



Single Use XactTrace™ Belt System User Instructions

The Single Use XactTrace belt system is used during sleep studies to acquire and transfer data related to thoracic and abdominal respiratory effort to a compatible sleep recorder.

This document describes how to use the Single Use XactTrace belt system and includes information on intended use, warnings and cautions, system components, adjusting and attaching the belts, storage and cleaning.

Intended Use

The Single Use XactTrace belt system measures respiratory effort to assist in the diagnosis of sleep disorders or sleep related respiratory disorders. The respiratory effort signals measured are processed to provide electrical signals suitable for the inputs of physiological recording equipment.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments. The Single Use XactTrace belt system is intended for diagnostic purposes only and is not intended to be used as an apnea monitor. Use the Single Use XactTrace belt system only under the direction and supervision of a physician or trained technologist.

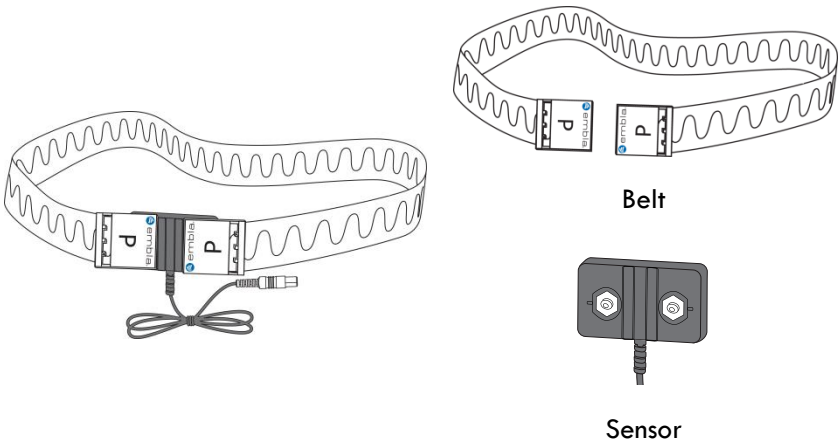
Warnings and Cautions

- The belts are intended to be worn over the patient's nightclothes.
- The belts are single use.
- Do not stretch the belts too tightly around the patient as this may cause discomfort
- Caution must be taken to ensure that cables do not encircle the patient's neck. Special attention is needed in the case of children.

- Use the device only under the direction and supervision of a physician or trained technologist.
- Avoid all unnecessary contact with moisture when using the device.
- Do not use damaged belts, sensors or cables.
- Caution: U.S. Federal law restricts this device to sale by, or on the order of, a physician.
- Portable and mobile RF communications can affect the performance of the device.
- Electrostatic discharges (ESD) may cause artifacts in the signal from the device. A trained operator should be able to recognize these artifacts easily. Avoid conditions where electrostatic charge can build up due to low humidity and friction against carpets, clothing, and sheets made from artificial fibers.

System Components

The system consists of a belt and a snap sensor with a cable that connects directly to an input on the recording device. The system converts changes in inductance to a digital signal that provides both qualitative and quantitative information on respiratory effort.



Attaching the Single Use XactTrace System

The belts are intended to be worn over nightclothes and should fit the patient snugly without being uncomfortably tight. Avoid all unnecessary contact with moisture when using the Single Use XactTrace belt system.



Note: Do not use two thorax sensors or two abdomen sensors in the same recording. Using two sensors of the same type will cause interference between the sensors and could result in poor signal quality.

Choosing a Belt Size

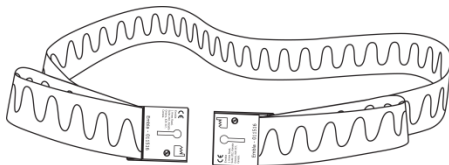
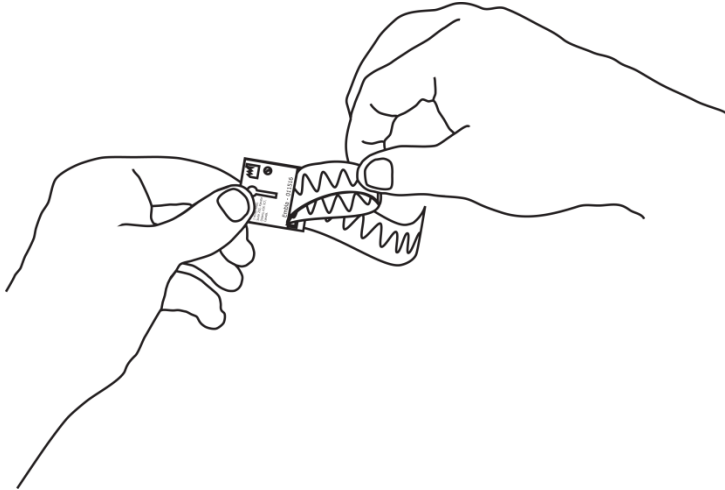
The Single Use XactTrace belts come in four sizes: Large, Medium, Small and Pediatric. The length of the belt size can be adjusted to ensure a good fit. The belts should fit the patient snugly without being uncomfortable tight. Measure the patient's circumference and use the table below as a guideline. The belts are single use.

XactTrace Belt Sizes

	Full Size		Reduced Size	
	cm	Inches	cm	Inches
Large	127 - 190	50 - 75	102 - 165	40 - 65
Medium	96 - 140	38 - 55	76 - 119	30 - 47
Small	61 - 89	24 - 35	40 - 69	16 - 27
Pediatric	35 - 56	14 - 22	28 - 48	11 - 19

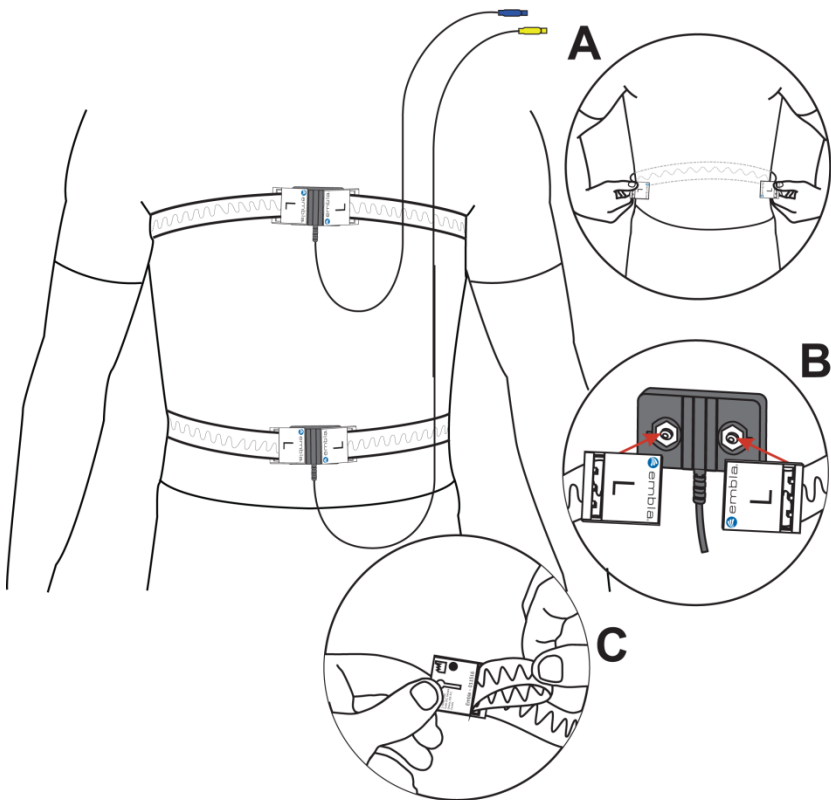
Adjusting the Belt Size

Adjust the belt by sliding the loop buckles on each end to maintain a snug fit around the patient circumference.



Attaching the Belts to the Patient

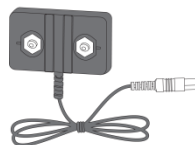
1. Encircle the belt around the patient chest and secure the snap ends of the belt to the buckle with the “blue” connector as shown in the figure below. The belt should fit snugly without being uncomfortably tight.
2. Prepare the abdomen belt in the same manner, only this time, fit the belt around the patients stomach and attached the snap ends of the belt to the buckle with the “yellow” connector.
3. Connect the abdominal (yellow) and the thoracic (blue) XactTrace connectors to the appropriate color-coded inputs on the recording device.



Storage

Proper storage extends the life of the Single Use XactTrace belt system. To prevent damage, do the following when storing the sensor and belts between studies.

- The belts are single use and should not be used for more than one study.
- Do not wrap the cable around the sensor.



Cleaning

No part of the Single Use XactTrace belt system requires sterilization. If desired, wipe the sensor and cables with a hospital grade cleaner that is not corrosive to plastic or metal, and then dry with a clean, dry cloth. Do not immerse the sensor in liquid and avoid contact of the cleaning solution with the connectors.

Labeling Definitions



The manufacture date is adjacent to this symbol.



This symbol indicates that the item should not be reused and is intended for a single-use only.

Maintenance

No special maintenance of the Single Use XactTrace belt system is required.

Materials List

Category	Properties
Belt	Elastic belt W=25,WHITE,TERYLENE,WITH WIRE,UL1571 #28,WHITE
Cable	CONN,2P+FLAT CABLE,NONULN#24(46/0.08)*2C,BLACK
Snaps	SCREW,M3,THREAD L=3.2,L=8.8,D=2.95,D=4.6
Over-molding	PVC,45P,WHITE,UL94V-0

Warranty

Embla warrants the sensor to be free of defects in materials and workmanship for 6 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 anything 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.

Certifications



The Single Use XactTrace system is certified to carry the CE mark. The CE mark is a declaration that the Single Use XactTrace system is in compliance with the essential requirements set forth by the European Union for medical devices.

The Embla Quality Management System complies with EN ISO 13485:2003. The Single Use XactTrace system is manufactured by Embla.

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Applies to the Single Use XactTrace system.

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