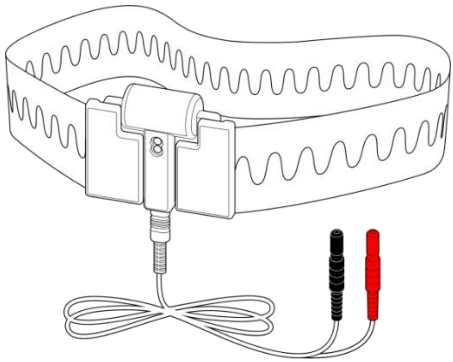
Universal XactTrace® User Instructions



The Universal XactTrace 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 Universal XactTrace system and includes information on intended use, warnings and cautions, system components, adjusting and attaching the belts, battery status, storage, cleaning, disposal, appropriate equipment to use with the system, and technical specifications.

Intended Use

The Universal XactTrace 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 Universal XactTrace system is intended for diagnostic purposes only and is not intended to be used as an apnea monitor. Use the Universal XactTrace system only under the direction and supervision of a physician or trained technologist.

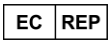
Essential Performance

In normal operational mode, essential performance is defined as the following:

- Output signals may contain electrical artifacts which are distinguishable to a medical professional and must self-recover after test. The signal can hesitate or freeze under immunity testing, as long as it recovers after stimulus is removed, with no net change in the signal.

Description of Symbols

Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.4.4	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60601-1 Table D.1 #10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.		
	N/A	N/A	Note	A note that contains important supplemental information
	IEC 60601-1 Table D.2 #10	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	Follow Instructions for Use	Refer to instruction manual/Booklet. NOTE on ME EQUIPMENT “Follow Instructions for use”.
	ISO 15223-1 Symbol 5.4.3	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Consult Instruction for Use	Indicates an instruction to consult an electronic instruction for use
	ISO 15223-1 Symbol 5.1.3	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Date of manufacture	Indicates the date when the medical device was manufactured.

Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1 Symbol 5.1.11	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Country of Origin	Indicates the country of origin.
	ISO 15223-1 Symbol 5.1.1	Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Legal Manufacturer	Indicates the medical device manufacturer.
	UK MDR 2002	UKCA Mark	UKCA Mark	Signifies Great Britain (England, Wales, and Scotland) conformity. UK Approved Body number appears under symbol.
	ISO 15223-1 Symbol 5.1.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	Swiss Medical Device Ordinance (MedDO)	Swiss Authorized Representative	Swiss authorized representative	Indicates the Authorized representative in Switzerland.
	Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 as applicable	Council Directive 93/42/EEC Regulation (EU) 2017/745	CE Marking of Conformity	Signifies European technical conformity. Notified body number appears under symbol if applicable.
	IEC 60601-1 Table D.1 #20 IEC 60417 Symbol 5333	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	TYPE BF APPLIED PART	Identifies a type BF applied part complying with IEC 60601-1.
	Based on ISO 15223-1, Annex B Negation of Symbol 5.4.5	Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Not made with natural rubber latex	Indicates the absence of natural rubber latex as a material of construction within the medical device or the packaging of a medical device.

Symbol	Standard Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	N/A	NA	N/A	Hand wash only
	N/A	NA	N/A	Do not tumble dry
	Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)	Disposal at end of operating life instructions	Indicates that electrical and electronic equipment waste should not be discarded together with unseparated waste but must be collected separately.
Rx only	21 CFR 801.109(b)(1)	Labeling-Prescription devices	Device is cleared for the US market as requiring a prescription	Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1 Symbol 5.1.8	Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Importer	Indicates the entity importing the medical device into the locale.
	ISO 15223-1 Symbol 5.1.9	Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Distributor	Indicates the entity distributing the medical device into the locale.

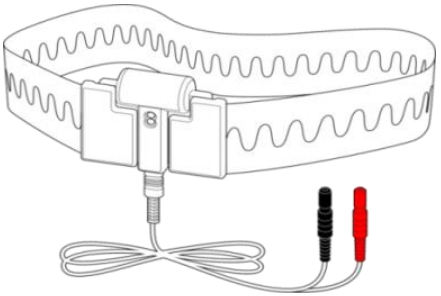
⚠ Warnings and Cautions

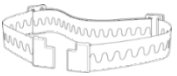
- XactTrace shall be worn over the patient's clothing.
- Do not stretch the belts too tightly around the patient as this may cause discomfort. To prevent the belt from slipping during the night, fix the position of the belt with medical tape.
- Caution must be taken to ensure that cables do not encircle 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 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 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 cables to patient inputs of medical physiological recording equipment that complies with IEC60601-1, type CF or BF.
- The device contains a battery and must be disposed of properly. Local, state, or national laws may prohibit disposal of batteries in ordinary trash. Contact your local waste authority for information regarding available recycling and disposal options.
- The device has no user serviceable parts and must be serviced by Embla and authorized parties only. Warranty void if opened. Contact Natus Technical Support (Ottawa.TechSupport@natus.com) for more information.
- The device is not defibrillator proof.
- As a result of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care and other environments, high levels of interference, due to close proximity or strength of the source, may disrupt the performance of the device. For these reasons, special precaution regarding electromagnetic compatibility (EMC) is needed when the device is installed and put into service.
- Use of cables with this equipment other than those specified or sold by the manufacturer may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2.
- 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 because of low humidity and friction against carpets, clothing, and sheets made from artificial fibers.

System Components

The Universal Kit – Complete (p/n 1421091) includes two XactTrace Universal belts (p/n 1421040), two XactTrace Universal respiratory effort sensors (p/n 1421026 for abdomen and p/n 1421027 for thorax) that measures inductance changes in the belt, and the XactTrace Universal cable (p/n 1451080) that connects the sensor directly to an input on the recording device. The system converts changes in inductance to an analog signal that provides both qualitative and quantitative information on respiratory effort.





Belt

Sensor

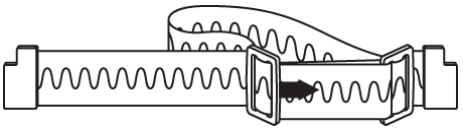
Bipolar Cable

Adjusting the Belt Size

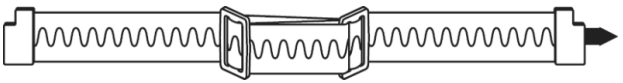
Adjust the belt by sliding the adjustment buckles together or apart to fit a patient circumference of 65–200 cm (26–78 in).

To lengthen the belt:

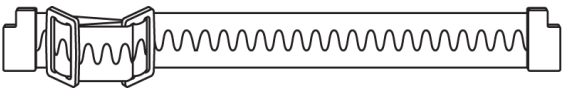
1. Slide the left adjustment buckle toward the center of the belt. A loop forms as shown.



2. To tighten the loop, hold the left end of the belt while pulling the right end. Keep the adjustment buckles in a central position with equal distance between the belt ends and adjustment buckles.

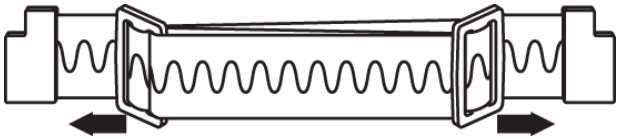


Note: Avoid sliding the adjustment buckles to the same end of the belt. This will make readjustment more difficult.



To shorten the belt:

- Slide the adjustment buckles apart, toward the belt ends.



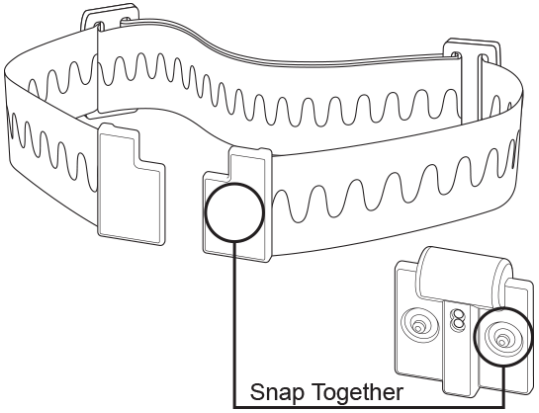
Attaching the Universal XactTrace System

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 Universal XactTrace system.

To attach the XactTrace belt to the patient:

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.

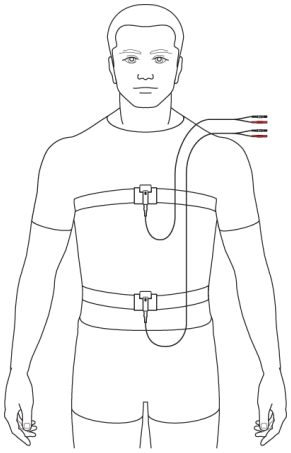
1. Connect a cable to the abdomen sensor (labeled Abdomen) and another cable to the thorax sensor (labeled Thorax).
2. Roughly estimate the abdominal and chest circumference of the patient, and adjust the belt sizes accordingly.
3. For each belt, snap one end of the belt to the sensor, as shown.



4. Place the abdominal belt around the patient's abdomen, and snap the other end of the belt to the sensor. Repeat with the thoracic belt around the

patient's chest. If a green light illuminates for a few seconds, the battery is sufficiently charged.

5. Using the adjustment buckles, adjust the belts so they fit the patient snugly.
6. Connect the cables to the appropriate inputs on the recording device. Plug the red and black connectors into the positive (+) and negative (-) inputs, respectively.



Proper placement of the Universal XactTrace system

Battery Status

The battery-operated sensor turns on when snapped to both ends of the belt. When the sensor turns on, the lights located on the front side of the belt lock illuminate for a few seconds to indicate the battery status.

- **Green light.** The battery is sufficiently charged.
- **Yellow light.** The battery charge is low and will be depleted in less than 10 studies.
- **No light.** Replace the sensor before performing a study.

Note: The battery cannot be replaced. Disconnect the sensor from the belt before storing the system.

Storage

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

- Hang the belt and cable on a hook. Do not fold the belt or wrap the cable around the sensor.
- To save battery power, disconnect the sensor from the belt when not in use.

Cleaning

No part of the Universal XactTrace system requires sterilization.

- **Sensor and Cables.** Wipe clean 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.
- **Belts.** Hand wash in a warm (not hot) solution of hospital grade laundry detergent, and then air dry.

Disposal

According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the WEEE may not be disposed of as unsorted municipal waste. Return the WEEE (Universal XactTrace sensor) to the Embla European Representative (see last page for contact information).

The sensor contains a lithium battery and must be disposed of properly. Local, state, or national laws may prohibit disposal of batteries in ordinary waste bins. Contact your local waste authority for information regarding available recycling and disposal options.

User Settings for Recording Equipment

XactTrace should be connected to recording equipment bipolar channels with a full-scale range of ±6 mV or similar. User settings for patient-connected input channels of the recording/monitoring equipment to which the Universal XactTrace connects are described below.

- Low Frequency Filter – 0.1 Hz
- High Frequency Filter – 15 Hz
- Sampling Rate (minimum recommended) – 25 Hz

Maintenance

No special maintenance of the Universal XactTrace system is required.

Technical Specifications

Description		Properties
Power	Battery	Non replaceable Li-SOCl2 type ER14250. Nominal operation time 2000 hours (approximately 250 eight-hour studies).
Environmental Specifications	Temperature	Operation: +5°C to +41º ºC (40°F to 106º F) Storage: -18°C to +48ºC (0°F to 120º F)
	Relative Humidity	Operation: 15–95% (non-condensing) Storage: 10–95% (non-condensing)
	Pressure	Withstands atmospheric pressures from 0.5–1.06 bar
Output Specifications	Output Signal	Maximum signal amplitude: ±5.6 mV; tolerance of ±2 mV Frequency range: 0.05–5.0 Hz Sensitivity: 4.7 mV/% circumference-change; tolerance of ±1 mV/% Noise level: < 20 µVpp Nominal signal amplitude: ±1.5 mV; tolerance of ±0.4 mV

Materials List

Category	Properties
Power	Non replaceable Li-SOCl2 type ER14250. Nominal operation time 2000 hours.

Category	Properties
Belt	Cotton with nylon-covered elastics and insulated wire. Does not contain natural rubber latex.
Sensor Element	Printed circuit board with components and battery
Sensor Housing	Thermoplastic elastomers (TPE)
Cable	Two-lead unshielded cable with tinsel wires; terminated at the recorder end with standard 1.5mm medical touchproof connectors and at the sensor belt end with a two-pin, 1mm medical safety touchproof (keyhole) female plug.
Snaps	Nickel-coated spring steel. Nickel is non-touchable during the intended use.
Over-molding	Thermoplastic elastomers (TPE)

Safety & Standards Conformity

Description		Properties
Classification	Type	Internally powered equipment
	Mode of Operation	Continuous
	Degree of Safety	Equipment not suitable for use in presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.
	Ingress of Liquids	Equipment classified as ordinary equipment regarding ingress of liquids; that is, it is not drip-proof, splash-proof or watertight.

Connect the Universal XactTrace only to recording/monitoring equipment with patient-connected input channels that comply with IEC60601-1, type CF or BF.

Safety Standards

This device complies with the following electrical safety standards:

- IEC 60601-1:Ed. 3.1 - General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-6:Ed. 3.1 – Collateral Standard: Usability

EMC Standards

- IEC 60601-1-2:Ed. 4.0 - Electromagnetic Disturbances – Requirements and Tests

Table 1 – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions
The **Universal XactTrace Belt** is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **Universal XactTrace Belt** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Universal XactTrace Belt is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Table 4 – Immunity Test Levels – Enclosure Port

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels – Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	See “Enclosure Port Immunity to RF Wireless Communications Equipment” Table below
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz

Table 8 – Immunity Test Levels – Signal Input / Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels – Professional Healthcare Facility Environment
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5,500						
5,						

Warranty

Embla® warrants the sensor to be free of defects in materials and workmanship for one year 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.

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

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MANUFACTURER

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle Oakville,
Ontario L6H 5S1 Canada
Tel : 613-254-8877
Fax : 716-200-1091

EUROPEAN REPRESENTATIVE

EC REP
Natus Manufacturing Limited
IDA Business Park
Gort Co. Galway, Ireland

Tel.: +353-(0)91-647400
Fax: +353-(0)91-630050

UK CA 0086
UK Responsible Person
Natus Nicolet UK Ltd
Baynards Green Trading Estate
Prospect House
Oxfordshire
Bicester
OX27 7SG
England, United Kingdom

CH REP
Arazy Group Switzerland GmbH
Bruderholzallee 53
4059 Basel
Switzerland
swiss.ar@arazygroup.com

1-888-662-7632 www.natus.com Ottawa.TechSupport@natus.com