

OxiEasy 300 S

Pulse Oximeter

User Manual

Easy, Reliable and Smart

@ www.justec.cn

Instruction for use

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Declaration of conformity



Complies with 93/42/EEC Medical Device Directive .

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Intended Use and Warnings


1 Intended Use


The OxiEasy Pulse Oximeter is indicated for spot monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adults and paediatrics in hospital, clinical & medical practices, transport and emergency care environments.


2 Warnings


Warnings are identified by the **WARNING** symbol shown above. Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.


 **Warning 1:** Do not make any clinical judgments based solely on the OxiEasy. The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The interpretation of the measurement values should be done only by trained health care professionals.


-  Warning 2: Explosion hazard. Do not use OxiEasy in the presence of flammable anaesthetic mixture with air, oxygen, or nitrous oxide.


-  Warning 3: Routinely monitor the patient to ensure that the OxiEasy is functioning and that the oximeter is correctly placed. Change the sensor application site, check skin integrity and circulatory status at least every 4 hours.


-  Warning 4: Pulse oximetry measurements and pulse signals can be affected by certain environmental conditions, oximeter application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.


-  Warning 5: For the measurement, the SpO_2 monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications.

-  Warning 6: In high ambient light conditions it is required to shield the sensor application site with opaque material. Too much ambient may result in inaccurate measurement.

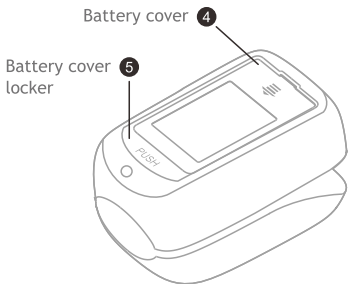
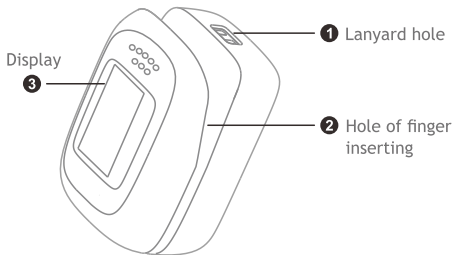
-  Warning 7: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then ensure that the OxiEasy is functioning correctly.

-  Warning 8: The OxiEasy is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or whilst an electrosurgical unit is in use. The measurements may be inaccurate throughout the defibrillation, or use of an electrosurgical unit, and shortly thereafter. To avoid shock, the caregiver should not touch the OxiEasy while using a defibrillator on a patient.

-  Warning 9: Disconnect the OxiEasy from the patient through-out magnetic resonance imaging(MRI) scanning. Induced current could potentially cause burns.


-  Warning 10: Do not use a device that appears damaged. Do not use the device when optical components are exposed.


Parts Instruction



Operation

1 Power supply

 Caution: Remove the batteries if the device is to be stored or not used for a longer period of time.

 Caution: The use of the rechargeable instead of alkali batteries is not advised, due to the lower cell voltage.

1. Release the lip of the battery compartment on the rear side of the device, in the direction of the arrow. Remove the battery-compartment cover. (Fig.1).
2. Insert two batteries (1.5 volt, AAA), ensuring the correct orientation in accordance with the polarity markings. Ensure that the transparent strips remain accessible once the batteries are inserted.
3. Fold the transparent strips over the batteries and replace the battery - compartment cover, press down until the lip returns to its original position.
4. Batteries can be removed by pulling the transparent strips. (Fig.2).

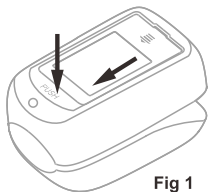


Fig 1

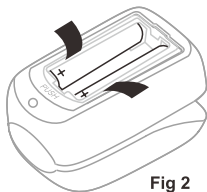
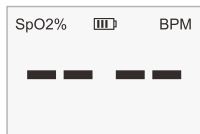


Fig 2

2 Switching on the Device

This device does not need button, while finger inserted, the device will be switched on automatically.

After the power-on self-test is successfully completed the device is ready for use.



Finger inserted, ready for use.

3 Symbols and Indicators



Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.

SpO₂%

98

The SpO₂ value shows the blood oxygen saturation level expressed as a percentage.

BPM

75

Pulse rate in beats per minute.



Bar graph for pulse amplitude. Indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars light with each pulse. The reverse is true for weak pulse. The colour of the bar graph is an indicator for signal quality:

Green: good signal quality, very accurate measurement.

Yellow: average signal quality, measurement may be inaccurate.

Red: poor signal quality, unreliable measurement.



Signal is bad

Low Bat Low voltage alarm

4 Insert the finger (as shown in Fig 3)

⚠ Warning: Externally applied colouring agents, such as nail polish may interfere with the monitor's ability to detect and display accurate measurement!

The light that is emitted by the pulse oximeter has to transmit from the upside of the pulse oximeter through the patient's finger nail.

- Turn the patient's hand so that you can see the finger nail.
- Raise the topside of the pulse oximeter away from the base slightly, to open.
- Insert the patient's finger, nail facing the top of the pulse oximeter, so that the finger is placed fully on the silicone pad.
- Release the topside of the pulse oximeter to secure it on to the patient's finger.

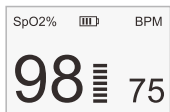


Fig 3

5 Commencing Monitoring

Once the pulse oximeter is switched on and the patient's finger is inserted correctly, monitoring will begin automatically.

 **Caution:** No alarm function is provided in the pulse oximeter.



Device in use

Description

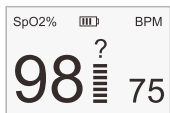
Digit reading includes SpO2 and pulse rate.



Waiting

Description

Waiting for finger insert into the device.



Description

Signal is bad.

6 Switching off the device

The OxiEasy will automatically power off after 15 seconds, when it is removed from the patient's finger.

Error and Remedy

General Information

Physiological conditions, medical procedures, or external agents that may interfere with the pulse oximeter's ability to detect and display accurate measurement include:

- Incorrect application of the pulse oximeter
- Excessive patient activity
- Intravascular dyes
- Externally applied colouring agents, such as nail polish
- Failure to shield the application site with opaque material in high ambient light conditions
- Venous pulsation
- Dysfunctional haemoglobin, e.g. caused by a carbon monoxide intoxication
- Low perfusion

Error Messages-Causes

Display shows "-- --"

The finger has been removed from the pulse oximeter. Check that the finger is correctly inserted into the pulse oximeter.

"Low battery! ", battery symbol blinking red

The battery is almost completely discharged. Replace batteries immediately.

"Too much ambient light symbol"

A red sun symbol is shown. There is too much ambient light around. Avoid bright sunlight. Cover the application site with opaque material.

Problems-Causes-Corrective Actions

Problem: There is no response to the power button.

Cause/Corrective Action: Ensure that the power button is fully depressed. The batteries may be missing, discharged, or oriented incorrectly.

Replace batteries immediately.

Problem: No pulse signal found

Cause/Corrective Action: Check the patient. Check that the pulse oximeter is placed correctly. Test the monitor on another subject.

Perfusion may be too low for the monitor to track the pulse. Check the patient. Test the monitor on yourself. Change the application site.


Interference due to patient activity may be preventing the monitor from tracking the pulse.

Keep the patient still, if possible.
Change the application site.

There may be interference due to ambient light, or the pulse oximeter may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the pulse oximeter, as necessary.

Electromagnetic interference may be preventing the monitor from tracking the pulse.
Remove the source of interference.

EMI(Electromagnetic Interference)

 Caution: This device has been tested and found to comply with the limits for medical devices according to BS EN 60601-1-2:2007, BS EN 60601-1:2006, BS EN 60601-1-1:2001, ISO 80601-2-61:2011 and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments, it is possible that high levels of such interference due to close proximity, or strength of a source, may result in disruption of performance of this device.


The pulse can be obscured by electro-magnetic interference. During such interference, measurements may seem inappropriate or the pulse oximeter may not seem to operate correctly.

Maintenance-Cleaning-Disinfection

Maintenance

There are no user-serviceable parts inside the OxiEasy. The housing should not be opened.

The pulse oximeter requires no calibration. If service is necessary, contact qualified service personnel or your local sales representative.

 **Caution:** Do not immerse the OxiEasy in any liquid. Do not spray, pour, or spill any liquid on the oxiEasy its accessories, connectors, switches, or openings in the enclosure as this may damage the monitor.

Surface-clean

Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water. Lightly wipe the surface of the pulse oximeter. Please clean the charging station at least once a month to ensure a good power transmission while charging.











Disinfection

Use a soft cloth saturated with a solution of 10% chlo-rine bleach in water. Lightly wipe the surface of the pulse oximeter. Remove any residues of the disinfectant prior to reusing the unit.

Test of the measurement accuracy

The only reliable method of testing the measurement accuracy of a SpO_2 monitor is the clinical validation of the measurement data, indicated by the system on the basis of a blood gas analysis. During extensive clinical studies, the monitor evidenced the accuracy required.

Symbol Definitions

	Attention! See instructions for use!
	Manufacturer
	Date of manufacture
	Type BF
	Serial number
	Part number
	Observe applicable waste disposal regulations
	Refer to instruction manual
	No alarm
	European Union approval

Technical Specifications

Measurement Range:

SpO_2 : 70 to 100%

Pulse Rate: 25 to 250 beats per minute (bpm)

Accuracy:

SpO_2 : +/- 2% (70 to 100%)

Pulse Rate: +/-1 digit (≤ 100 bpm); +/-1% (> 100 bpm)

LED:

Wavelengths: 660nm, 905nm; Output power: < 50 mW

Display:

OLED colour graphic display

Data displayed: oxygen saturation, pulse rate, plethysmogram, bar graph.

Indicators: signal quality, pulse amplitude, battery status

Environmental Condition:

Operating conditions:

5 to 40°C; 10 to 95%RH; 700 to 1060hPa

Storage conditions:

-40 to 60°C; 5 to 95%RH; 500 to 1060hPa

Power Supply:

2 batteries(1.5volt, AAA)

Battery life: approx.24h of continuous operation

Reaction time and averaging:

Average reaction time to change is 1.5 seconds, the averaging uses four pulse waves.

Other:

Classification(MDD 93/42/EWG)	Class II a
Degree of protection	IPx2
Type	BF
Dimensions(L*W*H)	60*35*32mm
Weight	Approx 50g

The pulse oximeter measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within \pm Arms of the value measured by a CO-oximeter.

Packing List

OxiEasy main unit
Lanyard
User Manual
2xAAA batteries, 1.5V