

Warranty

Embla warrants the sensor to be free of defects in materials and workmanship for a period of fourteen months from the date purchased. The sole liability of Embla and our distributors is limited to replacement or repair of the product at the option of Embla, with no charge for parts or labor if any part is proven to be defective in workmanship, performance, or materials during the warranty period. Under no circumstances shall Embla or our distributors be liable for any loss of revenues or damage, direct, consequential, or incidental, including loss of profit, property damage, or personal injury arising from the use of, or the inability to use this product. This warranty is intended for the original buyer and is in lieu of all other warranties or previous agreements, expressed or implied. This warranty is rendered void if the product is used for other than its intended purpose or is subject to abuse, misuse, tampering, neglect or unauthorized modifications. Use of this product constitutes acceptance of this warranty in total.

Trademarks

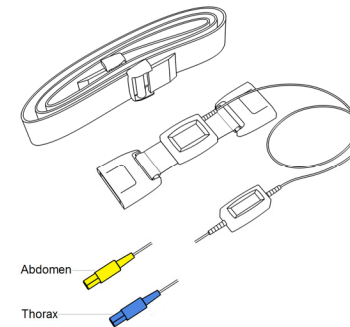
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For assistance, please contact Embla Technical Support (support@embla.com).

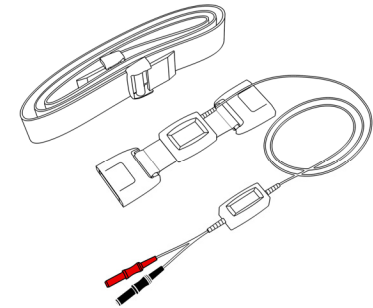


Piezo Respiratory Effort Kit Instructions

Embla Piezo Respiratory Effort sensors collect data related to thoracic and abdominal respiratory effort during a sleep study and transfers this data to a compatible sleep recorder. When attached to a VELCRO® brand faster, the Piezo crystal is stressed through the respiratory movements of the chest and abdominal wall. Stretching causes the Piezo crystal to produce a small voltage signal that is conditioned to provide a respiratory effort signal.



*Piezo Respiratory Effort Kit – Abdomen
(Order Code 1421101)
Piezo Respiratory Effort Kit – Thorax
(Order Code 1421100)*



*Piezo Respiratory Effort Kit – 1.5mm Connector
(Order Code 1421102)*

The Piezo Respiratory Effort Kits consist of a Piezo respiratory effort sensor encased in a molded box with plastic buckles extending on both sides, and a Velcro elastic strap for attaching the sensor to the patient.



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Three Piezo Respiratory Effort Kits are available for purchase online from shopEmbla (www.shopembla.com) or from a local Embla distributor:

• **Piezo Respiratory Effort Kit – Abdomen (Order Code: 1421101)** Measures abdominal effort. For use with Embla N7000 and S7000™ (with Z10 proxy only) and Embletta® (with Z10 or Z20 proxy) devices. Connects to the yellow sensor input on the proxy.

• **Piezo Respiratory Effort Kit – Thorax (Order Code: 1421100)** Measures thoracic effort. For use with Embla N7000 and S7000 (with Z10 proxy only) and Embletta (with Z10 or Z20 proxy) devices. Connects to the blue sensor input on the proxy.

• **Piezo Respiratory Effort Kit – 1.5mm Connector (Order Code: 1421102)** Measures thoracic and abdominal effort. Connects to the following units when plugged into their bipolar ports:
S4500, S4000
N7000, S7000
Embla titanium™

Because Z-series proxies are no longer available, it is recommended that XactTrace™ belts are used with the amplifiers listed above.

Warnings

- The Velcro straps are intended to be worn over nightclothes.
- Do not stretch the straps too tightly around the patient as this may cause discomfort.
- This product is for diagnostic purposes only and is not to be used as an apnea monitor.
- Federal law restricts this device to the sale by or on the order of a physician.
- Do not use damaged sensors or accessories.
- Caution must be taken to ensure that cables do not encircle the patient's neck. Special attention is needed in the case of children.
- Do not use the equipment in an MRI environment.

Piezo Respiratory Effort Kit Instructions

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MANUFACTURER	DISTRIBUTOR	EUROPEAN REPRESENTATIVE
S.L.P., Ltd.	Embla Systems	Natus Europe GmbH
62 Anilevitz Street	1 Hines Road, Suite 202	Robert-Koch-Str. 1
Tel Aviv, 67060	Kanata, ON K2K 3C7	82152 Planegg
Israel	Canada	Germany
Tel: 972.3.6870640	Tel: +1.613.254.8877	Tel: +49 089 83942-0
Fax: 972.3.5371282	Fax: +1.613.270.0627	Fax: +49 089 83942-777

TOLL-FREE IN NORTH AMERICA: 888 NO APNEA (888.662.7632)

www.embla.com ● support@embla.com ● sale@embla.com

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Notes:

Certifications



The Piezo Respiratory Effort kit is certified to carry the CE mark. The CE mark is a declaration that the Piezo Respirator Effort kit is in compliance with the directive for medical devices set forth by the European Union.

The Embla Quality Management System complies with EN ISO 13485-2003.

Embla certifies that the development, manufacture, sales, and service of the Piezo Respiratory Effort Kit is in conformity with Annex II of the Directive 93/42/EEC on medical devices.

Attaching the Piezo Respiratory Effort Sensor

Piezo respiratory effort sensors are attached to Velcro straps and are intended to be worn over the patient's nightclothes.

To attach the sensor to the patient:

1. Fasten a strap clip to one of the buckles on the Piezo sensor.
2. Wrap the strap around the patient's chest or abdomen and fasten the other clip to the other buckle on the Piezo sensor.
3. Pull the strap to adjust for a comfortable fit. The belt should fit snugly but not uncomfortably tight. Grasp the buckle of the sensor in one hand during adjustment to minimize the tension applied directly to the sensor.



Placing the thoracic sensor in the center of the patient's breasts is not recommended. Moving the sensor slightly off center can avoid artifacts associated with obese or large-breasted patients.



When unplugging the belts, grasp the molded ends of the connectors.

Cleaning

The Piezo respiratory sensor can be wiped clean with hospital grade laundry detergent and dried with a clean, dry cloth. Care should be taken to avoid contact of the cleaning solution with the connectors. For sterilization, a standard procedure for gas sterilization should be implemented. Do not autoclave.

The Velcro straps can be machine washed in the gentle cycle or hand washed in a warm solution of hospital grade laundry detergent and then air dried.



To ensure patient safety, dry the entire assembly completely before each use.

Technical Specifications

The following table outlines technical specifications for Piezo Respiratory Effort Kit components.

Description	Properties
Piezo Sensor	2.8cm (1.1") x 2.3cm (0.9"); 7mm (0.28") in thickness
Sensor Wire	Two white conductors; Three different lengths: • Piezo Respiratory Effort Kit – Abdomen: 70cm (27.5") • Piezo Respiratory Effort Kit – Thorax: 40cm (15.7") • Piezo Respiratory Effort Kit 1.5mm connector: 200cm (79")
Filter Settings	• High Pass: 0.2Hz • Low Pass: 3Hz
Connectors	• Piezo Respiratory Effort Kit – Abdomen: Yellow 249 connector, 2 pole, 1mm female • Piezo Respiratory Effort Kit – Thorax: Blue 249 connector, 2 pole, 1mm female • Piezo Respiratory Effort Kit 1.5mm connector: Two 1.5mm touch proof connectors

Description	Properties
Signal Output	• Piezo Respiratory Effort Kit – Abdomen/Thorax: Normal Breath 0.1-0.3mV @ 200gr pull, 0.5Hz • Piezo Respiratory Effort Kit 1.5mm connector: Normal Breath 1-3mV @ 200gr pull, 0.5Hz
Output Impedance	Approximately 2MΩ
Velcro Straps	Black VELSTRETCH® Band – 2.5cm (1") wide, 150cm (59") long