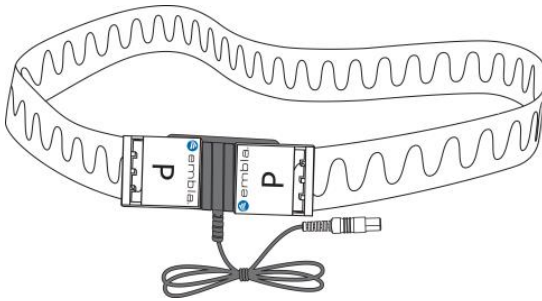


XactTrace[®] Single Use Pre-Sized Belt System User Instructions



The Single Use Pre-Sized XactTrace belt system (XactTrace belts) 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 XactTrace belts and includes information on intended use, warnings and cautions, system components, adjusting and attaching the belts, storage and cleaning.

Intended Use

The XactTrace[®] Single Use Respiratory Effort Belt System is intended to measure 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 connection to the inputs of physiological recording equipment.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

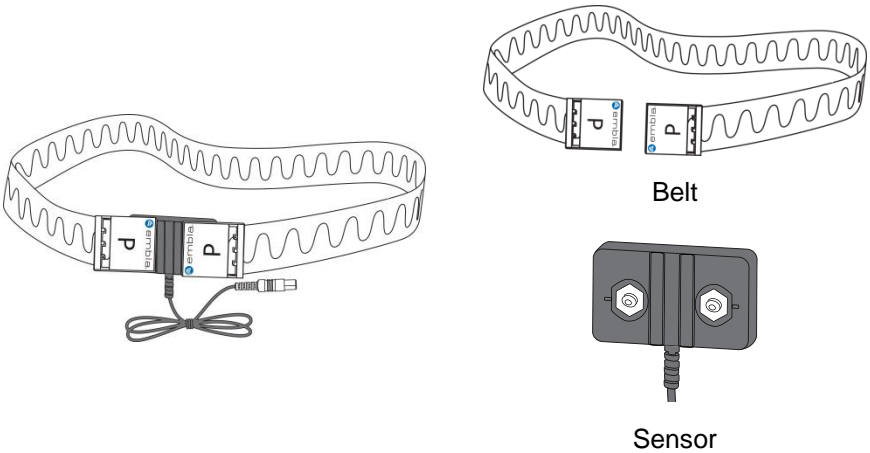
The XactTrace® Single Use Respiratory Effort Belt System is intended for diagnostics purposes only and is not intended to be used as an apnea monitor.

Warnings and Cautions

- XactTrace belts shall be worn over the patient's clothing. 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.
- This product is for diagnostic purposes only, and is not to be used as an apnea monitor.
- Do not use the device in an explosive environment—in other words, in the presence of flammable liquids, such as an anesthetic mixture with air, or with oxygen or nitrous oxide.
- Connect the XactTrace belts only to an input that is electrically isolated from the mains power. Do not plug the cables into electrical outlets, as this could result in serious electrical shock.
- 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.
- Universal applications require an external inductive interface cable which contains a battery; therefore, it must be disposed of properly. Local, state, or national laws might prohibit disposal of batteries in ordinary trash. Contact your local waste authority for information regarding available recycling and disposable options.

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. An optional inductive interface cable can be purchased to interface the locks with most PSG systems that accept the 1.5mm female touchproof connectors.



Fitting the XactTrace Belts

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 XactTrace belts.



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

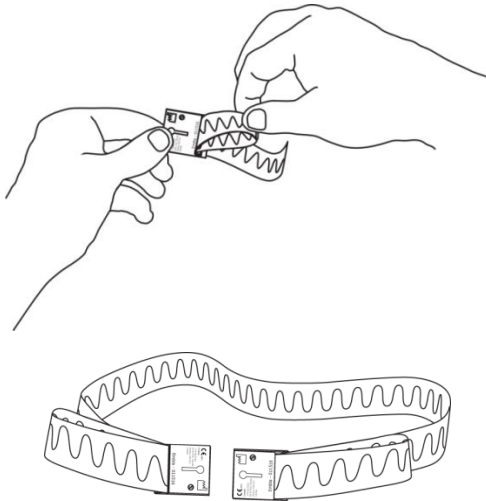
The XactTrace belts come in four sizes: Large, Medium, Small and Pediatric. The length of the belt size can be adjusted to ensure a good fit. The belts should fit the patient snugly without being uncomfortably tight. Measure the patient's circumference and use the table below as a guideline. The belts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

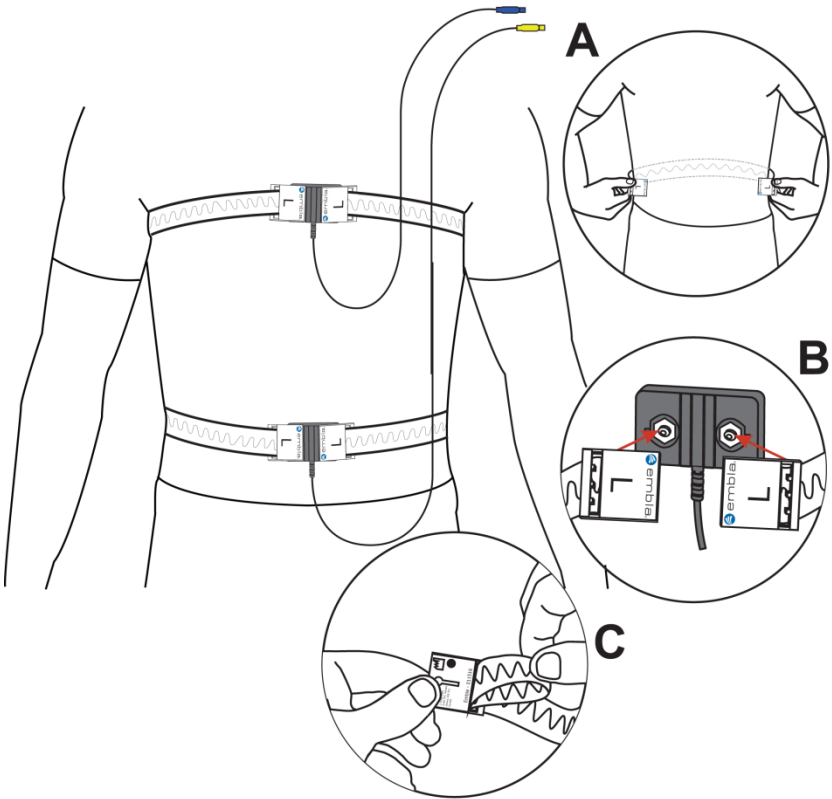
Adjusting the Belt Size

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

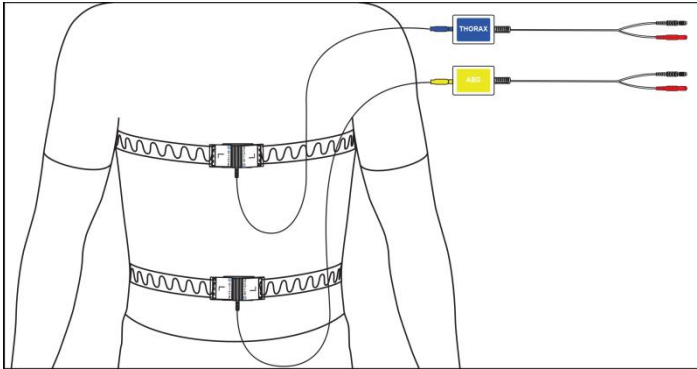


Attaching the Belts to the Patient

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 belt connectors to the appropriate color-coded inputs on the recording device.



- External inductive interface cables are required only with non-Embla amplifiers, referred to as “universal” applications. When using the inductive interface cables, insert the connector from the Chest belt into the processor module labeled THORAX, and then insert the connector from the Abdomen belt into the processor module labeled ABD. Both the Thorax (blue) and Abdomen (yellow) belt locks and inductive interface cable labels are color coded for easy identification and connection.



- Plug the thorax and the abdomen module outputs into the appropriate bipolar inputs on your polygraph. The red touch-proof plugs into (+) input, and the black plugs into (-) input.

User Settings

User settings are described below.

- Sensitivity** – Adjustment of the sensitivity up or down is typically required. Response is dependent upon variables, such as sensor application and patient effort.
- Low Frequency Filter / Time Constant** – 0.03 Hz (or 5 seconds or longer)
- High Frequency Filter** – 15 to 35 Hz.



Note: Shorter time constants or higher low frequency filter settings significantly attenuate waveforms.

Technical Specifications

See the table below for technical specifications for the XactTrace belts.

Physical Properties		
Belt	Length:	Pre-Sized lengths – Based on sizing chart found under Fitting the XactTrace Belts .
	Material:	Elastic belt W=25,WHITE,TERYLENE,WITH WIRE,UL1571 #28,WHITE
Cable	Length:	16 inches (41 cm) – Thorax 26 inches (66 cm) – Abdomen or 78 inches (200 cm) – Thorax/Abdomen
	Material:	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
Cable Extension (Optional)	Length:	78 inches (200 cm)
	Material:	PVC jacketed; zip-style cord
Inductive Interface Cable (Optional)	Box:	ABS
	Cable:	PVC jacketed; zip-style cord

Environmental Specifications		
Temperature	Operation:	40°F to 120°F (+5°C to +50°C)
	Storage:	0°F to 120°F (-18°C to +50°C)
Relative Humidity	Operation:	15 to 95% (non-condensing)
	Storage:	10 to 95% (non-condensing)
Pressure	Withstands atmospheric pressures from 7.3 psi to 29 psi	
Output Specifications (Inductive Interface Cable):		
Output Signal	Maximum signal amplitude:	< 2mV
	Frequency Range:	0.2 to 3 Hz
	Sensitivity:	Approximately 50µV/mm

Hardware Compatibility

Keyhole Connectors	Embla N7000	
	Embla S4500	
	Embletta MPR System	
	Natus Embla NDx/SDx, Natus Brain Monitor	
1.5mm Touch Proof Connections	Compatible with Amplifiers that meet the following input requirements <ul style="list-style-type: none"> • Can receive 1.5 mm touch proof connectors • Channel input range > 3mV • Amplifier filter characteristics that allows the following frequency range to pass • Signals from 0.2Hz to 3Hz 	

Storage

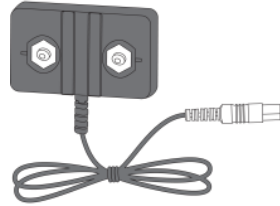
Proper storage extends the life of the XactTrace belts. To prevent damage, do the following when storing the sensor and belts between studies.

- The belts are single use and should not be used for more than one study.

- Do not wrap the cable around the sensor.



Incorrect



Correct

Cleaning

Wipe the snap sensor and inductive interface cables (if used) clean with a moist cloth containing hospital-grade laundry detergent, and dry with a clean, dry cloth. Take care to avoid contacting the sensor connector and plug of the snap sensors or processor modules with the cleaning solution. The snap sensors and inductive interface cables (if used) do not require sterilization.

The belts should be discarded after use, and do not require cleaning.

Labeling Definitions



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

Maintenance

No special maintenance of the XactTrace belts is required.

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.

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