Nasal Alar SpO_2™ Sensor

Directions For Use

EC REP

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The Netherlands

CE 0086

Rx only

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Indications for Use

The Assurance® Nasal Alar SpO_2™ Sensor is indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate from the nasal ala of adult and pediatric patients, (at least 4 years and older and weighing ≥ 15kg), who are well or poorly perfused. The sensor can be used in a variety of healthcare environments where compatible pulse oximetry monitors are indicated for use, under professional supervision.

Contraindications

- Do not use on patients less than 4 years old, weighing less than 15 kg, or when the sensor will not stay in place.
- Do not use on any patient site other than the alar region (side) of the nose.
- Do not use on sites with compromised tissue or non-intact skin.
- Do not use on any patient with a medical condition that decreases nasal/alar blood perfusion or that increases nasal/alar venous congestion or edema.

Instructions for Use

The Assurance® Nasal Alar SpO_2™ Sensor is for use with compatible pulse oximeters. These include: Nellcor OxiMax and Oxisensor II compatible monitors and Philips FAST compatible monitors.

The sensor incorporates a small plastic clip with soft silicon pads to locate and hold the sensor in place. The sensor is attached to the patient's nasal alar region – the fleshy region at the side of the nose. This site is supplied by the arterial plexus fed by the last branch of the external and first branch of the internal carotid arteries.

Before Applying the Sensor

Be sure to read and understand all Warnings and Cautions described below.

Inspect Sensor for Damage

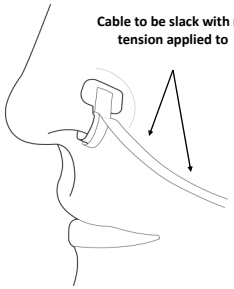
- Before using, inspect the sensor inside and outside. Be sure the silicon pads and cable are well affixed to the clip and that the surfaces are free of any debris.
- Any sensor showing signs of damage or alteration must not be used and should be disposed of using proper disposal procedures.

Prepare Application Site

- Remove sunscreens, foundations, powders, from the side of the nose.

Applying the Sensor

1. Use the applicator to position the sensor on patient's right or left ala as shown.
   Note: The larger "T" shaped pad should always be on the outside of the nose
2. Remove and retain the applicator for use in repositioning the sensor if needed.
3. Once the applicator is removed, push the sensor completely onto the ala.
4. Route the cable across the face, along the lower part of the cheek, clear of the mouth and eye. Without applying tension to the sensor, secure the cable with tape per hospital protocol. The cable may also be further routed around the patient's ear for additional securement if desired.
5. Plug the Sensor into the monitor patient cable.
6. Verify appropriate SpO_2 and pulse rate readings are displayed on the monitor.



Check and Change Application Site Periodically

The sensor application site should be inspected at least every 4 hours and changed as necessary if circulation or skin integrity is compromised.

Sensor Disposal

Sensors should be disposed of according to local laws regarding the disposal of hospital waste.

Definitions of Symbols on Packaging

	Consult Instructions For Use		Manufacturer
	Use-by-Date	EC REP	Authorized European Representative
REF	Catalog Number	Rx only	Prescription Use Only
LOT	Lot Number		Do Not Re-Use
NON STERILE	Non-sterile		Temperature limitation

Warnings / Cautions

- Federal (US) law restricts this device to sale by or on the order of a medical practitioner.
- This product is not manufactured with natural rubber latex.
- Single Patient Use Only – do not sterilize or re-use.
- Do not clean the sensor. Cleaning may damage it.
- Sensor life not to exceed 29 days.
- Reuse may cause unreliable readings and, if the sensor is used on two patients, there is a risk of cross-contamination.
- Connect the sensor only to the oximeters specified in the Instructions for Use section.
- Operator is responsible for checking the compatibility of the monitor and sensor before use.
- Performance is not assured when used with incompatible monitors.
- Make sure application site is clear of pigmented cream, sunscreen or powder, as these may cause inaccurate measurements.
- Be sure to apply the sensor to the patient at a proper application site, according to instructions provided. Failure to do so may cause inaccurate measurements.
- When a face mask is being used ensure the cable lays flat against skin and does not affect the seal of the mask.
- The sensor should not be used for longer than 24 hours when used with heated humidification through a mask.
- Retention of the sensor with unapproved accessories may result in patient injury due excessive pressure.
- Inspect the sensor application site every 4 hours to ensure skin integrity, correct optical alignment, and circulation distal to the sensor application site.
- If circulation or skin integrity is compromised, change the sensor location a minimum every 8 hours. Patients with pre-existing skin conditions may be more susceptible to tissue damage.
- Exercise caution with poorly perfused patients; skin erosion and/or pressure necrosis may occur.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- Carefully route cables to reduce the possibility of patient entanglement or strangulation.
- This sensor may present a choking hazard; keep clear of patient's mouth.
- At elevated temperatures, patient skin could be burned after prolonged sensor application at sites that are not well perfused. To prevent this condition, be sure to check patient application sites frequently. This sensor operates without risk of exceeding 41ºC on the skin if the initial skin temperature does not exceed 35ºC.
- Dysfunctional hemoglobin or intravascular dyes can cause inaccurate measurements.
- Protect all connectors from contact with any liquid.
- Do not use the sensor in MRI facilities. This may cause burns or inaccurate measurements.
- Pulse oximetry measurements are statistically distributed. Two-thirds of all pulse oximetry measurements can be expected to fall within the stated accuracy (refer to *Accuracy Specifications*).

Accuracy Specifications (A_{rms})

SpO_2 range 70-100%: $A_{rms} \leq 3$ HR range 30-240 bpm: ± 3bpm

The SpO_2 accuracy has been validated during no motion in human studies against arterial blood sample reference measured with a CO-Oximeter. The Nasal Alar SpO_2™ Sensor was validated with the Nellcor N-600x, N-595, and N -395; GE Dash 3000, Philips Intellivue Module Option A01, A02, and A04; and Datascope Passport 2 Pulse Oximeters in a controlled desaturation study; healthy adult volunteers with saturation levels between 70% and 100% SaO_2 were studied. The population characteristics for those studied were:

- Approximately 50% female and 50% male ranging in age from 18-45
- Skin tone: from light to dark

Due to the fact that pulse oximetry equipment measurements are statistically distributed, only approximately 2/3 of the pulse oximeter equipment measurements can be expected to fall within the +/- Arms value measured by a CO-Oximeter. Functional testers, such as an SpO_2 simulator cannot be used as the sole validation method to assess the accuracy of SpO_2 values. The pulse rate accuracy testing used a simulator as reference method.

Note: Wavelength ranges for the light emitting diodes used in this sensor are within 600nm-1000nm, with an optical output of less than 15mW.

The table below shows A_{rms} values measured using the Nasal Alar SpO2™ Sensor with the specified monitors in a clinical study.

	70-100%	90-100%	80-90%	70-80%
Nellcor N-600x	1.8	1.3	1.6	2.5
Nellcor N-595	2.1	1.1	1.7	3.0
Nellcor N-395	1.7	0.9	1.4	3.0
Philips Intellivue Mod A04	1.5	1.0	1.4	2.0
Philips Intellivue Mod A02	2.2	1.2	2.0	3.2
Philips Intellivue Mod A01	1.7	1.4	1.8	1.9
DataScope Passport 2	1.7	1.2	1.3	2.5
GE Dash 3000	2.2	2.1	2.2	2.4

Electrical Safety and Electromagnetic Compatibility (EMC)

EMC Warnings / Cautions

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these instructions

- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment
- The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacements parts for internal components, may results in increased emissions or decreased immunity of the equipment or system
- The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked used is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

GUIDANCE AND MANUFACTURER'S DECLARATION—EMISSIONS

The Assurance Alar Sensor is intended for use in the electromagnetic environment specified below. The customer or user of the Assurance Sensor should ensure that it is used in such an environments

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The Assurance Alar Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Assurance Alar Sensor is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

GUIDANCE AND MANUFACTURER'S DECLARATION—IMMUNITY

The Assurance Alar Sensor is intended for use in the electromagnetic environment specified below. The customer or user of the Assurance Sensor should ensure that it is used in such an environments

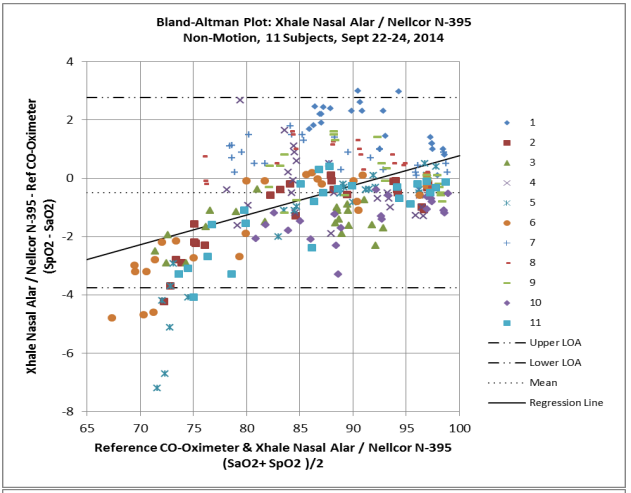
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
ESD IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	± 2kV Mains ± 1kV I/Os	± 2kV Mains ± 1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency—50/60Hz Magnetic Field—IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1) = 3Vrms (E1) = 3V/m	Portable and mobile communication equipment should be separated from the assurance Alar Sensor by no less than the distances calculated/listed below: D = (3.5/V1)(Sqrt P) - 150kHz to 80MHz D = (3.5/E1)(Sqrt P) - 80Hz to 800 MHz D = (7/E1)(Sqrt P) - 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1) Interference may occur in the vicinity of equipment containing a transmitter.

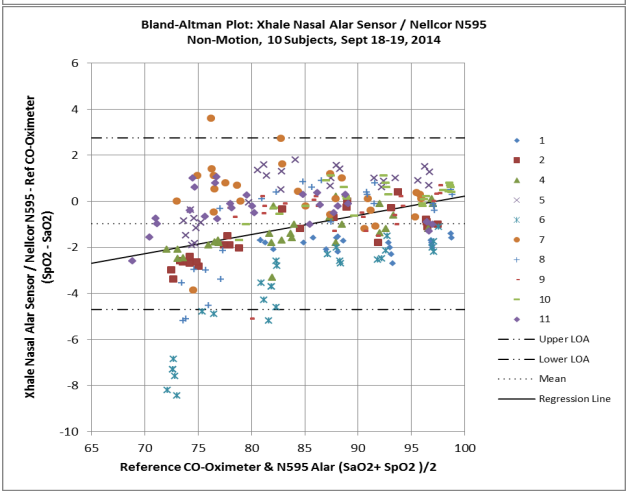
RECOMMENDED SEPARATIONS DISTANCES FOR THE ASSURANCE ALAR SENSOR

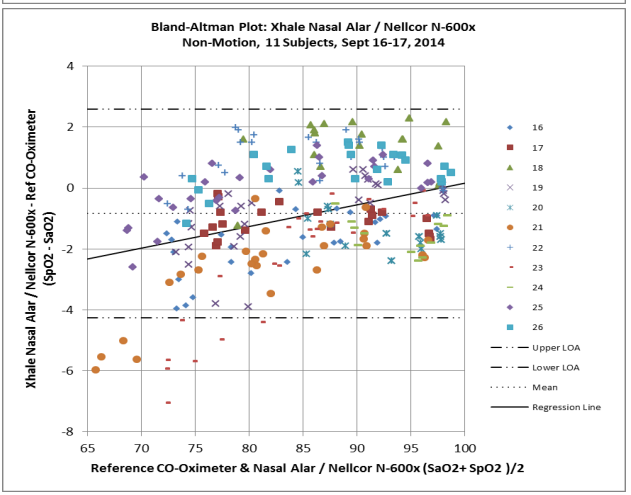
The Assurance Alar Sensor is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Assurance Alar Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Assurance Alar Sensor as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D = (3.5/V1)(Sqrt P)	Separation (m) 80 to 800 MHz D = (3.5/E1)(Sqrt P)	Separation (m) 800 MHz to 2.5 GHz D = (7/E1)(Sqrt P)
0.01	0.116667	0.116667	0.233333
0.1	0.368932	0.368932	0.737865
1	1.166667	1.166667	2.333333
10	3.689324	3.689324	7.378648
100	11.66667	11.66667	23.33333

Bland-Altman Plots







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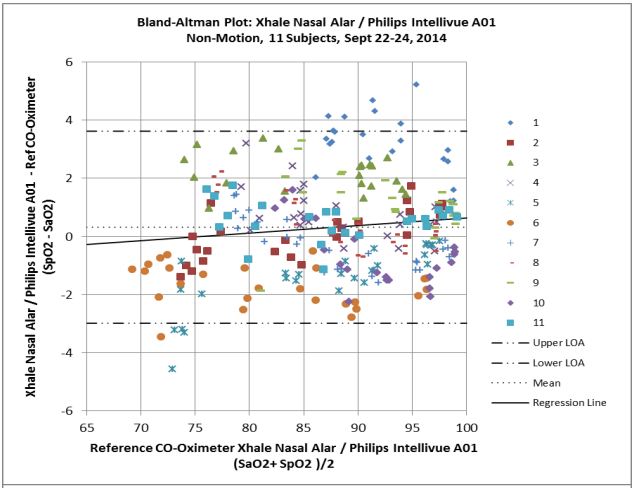

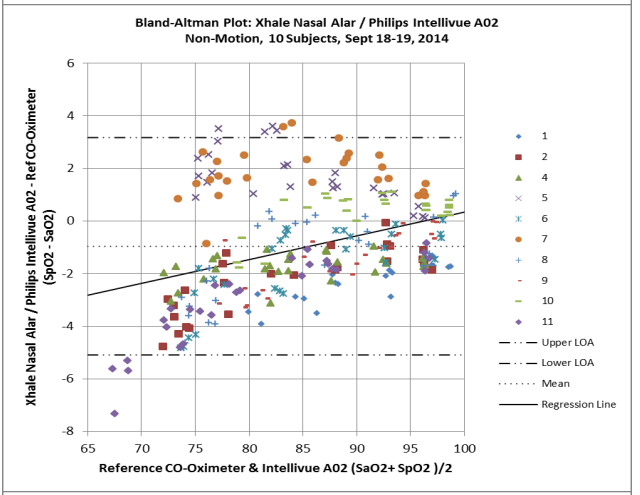

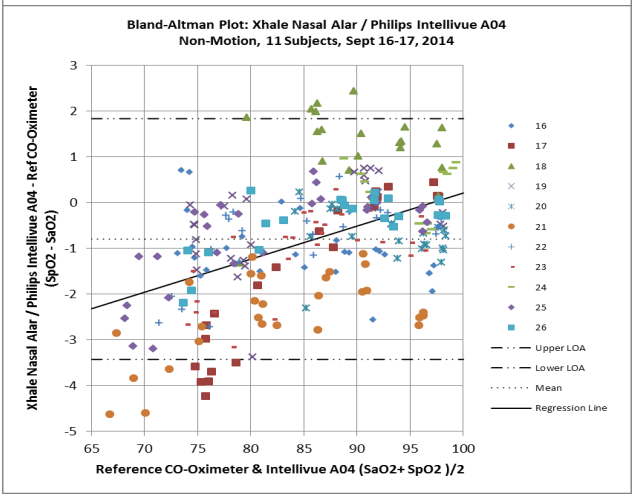

Bland-Altman Plots