ForeSight Pediatric Tissue Oximetry System

Setup guide

HemoSphere advanced monitor set up

1. Slide the HemoSphere tissue oximetry module into the monitor.
2. Connect the ForeSight tissue oximetry module cable into the HemoSphere tissue oximetry module *(Figure 1)*.
   Note: ForeSight module LED illuminates green when connected to port A, and blue when connected to port B.
3. Select **Continue Same Patient** or **New Patient**, enter patient data. Select corresponding patient mode. ***Note: Tissue oximetry works in invasive, minimally-invasive and non-invasive modes.***
4. Ensure StO_2 parameter tiles are selected to display tissue oximetry.

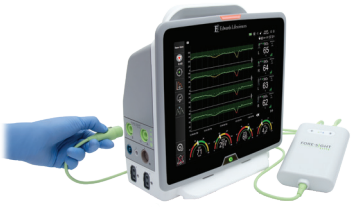


Figure 1

Sensor location setup

1. Touch the patient figure *(Figure 2)* to access **Sensor Location** tab.
2. Ensure correct body location is selected with corresponding sensor channel in **Sensor Location** tab *(Figure 2)*.
3. Sensor channel appears in the upper left of the parameter tile *(Figure 2)*. Select channel. Then select the appropriate StO_2 channel from tile configuration menu *(Figure 3)*.
4. Select the patient monitoring mode:
    adult or  pediatric

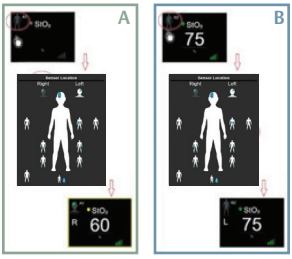


Figure 2

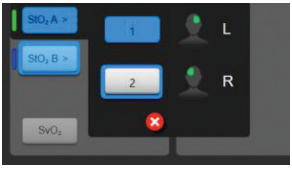


Figure 3

Edwards

Special focus

Pediatric and neonatal sensor selection for 3 – 8 kg pediatric patients

For cerebral use

The selection of the sensor size for patients between 3 kg and 8 kg is determined by the available forehead space.

- Any patient ≥ 3 kg may use medium sensors if anatomy allows
- Cerebral patients < 8 kg use small

Skin check assessment

1. Select parameter tile, then select **Sensor Location** tab.
2. Select **Skin Check Reminder** button for time interval between skin checks notifications.
3. When performing skin check assessment lift the sensor to assess the skin integrity under the sensor. Move sensor if circulatory condition or skin integrity has deteriorated.

Applying the sensors to the patient

1. Remove the sensor from the package. Carefully inspect the sensor for damage.
2. Select appropriate sensor location on the monitor.
3. Clean and dry the sensor site *(Figure 6)*.
4. Remove the protective liner from the sensor *(Figure 7)*.
5. Apply the sensor to the patient: cerebral use *(Figure 8)* and non-cerebral use (Figure 9)*. Do not apply the sensor over hair, air sinuses, hematomas, birthmarks, places with externally applied coloring, or broken skin.
6. Insert the sensor straight into the sensor cable connector until it snaps into place *(Figure 10)*. Use the bedsheet clip on the preamp cable to secure the cable and prevent pulling on the sensor
7. If needed, fold the sensor's flat cable to route the sensor connector in the desired direction *(Figure 10 arrows)*.
8. Lift the sensor and any places where the flat cable contacts skin to assess the skin under the sensor at least every 12 hours, or more often as required by the institution's protocol. Move the sensor to a different site if circulatory condition or the skin integrity has deteriorated.

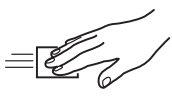
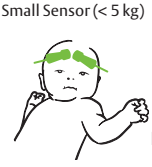


Figure 6

Figure 7



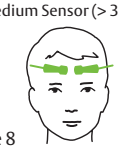


Figure 8

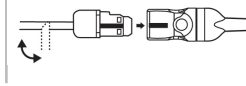
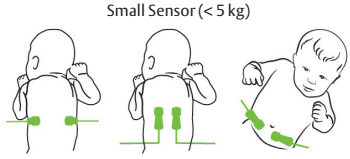


Figure 10



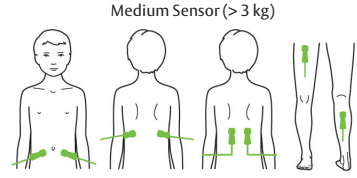


Figure 9

* Do not use small sensor on a leg muscle.

Note: You may use Tegaderm between the sensor and skin in patients with delicate skin. Using when edema is present may result in poor signal quality and error messages.

Parameter tile area (Figure 4)

1. **StO_2** reading displays current StO_2% level (a).
2. **Sensor Location** displays location and side of body sensor is placed (b).
3. **Channel Location** displays which channel each sensor is connected (c).
4. **Parameter** displays which parameter is being monitored (d).
5. **Reference Value** displays the reference value from timepoint which menu selection is made (e).
6. **Signal Quality Indicator** displays the quality of the signal (f).

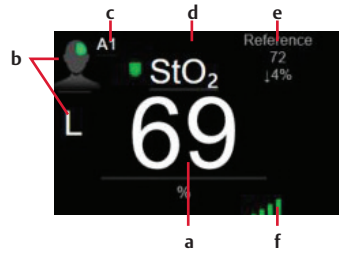


Figure 4

Display reference value

1. Select parameter tile, then select **Intervals/Averaging** tab *(Figure 5)*.
2. Select **Change Interval** tab and select **Reference.**
3. Select **% Changed** or **Value Difference** in **Change Display** button.

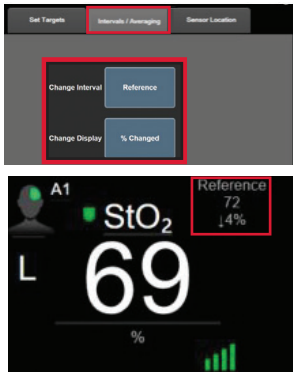


Figure 5

Selecting the appropriate sensor

When selecting a sensor, stay within the Indications for Use for the corresponding patient weight.

Small: cerebral - pediatric patients < 8 kg; non-cerebral - pediatric patients < 5 kg

Non-adhesive small: cerebral - pediatric patients < 8 kg; non-cerebral - pediatric patients < 5 kg

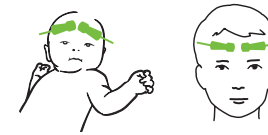
Medium: cerebral and non-cerebral - pediatric patients ≥ 3 kg

Large: cerebral and non-cerebral - adults and transitional adolescents ≥ 40 kg

Note: The monitor will prompt the user to switch the patient mode if a sensor is connected that conflicts with the current patient mode.

Recommended sensor placement for cerebral monitoring

As sufficient forehead space allows, it is recommended to place the largest sensor available as guided by the Indications for Use. Place sensors symmetrically across forehead as close to hairline as possible.

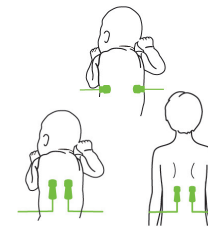


Recommended sensor placements for non-cerebral monitoring

Flank: Most commonly used to detect the oxygenation of tissue near the kidneys. Neither the light source nor the far detector should be higher than the lowest rib, as air from the lungs could impair the readings. May be placed either horizontally or vertically (per clinician's discretion)

a. **Option 1:** Horizontal (perpendicular to spine) – placed on either side of the spine. Place below 12th rib and above the iliac crest. Avoid curvature of sensor around side of patient.

b. **Option 2:** Vertical (parallel to spine) – placed on either side of the spine. This placement follows the vertical orientation of the kidneys. The left back is preferred to avoid monitoring over the liver region. Route the sensor lead and connector beyond the side of the patient to avoid pressure-induced skin injury.



Note: The sensor flat cable may be folded to facilitate positioning of the connector away from the patient.

Abdomen: Most commonly used to monitor the oxygenation of the tissue over the intestines. Can be placed on either side (more commonly on left) below the umbilicus. This position allows the user to avoid the liver (right upper abdomen) and bladder (immediate suprapubic) area.

Note: The sensor flat cable may be folded to facilitate positioning of the connector away from the patient.

Messages	Condition	Recommended action
High ambient light	External high intensity light is interfering with the sensor's detection, sensor with opaque material.	Verify sensor is well-adhered to the patient's skin. If present, move external light source away from sensor site. Cover the sensor with opaque material.
Sensor over temp	Internal sensor temperature is too high; the sensor will deactivate, and StO_2 is not displayed.	Determine source of extraneous heat. If possible, move external heat source away from sensor site or cover to shield from heat source.
Signal out of range	TPI symbol may show one or no bar. Tissue under sensor may have birth marks, edema, hematoma, scar tissue, low perfusion.	Verify that sensor is well adhered to patient's skin. Move sensor to a location where SQI is 3 or 4. In the case of edema, remove the sensor until tissue condition returns to normal. Replace large sensor with medium or small sensor in pediatric patients (< 18 years of age).
Stool interference high	The sensor is interrogating primarily stool.	This condition may be transient while stool moves through the bowel. If persistent, move the sensor to a new location.
Incorrect sensor size	The sensor is incompatible with the body location or patient mode.	Change either the body location, patient mode or sensor size.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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