# XactTrace® Single Use Cut-to-Fit Respiratory Effort System Instructions
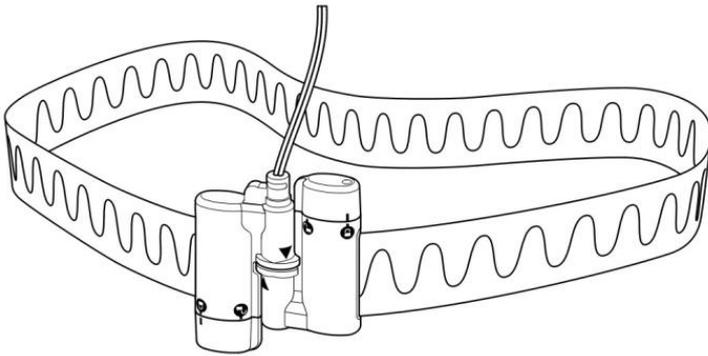
The XactTrace Single Use Cut-to-Fit Respiratory Effort System (XactTrace belts) is a respiratory effort sensor used in the diagnosis of sleep disordered breathing. The XactTrace Respiratory Inductive Plethysmograph (RIP) sensor measures changes in inductance, and converts it into a digital signal that gives both qualitative and quantitative data. This sensor is more sensitive and reliable than typical respiratory effort sensors, especially in cases of paradoxical breathing.

## 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.

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.
- Take care not to cut any cables when cutting the belts.
- Do not overtighten the belt locks. Over-tightening the belt lock could sever the belt or result in impaired signal quality.
- 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 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 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 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.    An optional RIP Processor can be purchased to interface the locks with most PSG systems that accept the 1.5mm female touchproof connectors.
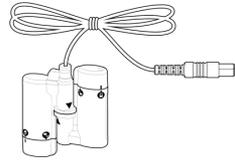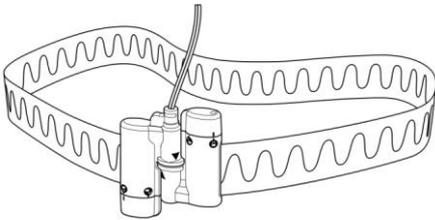
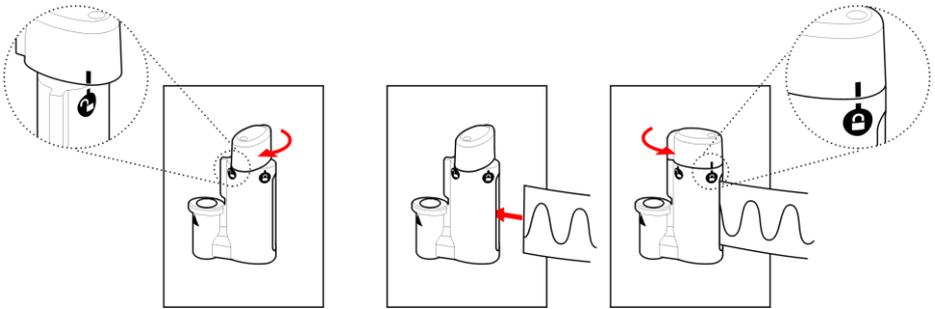

Lock



Belt Material

# Fitting the XactTrace Belts

The XactTrace belts must be custom fitted 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. |

⚠ **Warning:** Do **NOT** tighten the belt locks beyond the closed lock symbol printed on the unit. Over-tightening the belt lock could sever the belt or result in impaired signal quality.

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 to the Patient

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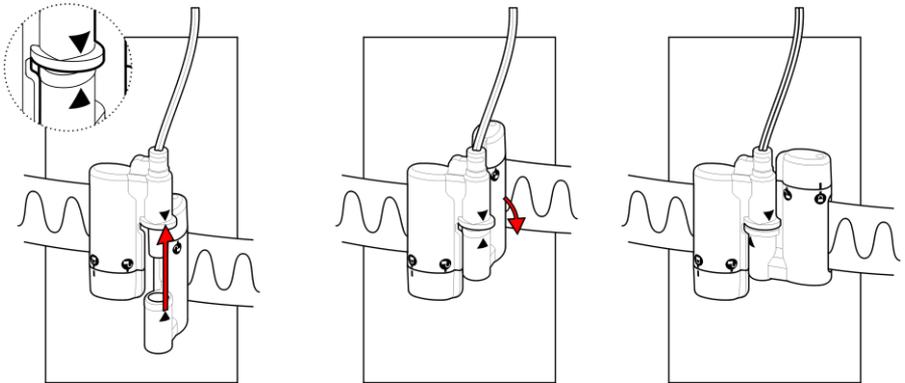
3. Place the second belt with the blue connector around the patient's chest, under the arm.

4. Connect the second belt lock as shown above.

5. External inductive interface cable modules 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.
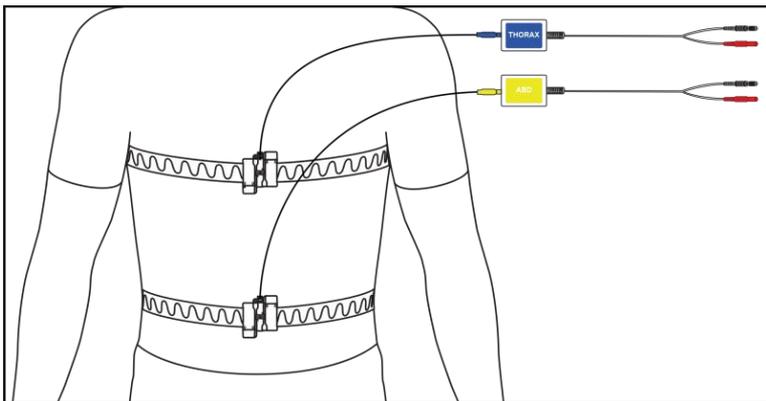


6. Plug the thorax and the abdomen module outputs into the appropriate bipolar inputs on your polygraph. The red touch-proof plugs into (+) input, and the black plugs into (-) input.

> **Note:** Do **NOT** use two abdomen or two thorax modules in the same recording. This can cause interference between the two sensors, which can result in unusable signals.

# 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: | Roll of 65.5 feet (20m), cut to fit each patient. |
| | Material: | Elastic band with wire. |
| Cable | Length: | 27.5 inches (70 cm) or15.7 inches (40 cm) |
| | Material: | PVC jacketed; zip-style cord |
| 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 |

| 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 (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><li>Can receive 1.5 mm touch proof connectors</li><li>Channel input range > 3mV</li><li>Amplifier filter characteristics that allows the following frequency range to pass</li><li>Signals from 0.2Hz to 3Hz</li></ul> |

# 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 cables around the belt locks, as it may cause the wire to break due to excessive strain on the cable.
- To save battery power, the modules MUST be disconnected from the belt locks when not in use.
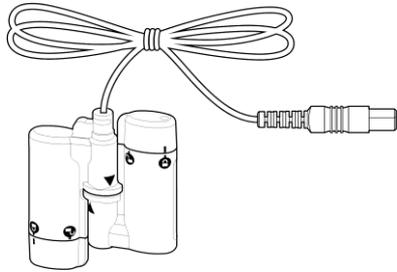


Incorrect                                        Correct

# Cleaning and Disposal

Wipe the belt locks and inductive interface cable (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 belt locks or processor modules with the cleaning solution. The belt lock and inductive interface cable modules (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

Natus warrants the sensor to be free of defects in materials and workmanship for 12 months from the date purchased. The sole liability of Natus and our distributors is limited to replacement or repair of the product at the option of Natus, 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 Natus 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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Printed in China

|REF| 022744, Rev. 03

Issued in March 2019.

For assistance, please contact Embla Technical Support (Ottawa.TechSupport@natus.com).

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REF: 022744, Rev. 03