MEDSOURCE

Adult, Pediatric & Neonatal
SpO_2
Finger Sensor
Directions For Use

REF MS-74011P

8600 Shelby Court
Chanhassen, MN 55317

Intended Use

The sensor is intended to be used for continuous and non-invasive functional pulse rate monitoring and arterial oxygen saturation (SpO2) monitoring.

Weight of patient

Recommended for use on patient's as follows:

SIZE	Adult	Pediatric	Neonatal
Weight of Pateint	More Than 66lbs	More Than 22lbs	Less Than 6.6lbs.

Cleaning or Disinfection:

1. Please unplug the sensor from the monitor before cleaning or disinfection.
2. Clean or disinfect the sensor before attaching to a new patient.
3. Clean the sensor and patient contact surfaces with a soft cloth moistened in water or a mild soap solution.
4. To disinfect the sensor, wipe the sensor and patient contact surfaces with disinfecting solution. We recommend isopropyl alcohol as disinfecting solution.

Caution: Don't sterilize by radiation, steam or ethylene oxide.

Contraindictions

The sensor is contraindicted for use on active patients or for long term monitoring.

Warnings

1. This sensor is for use only with compatible monitors, instruments, or oximetry modules. If used with other instruments that are not compatible, improper performance may result. The user and/or operator needs to verify the compatibility of the monitor, sensor, and cable before use, otherwise patient injury may occur.
2. Intravascular dyes may affect the accuracy measurements of the sensor and/or the monitor.
3. Excessive motion will cause inaccurate measurements of the sensor and the monitor when using the sensor.
4. Fingernail polish, an artificial fingernail, poorly perfused finger, extreme finger size, or improper placement of the sensor can cause inaccurate result of measurements.
5. Operation may be affected in the presence of bright lights, if necessary please shield the sensor area with an opaque material.
6. Operation may be affected in the presence of strong electromagnetic sources.
7. The sensor is not recommended for use in the presence when imaging equipment working such as Magnetic Resonance Imaging (MRI), etc.
8. Do not immerse the sensor in any kind of liquid.
9. Please discontinue use of the sensor immediately if it is damaged in any way.
10. Please check and move the sensor to a new location a minimum of every 4 hours.
11. Carefully place cable to reduce the possibility of patient entanglement or strangulation.
12. Refer to the monitor's operations manual when connecting the sensor with the monitor.
13. The SpO2 Sensors belong to BF type applied parts.
14. The equipment is without a manual sensitivity adjustment, hence:
    The minimum amplitude or value of patient phsiological signal is 70% SPO2 Sensor.
    Operation of the equipment or system below this emplitude or value may cause inaccurate results.
15. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.
16. Disposal of the sensor shall comply with the local regulation.

Statement

The medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
Portable and mobile RF communications equipment can affect medical electrical equipment.
The functional tester can't be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
The year and month of manufacture are included in the Serial Number.
Matierals used are Bio compatible.
Information about wavelength range can be especially useful to clinicians.
Instructions for Use:

1. Select a suitable site for the sensor. The patient's first finger is the preferred location. Alternative sites recommended are the thumb or little finger.

2. Fit the sensor as illustrated. The patient's finger must be inserted right to the end of the sensor.

3. The sensor should be oriented in such a way that the cable is positioned along the top of the hand.

4. Plug the sensor into the monitor and verify proper operation as described in the instrument's operator manual.

Specifications
Accuracy:
Range of pulse rate (30 - 245) bpm: ± 3 bpm.
90% - 100% SpO2: ±2 digits; 70% - 89% SpO2: ±3 digits; 50% - 69% SpO2: unspecified.
Range of wavelength for LED of red light: 660nm (±3nm).
Range of wavelength for LED of infrared light: 880nm (±3nm), 905 nm (±3nm), 940nm (±3nm).
Maximum output power red light / Infrared light: 110/190mW
Operation temperature: +5°C - +40°C Storage/transportation temperature: -20°C - +70°C
Humidity: 10% - 80% (no condensation) Atmospheric pressure: 86kPa - 106kPa

The adult sensor is for a person who is older than 12 years old; the pediatric sensor is for a child whose age is between 23 months and 12 years old.

*Latex Free

Caution consult accompanying documents

Manufacturer

Importer

Country of manufacture

Storage/transportation temperature:

Humidity

Atmospheric pressure

MD Medical device