Addendum

for LX-7230N Operation Manual

- **Before using this equipment, read this operation manual thoroughly.**
- **Keep this manual near the device for future reference.**

FUKUDA DENSHI

⚠CAUTION
Federal Law restricts this device to sale by or on the order of a physician.

CAUTION:

- **This equipment for sale by or on the order of a physician.**
- **The company and product names used in this manual are trademarks or registered trademarks.**
- **If this manual has pages missing or out of order, contact Fukuda Denshi for replacement.**
- **Only physician or persons instructed by physicians are allowed to use the equipment.**
- **The information contained in this document is subject to change without notice due to improvement in the equipment.**

Printed in Japan

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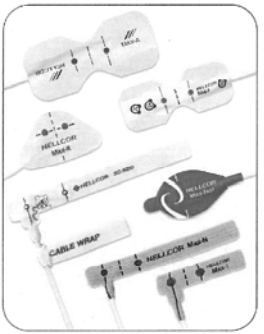
1. Clinicians Guide for SpO_2 Sensors

NELLCOR

CLINICIAN'S GUIDE TO NELLCOR® SENSORS



Be Certain.

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An Ongoing Commitment to Excellence

As the leading manufacturer of pulse oximetry monitors and sensors for more than two decades, Nellcor—a part of Tyco Healthcare—has remained steadfast in its commitment to excellence in patient safety monitoring. This commitment is evident in our sensor design and development over the years. Nellcor® *OxiMax*® sensors represent our latest innovations in pulse oximetry monitoring. Nellcor also continues to supply *Oxisensor*® *II* sensors for earlier-generation pulse oximeters.

Choosing and Positioning a Sensor

Nellcor offers a wide variety of single-patient-use and reusable pulse oximetry sensors, which are all latex-free. Nellcor sensors are developed and validated for specific patient sizes, sensor sites and to address particular clinical challenges, thus ensuring a high level of accuracy when sensors are used as directed.

Much of the reliability of pulse oximetry readings can be attributed to proper sensor application and fit. When selecting a Nellcor sensor, consider the following factors:

- Patient body weight
- Duration of monitoring
- Patient activity level
- Infection control concerns

Patient Body Weight

All sensors contain a light-emitting diode (LED) and a photodetector, which are the essential optical components necessary to determine arterial oxygen saturation by pulse oximetry (SpO_2). Nellcor sensors are designed so the LEDs and photodetector are precisely positioned to provide the best SpO_2 measurement.

A sensor should be chosen according to the patient's body weight to ensure that the optical components can be properly aligned at the recommended site. Nellcor tailors sensor design to optimize performance and fit for adult, pediatric, infant and neonatal patients. The LEDs are positioned specifically for the sensor site location and patient weight range. In addition, the bandage and surface material are selected based on the sensor type and patient population.

Duration of Monitoring

Skin integrity and distal circulation are two important concerns with sensor use. Single-patient-use sensors are appropriate for short- or long-term monitoring. Reusable sensors are generally indicated for spot-check measurements or for short-term monitoring of four hours or less.

SECTION 1

Because reusable sensors typically apply more pressure at the sensor site, they are less comfortable than single-patient-use sensors for long-term monitoring.

Always read the sensor's directions for use (DFU) carefully to determine how frequently the site for each sensor should be checked. Adhesive sensor sites should be checked for skin integrity and distal circulation typically at least once every eight hours and changed as appropriate. Reusable sensor sites must be checked and changed at least every four hours or as specified in the DFU.

Recommended Intervals for Inspecting and Changing Sensor Sites

Sensor Type	Patient Population	Inspect Sensor Site	Change Sensor Site
OxiMax® and *Oxisensor*® *II* Adhesive Digit and Nasal Sensors	Adult, Pediatric, Infant, Neonate	Every 8 hours	As appropriate
OxiCliq® Sensors	Adult, Pediatric Infant, Neonate	Every 8 hours	As appropriate
OxiMax SoftCare™ Nonadhesive Sensors	Adult, Neonate	Every 8 hours	As appropriate
OxiMax Max-Fast® Forehead Sensor	Adult, Pediatric	Inspect routinely	Within 12 hours
Oxisensor II RS-10 Forehead Sensor	Adult	Inspect routinely	Within 4 hours
OxiMax Reusable Sensors: *Durasensor*™ Adult Finger Clip Sensor *Dura-Y*™ Ear Clip Sensor *OxiBand*® Sensors	Adult, Pediatric, Infant, Neonate	Inspect routinely	Within 4 hours
PediCheck® Pediatric Spot-Check Clip (reusable)	Pediatric	Inspect routinely	Within 20 minutes

Patient Activity Level

With active patients, single-patient-use sensors are a better choice for monitoring than reusable sensors. Single-patient-use sensors have a "second-skin" fit that provides more stability, more secure positioning of the LEDs and improved patient comfort.

In general, reusable sensors are less secure on active patients than single-patient-use sensors and are recommended only for spot checking. Some models of reusable sensors are held in place with a wrap, so they may provide a more secure fit on active patients than reusable sensors with a finger-clip design. However, the wraps tend to make the sensor more bulky, which affects patient comfort.

Infection Control Concerns

Most types of single-patient-use sensors are packaged sterile. These sensors offer an advantage for patients at greater risk for infection, such as neonates or immunocompromised patients. Sterile, single-patient-use

sensors are also an appropriate choice to help limit the potential spread of nosocomial infection. Before opening the package, check the label to determine whether the sensor is sterile.

Reusable sensors are nonsterile. They require cleaning after use on each patient with 70% alcohol or 1:10 bleach solutions. Any unapproved cleaning solutions may cause early failure of the sensors.

Nellcor Sensor Choices by Patient Population

Single-Patient-Use Sensors

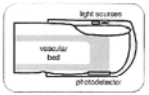
Brand	Sensor Line	Adult	Neonate	Infant	Pediatric
OxiMax	*OxiMax* Specialty Sensors	*Max-Fast* *SoftCare* SC-A	*SoftCare* SC-PR *SoftCare* SC-NEO		*Max-Fast*
OxiMax	*OxiMax* General Purpose Sensors	MAX-A/AL MAX-R	MAX-N	MAX-I	MAX-P
OxiMax	*OxiCliq* Sensors	A	N	I	P
Oxisensor II (not *OxiMax*)	*Oxisensor II* Sensors	RS-10 R-15 D-25/L	N-25	I-20	D-20

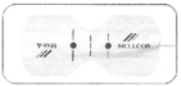
Reusable Sensors

OxiMax	*Oxisensor* *Dura-Y* *Oxiband*	DS-100A D-YS Multisite D-YSE Earclip OXI-A/N	D-YS Multisite OXI-A/N	D-YS Multisite OXI-P/I	D-YS Multisite D-YSPD *PediCheck*® *Spot-Check* Clip OXI-P/I

The Importance of Sensor Position

Transmittance Sensors – In most sensors (finger, toe, ear, etc.), the LEDs and the photodetector must be aligned directly across from one another, transmitting the light between the emitter/detector **through the digit** across the arteriolar bed. Incorrect sensor placement, including applying a sensor on a site other than those it was designed for (e.g., placing a digit sensor on the forehead) can result in very inaccurate SpO_2 readings. For specific sensor applications, always consult the directions for use (DFU).





SECTION 2

Reflectance Sensors – In a reflectance (forehead) sensor, the LEDs are aligned as part of the sensor design, reflecting the light from the emitter/detector across the skin surface. As with transmittance sensors, correct placement on the patient is critical to use and performance. Incorrect placement can result in inaccurate readings. For specific sensor directions, always consult the DFU.

Nellcor Sensors

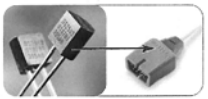
OxiMax® Pulse Oximetry System

The *OxiMax* Pulse Oximetry System, Nellcor's latest-generation technology, includes a line of bedside and handheld pulse oximetry monitors and comprehensive family of *OxiMax* sensors. In addition, many leading manufacturers of multiparameter monitoring systems incorporate *OxiMax*-compatible pulse oximetry modules within their products.

Nellcor *OxiMax* pulse oximeters are designed with Nellcor's highly advanced signal processing technology. This technology enables the pulse oximeter to operate reliably, even during the most challenging conditions such as patient motion, low perfusion and electrical interference. By combining advanced technology with innovative new sensor designs, the *OxiMax* platform allows clinicians to more effectively monitor a broader range of patients.

OxiMax Sensors

OxiMax sensors have a digital memory chip embedded in the sensor plug that contains the calibration coefficients needed for accurate operation. Earlier pulse oximetry technology—still used by other manufacturers—requires calibration data to reside within the monitor rather than the sensor. Placing the digital memory chip in the *OxiMax* sensor allows much greater flexibility in sensor design. It also enables two new features that communicate information to caregivers through the monitor display:



Nellcor *OxiMax* chip

Sensor Messages: Displays troubleshooting tips to help clinicians optimize sensor placement.

Sensor Event Report: Displays SpO_2 and pulse rate alarm event history for rapid assessment at various points of care (available on single-patient-use, adhesive sensors only).

Compatibility at a Glance

Sensor and Monitor Compatibility

	OxiMax Technology	Non-*OxiMax* Technology			
	5th generation	4th generation	3rd generation	2nd generation	1st generation
OEM Multiparameter Monitors	Contact individual companies for compatibility of particular instrument models with particular Nellcor sensor models.				
Nellcor Monitors	*OxiMax* N-595 *OxiMax* N-560 *OxiMax* N-75 *OxiMax* N-40 N-45*	N-395	N-3000 N-290 N-295	N-200 N-180 N-3000 N-190 N-195 N-4000 N-75 N-6000 N-20 series N-40	N-100 N-10
OxiMax Single-Patient-Use Sensors	●	●	●	●	●
OxiMax Reusable Sensors	●	●	●	●	●
OxiMax *OxiCliq* Sensors	●	●	●	●	●
Oxisensor II Sensors		●	●	●	●
OxiMax *Max-FAST* Sensors	○				
OxiMax *SoftCare* Sensors	○				

* *OxiMax*-compatible technology

■ light grey or light blue plug ■ dark purple plug □ white plug

Most *OxiMax* sensors are "backward-compatible" and can be used with previous-generation, non-*OxiMax* Nellcor technology. Such backward-compatible *OxiMax* sensor models are identified by their **dark purple** connector plugs. However, some of the new *OxiMax*-specific features will not be accessible when these sensors are used with non-*OxiMax* monitors.

The *Max-FAST*® Forehead Sensor and *SoftCare*™ Nonadhesive Sensor family were the first sensors to be engineered as part of the *OxiMax* system. Because they use unique operating characteristics and calibration curves outside of those established in legacy Nellcor systems (non-*OxiMax*), these sensors operate only with *OxiMax*-enabled monitors. A **white** connector plug identifies those sensors as exclusively for use with *OxiMax-enabled* monitors.

SECTION 2

Non-*OxiMax*, single-patient-use, adhesive sensors or older reusable sensors (with **light grey** or **light blue** plug) are not compatible with *OxiMax*-enabled monitors.

Single-Patient-Use, Adhesive Sensors (Transmittance)

Sterile, adhesive sensors do not present the risk of cross-contamination caused by products that are reused from patient to patient. Their durability makes them ideal for use with the patient who may require extended monitoring as the patient travels to various points of care within the hospital.

***OxiMax* Adhesive Sensors**—MAX-A/MAX-AL, MAX-P, MAX-N, MAX-I, MAX-R—have been designed with tear-resistant bandages and extra electronic shielding to protect the photodetector–light source relationship. These *OxiMax* sensors can be used with earlier-generation Nellcor pulse oximeters and Nellcor-compatible monitors. However, when used with non-*OxiMax* monitors, some *OxiMax*-specific sensor features, for example, Sensor Messages and Sensor Event Report, are not accessible.

OxiMax Adhesive Sensors

Adult	Neonatal/Adult	Infant	Pediatric	Adult Nasal
>30 kg	<3 kg or >40 kg	3–20 kg	10–50 kg	>50 kg

***OxiMax OxiCliq*® Sensors**—models A, N, I, P—are a cost-effective option for patients who have adequate pulsatile perfusion. The two-piece sensor combines a reusable cable with a single-patient-use adhesive sensor. The sensor clicks into place in the cable connector and is easy to detach if monitoring needs to be momentarily discontinued.

OxiMax OxiCliq Sensors

Adult	Neonatal/Adult	Neonatal/Adult	Infant	Pediatric
>30 kg	<3 kg or >40 kg	<3 kg or >40 kg	3–20 kg	10–50 kg

***Oxisensor II* Single-Patient-Use, Adhesive Sensors**—D-25/D-25L, D-20, I-20, N-25 and R-15—were designed for an earlier Nellcor sensor calibration system. They are not compatible with *OxiMax* monitors.

Oxisensor II Adhesive Sensors

Single-Patient-Use, Nonadhesive Sensors (Transmittance)

Nellcor developed the *OxiMax SoftCare* Nonadhesive Sensor in response to concerns that applying and removing adhesives can cause skin trauma for patients with fragile skin such as neonates, geriatric patients and patients with burn injuries. In addition, adhesives pose challenges in environments with elevated heat and humidity. When heated, adhesives can increase bonding and, in turn, the potential for skin trauma.

Unlike most single-patient-use sensors that use adhesive tape, the *SoftCare* Nonadhesive Sensor fastens with Velcro® The sensor bandage is made of a soft, pliable foam material that helps keep the sensor securely in place and provides a comfortable fit similar to that of adhesive sensors.

***OxiMax SoftCare* Sensors**—SC-A, SC-NEO and SC-PR—are also designed with high-efficiency LEDs that enhance the sensor's ability to acquire a pulsatile signal, even when challenged with thicker or darkly pigmented skin, or weak pulses. The sensor is available in a range of sizes, to accommodate preterm infants, neonates and adults.

OxiMax SoftCare Sensors

Forehead Sensors (Reflectance)

The forehead sensor was developed to provide an alternative site location to the digits, nose and ears. The forehead site often provides a pulse signal when other sites are unable to do so. In addition, the forehead site is preferred over the digits when the patient is cold or has poor circulation.

Nellcor offers two single-patient-use, adhesive forehead sensors: the *OxiMax MAX-FAST* Forehead Sensor, for use with *OxiMax* technology, and the *Oxisensor II* RS-10 Forehead Sensor, available for earlier, non-*OxiMax* technology.

Forehead Sensors

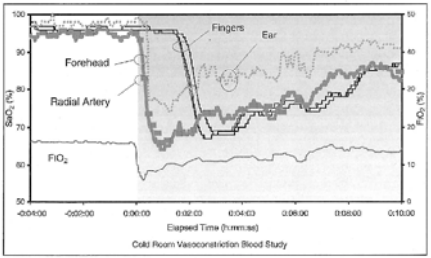
With unique calibration coefficients embedded in its digital memory chip, the *MAX-FAST* sensor is the forehead sensor of choice. It is more accurate than the earlier-generation RS-10 Forehead Sensor. Its SpO_2 accuracy level of ± 2% is comparable to most adhesive digit sensors. In addition, the *MAX-FAST* sensor has improved bandaging material and adhesive attachment compared with the RS-10.

Unlike the *MAX-FAST* Forehead Sensor, the RS-10 Forehead Sensor cannot be used on supine patients or on patients who are being mechanically ventilated. It has a larger margin of accuracy (± 3%) than the *MAX-FAST* sensor, and a narrower weight range.

To help ensure accurate readings, the headband packaged with the forehead sensors should be used. The slight pressure created by the headband helps prevent venous pooling, a potential source of error in the displayed saturation values.

Advantages of Forehead Sensors

The *MAX-FAST* Forehead Sensor detects changes in SpO_2 faster than finger sensors, and with accuracy that more closely tracks to arterial blood data.



Bebout DE, Mannheimer PD, Asbaugh NA. *Critical Care Medicine*. 2003;31(2):A72.

During poor peripheral perfusion, *OxiMax* systems using *Max-Fast* Forehead Sensors reflect changes in SpO_2 typically one to two minutes earlier than when digit sensors are used. The sensor can often obtain SpO_2 readings when digit sensors fail to detect pulsatile signals.[2] The forehead site is less vulnerable to peripheral vasoconstriction and hence maintains signals longer than digit sensors during poor peripheral circulation. Ear sensors show degraded signal strength during similar conditions.[3]

Other advantages of the forehead site include the following:

- The forehead is more accessible in areas such as the operating suite, where patients' hands are often covered and beyond the reach of the anesthesiologist.
- The head is typically a lower motion site than the hands, and thus often offers more reliable readings on moving patients.[4]

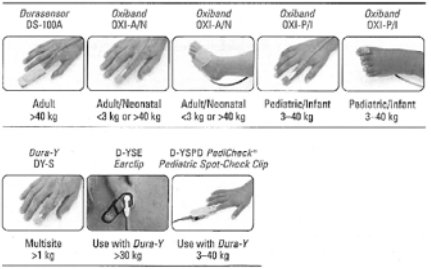
Reusable Sensors

Nellcor offers a broad line of reusable sensors for patients of all sizes. Reusable sensors are appropriate for monitoring relatively immobile patients, particularly when cross-contamination is less of an issue. These sensors are most appropriate for short-term or intermittent monitoring.

All Nellcor reusable sensors contain *OxiMax* technology, but they can also be used with earlier-generation Nellcor pulse oximeters and Nellcor-compatible monitors. However, since a reusable sensor is used on multiple patients, the *OxiMax* Sensor Event Report function that records patient alarm data is not available with these products.

OxiMax reusable sensors include the *Durasensor*,® *Oxiband*® and *Dura-Y*® sensors.

OxiMax Reusable Sensors



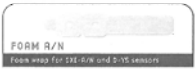
SECTION 2

Sensor Reusability

Completely Reusable		
Sensor Type	Sensor Model	Accessory
Adult finger clip	*Durasensor* DS-100A	
Pediatric finger clip	*Dura-Y* D-YS	D-YSPD finger clip
Adult ear clip	*Dura-Y* D-YS	D-YSE ear clip

Partially Reusable		
Sensor Type	Sensor Model (Reusable)	Accessory Options (Single-Patient-Use)
Adult finger or neonatal foot	*Dura-Y* D-YS *Oxiband* OXI A/N	Posey® wrap Foam A/N foam wrap ADH A/N adhesive wrap
Pediatric finger or infant toe	*Dura-Y* D-YS *Oxiband* OXI-P/I	Posey wrap Foam P/I foam wrap ADH-P/I adhesive wrap

Reusable Sensor Accessories



Tips and Troubleshooting for Optimal Sensor Use

All Sensors

- Read directions for use before using sensor.
- Choose a sensor according to patient size, duration of use, level of activity and infection control concerns.
- Observe alignment marks to ensure proper position of the light source and photodetector.
- Avoid placing a sensor on edematous tissue to reduce possible loss of light transmission.
- To reduce the incidence of nuisance alarms arising from transient threshold desaturation, consider use of pulse oximeter features such as Nellcor *SatSeconds*™ Alarm Management technology, if available.
- Exercise care when removing sensor to avoid damaging the skin.
- Reposition patients to adjust for compromised blood flow and to improve signal quality.
- Cover the sensor with a towel or opaque material in the presence of bright light sources (e.g., direct sunlight, surgical lamps and infrared warming lamps) to help minimize the potential for optical interference and unreliable readings.
- Avoid placing a sensor on the same extremity being used for automated noninvasive blood pressure monitoring, to reduce intermittent interference with pulsatility.
- Do not use a Nellcor sensor during MRI scanning procedures; the sensor is incompatible and may cause patient injury.
- If using digit sensors during peripheral shutdown, warm the sensor site with a cloth or blanket, or consider using an *OxiMax MAX-FAST* Forehead Sensor.

Neonatal and Pediatric Sensors

- For infants, the preferred site for adhesive sensors is the great toe, with the cable running along the sole of the foot toward the heel. Alternatively, apply the sensor to a thumb or other digit.
- For neonates, the preferred site for adhesive sensors is the foot below the toes, with the cable running along the sole of the foot toward the heel. Alternatively, apply the sensor to the palm of the hand. Do not place sensor on the wrist or ankles.
- Secure the sensor cord to the bottom of the foot using the extra tape strip that is provided, or with another piece of tape. If possible, place a sock over the patient's foot as well.

SECTION 3

- Because of its potential to tighten over time, avoid use of Coban tape to secure a sensor.
- For short-term or intermittent monitoring of infants and pediatric patients between 3 kg and 40 kg, consider using the Nellcor *PediCheck* reusable sensor instead of adhesive sensors.
- Consider using an *OxiMax SoftCare* Nonadhesive Sensor on neonates with fragile skin.
- The *SoftCare* model SC-PR Nonadhesive Sensor is especially designed for neonates weighing less than 1500 grams. The DFU recommends the foot as the site of choice for sensor placement.
- Use an opaque material to shield the sensor when phototherapy (bilirubin) lights are used.

Single-Patient-Use, Adhesive Sensors (Transmittance)

(Refer to page 6 for specific sensor models)

- Apply the sensor to a clean and dry site, according to the DFU.
- Fingers are the preferred sites for digit sensor application on adult and pediatric patients. Clinicians may consider the toes as alternative sites in active patients.
- If using on a finger site, apply the adhesive sensor on the ring finger instead of on the index finger to enhance finger-thumb mobility and because it is less prone to movement than the index finger.
- The adhesive sensor should be applied so that the LEDs and photodetector are opposing each other and are positioned over an arterial tissue bed.
- Circulation distal to the adhesive sensor site must be inspected every eight hours to ensure adhesion, skin integrity and correct optical alignment.
- Consider the use of Nellcor's "sticky dots" to extend the life of the *OxiMax* MAX-N and MAX-I (or *Oxisensor II* N-25 and I-20) sensors.
- When applying the *OxiMax* MAX-A or MAX-P (or *Oxisensor II* D-25 or D-20) sensor, apply the cable directed away from the fingers and then secure the cable to the back of the hand.
- Consider using the *OxiMax* MAX-N (or *Oxisensor II* N-25) sensor for adult patients with long fingernails, artificial nails or nail polish, or for situations where a stronger adhesive is needed.
- When extra-length cable is needed, consider use of the *OxiMax* MAX-AL (or *Oxisensor II* D-25L) sensor, which has a 36-inch cable.
- Replace any adhesive sensor if an odor is detectable, if wires are exposed or if adhesive has lost its effectiveness.

Forehead Sensors (Reflectance)

(*OxiMax MAX-FAST, Oxisensor II* RS-10)

- For difficult-to-monitor patients with impaired peripheral perfusion, consider using the *OxiMax MAX-FAST* Forehead Sensor as the sensor of choice.
- To help reduce artifact interference created by hand movement, consider using a forehead sensor instead of digit sensors during physical therapy, cardiac rehab and cardiac stress testing.
- The proper placement for the forehead sensor is above the right or left eyebrow, centered over the pupil. It should not be placed on the temple or in the center of the forehead. Follow the DFU for application of the sensor and the headband.

- Before applying the forehead sensor, clean the site with an alcohol prep pad to remove skin oils.
- Routinely check snugness of the forehead sensor headband to ensure enough pressure is applied to squeeze venous blood away from the sensor site.
- Forehead sensors are contraindicated for patients in Trendelenburg's (head down) position because of the increased tendency for venous pooling.

Reusable Sensors

(*Durasensor, Oxiband, Dura-Y* sensors)

- Surface-clean reusable sensors between patients with 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution. Any unapproved cleaning solutions may cause early failure of the sensors.
- Consider Nellcor reusable sensors for spot-check oximetry or short-term monitoring.
- For short-term monitoring of infants and pediatric patients, consider using the *PediCheck* reusable sensor.
- Carefully remove the adhesive wrap from the D-YS, OXI-P/I and OXI-A/N to avoid damage to the reusable sensor.
- The reusable sensor site should be changed no less than once every four hours; in younger patients, the site should be changed more often.
- To reduce the potential for motion artifact on an active patient, consider switching to a forehead sensor or an adhesive digit sensor with a second-skin fit.
- To limit loss, apply "Do not throw away" labels to cables of reusable sensors.

SECTION 4

Nellcor's Technology Partners

As the industry leader in pulse oximetry, Nellcor supplies its technology to far more patient monitoring system manufacturers than any other company. Most monitoring system manufacturers have standardized on Nellcor sensors or offer this compatibility as an option. Nellcor has arranged with many patient monitoring companies to either include Nellcor's technology in their products (via a printed circuit board) or license technology components to make their monitors compatible with Nellcor sensors.

Most leading companies now offer *OxiMax* compatibility in their products.

Please contact the individual company representatives for information on the compatibility of particular instrument models with particular Nellcor sensors. Visit www.nellcor.com for a list of active partners.

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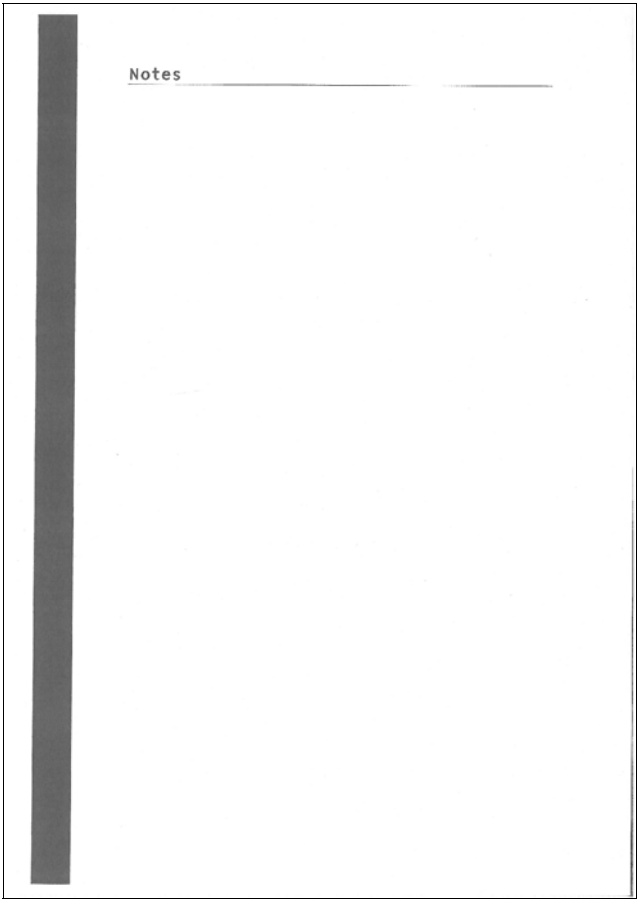
Notes


Notes

PRODUCT INFORMATION

- Contact your local Nellcor sales representative
- Call 1-800-NELLCOR (1-800-635-5267)
- Visit www.nellcor.com

TECHNICAL SUPPORT

Contact our Technical Services Department for questions related to pulse oximetry sensors and other Nellcor products.

- Call 1-800-NELLCOR, press 3
  (6:00 a.m. to 5:00 p.m. PST)

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2. Clinical Studies

Clinical study test data for the SpO_2 sensors is available from the manufacturer upon request.

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FUKUDA DENSHI CO.,LTD.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Phone: +81-3-3815-2121 Fax: +81-3-3814-1222

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