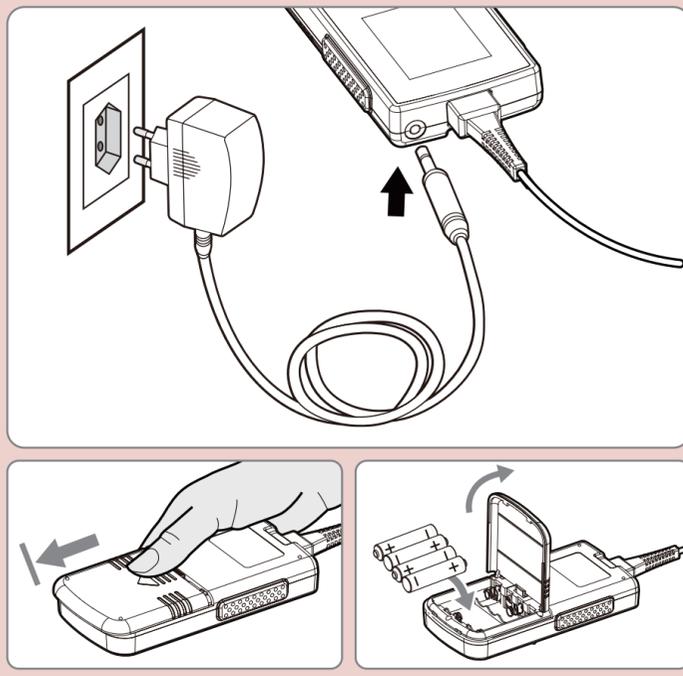
Batteries:

1. Use thumb to slide battery cover out.

2. Insert or replace 4 "AA" batteries according to the (+/-) polarity.

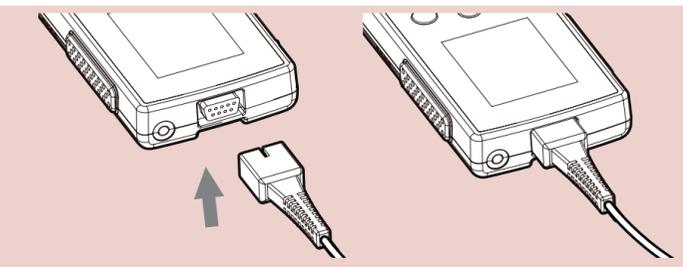
Caution: Need to replace when the batteries icon is blinking on display/ while pressed the function button and nothing appears on display.

Caution: Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for long time. Do not use different types or brand of batteries at the same time.



Probe connection

Rossmax PA100/PB100/PC100/PD100/PF1000 or compatible probe is used. (Please install carefully.) Caution: It may damage the efficiency of the device if not apply with a Rossmax compatible probe.



How to measure

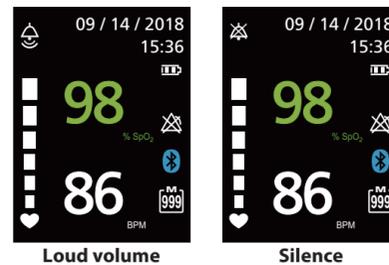
- Press the Power On button for 1 second, when the device activates, the beep sound will last for 2 second.
Note: After the device activates, the software version will pop up directly. For first time activates, please refer to setting instruction.
 - Information of software version appears; insert one finger to probe, nail side up, for self-test. Note: The device will turn itself off automatically after 1-minutes idling with two beep sounded.
 - The pulse strength shows ; pulse oximeter begins its measurement.
Note: The heartbeat is sounded though the buzzer. If need to become silence mode, press the sound button and the LCD screen will have the sound icon shown. If need the heartbeat sound, press the sound button to exit.
- Notes: 1. Don't remove your finger until the measurement is completed.
2. Any other problems or unrecognized icon, please refer to trouble shooting.

Sound volume control

- Press the button to control the sound volume.

for loud volume.

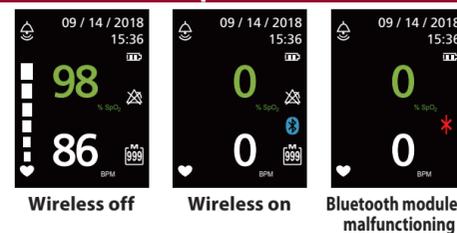
for silence.



Bluetooth Setup

- Adjust the bluetooth setting by press the button.

Note: If the icon appears, it means the Bluetooth module is malfunctioning.



Default Setting

Date: 2018/01/01 Alarm PR: 100 High / 60 Low Alarm SpO2: 86%
Time: 00:00:00 Memory: OFF

How to Change Default Setting

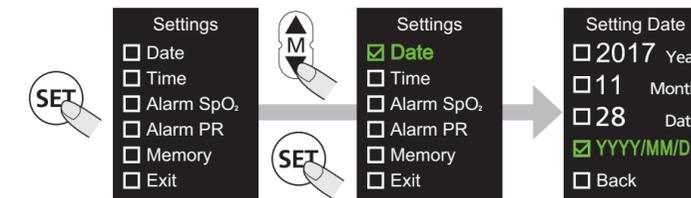
- Press the button to enter the "Settings" mode and press to scroll through option.
- Press button to select desired option.
- To exit setting, select "Back/Exit" or wait for 30 second.

Note:

- Press , the device will turn off and the setup value will be reserved.
- Waiting for 30 seconds to exit, the setup value will be reserved. Please check the setting value before use.

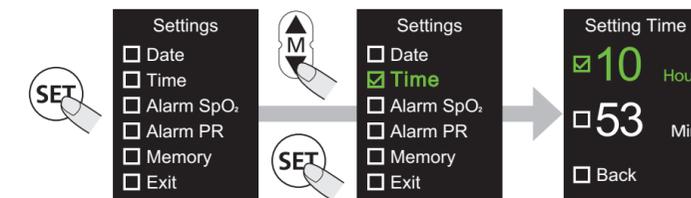
Date Setup

- Press the button and button to highlight "Date" option, and then press the button to select the option.
- Entry "Settings Date" mode, press the button to highlight the desired option and press the button to select the option.
- Press the button to change the value; press the button to save the desired value.
- Press the button to highlight another option or select "Back/Exit" to return.



Time Setup

- Press the button and button to highlight "Time" option, and then press the button to select the option.
- Entry "Settings Time" mode, press the button to highlight the desired option and press the button to select the option.
- Press the button to change the value; press the button to save the desired value.
- Press the button to highlight another option or select "Back/Exit" to return.

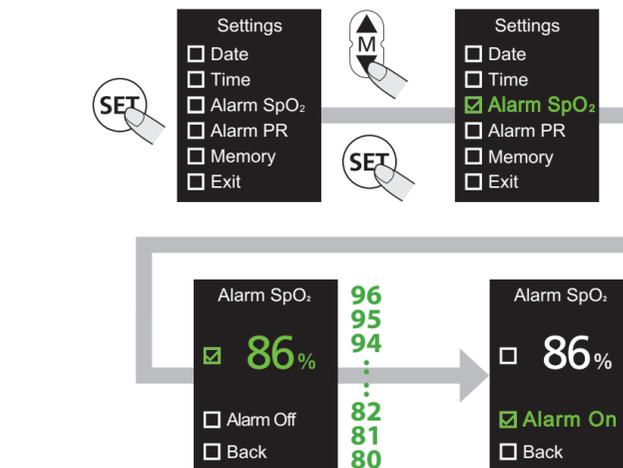


Alarm SpO2 Setup

Adjustment Range: 96, 95, 94 ... 83, 82, 81, 80.

The Unit of Adjustment: 5 BPM / per unit.

- Press the button and button to highlight "Alarm SpO2" option, and then press the button to select the option.
- Entry "Alarm SpO2" mode, press the button to highlight the desired option and press the button to select the option.
- Press the button to change the value; press the button to save the desired value.
- Press the button to highlight another option or select "Back/Exit" to return.

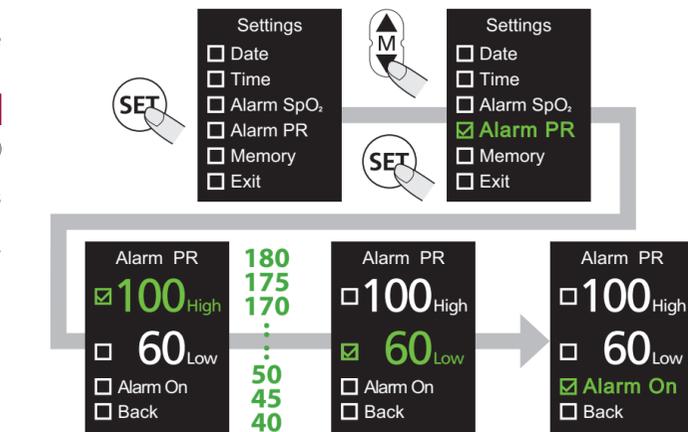


Alarm Pulse Rate Setup

Adjustment Range: 180, 175, 170 ... 50, 45, 40.

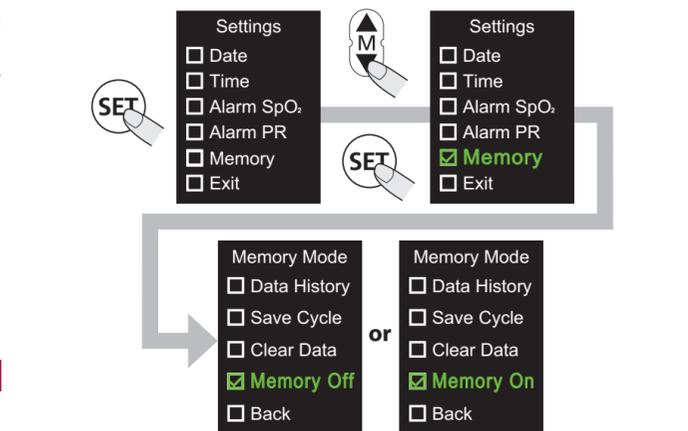
The Unit of Adjustment: 5 BPM / per unit

- Press the button and button to highlight "Alarm PR" option, and then press the button to select the option.
- Entry "Alarm PR" mode, press the button to highlight the desired option and press the button to select the option.
- Press the button to change the value; press the button to save the desired value.
- Press the button to highlight another option or select "Back/Exit" to return.



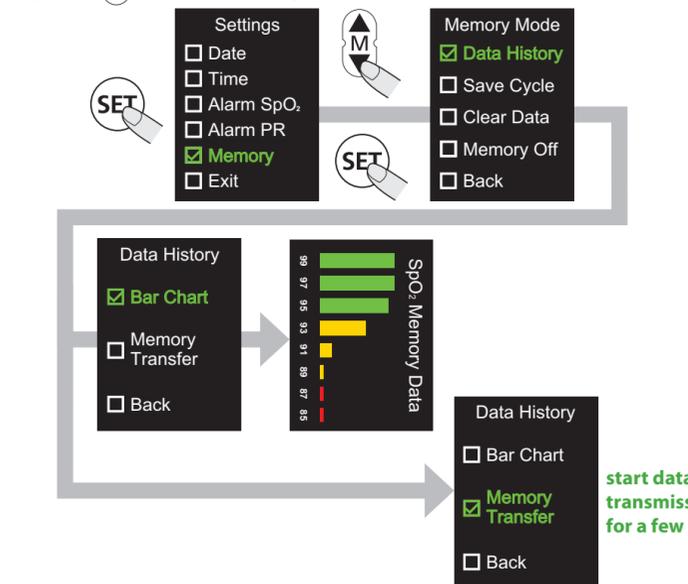
Memories mode -Memory On

- Press the button and button to highlight "Memory" option, and then press the button to select the option.
- Entry "Memory Mode", press the button to highlight "Memory Off" option, and then press the button to select the "Memory On" option.
- Press the button to highlight another option or select "Back/Exit" to return.



Memories mode- Data History

- Press the button and button to highlight "Memory" option, and then press the button to select the option.
- Entry "Memory Mode", press the button to highlight "Data History" option, and then press the button to select the option.



start data transmission for a few secs.