Instructions for Use—English

Choosing the Appropriate Sensor Size

- Please refer to the following table to select the appropriate sensor size for the patient's arm:

<table>
<thead>
<tr>
<th>Sensor Type</th>
<th>Measurement Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 8100SS (small)</td>
<td>7.5 – 12.5 mm (0.3 – 0.5 in.)</td>
</tr>
<tr>
<td>Model 8100SL (large)</td>
<td>12.5 – 25.5 mm (0.5 – 1.0 in.)</td>
</tr>
</tbody>
</table>

Limitations of Agreement

- For non-motion conditions, the SpO2 measurements should be within ±3 ±2 ±2 of the reference values.
- For motion conditions, the SpO2 measurements should be within ±3 ±3 ±3 of the reference values.

Contraindications

- The sensor is contraindicated in the presence of metallic objects or tattoo/scar tissue in the area of measurement.
- It is also contraindicated in the presence of unhealed wounds, tumors, burns, or any other abnormalities that affect tissue perfusion.

Symbols

- The following symbols are used to indicate important information:

1. Carefully remove the sensor from the plastic pouch and uncoil the sensor cable.
2. Allow the sensor to dry thoroughly before reusing.
3. Secure the sensor cable with medical tape so the cable does not become caught or poorly perfused, during both motion and non-motion conditions. It is intended for checking and/or continuous monitoring of adult and pediatric patients who are well or critically ill.

Warning

- Use the measurements provided below to determine which sensor should be used.

Caution

- For use only with the SenSmart oximetry system.

Indications for Use

- Nonin's Model 8100S(X) reusable soft sensor is indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or critically ill.

Instructions for Use—English

- Reusable, Soft Pulse Oximeter Sensor

1. Carefully remove the sensor from the plastic pouch and uncoil the sensor cable.
2. Allow the sensor to dry thoroughly before reusing.
3. Secure the sensor cable with medical tape so the cable does not become caught.
4. Clean the sensor before applying it to a new patient.
5. Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from other sensors.
6. Avoid excessive pressure to the sensor application site(s) as this may cause discomfort.
7. Verify proper operation as described in the system operator's manual. Verify the displayed data correctly correlates with the sensor application site.

NOTES:

- The sensor should be worn with the narrow end朝 down.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- Disconnect the sensor from the signal processor before cleaning.
- Clean the sensor before applying it to a new patient.
- Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from other sensors.
- Avoid excessive pressure to the sensor application site(s) as this may cause discomfort.
- This device is only defibrillation proof per IEC 60601-1 when used with the X-100SP signal processor.

Accuracy

- The sensor reads ±1 change in SpO2 from 60% - 100%.

Environmental Limitations

- The sensor is not recommended for use in environments with an operating temperature range of 0°C - 40°C (32°F - 104°F).

Recycling

- Nonin Medical, Inc. participates in a recycling program for the disposal of medical devices. Contact your local hospital for information on the disposal of medical devices.

Warranty

- For warranty and support information, please visit the Nonin Medical, Inc. website or contact the nearest Nonin Medical, Inc. office.

For more information, please visit the Nonin Medical, Inc. website or contact the nearest Nonin Medical, Inc. office.