Reusable Pulse Oximetry (SpO2) Sensor

**Product Description:**
Pulse Oximetry sensor is used to noninvasively measure oxygen saturation (SpO2), pulse rate and plethysmographic pulse waves. Pulse Oximetry sensor is designed for multiple patient use with compatible monitors, instruments or oximetry modules. It can be used for other spot check or long term monitoring. Use FMT Reusable Pulse Oximetry (SpO2) Sensors Compatibility Chart in www.metkold.com to determine the appropriate sensor for your needs.

- **FMT-RAF/XXX** and **FMT-RAF(B)/XXX Adult Finger Clip Sensor** are recommended for use with patients weighing greater than 40 kg, application sites are index or other finger.
- **FMT-RPF/XXX Pediatric Finger Clip Sensor** is recommended for use with pediatric patients weighing between 10 - 40 kg, application sites are index or other finger.
- **FMT-REC/XXX Adult Ear Clip Sensor** is recommended for use with patients weighing greater than 40 kg, application site is ear lobe.
- **FMT-RAS/XXX and FMT-RAS(B)/XXX Adult Soft Finger Sensor** is recommended for use with patients weighing greater than 40 kg, application sites are index or other finger.
- **FMT-RPS/XXX Pediatric Soft Finger Sensor** is recommended for use with pediatric patients weighing between 10 - 40 kg, application sites are index or other finger.
- **FMT-RSX/XXX Infant Soft Finger Sensor** is recommended for use with infant patients weighing between 3-15 kg, application sites are index or other finger.
- **FMT-RNS/XXX Neonate Wrap Soft Sensor** is recommended for use with neonate patients weighing between 1-4 kg, application sites are foot or hand palm.
- **FMT-RWS/XXX Wrap Y Sensor** is recommended for use with patients weighing greater than 40 kg, application sites are index or other finger, pediatric patients weighing between 10 - 40 kg, application sites are index or other finger, infant patients weighing between 3-15 kg, application site is great toe, neonate patients weighing between 1-4 kg, application sites are foot or hand palm.
- **FMT-RYS/XXX Y Sensor** is recommended for use with patients weighing greater than 40 kg, application sites are index or other finger and ear with ear clip, pediatric patients weighing between 10 - 40 kg, application sites are index or other finger, infant patients weighing between 3-15 kg, application site is great toe, neonate patients weighing between 1-4 kg, application sites are foot or hand palm. (XXX shows compatible brand code).

**Functional Specifications:**
- **Range of detecting SpO2**: 0-100%
- **Range of detecting pulse rate**: 20-250 BPM
- **SpO2 Accuracy**: ± 1% for reading between 90-100%
- ± 2% for reading between 70-90%
- below 70% unspecified

**Environmental Requirements:**
Device is intended for use under normal operations in a hospital.
- Operating temperature range: 5 - 40 °C (41 - 104 °F)
- Storage temperature range: 0 - 50 °C (32° - 122°F)

**Instructions for Use:**

**Warning:**
Before applying to the patient check compatibility with the monitor and all functions including alarming perform properly. Clean sensor before first use and before applying it to a new patient.

- This sensor is for use only with compatible monitors, instruments or oximetry modules. Use of this sensor with instruments other than compatibles may result in inaccuracies, faulty measurements or no measurement at all.
- All SpO2 sensors may be used on the same site for a maximum of three (3) hours, provided the site is inspected routinely to ensure skin integrity, circulatory status and correct positioning. Check the site more frequently if perfusion is poor. Because individual skin condition affects the ability of the skin tolerate sensor placement, it may necessary to change the sensor site more frequently with some patients. Patient conditions such as reddening, blistering, skin discoloration, ischemic skin necrosis and skin erosion may warrant changing the site or using a different type of sensor.
- Proper sensor placement is critical for good performance. Failure to apply the SpO2 sensor properly may cause incorrect measurements.
- **Warning:** When selecting the sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
- **Warning:** Application site should be cleaned of debris prior to sensor placement.

**To apply the sensor (FMT-RAF/XXX, FMT-RPF/XXX, FMT-RAS/XXX, FMT-RPS/XXX and FMT-RSX/XXX):**
1. Clip sensor onto fleshy part of the lobe. Do not position sensor on cartilage or pressed against the head. Clip soft plastic fixing mechanism on top of the ear. The fixing mechanism minimizes movement that the least restricts a conscious patient's movements. The patient's index finger of the non-dominant hand is the preferred location. Alternatively middle finger, ring finger or little finger of the hand may be used. Always choose a site that will completely cover the sensor's detector window. Thumb, the great toe or long toe (next to great toe) may be used as secondary alternatives.
2. Fit the sensor as illustrated. The patient's finger must be inserted until the tip of the finger reaches the finger stop. If the fingernail is long, it may extend over and pass the finger stop. Direct the cable along the patient's finger and parallel to the arm.
3. - Uncoopative or very active patients may require the addition of medical tape to secure the sensor. For added stability, secure the sensor cable independently from the sensor with a medical tape, preferably around the base of the finger or wrist. Make sure that the tape securing the cable does not restrict the blood circulation.
4. - Connect the sensor cable to the monitor or to the adaptor & extension cable and verify proper operation as described in the instrument's operator manual. To disconnect, grasp the connector (not the cable) and pull straight out. If extra cable length is needed, use a FMT adaptor & extension cable. Verify operation of the oximeter by observing the red light of the sensor.

**Warning:** Finger clip type sensor is contraindicated for use on active (mobile) patients. Soft type silicone sensors tolerate a moderate amount of patient activity. Please use soft type silicone SpO2 sensors for active patients.

- **Warning:** Finger clip type sensors are not intended for use on the thumb or across infant or neonate patient's hand or food.

**To apply the sensor (FMT-RYS/XXX):**
1. Open the ear clip by pressing at the ends with the thumb and index finger.
2. Slide each sensor head into an ear clip slot with both optical component sides facing inwards.
3. The sensor is now ready to be applied to the patient. The appropriate sensor site are either the ear lobe (a), or the ear pinna (b).
4. - For fast response, rub the application site on the ear in order to increase the circulation before applying the sensor.
5. - If the sensor is not positioned properly, light may bypass the tissue and result in SpO2 inaccuracies. If measurement cannot be obtained try another site on the same ear or a site on the other ear. If measurement still cannot be obtained consider using the sensor with an adhesive tape wrap instead of ear clip on another body site.
6. - To remove the ear clip sensor from the patient's ear, press open the ear clip and remove. When removing the sensor from the ear clip, hold each sensor head and gently slide it out of the ear clip slot. Do not pull on the cable.

**To apply the sensor (FMT-REC/XXX):**
1. Open the ear clip by pressing at the ends with the thumb and index finger.
2. - Slide each sensor head into an ear clip slot with both optical component sides facing inwards.
3. The sensor is now ready to be applied to the patient. The appropriate sensor site is the ear lobe (a).
4. - Clip sensor onto soft plastic fixing mechanism on top of the ear. The fixing mechanism minimizes movement that the least restricts a conscious patient's movements. The patient's index finger of the non-dominant hand is the preferred location. Alternatively middle finger, ring finger or little finger of the hand may be used. Always choose a site that will completely cover the sensor's detector window. Thumb, the great toe or long toe (next to great toe) may be used as secondary alternatives.
5. - If the sensor is not positioned properly, light may bypass the tissue and result in SpO2 inaccuracies. If measurement cannot be obtained try another site on the same ear or a site on the other ear. If measurement still cannot be obtained consider using the sensor with an adhesive tape wrap instead of ear clip on another body site.
6. - To remove the ear clip sensor from the patient's ear, press open the ear clip and remove. Do not pull on the cable.

**Note:** Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO2 inaccuracies. If measurement cannot be obtained try another site on the same ear or a site on the other ear. If measurement still cannot be obtained consider using the sensor with an adhesive tape wrap instead of ear clip on another body site.

**Warning:** Keep the ear clip out of the reach of children under the age of 3, it is small enough to be swallowed and may block the trachea.

**Warning:** Do not use the sensor with ear clip on any site other than those on the ear. This may result in inaccurate measurements due to improper positioning of the sensor's optical components.

**Warning:** Ear clip sensors are not recommended for pediatric or neonatal use; their accuracy of these sensors has not been established.

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To apply the adhesive tape (FMT-RYS/XXX and FMT-RWS/XXX):
1- Cut the adhesive tape with appropriate length for the selected sensor site. Position the back of the sensor heads on the adhesive tape. Both optical component sides should face outwards.
2- The sensor is now ready to be applied to the patient. The preferred sensor sites are the index finger for adult and pediatric patients, the great toe or thumb for infants, fleshy part of foot or hand palm for neonates.
3- Apply the sensor on the patient. Ensure that sensor heads are directly opposite each other through the tissue.
4- Once positioned on the patient, smooth down the tape with a steady even motion. Do not wrap the tape around the limb so tightly that normal blood flow may be restricted.
5- Secure the "Y" junction to the patient with additional tape. Be sure to leave slack in the wires between the sensor heads and the "Y" junction.
6- When removing the sensor, first remove the tape from the patient’s skin gently. Then separate the adhesive tape from the sensor heads by peeling it away. Do not pull on the cable.

To apply the sensor (FMT-RWS/XXX):
1- The preferred sensor sites are fleshy part of the foot or hand palm for neonate patients.
2- Apply the sensor on the patient. Position the inner face of the “C” shaped sensor on the limb.
3- Insert the tip of the belt into first slot on the back of the sensor and draw on the belt. Then put the belt tip through the second slot to fasten the sensor. Do not pull the belt too much since this may restrict the normal blood flow.
4- Ensure that optical components of the sensor are directly opposite each other through the tissue.
5- When removing the sensor, first remove the belt from second slot then loosen the sensor. Do not pull on the cable.

Warning: Do not pull the belt too tight as normal blood circulation may be affected.

Cleaning or Disinfecting the Sensor:
The sensor may be surface-cleaned by wiping it with a solution such as 70% isopropyl alcohol or mild soap. If low level disinfection is required use 1:10 bleach or 2% glutaraldehyde (Cidex®) solution. Do not use undiluted bleach (5% – 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here, because permanent damage to the sensor could occur.

To clean or disinfect the sensor:
1- Unplug the sensor from the instrument before cleaning or disinfecting.
2- Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with gauze pad.
3- Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
4- Dry the sensor and the cable by wiping all surfaces with a clean, dry gauze pad. Do not use wet sensors.

Warning: Clean or disinfect the sensor before attaching to a new patient.

Caution: Do not expose connector pins to cleaning solutions as this may damage sensor. Do not immerse in liquid of any kind.

Caution: Do not autoclave. Do not sterilize by irradiation, steam or ethylene oxide.

Warnings:
1- It is not recommended to use the sensors in MRI, CT etc. applications. Conducted current may cause burns. MRI or CT unit may affect the accuracy of SpO2 measurements.
2- Intravascular dyes may cause inaccurate SpO2 measurement.
3- Fingernail polish or artificial fingernail can cause inaccurate SpO2 measurements.
4- Elevated levels of Carboxyhemoglobin (COHb) and Methemoglobin (MetHb) will lead to inaccurate SpO2 measurements.
5- Shock, anemia, hypothermia and application of vasocostriction drug may lead to inaccurate SpO2 measurements.
6- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify pulse rate against the ECG heart rate.
7- Sensors should not compress the limb. A tight sensor will compromise venous return and may give rise to inaccurate measurements. When selecting sensor type it is important to check if the patient's weight is in the recommended patient weight range.
8- Using the sensor in the presence of bright light sources may cause inaccuracy in the SpO2 measurements. In such cases cover the sensor with opaque material.
9- Avoid placing sensor onto an extremity with either a blood pressure cuff or any kind of catheter.
10- Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.
11- Do not apply sensor on the injured skin.
12- Check and reposition the sensor to an alternate position every 3 hours (more frequently if perfusion is poor).
13- The performance of the sensor is compromised by motion. Use of the sensor is contraindicated for active patients.
14- Do not use wet sensors. This may cause burns during application of high frequency devices.
15- Do not use damaged sensors. Dispose sensors according to local laws and regulations.
16- Do not alter or modify the sensor. Alternations or modifications may affect performance or accuracy. Never repair a damaged sensor or cable, never use a sensor or cable repaired by others.
17- Do not use damaged by causes external to the product; or that has been used in violation of the operating instructions supplied with the product.
18- Do not twist unnecessarily or use excessive force when using, connecting, disconnecting, or storing the sensor.
19- This product should be connected and activated by qualified medical personnel only.
20- Refer to the monitor's operations manual for additional cautions and warnings.

If you have questions regarding to any of the above information, please contact METKO or your local representative.

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

Warranty:
FMT reusable SpO2 sensors are under twelve (12) months warranty against material and workmanship defects from the date of original purchase. In warranty period, METKO will be responsible for repairing the sensor or change the sensor free of charge if the defect is proven. This warranty does not extend to any product that has been subject to misuse, neglect or accident; or that has been damaged by causes external to the product; or that has been used in violation of the operating instructions supplied with the product.

The information in this instruction insert has been carefully checked and it is believed to be accurate. In the interest of continued product development, METKO reserves the right to make changes and improvements to this insert and the product it described any time, without notice or obligation.

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All FMT sensors are Latex free.

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