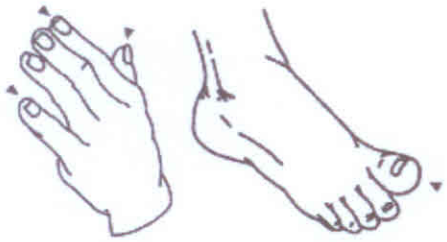
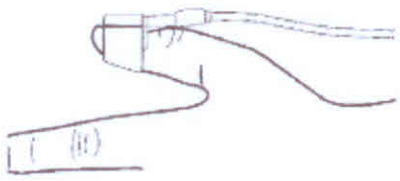
Instructions for use

Rev. A0

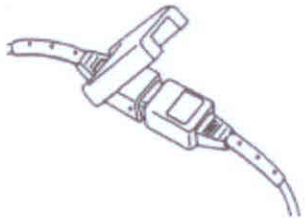
1.



2 & 3.



4.



1. Select a suitable site for the sensor. The patient`s Index finger is the preferred location. Alternative sites recommended are the thumb, large toe, or smaller finger.
2. Remove the adhesive backing and position the detector on the toe pad. Align the light source on the top of the toe directly opposite the detector.
3. Route the cable along the top of the foot and secure with the tape if necessary. If using heel of hand, route the cable along side the arm and secure with tape if necessary.
4. Connect the sensor cable into the patient cable and verify proper operation as descrbed in the instrument's operator manual.

Indications

The sensor is indicated for use for continuous non-invasive or spot monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for patients in hospitals, hospital-type facilities, mobile.

The sensor is indicated for single patient use only.

Patient weight

Recommended for use on patients weighing between 3 kg -20 kg.
6.6 lbs - 44 lbs.

Accuracy

1. SpO2 70% - 100% SpO2 ± 2 digits
   < 70% SpO2 : unspecified

Verified by clinical tests, where the measured values of the sensors were compared with those of the arterial co-oximetry in adult subjects over the specified SpO2 range.

2. Pulse Rate 30 - 250 BPM : ±3 BPM

Storage temperature - 20°C - + 70°C
Operating temperature + 5°C - + 40°C

Symbols and indications

Do not re-use. Single use product

Latex FREE

Non-sterile product

Dispose according to the local legislation on W.E.E.E.

Consult instructions for use

Keep away from sunlight

REF Catalogue number

Manufacturer

CE 0197 European conformity

Use-by date

IPX2 IP Classification indicating

Temperature limit

Keep dry

Rx ONLY For prescription use only

LOT Lot number

Warnings and precautions

1. This sensor is for use only with compatible monitors,instruments, or oximetry modules. Use of this sensor with instruments other than compatibles may result in improper performance.
2. Verify proper operation before use.
3. Operations may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment.
4. The product is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
5. Do not autoclave or immerse in liquid of any kind. Do not sterilize with ETO.
6. Do not stretch the adhesive tape too tighten to assure that the blood-circulation is not restricted.
7. If the sensor is damaged in any way, discontinue use immediately.
8. Operation may be affected in the presence of high ambient light (also because of IR and UV light). Shield the sensor area with a surgical towel if necessary.
9. Check and reposition the sensor to an alternate location every 4 hours.
10. Intravascular dyes may interfere with performance of the sensor and the monitor which may cause inaccurate measurements.
11. The performance of the sensor and the monitor may be compromised by excessive motion. To decrease this motion, make a loop with the sensor cable and secure it to the patient using tape.
12. Fingernail polish or an artificial fingernail can cause inaccurate SpO2 readings.
13. Refer to the monitor's operations manual for additional cautions and warnings.
14. Significant levels of dysfunctional hemoglobin's, such as Carboxyhemoglobin or Methemoglobin will affect the accuracy of the oxygen measurement.
15. Application of the sensor to edematous or fragile tissue must be avoided.
16. Venous pulsations that could potentially lead to inaccurate saturation measurements may be caused when the sensor is wrapped too tightly or supplemental tape is applied.

EC REP

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CE 0197

Disposable SpO2 Sensor infant

Model: DI-2231 **Nonin compatible**
Type: 7-IP-VM (Plaster)

VIAMED