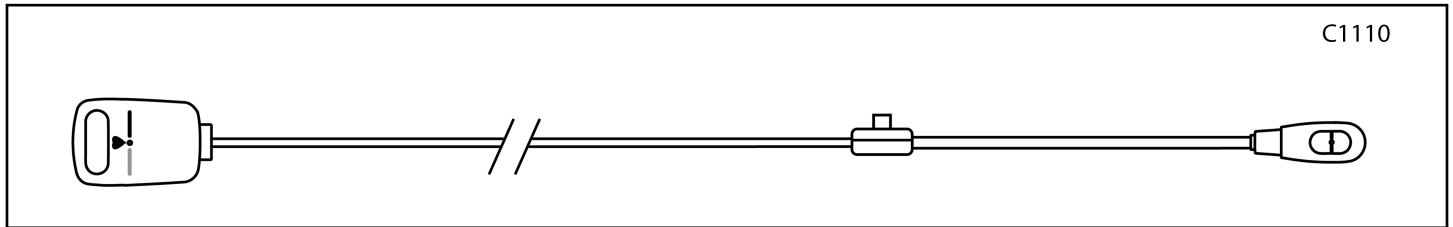




Edwards

Heart Reference Sensor (HRS)

EVHRS



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

1.0 Description

The heart reference sensor (also referred to as 'HRS') can be used with the EV1000 clinical platform NI and HemoSphere advanced monitoring platform to noninvasively measure blood pressure and key hemodynamic parameters using a compatible Edwards finger cuff(s) wrapped around the finger. When using this method it is necessary to use a heart reference sensor, which compensates the hydrostatic pressure changes due to difference in height between the finger and heart. The heart reference sensor is a non-serviceable part.

2.0 Intended Use

The heart reference sensor is intended for use with a compatible Edwards noninvasive monitoring system - composed of compatible monitor, pressure source (pump), heart reference sensor, compatible Edwards finger cuff(s) and pressure controller - for noninvasive measurement of blood pressure and associated hemodynamic parameters. Refer to the operator's manual of the compatible Edwards monitor being used for specific information on the intended use environment and patient population.

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.

3.0 Instructions for Use

Refer to the operator's manual of the compatible Edwards monitor for instructions for use.

CAUTION: Do not use a damaged heart reference sensor. This may result in inaccurate measurements or may damage the EV1000 clinical platform NI or HemoSphere advanced monitoring platform.

4.0 Cleaning Instructions

The heart reference sensor can be cleaned using the following disinfectants:

- 70% isopropyl alcohol solution
- 10% sodium hypochlorite water solution

Step	Procedure
1	Moisten a clean cloth with disinfectant and wipe the surfaces.
2	Dry the surface with a clean, dry cloth.

WARNING: Do not disinfect the heart reference sensor by autoclave or gas sterilization.

CAUTION: Do not immerse the heart reference sensor.

CAUTION: Do not immerse any cable connectors in fluid.

CAUTION: Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

CAUTION: Clean and store the heart reference sensor after each use.

5.0 Preventive Maintenance

The finger component of the heart reference sensor may be damaged if subjected to moderate to significant surface impact. Although the likelihood of damage is small, the resulting displayed values would be biased by the difference in height from the heart to the finger cuff. Even though this damage cannot be seen by looking at the heart reference sensor, it is possible to confirm whether the damage has occurred by following the below procedure prior to each use:

Step	Procedure
1	Connect the heart reference sensor to the port on compatible Edwards noninvasive monitoring system and go to the zeroing screen.
2	As instructed in the Instructions for Use section, bring the two ends of the heart reference sensor level with each other.
3	Observe the value shown on the zeroing screen.
4	Raise one end of the heart reference sensor 6 inches (15 cm) above the other end.
5	Observe that the value shown has changed by at least 5 mmHg.
6	Reverse the ends such that the other end is now 6 inches (15 cm) above the first end.
7	Observe the value shown changed in the opposite direction by at least 5 mmHg from the original value.

If the value does not change as described, then the heart reference sensor may have been damaged. Contact your local Technical Support office as indicated in the Technical Assistance section. A replacement unit shall be provided. If the value does change, the heart reference sensor is functioning normally and can be used for hemodynamic monitoring.

6.0 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

This document is subject to change without prior notice. Refer to the latest version of the EV1000 clinical platform NI or HemoSphere advanced monitoring platform operator's manual for additional 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.

Symbol Legend

English	
	Model Number
	Serial Number
	Quantity
	Use-by date
	Conformité Européenne (CE Mark)
	Authorized representative in the European Community/European Union
	Manufacturer
	Follow instructions for use

English	
	Follow instructions for use on the website
	Separate collection for electrical and electronic equipment in accordance with EC Directive 2012/19/EU
	Importer
	Caution
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Unsafe
	Fragile, handle with care

English	
	Medical device
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use
	Unique device identifier
	Store in a cool, dry place
	Environment-friendly use period (EFUP) - China only
	Restriction of hazardous substances (RoHS) – China only

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



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