Instructions for Use Spo2 Sensors

Instructions for Use

Product Name

Disposable Spo2 Sensors

Patient	Weight	Part Number	Recommended Site
Adult	>40Kg	M-NK-S2S-ADT	Index Finger
Pediatric	10-50 Kg	M-NK-S2S-PED	Index Finger
Infant	1-20 Kg	M-NK-S2S-INF	Foot or Index Finger
Neonate	>3Kg	M-NK-S2S-Neo	Foot

Intended Use

Intended to be used on corresponding parameter monitors or pulse oximeters by healthcare professionals to collect and transfer the SpO2 and pulse rate signals of the patient.

Specifications

1. Sp02 Testing Range: not lower than 70%-100%
2. SpO2 Testing Accuracy: tolerance of ±2% above 90%; tolerance of ±3% from 70%-89%
3. Pulse Rate Testing Range: not lower than (30-245 bpm) Pulse Rate Testing Accuracy ±3bpm
4. Testing Wavelength and Power Output
   Class A: Red 660nm; IR 905nm
   Class B: Red 660nm; IR 940nm

Working Conditions

1. Ambient Temperature: 5°C-45°C
2. Relative Humidity: 10%-95% (Non-Condensing)
3. Atmospheric Pressure: 70kPa-106kPa
4. Compatible Power Supply: DC 5V, with relative tolerance of -10% - +5%.
5. Product Compositions: the SpO2 sensor is mainly composed by connector, cable and sensor

Monitor Documentation

For accuracy specifications and further instructions, warnings and cautions, please be sure to read and follow the OEM patient monitor instructions for use.

Maintenance and Testing

Ensure the connectors are in good condition and check for cracks, cuts, tears or breaks in the insulation. Do not use if you see any signs of damage or deterioration.

Instructions for Use

1. Neonates/Infants: Foot or index finger recommended, refer to the pictures below

2. Adults/Pediatrics: Index finger recommended, while other fingers are acceptable too. The cable shall be placed on the back of the hand and parallel to the arm, refer to the picture below

3. Wrap and affix the SpO2 sensor, do not wrap too tightly

4. Connect the sensor to the monitor as described in the operation manual.

Contraindications

1. Avoid using on active patients or long-term monitoring at one single point
2. Avoid being fixed to patient's damaged tissues.

Warnings

1. Inaccurate data might be caused by foreign materials into the vessels
2. Inaccurate data might be caused if the sensor is wrapped too tightly
3. Not recommended for using on active patients
4. Inaccurate data might be caused by manicure (nail buffing or polishing), man-made fingers,over-sized fingers or improper placing of the sensor
5. Avoid using under highlighted condition since the observed data can be affected by strong light

MR Unsafe

See instructions before use

Single Patient Use

Nonsterile Packaging

Federal law restricts this device to sale by or on the order of a physician.

Not made with Natural Latex

Do Not Immerse

Printed in the USA.
IFU-0002 R1

Rising Eagle Medical, LLC
75 Waneka Parkway
Lafayette, CO 80026
888.399.0119

www.rem-supplies.com

6. Testing accuracy can be affected while used together with strong electromagnetic source devices
7. Not recommended to be used together with imaging devices such as MRI devices
8. Avoid immersion or sterilization by ETO
9. Stop using under any kind of damages
10. Check and change the contacting point every 4 hours to assure its adhesiveness
11. Place the cable properly to prevent the patient from being entangled
12. Refer to the operation manual of corresponding monitor
13. Circuit diagram and BOM list can be provided upon user's request
14. Dispose under relevant laws and regulations after use without throwing away freely
15. Safety Grade: Meets the requirements of compatible parameter monitor or pulse oximeter
16. Protection Types: Meets the BF requirements of compatible parameter monitor or pulse oximeter
17. For single use only

Electromagnetic Compatibility.

- Comply with the electromagnetic compatibility standards required by EN 60601-1-2;
- Install and use the sensor according to the electromagnetic compatibility information on the accompanying files
- Avoid strong electromagnetic interference from mobile phones, microwave oven and so on while in service since portable or mobile RF communication devices will affect performance of the (device or system)

Biological compatibility

The materials in contact with skin are in accordance with EN ISO 10993

Cautions

1. The sensor can only be used on specified compatible devices, while the user is responsible to read this IFU or contact our company before operation to confirm the compatibility of the sensor and the expected device.
2. (Device or system) shall not be used while placed near to or stacked up with other electric devices, or micro electromagnetic interference might be caused to other electric devices.
3. Do not throw away the product freely, dispose the product and its package under every applicable local and (or) governmental regulations; please consult local government for the applicable regulations.
4. Proper operation or misuse of the SpO2 sensor might cause inner cable damage and electric insulation failure of the cable or inaccurate data.
5. The SpO2 sensor cannot be calibrated by itself, to assure its normal operation, the SpO2 sensor can be tested by corresponding devices, the inner cables must have been broken once open circuit, short circuit, intermittent or totally wrong data occurs. Stop using when the SpO2 sensor's accuracy is beyond its tolerance range. Any damage of the SpO2 sensor shall be dealt with under relevant regulations of the hospital.
6. Do not use the sensor on active patients or for long-term monitoring. It must be moved every 4 hours.
7. Performance or accuracy of the sensor might be affected when modified or revised without permission.

Cleaning and Disinfection

1. Cleaning and disinfecting shall be done by healthcare professionals only
2. Clean the cable by wiping it with 75% ethanol.
3. Disconnect the connector from the monitor before cleaning or disinfecting.

Transportation and Storage

1. Transportation: Transport the products under purchasing instructions while preventing fierce strike,shock or splashing.
2. Storage: Packaged products shall be stored under a non-corrosive and drafty indoor condition with ambient temperature of -20°C~55°C, relative humidity of 95% (Non-Condensing) and atmospheric pressure of SOkPa-106 kPa.

Product Life Time: 2 years (with manufacturing date printed on the inner bag).

WARNINGS

- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, Spo2 Technology, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- The sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site as frequently as every (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the reading may read lower than core arterial oxygen saturation.
- Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- Misapplications due to wrong sensor types can cause inaccurate or no readings.
- Where possible the application site for the sensor should be an extremity free of arterial catheters, blood pressure cuffs, or intravascular infusion lines.
- Do not use sensors during MRI scanning

Printed in the USA.

Rising Eagle Medical, LLC
75 Waneka Parkway
Lafayette, CO 80026
888.399.0119
www.rem-supplies.com