Instructions for Use
Reprocessed Pulse Oximeter Sensors – Rev 7-6-2020

a) This device has been reprocessed by Green OR.
b) This device is a reprocessed device designed for an additional Single Use.
c) This device has been processed using high level disinfection techniques. This device is non-sterile.
d) Federal law restricts this device to sale by or on the order of a licensed physician.
e) To ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
f) For further information regarding this device, contact Green OR at 1-866-783-6006.

Device Description:
Pulse oximeters provide noninvasive continuous measurement of blood oxygen saturation. They are available in several sizes including Adult, Pediatric and Infant S_pO_2 adhesive sensors. A pulse oximeter sensor is placed on a thin extremity on the patient's body, usually a fingertip or earlobe, or in the case of an infant, across the foot. The device passes two wavelengths of light through the body part to a photodetector.

Product selection guide for the Masimo's Set Radical™:

	1859 and 2317 Adult	1860 Pediatric	1861 Infant	1862 Adult	2319 & 2328 Infant	2320 & 2329 Adult
	>30 kg	10-50 kg	3-20 g	>40 kg	3-20 kg	>40 kg
Application Site	Finger	Finger or Toe	Thumb or Great Toe	Adult Finger or Toe	Thumb or Great Toe	Adult Finger or Toe
Saturation Accuracy, No Motion	+/- 2.3%	+/- 2.3%	+/- 2.3%	+/- 2.3%	+/- 2%	+/- 2%
Pulse Rate Accuracy, No Motion	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm

Following the use of this device within a clinical setting, Green OR received this device and subsequently performed a complete reprocessing of the device including identification, decontamination, cleaning, refurbishing, testing, inspection, packaging, labeling and high-level disinfection.

Indications for Use:
A pulse oximeter is a device that indirectly monitors the oxygen saturation of a patient's blood and changes in blood volume in the skin.

Contraindications for Use:
Pulse Oximeters are contraindicated in patients who have allergic reactions to foam rubber and/or adhesive tape.

Warnings and Precautions:
a) Original Equipment Manufacturers (OEMs) provide Instructions for Use (IFUs) with the original device. When a health facility reprocesses that original device through a third-party FDA registered reprocessing company, the health facility needs to keep the original OEM IFU as this original OEM IFU, and any materials associated with it, supersede all other instructions.
b) These instructions apply to Green OR's Pulse Oximeters only and are not to be used as instructions for use for any other device or techniques, nor are they intended to be used as instructions for use of the complementary components that are be used in this system. Read and follow the instructions for this device as well as those for the other instruments to be used in combination with this device prior to use.
c) This device is intended for use by a licensed physician.
d) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity and do not use the device if any damage is identified. If the device is damaged in any way, return the device along with its packaging to Green OR for evaluation.
e) Do not use this device for any other purpose other than those indicated in these instructions.
f) Since this device is used along with other devices, prior to use, ensure compatibility with all devices to be used during this surgical procedure.
g) Inspect the pulse oximeter sensor regularly to ensure that it is properly aligned and properly adhered to the patient's body. If there is irritation to the skin or if circulation appears to be compromised, relocate the sensor to another site.
h) Incorrect application or duration of use may cause tissue damage to the patient.
i) Errors in the readings from the device may be noted if the device is applied too tightly.
j) Do not use tape to secure the device to the patient as the tape may restrict blood flow which will result in inaccurate

readings from the device. In addition, tape may cause damage to the skin and/or the pulse oximeter.

k) High levels of Carboxyhemoglobin (COHb) may lead to inaccurate S_pO^2 measurements.

l) Elevated levels of Total Bilirubin may lead to inaccurate S_pO^2 measurements.

m) High levels of Methemoglobin (MetHb) will lead to inaccurate S_pO_2 measurements.

n) Venous congestions may cause measurements that are lower than actual arterial oxygen saturation.

o) Do not use pulse oximeters during magnetic resonance imaging (MRI) as the conducted current may cause burns. In addition, the cross-interference between the two devices may cause inaccurate readings on both devices.

p) Do not use pulse oximeters during full body irradiation or position the sensor outside the radiation field to prevent inaccurate measurements.

q) Since these devices have cable wires that connect the sensor to the photodector, carefully position the wired to prevent entanglement or strangulation.

r) Do not lift the sensor by its power cord or lead wires as this may cause the sensor to disconnect from the device.

s) If, at any time, the user is concerned about the readings being provided by the device, the user should check the patient's vital signs using traditional methods to ensure that the pulse oximeter is working properly.

t) Inaccurate readings may occur if the pulse oximeter is placed on an extremity which also contains an arterial catheter, blood pressure cuff or intravascular infusion line.

u) Locate sensor at a stationary site on the patient and minimize patient motion.

Directions for Use:

General

a) Store pulse oximeters away from moisture, freezing and/or direct heat.

b) Do not immerse pulse oximeters in water as the water will compromise the device performance.

c) Do not use expired devices. If the expiration date has passed, either return the device to Green OR for consideration to be reprocessed or discard the device.

d) This device is used in combination with a plethysmograph. Consult the manufacturer's Operator's Manual for these accessories for direction on making the proper connections, and for other parameters of use such as disinfection and maintenance of complementary components.

Packaging

a) Do not use this device is the packaging has been prematurely open or if there is damage to the package.

b) The packaging of this device contains removable labels which can be affixed to the patient's medical records file.

Device Inspection

a) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for patient use, do not use the device. Return the damaged device along with this packaging to Green OR for evaluation.

b) Prior to the utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

Device selection:

	1859 and 2317 Adult	1860 Pediatric	1861 Infant	1862 Adult	2319 & 2328 Infant	2320 & 2329 Adult
Patient Weight	>30 kg	10-50 kg	3-21 g	>40 kg	3-21 kg	>40 kg
Application Site	Finger	Finger or Toe	Thumb or Great Toe	Adult Finger or Toe	Thumb or Great Toe	Adult Finger or Toe
Saturation Accuracy, No Motion	+/- 2.3%	+/- 2.3%	+/- 2.3%	+/- 2.3%	+/- 2%	+/- 2%
Pulse Rate Accuracy, No Motion	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm	+/- 3 bpm

Infant Application:

a) Once the device has been selected, open the pouch and remove the sensor.

b) Remove the backing from the sensor.

c) Adjust the sensor so that the tail points away from the patient or so that it runs along the bottom of the foot. Attach the sensor to the fleshy part of the anatomy.

d) Wrap the adhesive wrap around the anatomy. Ensure that the emitter window aligns on top of the anatomy directly opposite the detector.

e) Check the sensor to confirm the correct positioning of the device and reposition if necessary. Note that it is important that entire coverage of the detector window is achieved to ensure accurate data transmission.

f) Place the entire sensor connector into the patient cable connector.

g) Close the protective cover.

h) When disconnecting the sensor, lift the protective cover and firmly pull on the sensor connector.

Note: If reattachment of the sensor is necessary, check to make sure that the emitter and detector windows are clear and that the adhesive is still sufficient to adhere to the skin. If not, discard this device and use another sensor.

Application in Pediatric and Adult Patients:

a) Once the device has been selected, open the pouch and remove the sensor.
b) Remove the backing from the sensor.
c) Adjust the sensor tail so that the detector can be place first. Press the detector onto the part of the finger near the tip of the finger. Press the t-shaped adhesive ends of the sensor onto the finger.
d) Wrap the sensor with the emitter over the fingernail and secure the wings down around the finger. The emitter and the detector should be vertically aligned.
e) Check the sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data transmission.
f) Check the sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data transmission.
g) When disconnecting the sensor, lift the protective cover and firmly pull on the sensor connector.

Note: If reattachment of the sensor is necessary, check to make sure that the emitter and detector windows are clear and that the adhesive is still sufficient to adhere to the skin. If not, discard this device and use another sensor.

Note: Do not reuse or re-sterilize this device. Return the used device to Green OR in the collection containers provided to your facility.

Note: The names of other companies and products which may have been mentioned herein may be trademarks of their respective companies.

Note: Green OR is not liable for any damages caused by any defect in material, design or workmanship by the OEM or by any act of omission by the OEM.

Packaging Symbols:

	Production batch number
	Green OR, LLC's part number
	Quantity of devices in package
	Manufacturer
	Date of manufacture
	Date of expiry
	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Do not reuse
	Do not re-sterilize

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