Riester
The familiar way

Operator´s manual
Gebrauchsanweisung
Mode d' emploi
Instrucciones para el uso
Istruzioni per l'uso
Инструкции по эксплуатации

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99151 Rev. 0 2010-10 Änderungen vorbehalten - Subject to alterations - Sous réserve de modifications
Sujeto a modificationes - Con riserva di apportare modifiche - Возможны изменения

CE 0124

ri-fox N

OPERATOR'S MANUAL
Pulse Oximeter ri-fox N

ENGLISH

General Description

Oxygen Saturation is a very important parameter for the Respiratory Circulation System. Many respiratory diseases can result in oxygen saturation being lowered in human blood. Additionally, the following factors can reduce oxygen saturation: organ dysfunction caused by anesthesia, intensive postoperative trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems in a timely manner.

The fingertip pulse oximeter ri-fox N features small size, low power consumption, convenient operation and portability. It is only necessary for a patient to put one of his fingers into the fingertip photoelectric sensor for diagnosis, and a display screen will show oxygen saturation. It has been proven in clinical experiments that it also features high precision and repeatability.

Product Operation Scope

ri-fox N is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients at home and hospital (including clinical use in internal medicine/surgery, anesthesia, etc). The device is not intended for continuous monitoring.

The ri-fox N requires no routine calibration or maintenance other than replacement of batteries.

Technical Specifications

1. **Display:** LED
2. **SpO_2:**
   Measurement range: 70~99%
   Accuracy: 70% ~ 99%, ±3%; <70% no definition
3. **Pulse Rate:**
   Measure range: 30~235 bpm
   Accuracy: 30~100bpm ±2bpm; 101~235bpm, ±2%
   Pulse Intensity: Bar graph Indicator

4. **Power Requirements:**
   Two AAA alkaline Batteries
   Power consumption: Less than 30mA
   Low power indication: 
   Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 30 hours.
5. **Dimension:**
   Length: 66mm
   Width: 39mm
   Height: 32mm
   Weight: 34g (without batteries)
6. **Environment Requirements:**
   Operation Temperature: 5°C~40°C
   Storage Temperature: -20~55°C
   Ambient Humidity: ≤80%, no condensation in operation;
   ≤93%, no condensation in storage
7. **Measurement Performance in Low Perfusion Condition:** The pulse wave is available without failure when the simulation pulse wave amplitude is at 0.6% using the test equipment (Biotek Index Pulse Oximeter Tester).
8. **Interference Resistance Capacity against Ambient Light:** Device works normally when mixed noise produced by Biotek Index Pulse Oximeter Tester.

Precautions for use

1. Do not use the pulse oximeter in an MRI or CT environment
2. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
3. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
4. The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
5. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
6. Before use, carefully read the manual.
7. ri-fox N has no SpO_2 alarms; it is not for continuous monitoring, as indicated by the symbol.
8. Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

9. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
10. SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area if necessary.
11. Excessive patient movement may cause inaccurate readings.
12. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line may cause inaccurate readings.
13. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

Contraindication

14. Significant levels of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin) may cause inaccurate readings
15. Intravascular dyes such as indocyanine green or methylene blue may cause inaccurate readings
16. Venous pulsations may cause inaccurate readings.
17. Hypotension, severe vasoconstriction, severe anemia or hypothermia may cause inaccurate readings.
18. Cardiac arrest or shock may cause inaccurate readings.

No side effects known

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

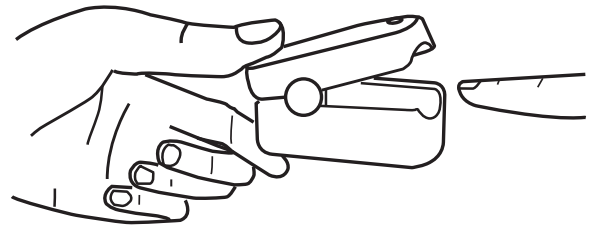
Product specifications

1. Easy to use.
2. Small in volume, light in weight.
3. Low power consumption.
4. Low voltage warning will be indicated in visual window when battery voltage is low.
5. The product will automatically be powered off when no signal is registered for longer than 8 seconds.

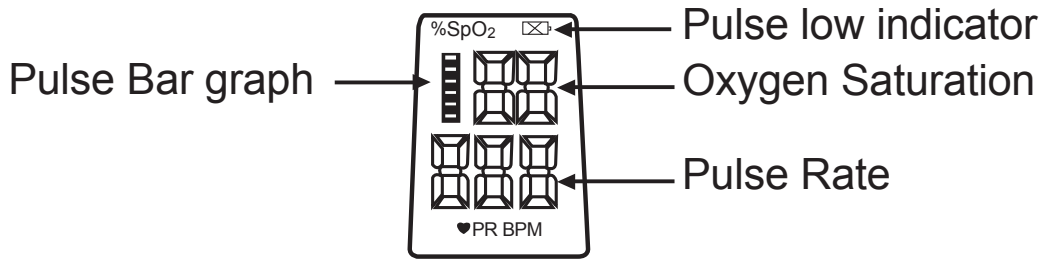
Operation Instructions

1. Install two AAA batteries into the battery cassette, and then close its cover.
2. Open the clamp as shown in the picture below.
3. Insert one finger completely into the opening of the pulse oximeter.
4. Press the power switch once on the front panel.
5. The patient's finger should remain still while the pulse oximeter is working.
6. Read corresponding data from display screen.

When you insert a finger into the Oximeter, your nail surface must be upward.



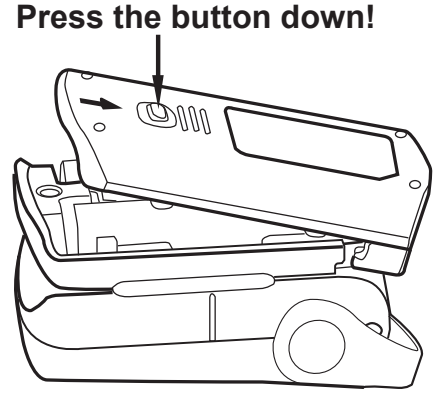
Brief Description of Front Panel



The Pulse Bar graph displays the strength of the pulse rate signal. The height of the bar graph shows the patient's pulse strength.

Battery Installation

1. Put the two AAA batteries into battery cassette in correct polarities.
2. Press the button down along the arrow and push the battery cover shown as below:



Maintenance and Storage

1. Replace batteries in time when low voltage lamp is lighted.
2. Clean surface of the ri-fox N before it is used in diagnosis for patients.
3. Remove batteries inside the battery cassette if the oximeter will not be used for a long time.
4. It is best to preserve the product in a place where ambient temperature is –20~55°C and humidity is <93%, no condensation.
5. It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
6. Please follow the law of the local government to deal with used batteries.

Calibrating the Oximeter

1. The functional tester cannot be used to assess the accuracy of the oximeter.
2. The test method used to establish the SpO_2 accuracy is clinical testing. The oximeters used to measure the arterial haemoglobin oxygen saturation levels are compared to the levels determined from arterial blood sampling with a CO-oximeter.
3. Index 2 that is made by Biotek company is a function tester. Set Tech to 1, R curve to 2, and then users can use this particular calibration curve to measure the oximeter.

Declaration

EMC of this product complies with IEC60601-1-2 standard. Portable and mobile high frequency appliances can influence medical electronic devices. Medical electronic devices need special safety requirements concerning EMC. You can get a detailed description of the EMC-requirements at www.riester.de.

The materials which the user can come into contact have no toxicity and no action on tissues, comply with ISO10993-1, ISO10993-5 and ISO10993-10.

Guidance and manufacture's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The ri-fox N is intended for use in the electromagnetic environment specified below. The customer or the user of the ri-fox N should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ri-fox N uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The ri-fox N is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Possible Problems and resolutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1.Finger is not plugged correctly 2.Patient's Oxyhemoglobin value is too low to be measured.	1. Retry by plugging the finger. 2. Try some more times, If you can make sure about no problem existing in the product. Please go to a hospital for exact diagnosis.
SpO_2 or PR is shown unstably	1.Finger might not be plugged deeply enough. 2.Finger is trembling or patient's body is in movement status.	1.Retry by plugging the finger. 2.Try not to move.
The Oximeter can not be powered on	1.Power of batteries might be inadequate or not be there at all. 2.Batteries might be installed incorrectly. 3.The Oximeter might be damaged.	1.Please replace batteries 2.Please reinstall the batteries 3.Please contact with local customer service centre.
Indication lamps are suddenly off	1.The product is automatically powered off when no signal is detected longer than 8 seconds 2. Lower power	1.Normal 2.Replace the batteries
"Error3"or "Error4" is displayed on screen.	1.Low power 2.Mechanical malfunction for receive-emission tube 3. Amp circuit malfunction.	1.Change batteries. 2.Please contact the local customer service center. 3.Please contact the local customer service center.

Symbol Definitions

Symbol	Definition
	Type BF applied part
	Attention, consult accompanying documents.
%SpO_2	Oxygen saturation
♥ PR BPM	Pulse rate (BPM)
	Low power indication
	NOT for continuous monitoring
SN	Serial No.

Note:
The illustrations used in this manual may differ slightly from the appearance of the actual product.

Disinfection

Please use medical alcohol to clean the plastic material touching the finger inside of the pulse oximeter, and clean the test sensor using alcohol before and after operation.

Warranty

This product has been manufactured under the strictest quality standards and has undergone a thorough final quality check before leaving our factory. We are therefore pleased to be able to provide a warranty of 30 months from the date of purchase on all defects, which can verifiably be shown to be due to material or manufacturing faults.

A warranty claim does not apply in the case of improper handling. All defective parts of the product will be replaced or repaired free of charge within the warranty period. This does not apply to wearing parts.

Please remember that all warranty claims have to be made during the warranty period. We will, of course, be pleased to carry out checks or repairs after expiry of the warranty period at a charge. You are also welcome to request a provisional cost estimate from us free of charge. In case of a warranty claim or repair, please return the RIESTER product to your dealer.