Nasal Alar SpO2™ Sensor

Directions For Use

Manufactured by:
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Rx only
Nasal Alar SpO2™ Sensor

Directions for Use

Indications for Use
The Assurance® Nasal Alar SpO2™ Sensor is indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate from the nasal ala of adult and pediatric patients (weighing > 30kg). 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 weighing less than 30 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 SpO2™ 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 SpO2 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 8 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>i</td>
<td>Consult Instructions For Use</td>
</tr>
<tr>
<td>Use-by-Date</td>
<td>Only</td>
</tr>
<tr>
<td>Catalog Number</td>
<td>Only</td>
</tr>
<tr>
<td>Lot Number</td>
<td>Only</td>
</tr>
<tr>
<td>Non-sterile</td>
<td>Only</td>
</tr>
<tr>
<td>Authorized European Representative</td>
<td>Only</td>
</tr>
<tr>
<td>Prescription Use Only</td>
<td>Only</td>
</tr>
<tr>
<td>Do Not Re-Use</td>
<td>Only</td>
</tr>
<tr>
<td>Temperature limitation</td>
<td>Only</td>
</tr>
</tbody>
</table>
### 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 8 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 41°C on the skin if the initial skin temperature does not exceed 35°C.
- 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 ($A_{rms}$)

<table>
<thead>
<tr>
<th>$SpO_2$ range</th>
<th>$A_{rms}$, %</th>
<th>HR range 30-240 bpm</th>
<th>±1 bpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>70-100%</td>
<td>1.3</td>
<td>1.6</td>
<td>2.5</td>
</tr>
<tr>
<td>90-100%</td>
<td>1.1</td>
<td>1.7</td>
<td>3.0</td>
</tr>
<tr>
<td>80-90%</td>
<td>0.9</td>
<td>1.4</td>
<td>3.0</td>
</tr>
<tr>
<td>70-80%</td>
<td>1.5</td>
<td>1.0</td>
<td>1.4</td>
</tr>
<tr>
<td>100%</td>
<td>1.0</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Philips Intellivue Mod A04</td>
<td>2.2</td>
<td>1.0</td>
<td>1.4</td>
</tr>
<tr>
<td>Philips Intellivue Mod A02</td>
<td>1.7</td>
<td>1.3</td>
<td>1.8</td>
</tr>
<tr>
<td>Philips Intellivue Mod A01</td>
<td>2.5</td>
<td>1.2</td>
<td>2.0</td>
</tr>
<tr>
<td>DataScope Passport 2</td>
<td>2.4</td>
<td>1.3</td>
<td>2.5</td>
</tr>
<tr>
<td>GE Dash 3000</td>
<td>2.2</td>
<td>2.1</td>
<td>2.2</td>
</tr>
</tbody>
</table>

The table below shows $A_{rms}$ values measured using the Nasal Alar $SpO_2^\text{TM}$ Sensor with the specified monitors in a clinical study.

Due to the fact that pulse oximeter equipment measurements are statistically distributed, only approximately 2/3 of the pulse oximeter equipment measurements can be expected to fall within the $+/−A_{rms}$ 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.

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Assembled in the USA

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**Nasal Alar $SpO_2^\text{TM}$ Sensor**

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**10412_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 result 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 Alar Sensor should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td>Group 1</td>
<td></td>
</tr>
</tbody>
</table>

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 Alar Sensor should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment—Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESD</td>
<td>± 6 kV Contact ± 8 kV Air</td>
<td>± 6 kV Contact ± 8 kV Air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%</td>
</tr>
<tr>
<td>EFT</td>
<td>± 2 kV Mains ± 3 kV/μA</td>
<td>± 2 kV Mains ± 1 kV/μA</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Conducted RF

Radiated RF

<table>
<thead>
<tr>
<th>Max Output Power (Watts)</th>
<th>Separation (m) 150kHz to 80MHz</th>
<th>Separation (m) 80 to 800 MHz</th>
<th>Separation (m) 800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.116667</td>
<td>0.116667</td>
<td>0.233333</td>
</tr>
<tr>
<td>0.1</td>
<td>0.368932</td>
<td>0.368932</td>
<td>0.737865</td>
</tr>
<tr>
<td>1</td>
<td>1.166667</td>
<td>1.166667</td>
<td>2.333333</td>
</tr>
<tr>
<td>10</td>
<td>3.688524</td>
<td>3.688524</td>
<td>7.378654</td>
</tr>
<tr>
<td>100</td>
<td>11.66667</td>
<td>11.66667</td>
<td>23.33333</td>
</tr>
</tbody>
</table>
Bland-Altman Plots

Bland-Altman Plot: Xhale Nasal Alar / Nellcor N-99S
Non-Motion, 11 Subjects, Sept 22-24, 2014

Bland-Altman Plot: Xhale Nasal Alar Sensor / Nellcor NS95
Non-Motion, 10 Subjects, Sept 18-19, 2014

Bland-Altman Plot: Xhale Nasal Alar / Nellcor N-600x
Non-Motion, 11 Subjects, Sept 16-17, 2014
Bland-Altman Plots

Bland-Altman Plot: Xnose Nasal Alar / Philips Intellivue A01
Non-Motion, 11 Subjects, Sept 22-24, 2014

Bland-Altman Plot: Xnose Nasal Alar / Philips Intellivue A02
Non-Motion, 10 Subjects, Sept 18-19, 2014

Bland-Altman Plot: Xnose Nasal Alar / Philips Intellivue A04
Non-Motion, 11 Subjects, Sept 16-17, 2014

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Bland-Altman Plots

Bland-Altman Plot: Xhale Nasal Alar / GE Passport 2
Non-Motion, 11 Subjects, Oct 6-10, 2014

Bland-Altman Plot: Xhale Nasal Alar / GE Dash 3000
Non-Motion, 11 Subjects, Oct 6-10, 2014