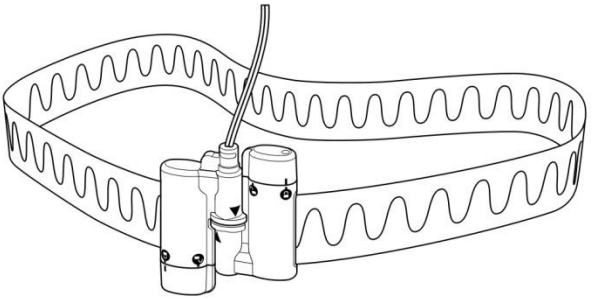
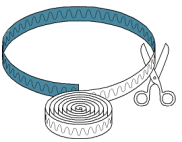
Universal–Single Use XactTrace™ Instructions



The Universal-Single Use XactTrace Respiratory Inductive Plethysmogragh (RIP) sensor belt is a respiratory effort sensor used in the diagnosis of sleep disordered breathing. XactTrace measures changes in inductance, and converts it into a digital signal that gives both qualitative and quantitative data. This sensor is more sensitive and reliable than typical respiratory effort sensors, especially in cases of paradoxical breathing. The Universal-Single Use XactTrace belts consist of a belt roll that can be cut to appropriate lengths for each patient and two Belt Locks for the abdomen and thoracic regions.

Fitting the XactTrace Belts

The XactTrace belts must be custom fit for each patient. When using the XactTrace belts, avoid all unnecessary contact with moisture.



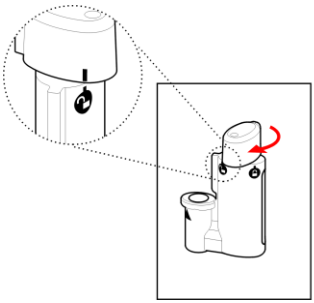
1. Encircle the belt around the patient's chest under the arm to approximate the

circumference for the thoracic belt.

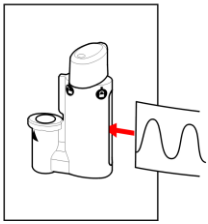
2. When cutting the belt, reduce its circumference by 10-15cm (4-6 in) so it stretches around the thorax. The belt should fit snugly to prevent slippage during the study. It is important to use sharp scissors for a clean cut.

   The wire should not exceed the end of the belt.

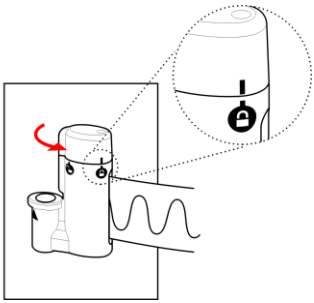
3. Secure the cut ends of the belt into the Belt Lock with the blue connector according to the following steps:



Twist the top end of the Belt Lock clockwise to open the catch. The white mark on the top should match the open lock symbol on the catch.



Insert the cut end of the belt into the catch. Make sure to insert the end all the way to the bottom of the catch.



Twist the top end of the Belt Lock counter-clockwise to close the catch. When the white mark on the top matches the closed lock symbol on the catch, the Belt Lock is properly closed.

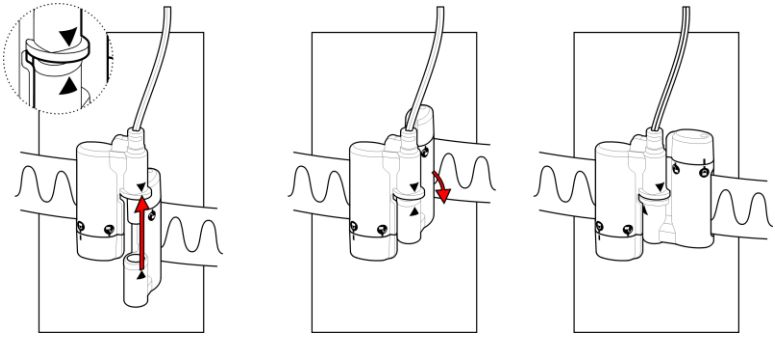
4. Prepare the abdominal belt in the same manner, only this time, fit the belt around the patient's stomach at the navel, and use the Belt Lock with the yellow connector.

Attaching the XactTrace Belts

The XactTrace belts are intended to be worn over the patient's nightclothes.

1. Place the belt with the yellow connector around the patient's stomach, at the navel.

2. Take the two components of the Belt Lock and connect them, as shown below.

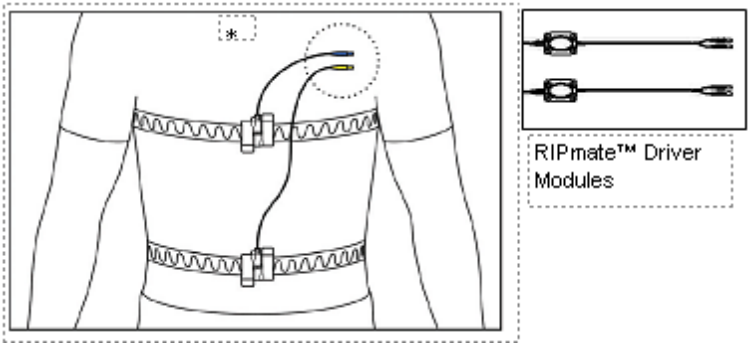


3. Place the second belt with the blue connector around the patient's chest, under the arm.

4. Connect the second Belt Lock as shown above.

5. Insert the connector from the Chest belt into the driver module labeled Thorax (* in the following drawing).

6. Insert the connector from the Abdomen belt into the driver module labeled Abdomen.



7. Plug the thorax module output into the appropriate bipolar input of your polygraph. The red touch-proof plugs into (+) input, and the black plugs into (-) input.

8. Plug the thorax module output into the appropriate bipolar input of your polygraph.

Note: Do not use two abdomen or two thorax modules in the same recording. This causes interference between the two sensors, resulting in bad signals.

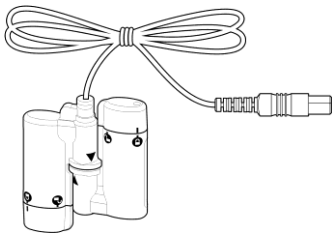
Storage

Proper storage of the XactTrace Belt Locks between recordings is important.
To protect the sensor cable from damage, do not wrap it tightly around the Belt Lock, as it might cause the cable to break where it connects to the Lock.

- Do not wrap the wires around the Belt Locks, as it may cause the wire
  to break.

- To save battery power, the modules MUST be disconnected from the Belt Locks when not in use.

Incorrect



Correct

Cleaning and Disposal

Wipe the Driver Modules and Belt Locks clean with a moist cloth in hospital-grade laundry detergent, then dry them with a clean, dry cloth. Take care to avoid contact of the cleaning solution with the sensor connector and plug of the Belt Lock. The Belt Lock does not require sterilization.

The belts do not need cleaning, as they should be discarded after use.

Warnings

See the list of warnings below.

- Do not stretch the belts too tightly around the patient, as this may cause discomfort. To prevent the belt from slipping during the study, fix the position with medical tape.
- The belts shall be worn over night clothes.
- This product is for diagnostic purposes only, and is not to be used as an apnea monitor.
- Take care not to cut any cables when cutting the belts.
- Do not use damaged sensors or accessories.
- Be certain that cables or sensors do not encircle the patient's neck.
- Do not use the equipment in a magnetic resonance imaging (MRI) environment.
- Do not use the device in an explosive environment—in other words, in the presence of flammable liquids, such as aesthetic mixture with air, or with oxygen or nitrous oxide.
- Connect the XactTrace sensors to an electrically isolated input only. Do not plug the cables into electrical outlets, as this could result in serious electrical shock.
- The device 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.
- Portable and mobile radio frequency (RF) communications can affect the performance of the device.

Single Use – Universal XactTrace 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 – 0.16 Hz (or 1 second or longer)
- Shorter time constants or higher low frequency filter settings significantly attenuate waveforms.
- High Frequency Filter – 15 to 35 Hz.

Technical Specifications

See the table below for technical specifications for the Single Use – Universal XactTrace.

Physical Properties	
Belt	Length: Roll of 35 yards, cut to fit each patient. Material: Elastic band with wire.
Cable	Length: 80 inches (205 cm) Material: PVC jacketed; zip-style cord
Module	Box: ABS Cable: PVC jacketed; zip-style cord
Power	
Battery	Non-replaceable lithium coin cell battery. Nominal operation time: 2000 hours (approximately 250 eight hour studies) The battery is activated once the sensor module is connected to the belt.

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	
Output Signal	Maximum signal amplitude: +/- 5mV Frequency Range: 0.2 to 3 Hz Sensitivity: Approximately 50µV/mm

Certifications

CE 0413

The Universal Single-Use XactTrace system is certified to carry the CE mark. The CE mark is a declaration that the Universal 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 Universal XactTrace system is manufactured by Embla.

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