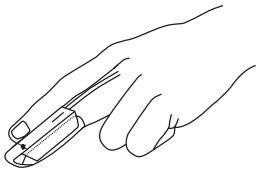
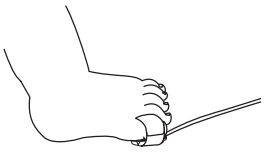
M-LNCS™ Series, LNCS® Series

Adult, Pediatric, Infant, Neonatal and Preterm SpO2 adhesive sensors





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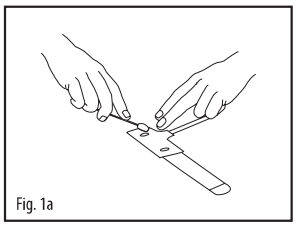


Fig. 1a

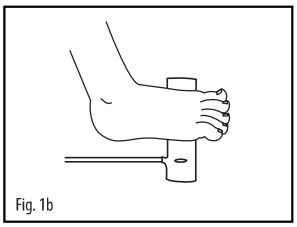


Fig. 1b

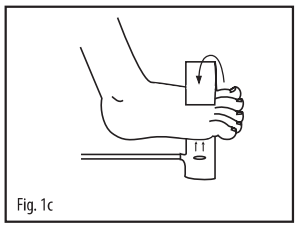


Fig. 1c

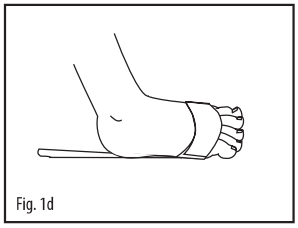
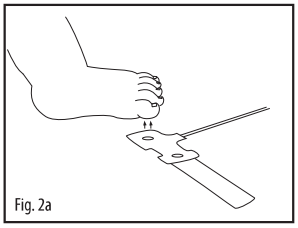


Fig. 1d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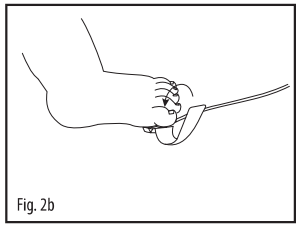
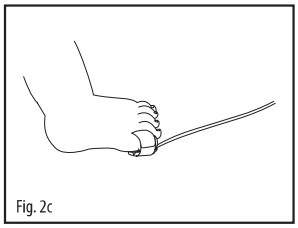


Fig. 2b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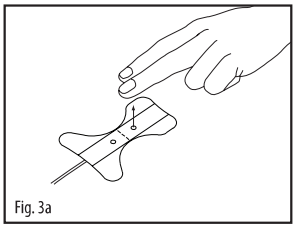
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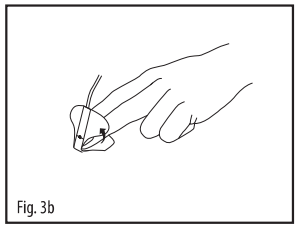
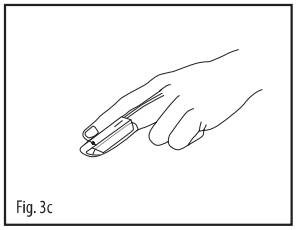


Fig. 3b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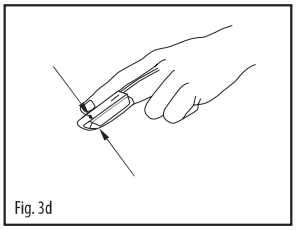
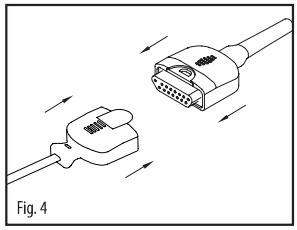


Fig. 3d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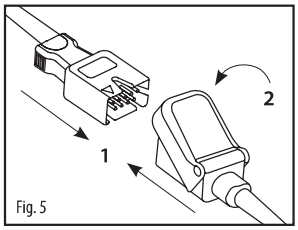

Fig. 5

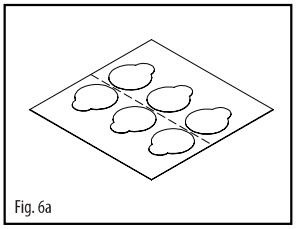
Fig. 6a

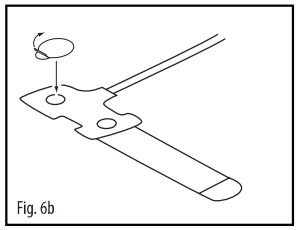
Fig. 6b

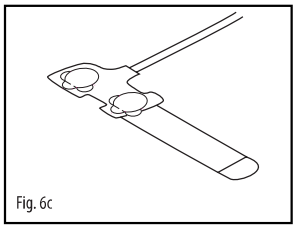
Fig. 6c

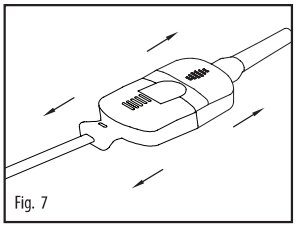
Fig. 7

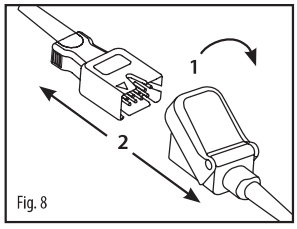

Fig. 8

M-LNCS™ Series, LNCS® Series

en

Adult, Pediatric, Infant, Neonatal and Preterm SpO2 adhesive sensors

DIRECTIONS FOR USE

Single Patient Use Only | Not made with natural rubber latex | Non-sterile

INDICATIONS - When Used With Masimo Set® and Masimo compatible Pulse Oximeters:

The M-LNCS™, LNCS® Adult, Pediatric, Infant, Neonatal and Preterm adhesive sensors are indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Sensor	Adtx Adtx-3	Pdtx Pdtx-3	Inf, Inf-L Inf-3	Neo, Neo-L Neo-3	NeoPt, NeoPt-L NeoPt-3	NeoPt- 500
	> 30 kg	10 - 50 kg	3 - 20 kg	< 3 kg > 40 kg	< 1 kg	< 1 kg
Application site	Finger or toe	Finger or toe	Thumb or great toe	Neonatal: hand or foot Adult: finger or toe	Hand or foot	Hand or foot
Saturation Accuracy, No Motion	± 2%	± 2%	± 2%	Neonatal ± 3% Adult ± 2%	± 3%	± 3%
Saturation Accuracy, Motion	± 3%	± 3%	± 3%	± 3%	± 3%	± 3%
Pulse Rate Accuracy, No Motion	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm
Pulse Rate Accuracy, Motion	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm
Low Perfusion Accuracy	SpO_2 ± 2%	SpO_2 ± 2%	SpO_2 ± 2%	SpO_2 Neonatal ± 3% Adult ± 2%	SpO_2 ± 3%	SpO_2 ± 3%
	Pulse ± 3 bpm	Pulse ± 3 bpm	Pulse ± 3 bpm	Pulse ± 3 bpm	Pulse ± 3 bpm	Pulse ± 3 bpm

INDICATIONS- When used with Nellcor® and Nellcor Compatible Pulse Oximeters:

The M-LNCS, LNCS Adult, Pediatric, Infant, Neonatal and Preterm adhesive sensors are indicated for single patient use for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Sensor	Adtx Adtx-3	Pdtx Pdtx-3	Inf, Inf-L Inf-3	Neo, Neo-L Neo-3	NeoPt, NeoPt-L NeoPt-3	NeoPt- 500
	> 30 kg	10 - 50 kg	3 - 20 kg	< 3 kg > 40 kg	< 1 kg	< 1 kg
Application site	Finger or toe	Finger or toe	Thumb or great toe	Neonatal: hand or foot Adult: finger or toe	Hand or foot	Hand or foot
Saturation Accuracy, No Motion	± 2%	± 2%	± 2%	Neonatal ± 3% Adult ± 2%	± 3%	± 3%
Pulse Rate Accuracy, No Motion	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

DESCRIPTION

The M-LNCS, LNCS sensors are for use with instruments containing Masimo SET® oximetry or licensed to use M-LNCS, LNCS sensors and also with Nellcor and Nellcor compatible pulse oximeters, except Nellcor OxiMax® enabled instruments. Consult individual instrument manufacturer for compatibility of particular instrument and sensor models. Each instrument manufacturer is responsible for determining whether its instruments are compatible with each sensor model.

The M-LNCS, LNCS series has been validated with Masimo SET Oximetry Technology and on Nellcor's N-200 Pulse Oximeter. The saturation accuracy of the Neonate and Preterm sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

The sensor site must be inspected at least every eight (8) hours; and if the circulatory condition or skin integrity has changed, the sensor should be applied to a different site.

WARNING: Masimo sensors and cables are designed for use with instruments containing Masimo SET® oximetry or licensed to use Masimo sensors.

CONTRAINDICATIONS

The M-LNCS, LNCS sensors are contraindicated for patients who exhibit allergic reactions to foam rubber products and/or adhesive tape.

WARNINGS

- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- 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.
- Circulation distal to the sensor site should be checked routinely.
- 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.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).
- Venous pulsations may cause erroneous low SpO_2 readings (e.g. tricuspid value regurgitation).
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- 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.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the radiation, the reading might be inaccurate or the unit might read zero for the duration of the active radiation period.
- Do not use the sensor during MRI scanning or in a MRI environment.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.
- High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.

- Elevated Total Bilirubin levels may lead to inaccurate SpO_2 measurements.
- Intravascular dyes such as indocyanine green or methylene blue or externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc. may lead to inaccurate SpO_2 measurements.
- Inaccurate SpO_2 readings may be caused by severe anemia, low arterial perfusion or motion artifact.
- To prevent damage, do not soak or immerse the sensor in any liquid solution.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- **Caution:** Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- **Note**: The sensor is provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The sensor will provide up to 168 hours of patient monitoring time or up to 336 hours for sensors with a replaceable tape. After single-patient use, discard sensor.

INSTRUCTIONS: SENSOR AND CABLE

A) Site Selection

- Always choose a site that is well perfused and will completely cover the sensor's detector window.
- Site should be cleaned of debris and dry prior to sensor placement.

M-LNCS, LNCS NeoPt, Neo-Pt-L, NeoPt-3 and NeoPt-500 Preterm Sensors

- < 1 kg The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

M-LNCS, LNCS Neo, Neo-L and Neo-3 Neonatal/Adult Sensors

- < 3 kg The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.
- > 40 kg The preferred site is the middle or ring finger of non-dominant hand.

M-LNCS, LNCS Inf, Inf-L and Inf-3 Infant Sensors

- 3-20 kg The preferred site is the great toe. Alternatively, the toe next to the great toe, or the thumb can be used.

M-LNCS, LNCS Pdtx and Pdtx-3 Pediatric Sensors

- 10-50 kg The preferred site is middle or ring finger of non-dominant hand.

M-LNCS, LNCS Adtx and Adtx-3 Adult Sensors

- > 30 kg The preferred site is the middle or ring finger of non-dominant hand.

B) Attaching the sensor to the patient

1. Open the pouch and remove the sensor. Remove the backing from the sensor, if present.

PRETERM (< 1kg) and NEONATES (< 3 kg)

2. Refer to Fig. 1a. For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or with gauze. This step does not apply to the NeoPt-500.
3. Refer to Fig. 1b. Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Apply the detector onto the fleshy part of the lateral aspect of the sole of the foot aligned with the fourth toe. Alternatively, the detector may be applied to the top of the foot (not shown). Complete coverage of the detector window is needed to ensure accurate data.
4. Refer to Fig. 1c. Wrap the adhesive/foam wrap around the foot and ensure that the emitter window (red star) aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor.
5. Refer to Fig. 1d. Verify correct positioning and reposition if necessary.

INFANTS (3 - 20 kg)

2. Refer to Fig. 2a. Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Position the detector onto the fleshy part of the great toe. Complete coverage of the detector window is needed to ensure accurate data.
3. Refer to Fig. 2b. Wrap the adhesive wrap around the toe and ensure that the emitter window (red star) aligns on the top of the toe directly opposite the detector.
4. Refer to Fig. 2c. Verify correct positioning and reposition if necessary.

PEDIATRIC (10 - 50 kg) and ADULT (> 30 kg)

5. Refer to Fig. 3a. Orient the sensor cable so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the detector window. Refer to Fig. 3b. Press the adhesive wings one at a time onto the finger. Complete coverage of the detector window is needed to ensure accurate data.
6. Refer to Fig. 3c. Fold the sensor over the finger with the emitter window (red star) positioned over the fingernail. Secure the wings down one at a time around the finger. Refer to Fig. 3d. When properly applied, the emitter and detector should be vertically aligned.
7. Verify correct positioning and reposition if necessary (the black lines should align).

C) Attaching the Sensor to the Patient Cable

M-LNCS

Refer to Fig. 4. Insert the sensor connector completely into the patient cable connector and lock into place.

LNCS

Refer to Fig. 5. Insert the sensor connector completely into the patient cable connector (1). Completely close the protective cover (2).

Reattachment

ADULT and PEDIATRIC

- The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

INFANT and NEONATAL

- Refer to Fig. 6a. The adhesive tabs included with the M-LNCS, LNCS Inf, Inf-L, Inf-3, Neo, Neo-L and Neo-3 sensors are double sided adhesive tabs used when the stickiness of the adhesive covering the optical components are no longer effective.
- Refer to Fig. 6b. Place an adhesive tab over each window of the sensor with the white area outside the adhesive area as shown, remove the protective paper that covers each tab and reapply the sensor to the same patient.
- Refer to Fig. 6c. When the adhesive on the first set of tabs is no longer sticky, a second set may be applied. Up to 3 sets of adhesive tabs may be applied to each window, placing one on top of the other.
- If the adhesive no longer adheres to the skin, use a new sensor.

NOTE: When changing application sites, or reattaching sensor, first disconnect sensor from the patient cable.

Disconnecting the Sensor from the Patient Cable

M-LNCS

Refer to Fig. 7. Pull firmly on the sensor connector to remove it from the patient cable.

LNCS

Refer to Fig. 8. Lift the protective cover to gain access to the sensor connector (1). Pull firmly on the sensor connector to remove from the patient cable (2).

CAUTION

To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize by irradiation, steam, autoclave or any method other than ethylene oxide as indicated.

STERILIZATION

The M-LNCS, LNCS Adtx, Adtx-3, Pdtx, Pdtx-3, Neo, Neo-L, Neo-3, NeoPt, NeoPt-L, NeoPt-3, NeoPt-500, Inf, Inf-L and Inf-3 sensors have been validated for sterilization by Ethylene Oxide (EO). The sensors may remain within their pouch,
or be wrapped in sterilization wrap, for the sterilization process. If a sterilization wrap is used, only FDA-cleared sterilization wraps are to be used. The following is the validated sterilization cycle:

Preconditioning Parameters	
Temperature	54°C
Relative Humidity	40%
Vacuum Set Point	1.3 psia
Preconditioning Time	30 minutes
Sterilization Parameters	
Temperature	54°C
Relative Humidity	40%
EO Concentration	600-750 mg/L
Gas Exposures Time (full cycle)	
M-LNCS, LNCS Adtx, Adtx-3, Pdtx or Pdtx-3 Wrapped or Pouched	120 Minutes
M-LNCS, LNCS Inf, Inf-L, Inf-3, Neo, Neo-L, Neo-3, NeoPt, NeoPt-L, NeoPt-3 or NeoP-500 Pouched	120 Minutes
M-LNCS, LNCS Inf, Inf-L, Inf-3, Neo, Neo-L, Neo-3, NeoPt, NeoPt-L, NeoPt-3 or NeoPt-500 Wrapped	180 Minutes
Aeration Time (full cycle)	12 Hours
Aeration Temperature	51-59°C

SPECIFICATIONS

When used with Masimo SET pulse oximetry monitors, or with licensed Masimo SET pulse oximetry modules and patient cables, during no motion, the saturation accuracy of the M-LNCS, LNCS sensor from 70% to 100% SpO_2 is ± 2 digits (1 Std. Dev.) for adults/pediatrics/infants and ± 3 digits (1 Std. Dev.) for neonates. Pulse rate accuracy from 25–300 bpm is ± 3 bpm (1 Std. Dev.) for adults/pediatrics/infants/neonates.

During motion, the saturation accuracy of the M-LNCS, LNCS sensors from 70% to 100% SpO_2 is ± 3 digits (1 Std. Dev.) for adults/pediatrics/infants/neonates.The pulse rate accuracy from 25-300 bpm is ± 5 bpm (1 Std. Dev.). Low perfusion accuracy from 70% to 100% SpO_2 is ± 2 digits (1 Std. Dev.) for adults/pediatrics/infants and ± 3 digits (1 Std. Dev.) for neonates and pulse rate accuracy from 25–300 bpm is ± 3 bpm (1 Std. Dev.). The M-LNCS, LNCS series has been validated with Masimo SET Oximetry Technology. The saturation accuracy of the Neonate and Preterm sensors were validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.

When used with Nellcor and Nellcor compatible pulse oximeters during no motion, the accuracy of the M-LNCS, LNCS sensors from 70–100% SpO_2 is ± 2 digits (1 Std. Dev.) for adults/pediatrics/infants and ±3 digits (1 Std. Dev.) for neonates. Pulse rate accuracy from 25–240 bpm is ± 3 bpm (1 Std. Dev.). The M-LNCS, LNCS series has been validated on Nellcor's N-200 pulse oximeter.

INSTRUMENT COMPATIBILITY

This sensor is intended for use only with instruments containing Masimo SET oximetry or pulse oximetry monitors licensed to use M-LNCS, LNCS sensors and also with Nellcor and Nellcor compatible pulse oximeters. Each sensor is designed to operate correctly only on the pulse oximetry systems from the original instrument manufacturer. Use of this sensor with other instruments may result in no or improper performance.

For Compatibility Information Reference: www.masimo.com

WARRANTY

MASIMO WARRANTS TO THE INITIAL BUYER ONLY THAT THESE PRODUCTS, WHEN USED IN ACCORDANCE WITH THE DIRECTIONS PROVIDED WITH THE PRODUCTS BY MASIMO, WILL BE FREE OF DEFECTS IN MATERIALS AND WORKMANSHIP FOR A PERIOD OF SIX (6) MONTHS. SINGLE USE PRODUCTS ARE WARRANTED FOR SINGLE PATIENT USE ONLY. THE FOREGOING IS THE SOLE AND EXCLUSIVE WARRANTY APPLICABLE TO THE PRODUCTS SOLD BY MASIMO TO BUYER. MASIMO EXPRESSLY DISCLAIMS ALL OTHER ORAL, EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. MASIMO'S SOLE OBLIGATION AND BUYER'S EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY SHALL BE, AT MASIMO'S OPTION, TO REPAIR OR REPLACE THE PRODUCT.

WARRANTY EXCLUSIONS

This warranty does not extend to any product that has been used in violation of the operating instructions supplied with the product, or has been subject to misuse, neglect, accident or externally created damage. This warranty does not extend to any product that has been connected to any unintended instrument or system, has been modified, or has been disassembled or reassembled. This warranty does not extend to sensors or patient cables that have been reprocessed, reconditioned or recycled.

IN NO EVENT SHALL MASIMO BE LIABLE TO BUYER OR ANY OTHER PERSON FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION LOST PROFITS), EVEN IF ADVISED OF THE POSSIBILITY THEREOF. IN NO EVENT SHALL MASIMO'S LIABILITY ARISING FROM ANY PRODUCTS SOLD TO BUYER (UNDER A CONTRACT, WARRANTY, TORT OR OTHER CLAIM) EXCEED THE AMOUNT PAID BY BUYER FOR THE LOT OF PRODUCT(S) INVOLVED IN SUCH CLAIM. IN NO EVENT SHALL MASIMO BE LIABLE FOR ANY DAMAGES ASSOCIATED WITH A PRODUCT THAT HAS BEEN REPROCESSED, RECONDITIONED OR RECYCLED. THE LIMITATIONS IN THIS SECTION SHALL NOT BE DEEMED TO PRECLUDE ANY LIABILITY THAT, UNDER APPLICABLE PRODUCTS LIABILITY LAW, CANNOT LEGALLY BE PRECLUDED BY CONTRACT.

NO IMPLIED LICENSE

THIS SINGLE-PATIENT SENSOR IS LICENSED TO YOU UNDER THE PATENTS OWNED BY MASIMO FOR SINGLE-PATIENT USE ONLY. BY ACCEPTANCE OR USE OF THIS PRODUCT, YOU ACKNOWLEDGE AND AGREE THAT NO LICENSE IS GRANTED FOR USE OF THIS PRODUCT WITH MORE THAN A SINGLE PATIENT.

AFTER SINGLE-PATIENT USE, DISCARD SENSOR. PURCHASE OR POSSESSION OF THIS SENSOR CONFERS NO EXPRESS OR IMPLIED LICENSE TO USE THE SENSOR WITH ANY DEVICE WHICH IS NOT SEPARATELY AUTHORIZED TO USE M-LNCS, LNCS SENSORS.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

The following symbols may appear on the product or product labeling:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult Instructions for Use	EC REP	Authorized representative in the European community
	Follow Instructions for Use		Separate collection for electrical and electronic equipment (WEEE).
	Manufacturer	LOT	Lot code
	Use-by date YYYY-MM-DD	REF	Catalogue number (model number)
	Do not re-use/Single patient use only	####	Masimo reference number
NON STERILE	Non-sterile		Body weight
	Not made with natural rubber latex	>	Greater than
Rx ONLY	**Caution**: Federal (USA) law restricts this device to sale by or on the order of a physician.	<	Less than
CE 0123	Mark of conformity to European medical device directive 93/42/EEC		Storage temperature range
	Keep Dry	%	Storage humidity limitation
	Do not use if package is damaged		Atmospheric pressure limitation
	Fragile, handle with care		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.masimo.com/TechDocs **Note: eIFU is not available for CE mark countries.**

Patents: http://www.masimo.com/patents.htm

M-LNCS is a trademark of Masimo Corporation.

Masimo, SET, and LNCS are federally registered trademarks of Masimo Corporation.

Nellcor and OxiMax are federally registered trademark of Nellcor Puritan Bennett Incorporated.

Printed in USA

M-LNCS™ Series, LNCS® Series

fr

Capteurs adhésifs de SpO2 pour adultes, enfants, nourrissons, nouveau-nés et prématurés

MODE D'EMPLOI

Patient à usage unique | N'est pas faite de latex de caoutchouc naturel | Non stérile

INDICATIONS - Pour Utilisation avec Masimo SET®:
Les capteurs adhésifs M-LNCS™, LNCS® adultes, pédiatriques, nourrissons, néonatals et prématurés sont des produits à usage unique et sont indiqués pour le monitorage continu et non invasif de la saturation du sang artériel en oxygène fonctionnel (SpO_2) et de la fréquence cardiaque (mesurée à l'aide d'un capteur SpO_2) chez les patients adultes, pédiatriques, nourrissons et néonatals, avec mouvement et sans mouvement, et chez les patients bien ou mal perfusés à l'hôpital, dans des installations de type hospitalier, des installations mobiles et à domicile.

Capteur	Adtx Adtx-3	Pdtx Pdtx-3	Inf, Inf-L Inf-3	Neo, Neo-L Neo-3	NeoPt, NeoPt-L NeoPt-3	NeoPt-500
	> 30 kg	10 - 50 kg	3 - 20 kg	< 3 kg > 40 kg	< 1 kg	< 1 kg
Site d'application	Doigt ou orteil	Doigt ou orteil	Pouce ou gros orteil	Nouveau-né : main ou pied Adulte : doigt ou orteil	Main ou pied	Main ou pied
Précision de la saturation, en l'absence de mouvement	± 2%	± 2%	± 2%	Nouveau-né : ± 3% Adulte : ± 2%	± 3%	± 3%
Précision de la saturation, en présence de mouvement	± 3%	± 3%	± 3%	± 3%	± 3%	± 3%
Précision de la mesure de fréquence du pouls, en l'absence de mouvement	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm
Précision de la mesure de fréquence du pouls, en présence de mouvement	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm	± 5 bpm
Précision de la mesure en cas d'irrigation faible	SpO_2 ± 2%	SpO_2 ± 2%	SpO_2 ± 2%	SpO_2 Nouveau-né : ± 3% Adulte : ± 2%	SpO_2 ± 3%	SpO_2 ± 3%
	Pouls ± 3 bpm	Pouls ± 3 bpm	Pouls ± 3 bpm	Pouls ± 3 bpm	Pouls ± 3 bpm	Pouls ± 3 bpm

INDICATIONS -Pour Utilisation avec les Oxymètres de pPouls Nellcor® et Nellcor Compatibles :

Les capteurs adhésifs M-LNCS, LNCS adultes, pédiatriques, nourrissons, néonatals et prématurés sont des produits à usage unique et sont indiqués pour le monitorage continu et non invasif de la saturation du sang artériel en oxygène fonctionnel (SpO_2) et de la fréquence cardiaque (mesurée à l'aide d'un capteur SpO_2) chez les patients adultes, pédiatriques, nourrissons et néonatals, pour utilisation à l'hôpital, dans des installations de type hospitalier, des installations mobiles et à domicile.

Capteur	Adtx Adtx-3	Pdtx Pdtx-3	Inf, Inf-L Inf-3	Neo, Neo-L Neo-3	NeoPt, NeoPt-L NeoPt-3	NeoPt- 500
	> 30 kg	10 - 50 kg	3 - 20 kg	< 3 kg > 40 kg	< 1 kg	< 1 kg
Site d'application du capteu	Doigt ou orteil	Doigt ou orteil	Pouce ou gros orteil	Néonatal : main ou pied Adulte : doigt ou orteil	Main ou pied	Main ou pied
Précision de la saturation, Sans mouvement	± 2%	± 2%	± 2%	Néonatal ± 3% adulte ± 2%	± 3%	± 3%
Précision de la mesure de fréquence du pouls, en l'absence de mouvement	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm	± 3 bpm

DESCRIPTION
Les capteurs M-LNCS, LNCS ne doivent être utilisés qu'avec les instruments équipés d'un oxymètre Masimo SET® ou autorisés à utiliser des capteurs M-LNCS, LNCS et des oxymètres de pouls Nellcor ou Nellcor compatibles, excepté Nellcor OxiMax® a permis des instruments. Vérifiez la compatibilité de modèles d'instruments et de capteurs particuliers auprès du fabricant des instruments individuels. Il appartient aux fabricants de s'assurer de la compatibilité de leurs instruments avec les différents modèles de capteur.

Les capteurs M-LNCS, LNCS ont été validés sur le Oxymètre de technologie Masimo SET et Nellcor N-200. La précision de saturation des capteurs pour nouveau-nés et prématurés a été validée sur des adultes volontaires et 1% a été ajouté pour tenir compte des propriétés de l'hémoglobine fœtale.

Le site du capteur doit être inspecté au moins toutes les huit (8) heures ; et si les conditions de circulation ou l'intégrité cutanée ont changé, le capteur doit être appliqué sur un site différent.

AVERTISSEMENT : Les capteurs et câbles Masimo sont conçus pour être utilisés avec des appareils équipés de l'oxymètre de pouls Masimo SET® ou autorisés à utiliser les capteurs Masimo.

CONTRE-INDICATIONS
Les capteurs M-LNCS, LNCS sont contre-indiqués chez les patients démontrant une réaction allergique aux produits en caoutchouc mousse et/ou au ruban adhésif.

AVERTISSEMENTS
- Tous les capteurs et les câbles sont conçus pour être utilisés avec des moniteurs spécifiques. Vérifiez la compatibilité du moniteur, du câble et du capteur avant de les utiliser, afin d'éviter toute dégradation des performances et/ou blessure éventuelle du patient.
- Le site doit être contrôlé fréquemment afin d'assurer une bonne adhérence, de ne pas gêner la circulation, de maintenir l'intégrité de la peau et de corriger l'alignement optique.
- Procédez avec précaution sur les patients ayant une mauvaise perfusion ; si le capteur n'est pas régulièrement déplacé, une érosion cutanée et une nécrose due à la pression peuvent apparaître. Inspectez le site toutes les heures sur les patients ayant une mauvaise perfusion et déplacez le capteur si des signes d'ischémie tissulaire apparaissent.
- La circulation distale par rapport au capteur doit être vérifiée régulièrement.
- En cas de mauvaise circulation, le site du capteur doit être vérifié fréquemment afin d'identifier tout signe d'ischémie tissulaire, pouvant entraîner une nécrose due à la pression.
- Si le site surveillé est très faiblement perfusé, la mesure peut être inférieure à la saturation de base du sang artériel en oxygène.
- N'utilisez pas de bande pour fixer le capteur sur le site ; vous risqueriez de bloquer le flux sanguin et de provoquer des erreurs de mesure. L'utilisation d'une bande supplémentaire peut endommager la peau et/ou provoquer une nécrose par compression ou peut détériorer le capteur.
- Les capteurs trop serrés dès l'application ou à la suite d'un œdème sont à l'origine d'erreurs de lecture et peuvent provoquer une nécrose de pression.
- Un capteur mal positionné ou déplacé peut entraîner une mesure inexacte.
- En cas de congestion veineuse, la valeur mesurée de la saturation du sang artériel en oxygène risque d'être inférieure à la valeur réelle. Veillez à assurer un débit veineux correct au niveau du site de mesure. Le capteur ne doit pas être placé sous le niveau du cœur (par exemple, capteur sur la main d'un patient alité dont le bras pend au sol).
- Les pulsations veineuses peuvent fausser les mesures de la SpO_2 (par exemple, régurgitation tricuspidienne).
- Les pulsations provenant d'un ballon intra-aortique peuvent s'ajouter à la fréquence du pouls sur l'écran de l'oxymètre. Comparez la fréquence du pouls du patient à la fréquence cardiaque de l'ECG.
- Le capteur ne doit pas présenter de défauts visibles ni de traces de décoloration. Si le capteur est décoloré ou endommagé, ne l'utilisez plus. Ne jamais utiliser de capteur endommagé ou de capteur dont un composant électrique est accessible.
- Positionnez le câble et le câble patient de façon à réduire le risque d'enchevêtrement ou de strangulation.
- Évitez de placer le capteur sur une extrémité dotée d'un cathéter artériel ou d'un brassard de pression non invasive.
- En cas d'utilisation de l'oxymétrie du pouls pendant une exposition du corps entier aux rayonnements, il faut maintenir le capteur hors du champ d'irradiation. Si le capteur est exposé aux rayonnements, la mesure peut être inexacte ou égale à zéro pendant la durée de l'irradiation active.
- N'utilisez pas le capteur pendant un examen IRM ou dans un environnement d'IRM.
- Des sources d'éclairage ambiant de forte intensité telles que des lampes chirurgicales (plus particulièrement celles au xénon), des lampes à bilirubine, les éclairages fluorescents, les lampes de chauffage à infrarouge ou une exposition directe au soleil peuvent interférer avec les performances du capteur.