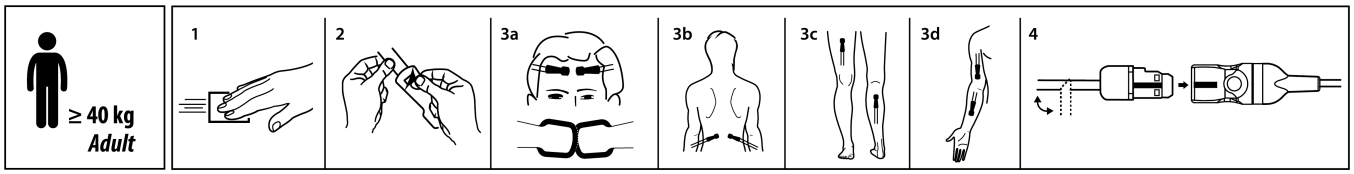
Edwards

ForeSight IQ Large Sensor

FSESLIQ

≥ 40 kg - Adult



Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

1.0 Description

The sensor, when used in combination with the ForeSight oximeter cable is a single use applied part that measures hemoglobin allowing the clinician to continuously and accurately determine absolute levels of blood oxygenation saturation in the tissue (StO_2). This device is supplied non-sterile.

Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions for Use.

The device is used by clinicians who have been trained in the use of tissue oximetry devices in accordance with their institutional policies.

The benefit of using ForeSight sensor is to non-invasively provide tissue oxygen saturation and hemoglobin values to allow clinicians to manage their patients. Potential risks include burns, electrical shock, tissue damage, transient hypoxia, adverse reaction to device materials, and/or inappropriate/unintended treatment.

2.0 Intended Use/Purpose

When used with the HemoSphere Alta advanced monitoring platform in combination with the ForeSight oximeter cable, the intended purpose is to monitor absolute regional hemoglobin oxygen saturation of blood under the sensor.

3.0 Indications for Use

When used in conjunction with the ForeSight oximeter cable:

The ForeSight IQ large sensor is indicated for monitoring of absolute regional hemoglobin oxygen saturation of blood under the sensor in individuals at risk for reduced flow or no-flow ischemic states. It is intended for use on adults and transitional adolescents ≥ 40 kg.

4.0 Contraindications

The sensor is contraindicated for use on patients:

- With a physical site area too limited for proper sensor placement
- With allergic reactions to sensor adhesive
- Undergoing an MRI scan because of associate risk of injury

5.0 Warnings

- **Assess the sensor site at least every 12 hours, or more often as required by the institution's protocol.**
- **Remove the sensor if the circulatory condition or skin integrity has deteriorated.**
- **Do not lay patient on the sensor or cable.**
- **Do not use in an MR environment due to risk of burn as result of sensor heating.**
- **Do not attach the sensor to skin with unapproved devices, such as headbands, hats, etc.**
- **Do not place the sensor or accessories over eyes, nose, or mouth.**
- **Do not cut the sensor. Cutting the sensor can result in injury to the patient.**
- **Do not use in an MRI environment.**
- **When used in settings with LED lighting, sensors should be covered with a light blocker prior to connection to the preamp cable, as some high intensity systems can interfere with the sensor's near infrared light detection.**
- **Failure to remove the protective liner may cause erroneous StO_2 readings.**

6.0 Cautions

- **Avoid positioning the sensor over hair, air sinus, hematomas, or broken skin.**
- **Avoid attaching the sensor to sites with excess adipose, ascites, or edema.**
- **The materials used in the manufacture of the sensor were NOT designed for reuse. Reuse can cause the sensor not to perform as intended.**

7.0 Instructions

Step	Procedure
1	Remove the sensor from the package. Carefully inspect the sensor for damage. Discard and replace if damage is found.
2	Select sensor location on the monitor.
3	Clean and dry the sensor site (1).
4	Remove protective liner from the sensor (2).
5	Apply the sensor to the patient: a) **Cerebral Use** (Fig. 3a): Select the site on the forehead well above the eyebrow and just below the hairline. Do not attach sensor over hair. b) **Somatic Use** (Fig. 3b, 3c, 3d): Select the site that provides ideal access to the desired skeletal muscle tissue, for example: • Biceps (upper arm), brachioradialis (forearm), or deltoid (shoulder). • Quadriceps (upper leg), or gastrocnemius and tibialis (calf). Apply the sensor with the connector towards the feet. • Latissimus dorsi (flank) or external oblique (abdomen). **Note: Somatic monitoring only available with ForeSight oximeter cable software version 4.0.1 or above.** **Note: Do not attach sensor over hair.** **Note: You may use Tegaderm under the sensor in patients with delicate skin or edema.**
6	Insert the sensor connector straight into the sensor cable connector until it snaps into place (Figure 4). Use the bedsheet clip to secure the cable and prevent pulling on the sensor.
7	If needed, fold the sensor flat cable to route it in the desired direction.

For use only with ForeSight oximeter cable software version 2.5.7 or above.

8.0 Disposal

Sensors are designed for single-patient use, and are not to be reprocessed. Re-used sensors present a risk of cross-contamination or infection. Use a new sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies.

9.0 Storage

Store in a cool, dry place.

10.0 Shelf Life

The recommended shelf life is as marked on each package. Storage beyond the expiration date may result in product deterioration and malfunction.

11.0 Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 - Option 4

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Refer to the latest version of the monitoring system operator's manual for more information.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Refer to the symbol legend at the end of this document.

Symbol Legend

	English
#	Model Number
MD	Medical device
SN	Serial Number
LOT	Lot Number
QTY	Quantity
CE 0123	Conformité Européenne (CE Mark)
EC REP	Authorized representative in the European Community/European Union
	Date of manufacture

	English
	Manufacturer
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Use-by date
	Separate collection for electrical and electronic equipment in accordance with EC directive 2012/19/EU
	Follow instructions for use
MR	MR Unsafe

	English
	Fragile, handle with care
NON STERILE	Non-sterile
LATEX	Not made with natural rubber latex
eifu.edwards.com + 1 888 570 4016	Follow instructions for use on the website
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Importer
	Store in a cool, dry place
UDI	Unique device identifier

Note: Not all symbols may be included in the labeling of this product.

Edwards

EC REP

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CE 0123

06/24
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