

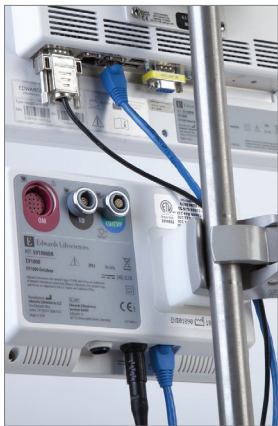


Edwards PediaSat Oximetry Catheter Edwards Oximetry Central Venous Catheter EV1000 Clinical Platform

Setup guide

Oximetry setup

1. Press the **Power on**  button on the panel.
2. When the system boot up process is complete, enter new patient data (patient ID, gender, age, height, and weight) or continue same patient.
3. If entering new patient data, use the touch screen to select and enter values. Press **Home**  button to continue.



EV1000 clinical platform
monitor and EV1000 clinical
platform databox



EV1000 clinical platform touch
screen for entering patient data

Oximetry catheter

If catheter is already in place, skip to next section (EV1000 clinical platform monitor calibration)

1. Connect the optical module cable (A) to the oximetry color-coded connection port (B) on the back of the EV1000 clinical platform databox. Allow several minutes for optical module to warm up, or until *in vivo/in vitro* buttons are active.
2. Open side 1 of the oximetry catheter tray, exposing only the optics connection (C), and remove optics connection, being careful not to contaminate tray contents in side 2.
3. Connect the oximetry catheter to the optical module, matching "TOP" (D) on both the optical module and the optics connection.



Optical module cable (A)



EV1000 clinical platform databox color-coded connection port (B)



Optics connection in side 1 of oximetry catheter tray (C)



Optical module "TOP" (D)

EV1000 clinical platform monitor calibration

1. On the EV1000 clinical platform touch screen menu, touch **Clinical Actions**.
2. Touch **Oximetry Calibration**.
3. Use *In vitro* calibration if the catheter has not been inserted into the patient yet.



EV1000 clinical platform monitor Clinical Actions touch screen

***In vitro* Calibration** (if catheter has not been inserted yet)

1. Select **ScvO₂** or **SvO₂**.
2. Touch ***In vitro* Calibration**.
3. Touch **HGB** (hemoglobin) OR **Hct** (hematocrit), and enter the lab value if available or else use default values.
4. Select **Calibrate**. Calibration is complete in 20 seconds.
5. When ***In vitro* Calibration OK** message appears, insert catheter.
6. Touch **Start**. Catheter is ready in 25 seconds.

***In vivo* Calibration** (performed after catheter has been inserted)

1. Touch ***In vivo* Calibration**. Baseline setup is complete in 25 seconds.
2. Touch **Draw**, then withdraw the blood sample slowly and send sample to lab for analysis.
3. Upon receipt of lab values, enter **HGB** (hemoglobin) OR **Hct** (hematocrit), and **ScvO₂** values.
4. Touch **Calibrate**. Catheter is ready in 25 seconds.

EV1000 clinical platform monitor

How to move data during and after patient transfer

Patient data and system calibration information can be transferred with the patient via the optical module. With the PediaSat oximetry catheter or Edwards oximetry central venous catheter (CVC) connected to the optical module, unplug the optical module from the EV1000 clinical platform databox. Do not disconnect the catheter from the optical module. Once the patient has been transferred, reconnect the optical module to the EV1000 clinical platform databox.

1. On the EV1000 clinical platform touch screen menu, touch **Clinical Actions**.
2. Touch **Oximetry Calibration**.
3. Select **Recall OM Data**.
4. The calibration data in the optical module is displayed if the data is less than 24 hours old. Select **Yes** to recall data from optical module or select **No** to perform an *in vivo* calibration. If the optical module data is more than 24 hours old, the data cannot be recalled and a new calibration must be performed.

NOTE: Keep the date and time of all EV1000 clinical platform monitors current. If the date and/or time of the EV1000 clinical platform monitor being transported "from" differ from the EV1000 clinical platform monitor being transported "to," then the 24-hour test may not work properly.

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences 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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