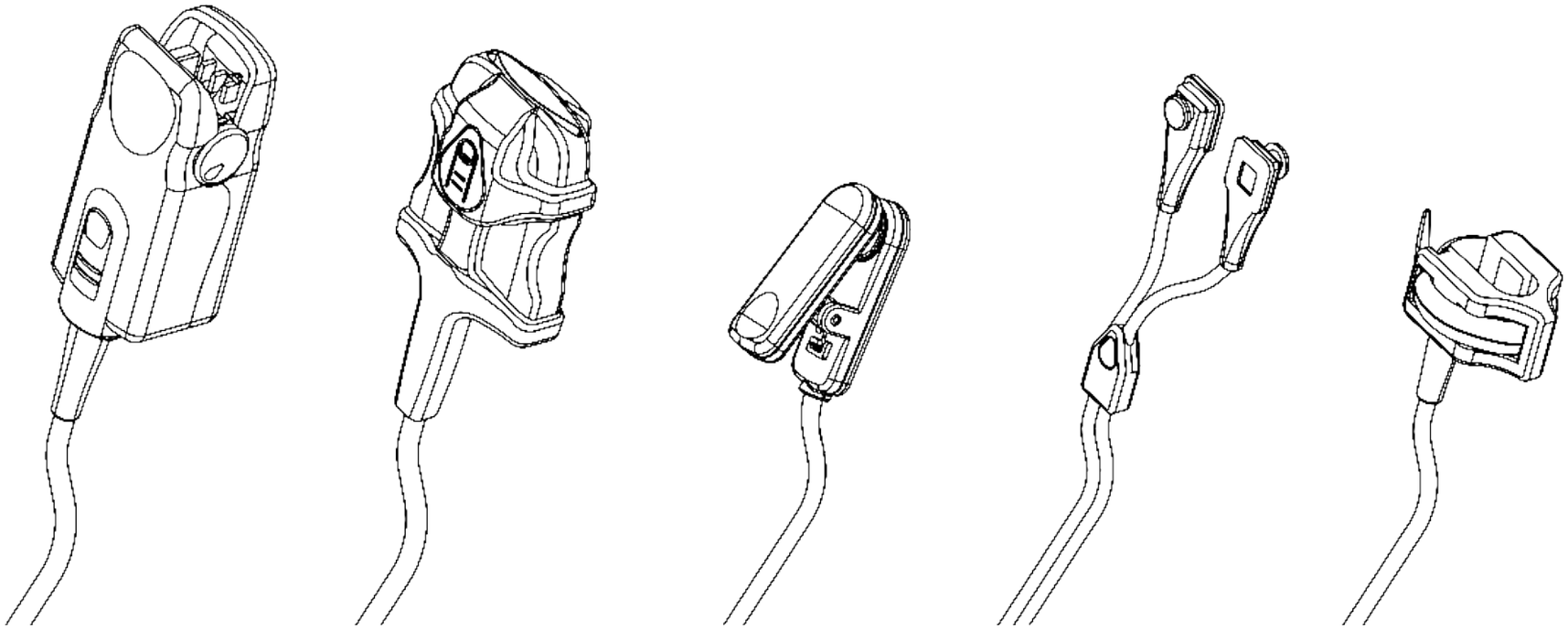
Drantech

The **difference** you can **sense**

CE 0123



Reusable SpO_2 Sensors

User Manual

Intended Use & Indications for Use

The SpO_2 sensors are intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR). These compatible replacement sensors are intended for use with major pulse oximeter brands. The SpO_2 sensors are designed to match the specifications of the original equipment manufacturer, therefore confirm that the appropriate sensor model numbers are being used with the correct pulse oximeter technology.

The sensors are available for the following patient sizes:

- Adult (weight greater than 40 kg)
- Pediatric (10-50 kg weight)
- Infant (3-20 kg weight)
- Neonate (weight less than 3 kg)

Principle of Operation

The sensors must be connected to its corresponding monitor. Blood oxygenation is measured by detecting the infrared and red light absorption characteristics of deoxygenated hemoglobin and oxygenated hemoglobin, which consists of a probe attached to the patient. The sensor is connected to a data acquisition system which is used to calculate and display oxygen saturation levels and

heart rate conditions.

Installation

- Connect the SpO_2 sensor to the oximeter's adapter cable (or directly into the monitor).
- Turn the oximeter on and verify proper operation.
- Select the sensor site on the patient. The preferred sensor sites are the index finger for adult and children, the great toe for infants, and on the foot below the toes for neonate.
- Place the sensor on the patient.
- Position the emitter and detector directly opposite each other.
- Visually monitor the sensor site to ensure that over time there is no harm to the patient's skin.

Caution

- The sensor and its cable must be cleaned before each patient use.
- Place the sensor on the index finger ensuring the finger is fully inserted and the tip of the finger rests against the finger stop inside the sensor.
- Possible alternate sites are small-sized thumb, middle and ring fingers as well as the little finger or the big toe.

- Ensure the fingernail is located under the finger stop on the SpO_2 sensor clamp.
- The sensor must not be located on the same arm as the blood pressure cuff, arterial catheter or intravascular line.
- Remove all nail polish as this can affect accuracy.
- Do not use the sensor inside or near an MRI.
- Avoid intense light sources near the sensor.
- For long-term use, the measurement site must be checked and changed every 2-4 hours in order to guarantee the integrity of the patient's skin.
- In restless patients (excessive motion) use the soft tip, wrap or multi-site sensor to help secure the sensor to the patient.

Equipment

- Connect the sensor adapter cable to the appropriate equipment (or pulse oximeter).
- Turn on the equipment and check correct operation by consulting the monitor's operation instructions.
- To ensure proper monitor operations, connect and disconnect the sensor cable from the monitor cable. The correct, safe use of the sensor and its connecting cable requires systematic checks to be carried out at least once or more per month depending on the frequency of use, as well as disinfecting the cable.

- Do a visual check (appearance of insulators, connector contact pins, etc.).
- Verify the mechanical integrity of the connectors.
- Do not use and discard any sensor that appears to have any mechanical or electrical flaws.

Performance, Reliability, Safety, Compatibility & Mechanical Integrity

- **Performance and Reliability**

This SpO_2 sensor with its compatible pulse oximeter has been validated and tested for compliance with ISO 80601-2-61.
Comparative value measurement in % saturation:
SpO_2 range (70%-100%) -Accuracy ±3%
SpO_2 range (<70%) -Not specified
Pulse rate range: 35-240 bpm -Accuracy ±2 bpm
Low perfusion: SpO_2 range (70%-100%) -Accuracy ±3%
Pulse rate range: 35-240 bpm -Accuracy ±3 bpm

- **Peak Wavelength and Maximum Output Power:**

LED Type	Red Peak Wavelength	Red Maximum Output Power	IR Peak Wavelength	IR Maximum Output Power
2-Leads	663 nm	1.2 mW	890 nm	1.0 mW
3-Leads	661 nm	1.2 mW	940 nm	1.2 mW
4-Leads	660 nm	1.2 mW	905/940 nm	1.0 mW

- **Safety**

Degree of protection from electric shocks: type BF
Classification is in accordance with MDD 93/42/EEC: Class IIb
Degree of protection against the ingress of water: IPX2

- **Compatibility**

In order to ensure compatibility and claimed accuracy of the devices, the SpO_2 sensor should only be used with the specified equipment for which they have been designed and labeled for use.

- **Mechanical Integrity**

This sensor is designed to be extremely durable. We use only the highest quality materials to ensure the sensors stand up to the demanding hospital environment. The solid connectors are fitted with flexible sleeves to minimize the risk of cable breakage. They

have no accessible metallic parts.

Cleaning & Disinfecting

Clean the sensor and its connecting cable with warm soapy water or 70% isopropyl alcohol using a soft, moistened cloth. Carefully avoid damaging the surface of the visual indicator and the detector. Allow the sensor and the cable to dry thoroughly before use. Do not use any abrasive agents or chemical product except 70% isopropyl alcohol.
Do not irradiate, autoclave, soak or immerse the sensor in any kind of solution. Keep the sensor clean and dry.
The average life expectancy of a SpO_2 sensor is more than a year under the conditions of use defined in these operating instructions.

Storage & Handling

When not in use, sensors should be loosely coiled and stored at room temperature. Don’t wrap sensors around equipment cases to avoid damaging internal wires.

Operating Conditions

- Ambient temperature: 0°C to +40°C

- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~ 106 kpa

Storage & Packaging

Each sensor is individually packaged.
The sensor must be stored in its original packaging and within the storage conditions to maximize the storage life.
Storage conditions are as follows:

- Ambient temperature: -10°C to +40°C
- Relative humidity: 15% to 85%
- Atmospheric pressure: 86 kpa ~106 kpa

Shelf Life

5 years.

Warranty & Liability

Orantech offers 12 months warranty against defects in material or workmanship from the date of purchase. But does not include the damage or breakage due to the abusive use or negligent care of the sensors.
Orantech reserves the right to perform warranty service at its own facility. We guarantee that the products conform to the

specifications of the safety and performance standards currently in force and applicable to it.

Warning

 The sensors should not be fixed to an exposed tissue injury site. Do not use for hyperactivity blood oxygen monitoring.

- The sensors are designed for use with specific monitors.
- The operator is responsible for checking the compatibility of the monitor, sensor and cable before its use.
- Incompatible components can result in degraded accuracy and performance.
- Consult the operation instructions for the equipment and the related accessories before operating equipment to ensure their compatibility.
- Portable and mobile RF communications equipment can affect the equipment.
- Do not immerse connector ends in cleaning solution(s).
- Do not allow service or maintenance on the sensor while being used on a patient.
- No modification of this sensor is allowed.
- The sensors are tested for biocompatibility, there is no risk to

the human body.

Warning: MR Unsafe!

Do not expose the device to a magnetic resonance (MR) environment.

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- The device may generate artifacts in the MR image.
- The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

Caution

Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

Waste Disposal

Please refer to your local laws and regulations for information on how to dispose of SpO_2 sensors.

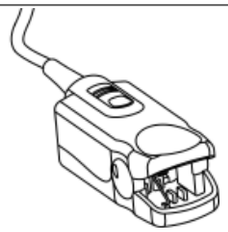
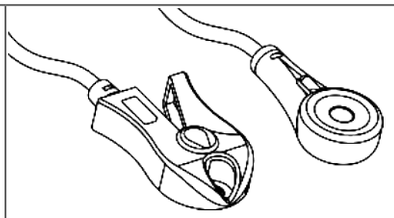
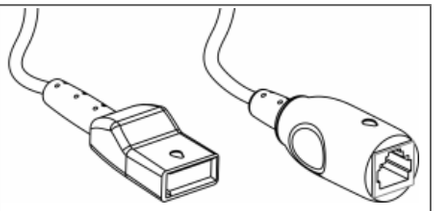
Title of Symbol

	Manufacturer
REF	Catalogue number
LOT	Batch code
SN	Serial number
	Not made with natural rubber latex
	Consult electronic instructions for use
	Non-sterile
Rx only(U.S.)	Federal (U.S.) Law restricts this device to sale by or on the order of a physician
	Type BF Applied Part
	Caution

	Date of manufacture
EC REP	Authorized Representative in the European ACommunity
CE 0123	CE Mark
IPX2	Protection against vertically falling water drops when ENCLOSURE tilted up to 15^0
	Crossed out wheelie bin indicates separate treatment from general waste at end of life. Waste of Electrical and Electronic Equipment Directive (WEEE)
MD	Medical device
UDI	Unique Device Identifier

Support

To get the support, please contact the representative of manufacturer or local distributor.
The categories shown below are available for sale through the local distributors or e-commerce.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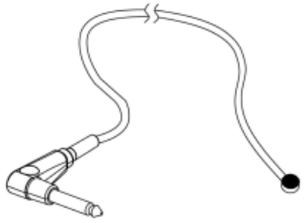	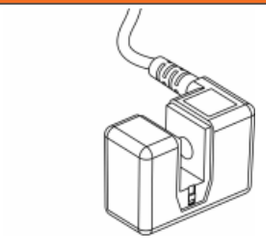	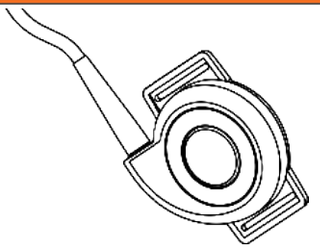	
TEMP	$EtCO_2$	FETAL	EEG

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REF: M20-M006
Rev: A2