



TS-F-D



TS-SA-D/TS-SP-D



TS-E-D



TS-W-D



TS-SE-3



Part number 21

TruSignal™ Reusable Sensors					
Description	Patient	Patient Weight	Length	Part Number	Quantity
Finger	Adult, Pediatric	≥ 20 kg	1 m/3.3 ft	TS-F-D	1
PediTip	Pediatric	15-30 kg		TS-SP-D	1
Fingertip	Adult	> 30 kg		TS-SA-D	1
Ear	Adult, Pediatric	≥ 10 kg		TS-E-D	1
Wrap	Adult, Pediatric, Infant	≥ 3 kg		TS-W-D	1
Sensitive Skin	Adult, Pediatric, Infant, Neonate	No limit		TS-SE-3	3

Requires Compatible Interconnect Cable



TS-G3

TruSignal™ Interconnect Cables			
Connector	Length	Part Number	Quantity
GE	3 m/9.8 ft	TS-G3	1
Ohmeda		TS-H3	
Datex		TS-N3	

Not available in all countries

4. Connecting to an interconnect cable (see Figure 5)

Align the connectors with the aid of alignment feature and push them together. Make sure the connectors are fully engaged. To disconnect, grasp the connectors (not the cable) and pull straight out.



Figure 5

5. Connecting to the monitor

TS-W-D
Depending on the monitor use the compatible interconnect cable as shown in Figure 6.

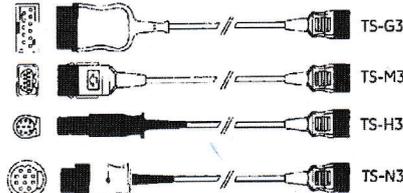


Figure 6

TS-W4-H

Align the connector with the matching receptacle on the monitor. Push the connector in fully. To disconnect, grasp the connector (not the cable) and pull straight out.

Maintenance

Cleaning

1. Clean the lenses and the sensor before and after each patient use with 60% isopropyl or 90% ethyl alcohol.
2. For cable and connector, when needed spray or wipe with pad moisturized with 60% isopropyl or 90% ethyl alcohol or 2% glutaraldehyde. Although discoloration may occur, <2% phenol, <5% chloramine, <10% sodium hypochlorite, <0.3% formaldehyde, <0.75% tartaric acid or <5% quarternary ammonium compounds may be used.
3. Let dry completely before use.

Warning

- Do not sterilize or immerse the sensor or any part of it in liquid.

Replacing the wrap

Gently remove worn wrap. Clean the light source and detector with 60% isopropyl or ethyl alcohol wipe. Place the sensor in a new wrap.

Disposal

Dispose of this product and its packaging in accordance with the local environmental and waste disposal regulations.

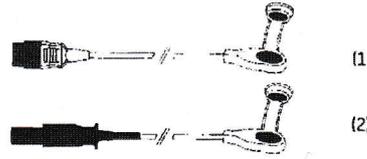
Warnings

- Use this sensor only with patient monitors and interconnect cables compatible with GE Healthcare oximetry. The operator is responsible for checking the compatibility of the monitor, sensor and interconnect cable before use. Incompatible components can result in degraded performance.
- This device is not intended for use in a magnetic resonance imaging (MRI) environment.
- Following types of interference may result in intermittent, inaccurate, or no readings in the pulse oximeter equipment. Ambient light (including photodynamic therapy); physical movement (patient and imposed motion); low perfusion; electromagnetic interference; electrosurgical units; elevated levels of Carboxyhemoglobin (COHb) or Methemoglobin (MetHb); presence of certain dyes; nail polish or artificial nail at the measurement site; misapplied sensor or sensor partially dislodged; inappropriate positioning of the sensor; improper connection to the monitor or interconnect cable; low signal strength; contaminants on the sensor in the optical path; diagnostic testing.
- Inspect the sensor for physical damage. Discard a damaged sensor or cable immediately. Never repair a damaged sensor or cable; never use a sensor or cable repaired by others.
- To avoid damaging the cable when disconnecting, pull from the connector, not the cable. Do not twist or bend the connectors.
- It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.
- Verify that the sensor is properly applied. Due to the sensor shape a loose sensor may affect measurement accuracy and delay a "Probe off" alarm.
- The protection against the effect of the discharge of a cardiac defibrillator is partly in the sensor and cable. Using other than GE Healthcare supplies and accessories might result in an impaired patient protection.
- Strangulation may result from baby or child entanglement in pulse oximeter cables.
- A healthcare professional prescribing the use of this device to home use shall provide sufficient guidance to the home user to operate the product safely and correctly.

TruSignal® SpO₂ Wrap Sensor

REF	TS-W-D (1 m/3.3 ft.)	(1)
	TS-W4-H (4 m/13 ft.)	(2)

Numbers in parentheses refer to numbers in the picture.



Explanation of symbols

REF	Catalog or model number.	Caution, consult accompanying documents.
LOT	Batch or lot number.	Consult instructions for use.
Reusable. May be used with more than one patient.		Manufacturer.
95% 5% Storage humidity.		The package can be recycled.
-40°C -40°F -60°C +140°F Storage temperature.		

Rx Only (USA)

U.S. Federal law restricts this device to sale by or on the order of a physician.

Intended use

The Wrap Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO₂) and pulse rate monitoring. The tape and foam wrap are single-patient use.

Patient weight range ≥ 3 kg (≥ 6.6 pounds)
Application site Finger, toe, palm of the hand, side of the foot

Contraindications

Sensitivity to adhesive tape may cause an allergic reaction.

Instructions for use

Always refer to the Instructions for use of the cable and monitor for additional instructions

1. Monitor compatibility

Use this sensor only with patient monitors and interconnect cables compatible with GE Healthcare oximetry. A complete list of compatible monitors is available from GE Healthcare upon request.

2. Selecting the measurement site (see Figure 1)

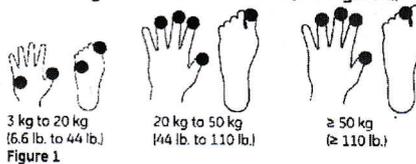


Figure 1

Preferably apply the sensor to:

- A well-perfused site.
- A non-dominant hand or foot.
- For patients weighing 3 kg to 20 kg (6.6 lb. to 44 lb.): close to toes preferred.

3. Applying the sensor (see Figure 2, 3, and 4)

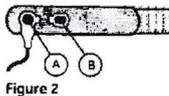


Figure 2

(A) Light source, (B) Detector



Figure 3



Figure 4

Slide the sensor through the slits in the wrap. Alternatively, align the star on the tape with the light source.

Hold the light source against the site:

- Fleshy part of hand or foot.
- Fingernail or toenail.

Wrap the sensor around the site, positioning the detector directly opposite the light source.

Ensure contact between the sensor and site. Do not restrict circulation. To minimize sensor movement, tape the cable to the limb.

Cautions

- Change the sensor site every four hours (more frequently if the perfusion is poor).
- Routinely check the measurement site and change it immediately if there is evidence of blistering, skin erosion, or symptoms of impaired circulation of the site (such as skin discoloration or reddening).
- Do not use a blood pressure cuff or arterial blood pressure measurement device on the same limb as the sensor.

SpO₂ accuracy (A_{max})*

GE Healthcare monitors containing TruTrak / TruTrak+ / TruSignal technology:
70% to 100% SpO₂ ± 2 digits, below 70% unspecified
Other GE Healthcare legacy Datex and Datex-Ohmeda monitors:
70% to 100% SpO₂ ± 3 digits, below 70% unspecified

*Because SpO₂ measurements are statistically distributed only about 2/3 of measurements can be expected to fall within ± 1 A_{max} of the value measured by a CO-oximeter.

Storage temperature: -40°C to +60°C (-40°F to +140°F)
Storage humidity: 5% to 95%

The peak wavelengths of the LEDs in TruSignal sensors are within 600 to 1000 nm and the maximum optical output power for each LED is less than 15 mW. This information can be useful for clinicians performing photodynamic therapy.

Trademarks

Datex®, Ohmeda®, OxyTip®, TruSignal® and TruTrak® are the property of GE Healthcare Finland Oy. All other product names are the property of their respective owners.

Patents

TruSignal SpO₂ sensors are covered by one or more of the following patents: U.S. Patent Nos. 5,827,182; 6,668,183; 6,505,061; 5,919,133; 6,466,809 and international equivalents.

Ordering information

For further information please visit www.gehealthcare.com or contact your local sales company.

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