Embla® S4500™

Clinical Manual

Embla S4500 Clinical Manual

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The Embla S4500 is manufactured by Cogent Technologies in the United Kingdom for Embla Systems Inc.

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Contents

About This Manual

This clinical manual is intended for all users of the Embla S4500 system. It is assumed that users have a basic knowledge of the Windows environment, working with a mouse, using toolbars, and arranging windows. Sections typically begin with an overview and description of main features, followed by instructions in simple action steps.

Embla's Knowledge Base contains helpful articles, product information, and information on the study of sleep. Access this resource at www.embla.com/support/knowbase.

For more information on any Embla product feature, or for technical support, please contact Embla Technical Support (support@embla.com).

About the Embla S4500 System

The Embla S4500 system is a full polysomnography (PSG) system used to perform online sleep studies in the sleep lab, hospital or clinical environment, under the supervision of a clinician or sleep technician.

The Embla S4500 system integrates advanced digital technology and precision engineering into a flexible, rugged, full polysomnography network. Featuring an Ethernet network connection, the system is simple to assemble, with cables streamlined for comfort and reliability.

Building on the proven convenience and quality of the Embla S4000 System, the S4500 system has 13 referential channels, 5 bipolar channels, an extensive set of respiratory data channels as well as auxiliary inputs and digital serial ports for additional devices such as CPAP and CO2 machines.

The Embla S4500 system can be used with Rembrandt and RemLogic.

Safety and Regulatory Information

Before using the Embla S4500 system, please read this clinical manual carefully, paying particular attention to the caution or warning that appears with each safety symbol.

Caution:

The CAUTION notice denotes a potential hazard. It calls attention to an operating procedure, practice, or the like, which, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a CAUTION notice until the indicated conditions are fully understood and met.

Warning:

The WARNING notice denotes a hazard. It calls attention to a procedure, practice, or the like, that, if not correctly performed or adhered to, could result in personal injury. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

Warnings, Cautions and Contraindications

Warnings and Cautions

The following warnings and cautions are applicable to the Embla S4500:

- The Embla S4500 is NOT TO BE USED FOR CONTINUOUS MONITORING where failure to operate can cause injuries or death of the patient.
- The system must not be used for direct cardiac application.
- Caution: U.S. Federal law restricts this system to sale by, or on the order of, a physician.
- No user serviceable parts inside. Serviced by Embla and authorized parties only. Warranty void if opened.
- The contact of liquids with the internal parts and connectors of the Embla should be avoided at all times. The system is neither water resistant, drip-proof nor splash-proof and the cleaning instructions in this manual need to be strictly adhered to.
- Do not use the Embla S4500 system in an MRI environment.
- Do not use the Embla S4500 device in an explosive environment, that is, in the presence of flammable liquids or gases.
- The system is not defibrillator proof.
- Caution must be taken to ensure that cables do not encircle the patient's neck. Special attention is needed in the case of children.
- The Embla S4500 system does not increase the safety risk for pacemaker patients as long as the pacemakers comply with the EN50061 standard of electrical safety of medical devices. Nevertheless, it is not advisable to do an impedance test on pacemaker patients since it might cause the pacemaker to switch to the interference mode. Prior to using the system with pacemaker patients, the operator should consult the pacemaker's accompanying documents regarding its certifications and requirements of use or, if necessary, contact the producer.

- Use only with sensors and electrodes provided by Embla or with sensors that have been validated by Embla. Use of other sensors with this device may impair the signal quality and device performance. Contact Embla Technical Support (support@embla.com) for an updated catalog of sensors and electrodes that may be used with the device.
- The Embla S4500 complies with the international standard IEC60601-1-2 for electromagnetic compatibility for medical electrical equipment. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of source might disrupt the device's performance. For these reasons, special precaution regarding EMC is needed when the device is installed and put into service.
- Portable and mobile RF communications can affect the performance of the Embla S4500 system.
- The Embla S4500 system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- Electrostatic discharges (ESD) may cause artifacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity and friction against carpets, clothing and sheets made from artificial fibers
- The operator must be trained to be able to recognize the difference between a valid bio-signal and signal artifacts caused by subject movements, RF disturbances or misplacement of sensors or electrodes.
- Before starting data acquisition with the system, always check the device profile and patient information in the Embla PSG software application.
- Always inspect the equipment, particularly the cables and connectors, for evidence of wear before each study. If evidence of wear is found, remove the worn equipment from use and contact Embla Technical Support (support@embla.com) for replacement or servicing.

Intended Use

The Embla S4500 system is intended for use by a physician or trained technician for the acquisition of Electroencephalogram (EEG) and polysomnography (PSG) signals and their transmission to a PC during neurophysiologic or sleep examinations. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

The use of the Embla S4500 system does not involve any patient monitoring or diagnosis.

Certifications

The following certifications are applicable to the Embla S4500:

CE 0413	The Embla S4500 is certified to carry the CE mark. The CE mark is a declaration that Embla is in compliance with the directive set forth by the European Union for medical devices.
ETL LISTED CONFORMS TO UL STD 2601-1 2001907 CERTIFIED TO CAN/CSA STD C22.2 NO. 601.1	The ETL mark is a safety symbol which shows that the product has been independently tested and certified to applicable U.S. and Canadian product safety standards.
ACN 003 765 142	The C-Tick mark indicates that the product complies with the applicable EMC standard and establishes a traceable link between the product and the supplier responsible for placing it on the Australian market.
	The Embla Quality Management System complies with EN ISO 9001:2000 and EN ISO 13485:2003.
	Embla certifies that the development, manufacture, sales, and service of the Embla is in conformity with Annex II of the Directive 93/42/EEC on medical devices.

Classifications

The following classifications are applicable to the Embla S4500:

The Embla S4500 is classified as Class II device.

Electric shock: According to the degree of protection against electric shock the Embla is classified as of type BF.

Ingress of liquids: The Embla S4500 is classified as an ordinary equipment regarding ingress of liquids, that is, it is not drip-proof, splash-proof or watertight.

Degree of Safety: The Embla 4500 is not suitable for use in presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.

Mode of operation: Continuous.

Where you see this symbol on any device label, it means *"Attention: consult accompanying documentation"*.

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. The Embla S4500 should be returned to Embla when it is ready to be disposed of. Contact Embla at support@embla.com for more information.

Where you see this symbol on the device, it means that the date of manufacture is indicated adjacent to this symbol.

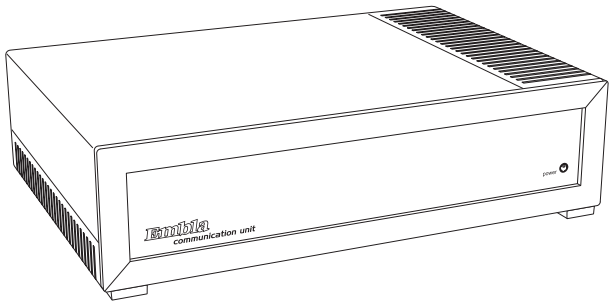
System Components

The Embla S4500 system is composed of two subunits that are connected together: the Communication Unit and the Bedside Unit (also known as the Physiological Unit). The enclosure of the Bedside Unit is connected to a bracket that holds the unit in place. The systems are connected to a remote standard commercial personal computer through Ethernet/LAN. The recording data is stored on the personal computer where viewing, reviewing and analysis of the data can be done in the application software used.

Communication Unit

About the Communication Unit

The Communication Unit supplies the power to the Bedside Unit and communicates between the Embla S4500 and an acquisition computer over a Local Area Network (LAN). It has additional inputs for external devices such as a CPAP, and functions in part as a patient isolation unit, preventing a direct electrical connection between the patient and the external devices connected to the system.



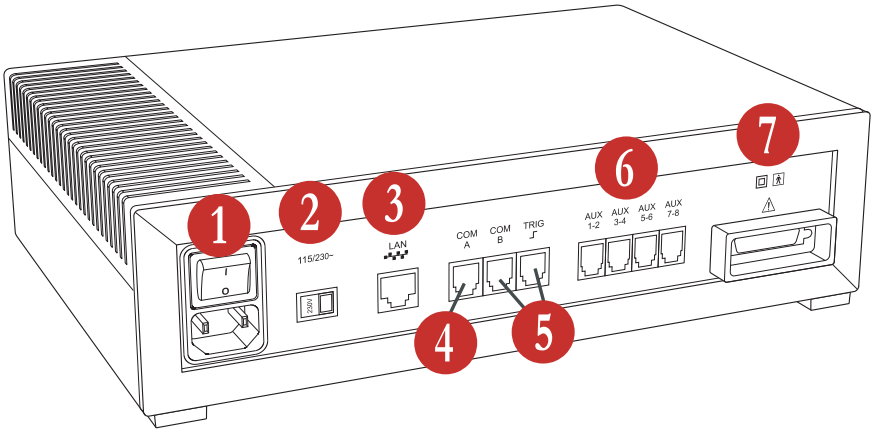
Communication Unit (front view)

Four plastic fasteners are supplied with the system that can be used to secure the Communication Unit to a wall. *See Mounting the Communication Unit for more information.*

The unit front panel features a power indicator light (labeled "power") which is green when the unit is turned on.

Rear Panel

The following figure shows the location of the rear panel components on the Embla S4500 Communication Unit:



Communication Unit (rear view)

Table 1 lists and describes the Communication Unit rear panel components and symbols.

Table 1: Communication Unit Rear Panel Components and Symbols

	Item	Description
1	**Mains power supply**	Includes an on/off switch and a mains power input.
2	**Voltage selector switch (115/230V~)**	Determines the voltage used.
3	**LAN Port**	Communication port to the LAN. The required network connection is twisted-pair (TP) Ethernet.
4	**COM A & COM B**	Serial ports intended for use with supported devices with digital outputs, such as a CPAP or CO2 devices. Contact Embla at support@embla.com for information on which external devices can be connected to these ports.
5	**TRIG**	Trigger input/output port. Intended for use with photic stimulators or other devices requiring a trigger interface. The Trigger input/output is only supported by the Embla N7000 system.

6	**AUX 1-8**	There are four dual channel auxiliary inputs on the rear panel. These inputs can each read 2 channels (8 total) and support devices that output analog signals.
7	**Unit Interface**	This connection communicates with and supplies power to the other units in the system.
		Class II power supply. Double isolation.
		Type BF applied part.
		**Attention:** consult accompanying documents.
		Where you see this symbol on the device, it means that the date of manufacture is indicated adjacent to this symbol.

Warning:

The Communication Unit is delivered with the appropriate default voltage setting. Ensure the voltage selector switch is correctly set before turning the unit on.

Warning:

The use of auxiliary devices compatibility-tested by Embla is recommended. Contact Embla technical support (support@embla.com) for information on which external devices can be connected to the Communication Unit inputs. When installing an auxiliary device ensure the tracing from the auxiliary input represents the same value observed on the display of the auxiliary device. Consult the auxiliary device clinical manual for applicable calibration routines.

Communication Unit Cables

Table 2 lists and describes cables used with the communication unit.

Caution:

⚠ Always inspect the equipment, particularly the cables and connectors, for evidence of wear before each study. If evidence of wear is found, remove the worn equipment from use and contact Embla Technical Support for replacement or servicing.

Table 2: Communication Unit Cables

Cable	Description
Power Cable	Plugs into the mains power input on the rear panel of the Communication Unit and to a standard wall outlet.
Standard Ethernet Cable	Plugs into the Local Area Network (LAN) port on the rear panel of the Communication Unit and to an Ethernet wall outlet. The cable is gray and 5m (197in) long. It is used to connect the system to an already installed network.
Crossover Ethernet Cable	Plugs into the LAN port on the rear panel of the Communication Unit and directly to an acquisition computer. The cable is black with red connectors on each end and 2.5m (98in) long. The crossover cable is used, for example, when testing the system and it cannot be used to connect to an Ethernet wall outlet.
Serial Communication Unit Cable	Connects COM A or COM B ports on the Communication Unit to an RS-232 serial port on a PC (not required for normal operation) or a device with an RS-232 port, e.g., an AutoSet device. This cable may be used for possible troubleshooting purposes.

Bedside Unit

The bedside unit features a color-coded input panel displaying the patient layout, a built-in impedance button with indicator lights, a one-step disconnect, and 2-pin sensor inputs to reduce patient hookup time and ensure polarity.

The Bedside Unit reads and transmits physiological channels used during a study, such as EEG, EOG, EKG/ECG, and respiratory signals. The interface connecting the unit to the

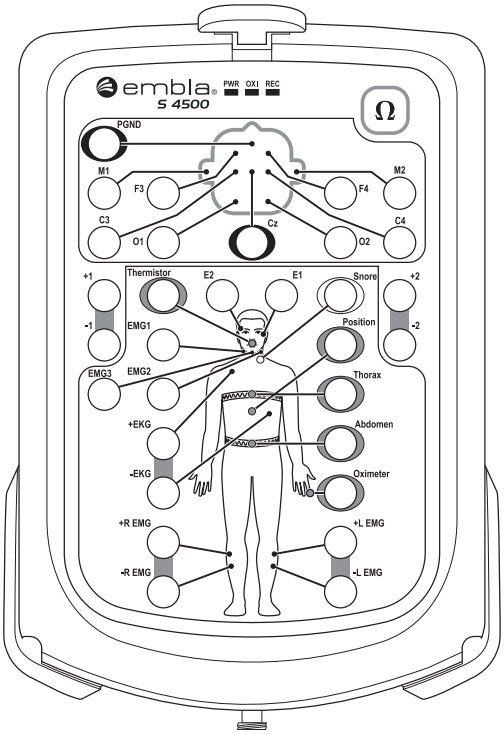
Communication Unit is on the underside of the Bedside Unit and is connected to the Bedside Unit bracket.

Warning:

The interface on the underside of the Bedside Unit should not be touched when the system is connected to the patient.

Caution:

When you see this symbol on the bedside unit, consult the accompanying documentation for information about the interface.



S4500 Input Panel

Status Lights

There are three status lights at the top of the Input Panel: PWR, OXI, and REC.

- **PWR:** Indicates the power supply. A green light indicates the unit is receiving power. If no light is visible, the unit is not receiving power.
- **OXI:** Indicates the status of the connection to the oximeter. A green light indicates connection to the oximeter. If no light is visible, the unit is not connected to the oximeter.

- **REC:** Indicates the status of the recording. A green light indicates the unit is recording. If no light is visible, the unit is not recording.

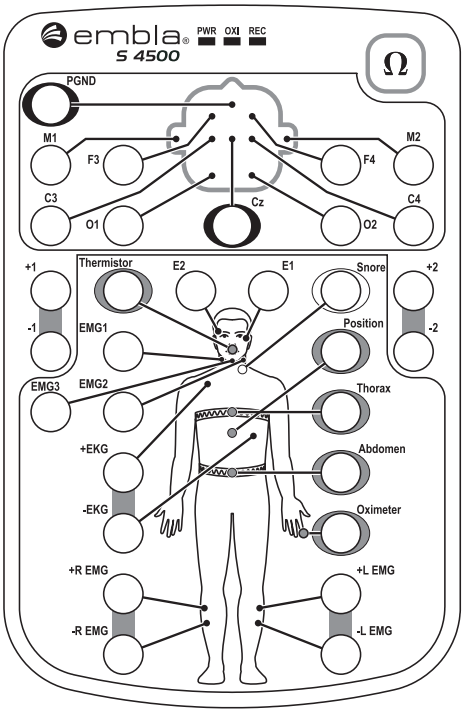
Impedance Test Button

The impedance test button Ω is located in the top right hand corner of the Input Panel. An impedance test can be performed when the bedside unit is recording or idle (not recording). To save the results of the impedance test (as part of a recording), press the impedance test button when a recording is in progress. For more information, see *Testing the Electrode Impedance*.

Although it is possible to test impedance using the test button on the input panel, it is recommended that you use your Embla PSG software to test impedance. If you require a specific impedance threshold, for example, 5kOhms (to meet AASM guidelines) you must perform impedance testing using your Embla PSG software.

Channel Inputs

The Bedside Unit reads and transmits a total of 21 channels and includes an input for a ground electrode (PGND) and a reference electrode. On the Embla S4500, the Reference input label refers is CZ.



Bedside Unit

Referential Channels

The beside unit has 13 referential channels:

- 8 channels (M1, M2, F3, F4, C3, C4, O1, O2) intended for EEG and labeled according to the international 10-20 System of electrode placement.
- 2 channels (E1, E2) intended for EOG.
- 3 channels (EMG1, EMG2, EMG3) intended for chin EMG signal.

Bipolar Channels

The bedside unit has 5 bipolar channels (indicated by ± symbol).

- ±EKG: intended for EKG/ECG.
- ±R EMG: intended for right limb EMG.
- ±L EMG: intended for left limb EMG.
- The 2 remaining channels, labeled ±1 and ±2, are extra bipolar channels.

Channel inputs on the Input Panel are intended for 1.5mm touch-proof plugs ONLY.

Sensor Input Channels

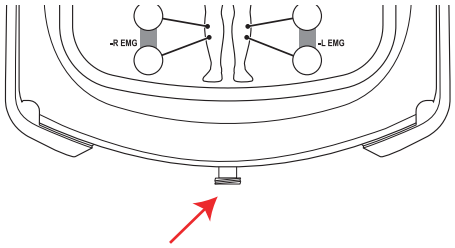
The beside unit has 6 sensor input channels: 5 respiratory data channels and 1 sensor input channel for position. These channels have a proprietary two pin connector with different labels, each with a unique color.

- Thermistor: intended for nasal flow (Color: gray).
- Snore: intended for snore (Color: white).
- Position: intended for body position (Color: purple).
- Thorax: intended for thoracic respiratory effort with XactTrace (Color: blue).
- Abdomen: intended for abdominal respiratory effort with XactTrace (Color: yellow).
- Oximeter: intended for oximetry data (Color: brown).

Sensor inputs on the Input Panel are intended for 2 pin touch-proof type connectors ONLY.

Luer Lock

The bedside unit has 1 Luer Lock Interface. A nasal pressure sensor connects to the Luer Lock and allows measurement of nasal flow/pressure. A flow generator with pressure tubing can also be connected to the Luer Lock to record mask pressure.



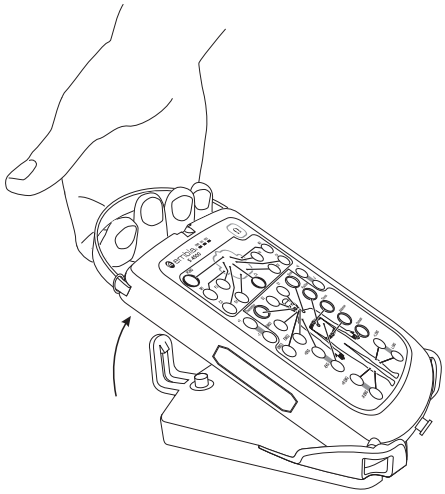
Luer Lock on Bedside Unit.

Cable

This bedside unit cable connects the Bedside Unit to the Communication Unit. It connects to the Interface marked with the ⚠ symbol, located on the rear panel of the Communication Unit. This cable is permanently fastened to the mounting bracket and should not be removed unless it needs to be replaced. When the patient needs to leave the bed, the technician can easily disconnect the Bedside Unit itself by releasing it from the mounting bracket.

Mounting Bracket

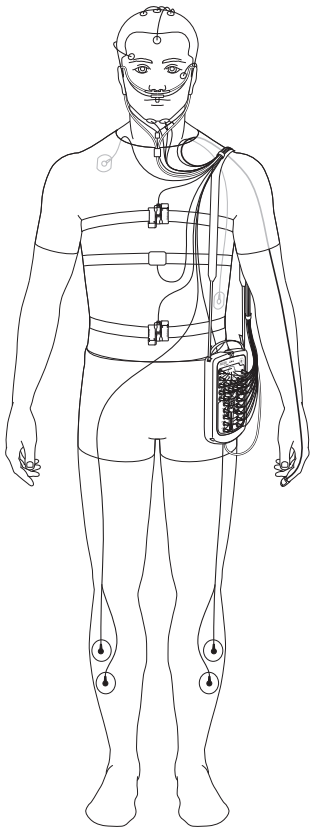
Rugged and mountable anywhere, the Bedside Unit is designed to be easily connected and disconnected. The mounting bracket included with the system has a quick release feature that can be mounted on a wall or bedside table. A handle is attached to the Bedside Unit to simplify mounting and dismounting from the mounting bracket.



Dismounting the Bedside Unit

Shoulder Strap

The Bedside Unit is lightweight and can easily be worn by the patient with a strap attachment. This allows the Bedside Unit to be easily carried when the patient needs to leave the bed. Use of this accessory, which can be easily fastened to the unit, is optional.



Patient carrying the Bedside Unit with shoulder strap

Sensors

The sensors used with the Embla S4500 system can be ordered online at ShopEmbla (www.shopembla.com) or from a local Embla distributor.

There are two types of sensors used with the Embla S4500:

Electrodes

The sensors used with the Embla Bedside Unit must have 1.5 mm touch-proof connectors. The majority of the sensors that are connected to the Bedside Unit are electrodes. The most common type of electrodes is cup-electrodes (gold, silver, silver-silverchloride). Cup-electrodes require

conductance paste and that the electrode site be properly prepared and cleaned for lower impedance values. Cup-electrodes are typically used in recording EEG, EOG, and submental EMG. Due to the different conduction properties of silver, silver/silver-chloride, and gold, the same metal type should be used for all unipolar electrodes including the common reference.

Single use electrodes are also frequently used. They are typically used in measuring EKG/ECG, and EMG from the anterior tibialis muscles. Single use electrodes are usually Ag-AgCl (silver-silverchloride) electrodes that can be fastened to the skin surface. As with cup-electrodes, the electrode site should be properly cleaned and prepared to achieve low impedance.

Sensor Inputs

The sensor inputs incorporate sensors for recording respiratory signals and body position signals.

Only sensors provided by Embla should be used. The Bedside Unit records signals from six external sensors and one built-in sensor. The external sensors that can be used are abdominal and thoracic respiratory effort, oral/nasal airflow (thermistor), snoring, oximetry, and position. The built-in sensor is an airflow pressure transducer. The arrangement of these sensors and optional sensors will be determined by the type of study being performed.

For a more detailed description of each sensor and their placement on the patient, consult the *Performing a Study* chapter.

Table 3: Bedside Unit Internal Sensors

Type	Name	Description
Internal	Pressure Sensor	The Bedside Unit has a built-in pressure sensor. The pressure is measured via a nasal cannula connected to the Luer Lock on the bottom of the unit. The pressure sensor can be used for measuring both nasal flow and mask pressure.
External	Respiratory Effort Sensors	The Bedside Unit accommodates two respiratory effort sensors: one around the thoracic region and the other around the abdominal region. The XactTrace – RIP respiratory effort sensors are used with the Bedside Unit.
External	Oximeter	The oximeter is external and measures continuously the degree of oxygen saturation of the circulating blood.
External	Snoring	An external piezo-electric snoring sensor can optionally be used with the system. When the snoring sensor is attached to a

Type	Name	Description
	Sensor	patient's throat, it generates a signal in response to vibration during snoring. Snoring can also be detected in the pressure signal from the nasal cannula.
External	Body Position Sensor	Used to collect data regarding patient sleep position changes.
External	Thermistor	Used to measure airflow. When used with a nasal cannula, assists in distinguishing apneas from hypopneas. Can also be used with a CPAP mask to detect mouth breathing.

The use of oral/nasal cannula is NOT recommended.

Assembling the System

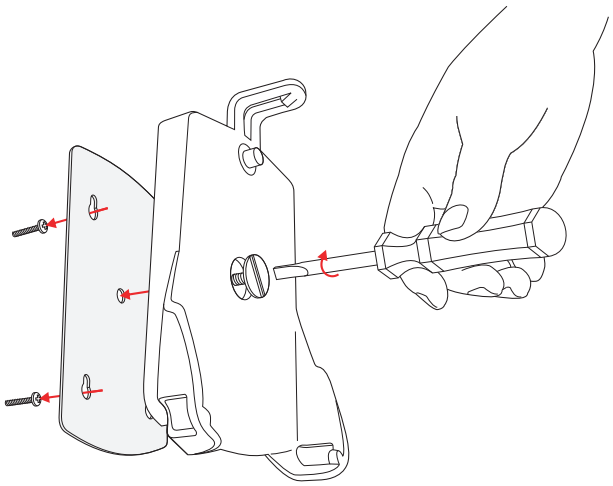
Mounting the Bedside Unit Bracket

The Bedside Unit sits in a bracket that should be mounted before any studies are performed. The bracket can, for example, be mounted on a wall or a bedside table next to the patient's bed. The cable from the Communication Unit is already locked into the mounting bracket. No setup is required.

To mount the bedside unit bracket:

1. Unscrew the bracket from the metal plate.
2. Fasten screws into the four key-shaped holes on the metal plate.
3. Slide the metal plate down so that the screws are held securely in the narrow end of the key-shaped holes.
4. Tighten the screws.
5. Place the bracket on the metal plate and secure it to the plate with the large screw.

The Bedside Unit can now be easily docked and undocked from the bracket.



Mounting the Bedside Unit bracket

Mounting the Communication Unit

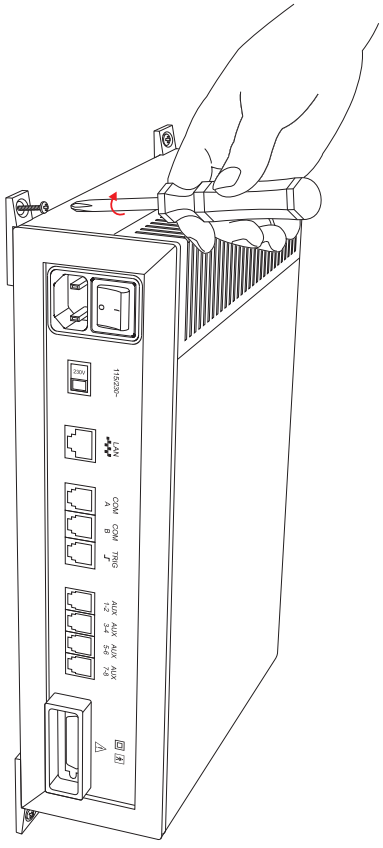
The Communication Unit should be mounted in a well-ventilated area to prevent overheating.

Caution:

Avoid installing the Communication Unit where there is danger of spilling or exposure to any kind of liquid.

To mount the Communication Unit:

1. Unscrew the gray rubber feet from the underside of the Communication Unit.
2. Replace the feet with the fasteners: slide the ridge of the fastener into the groove on the unit's underside so that the holes of the fasteners are aligned with the corresponding holes on the Communication Unit.
3. Attach the fasteners with two screws each.
4. Screw the Communication Unit to the wall.



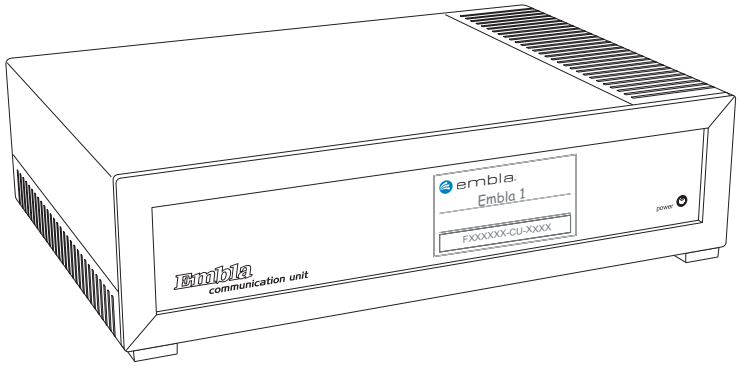
Mounting the Communication Unit

Creating and Attaching an ID Card to the Communication Unit

More than one Embla S4500 can be used to record on the same acquisition computer. Each device is identified in the acquisition application by its serial number and given a custom name. Clearly identify the physical devices in accordance with their identification in the application. Creating an ID card for the unit will ensure that each communication unit serial number and custom name are easily accessible.

To prepare and attach an ID card:

1. Create an ID card that includes both the custom name and the serial number (found on the bottom of the Communications Unit.
2. Place the card inside a plastic sleeve or other protective cover.
3. Attach the card to the Communication Unit where it is clearly visible and away from any ventilation opening.



Typical ID card location

Do not place the ID card on the ventilation opening.

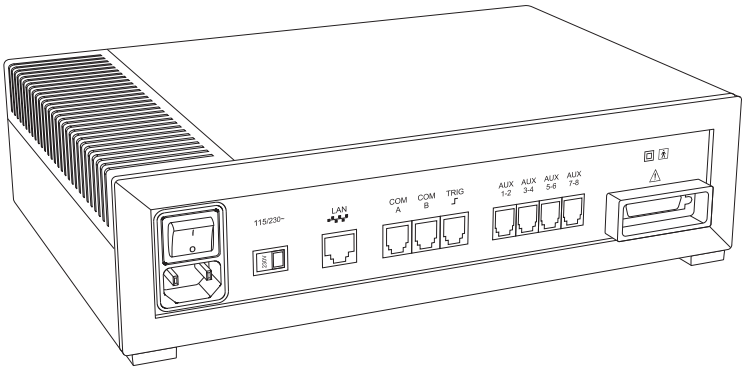
Connecting the Units

Connecting the Communication Unit

The Communication Unit should be placed in a well-ventilated area to prevent overheating.

Caution:

Avoid installing the Communication Unit where there is danger of spilling or exposure to any kind of liquid.



Communication Unit rear panel

To connect the communication unit:

1. Confirm that the voltage selector switch is set correctly.
2. Confirm that the Communication Unit is turned off.
3. Connect the gray Ethernet cable to the port labeled LAN on the Communication Unit rear panel.
4. Connect the cable to the Ethernet outlet on the wall. *It is recommended that the net being used for the sleep study be isolated from other net users.*
5. Connect any external devices that will be used with the system. Devices that have a digital output should be connected to the COM connections. Devices that have analog output signals should be connected to the connectors labeled AUX. *Check the input/output ranges before connecting external devices. Please contact support@embla.com for information on which devices are recommended and supported by Embla. See Technical Specifications for more detailed information on the AUX and COM inputs.*
6. Connect the Bedside Unit cable to the interface labeled with this symbol: ⚠.

7. Connect the power cable to the input located beneath the On/Off button, and then connect it to a wall outlet.

Connecting the Bedside Unit

The cable from the Communication Unit is already locked into the mounting bracket and does not require setup.

Connecting to the Bracket

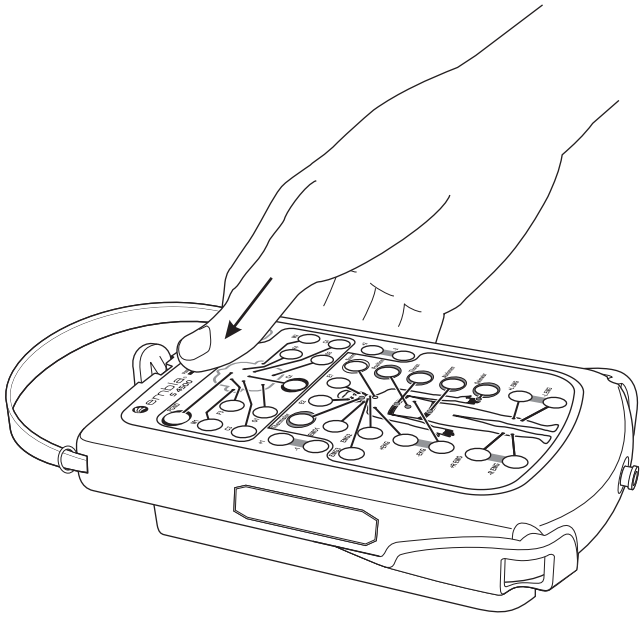
The lightweight bedside unit and mounting bracket provide mobility and stability. The bedside unit connects to a base bracket via a quick release mechanism.

Caution:

Do not touch the interface on the rear panel of the Bedside Unit when the system is connected to the patient.

To connect the bedside unit to the bracket:

1. Confirm that the mounting bracket has been properly secured.
2. Hold the Bedside Unit by the handle and rest its bottom end into the bracket.
3. Press the top end of the Bedside Unit down into the bracket until it clicks into place.



Securing the Bedside Unit in the bracket

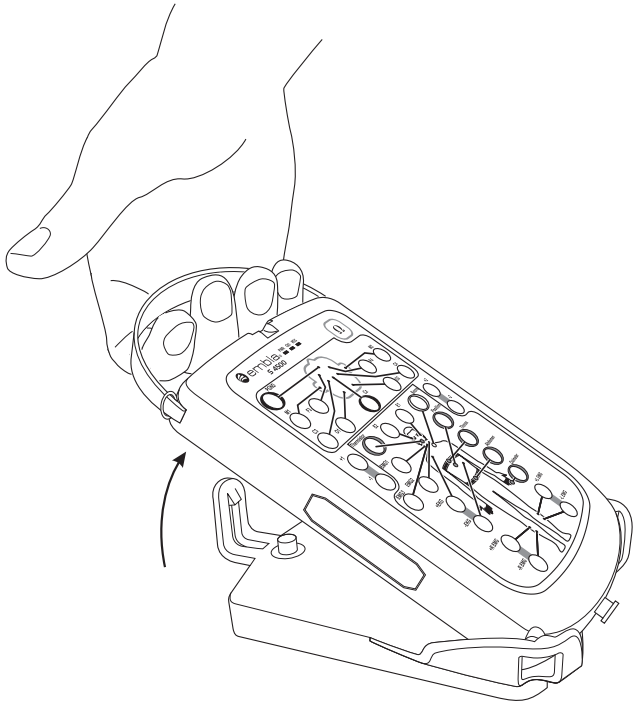
Disconnecting from the Bracket

The bedside unit is easily disconnected from the base bracket via the quick-release mechanism.

To disconnect the bedside unit from the bracket:

1. Push the quick-release clip away from the unit.
2. Hold the handle and pull the Bedside Unit out of the bracket.

Releasing the quick-release clip



Lifting the Bedside Unit from the bracket

Caution: Connections

Only a trained operator should connect and disconnect the Embla system.

The operator must check the input and output ranges before connecting third party devices to the system.

The system units may fall if they are not secured according to the instructions in this manual.

Do not pull on the system cables.

Do not connect units that have been exposed to liquid.

Do not use damaged cables and connectors.

Always inspect the equipment, particularly the cables and connectors, for evidence of wear before each study. If evidence of wear is found, remove the worn equipment from use and contact Embla Technical Support (support@embla.com) for replacement or servicing.

Installing the System on the Network

Installing the Embla S4500 on a network should only be done by a trained technician. For more detailed instructions, consult the following articles available on the Embla knowledge base Web site, or contact Embla Technical Support (support@embla.com):

- Connecting the Embla S4500
  Source: http://www.embla.com/support/knowbase/show.asp?ID=293
- Troubleshooting Network Connections with the Embla S4500
  Source: http://www.embla.com/support/knowbase/show.asp?ID=292

If you do not have Internet access, you can find these articles on your software installation CD.

The Embla system connects to the acquisition computer through an Ethernet network. An industry standard twisted-pair cable with RJ45 connectors is used to establish the connection.

The acquisition computer and the system need to be connected to the same Ethernet network. A standard Ethernet adapter is used for that purpose. Many new computers have Ethernet adapters integrated on the motherboard. In other cases a standard 10/100 Ethernet adapter can be added to the computer.

The Embla communicates with the computer using the TCP/IP protocol. On all Windows 2000 and XP installations, the TCP/IP protocol is enabled by default when Windows detects an Ethernet adapter.

Firewall software can block network traffic between the computer and the Communication Unit. To ensure proper operation, disable any firewall software that may be running on your computer.

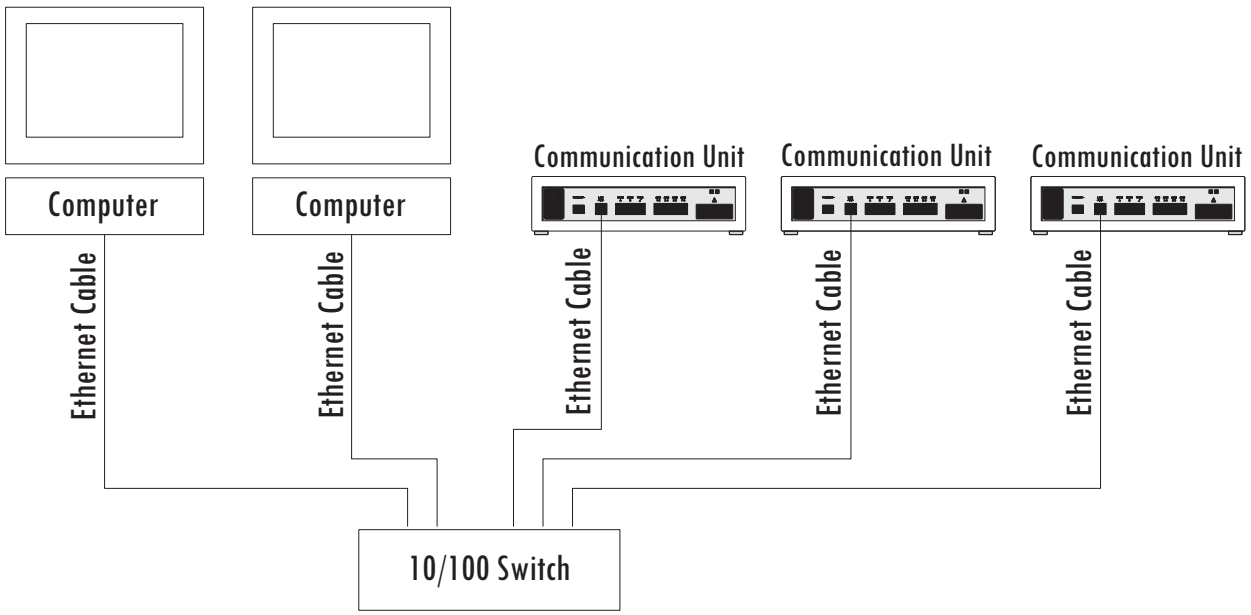
Connection Types

The Ethernet connection between the Embla system and the acquisition computer can be established in different ways. The most common configurations are detailed here. The conventional way to set up a network is to use a star topology with one central hub or switch. A switch, rather than a hub, is strongly recommended. Adequate 10/100 switches are widely available and cost effective.

Isolated Network

It is recommended to set up a small isolated network containing one or more Embla systems and one or more acquisition computers. By isolating the network it will not be affected by downtime or other limitations of the pre-existing network and vice versa.

The network can be installed by placing the network switch in the control room and connecting all the devices, both Emblas and computers, to the switch with standard Category 5 twisted-pair Ethernet cables. Most switches have a small green LED close to each port, which lights up if a device is connected to that port. After connecting all the devices and turning them on, make sure that the corresponding LED lights up on the switch. In case the acquisition computer needs to be connected to a larger hospital network, a second Ethernet adapter may be added to the computer.



Schematic diagram of a typical Embla S4500 network

Part of a Larger Network

It is possible to connect the Embla systems and the acquisition computers directly to a larger Local Area Network (LAN). This is typically carried out by the IT department of the hospital or organization running the network. To make the system a part of a larger network, each system should be connected to a central switch which is usually located in a central wiring cabinet out of reach. Coordination with the people responsible for running the network is critical.

Performing a Study

Study Types

The Embla system is designed to be flexible and can be used in different ways. Depending on the kind of study you desire, different sensors, and additional interfaces will be used. Table 4 describes the standard and physiological study setups for performing a sleep study with the Embla system.

Table 4: Study Type Setups

Study Type	Sensors
Standard	EEG, EOG, EKG/ ECG, and EMG electrodes and leads. (2) XactTrace – RIP Respiratory Effort Sensor, nasal cannula, Oximeter Flex Sensor, Body Position Sensor (optional), Thermistor (optional), Snoring Sensor (optional).
Physiological	EEG, EOG, EKG/ECG, and EMG electrodes and leads.

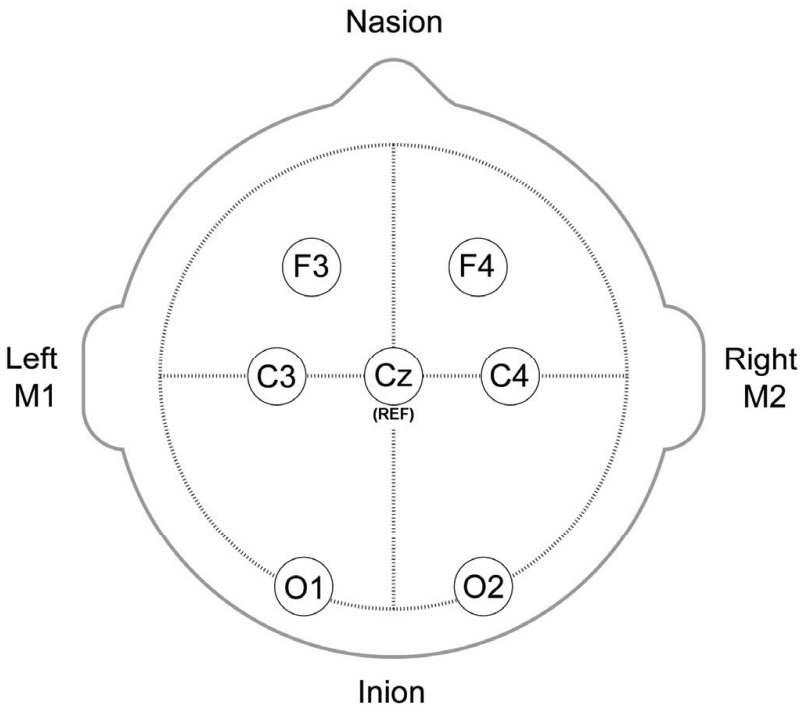
Attaching the Electrodes

Clinicians should use their own standard practices to attach electrodes to patients undergoing a sleep study. The instructions below refer to a study using the 10-20 system. Although the S4500 Bedside Unit only features electrode inputs commonly used in a PSG study, the same standards apply when attaching the electrodes. The instructions are meant only as a helpful reference and follow recommended sleep study guidelines.

Place the electrodes according to the desired study type.

Caution:

⚠ Always inspect the equipment, particularly the cables and connectors, for evidence of wear before each study. If evidence of wear is found, remove the worn equipment from use and contact Embla Technical Support (support@embla.com) for replacement or servicing.



Electrode placement in a standard Embla S4500 PSG study

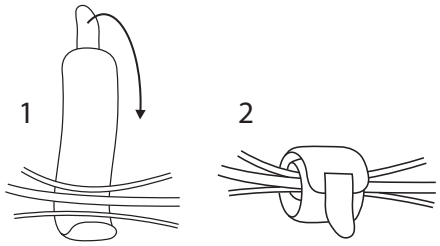
To attach the electrodes:

1. First prepare the sites for the electrodes: The skin should be cleaned with an approved skin erosion cream to obtain an electrode –skin resistance less than 10kΩ.
2. Measure the distance from the nasion to inion along the mid-line through the vertex.
3. Make a preliminary mark at the midpoint (Cz). In Embla S4500 recordings, a common reference (REF) electrode is placed here. The CZ input on the Embla S4500 can only be used as a REF placement. It is not intended to be an EEG input.
4. Center this point in the transverse plane by marking the halfway point between the left and right preauricular points. The intersection of marks from steps 1 and 2 give the precise location of Cz.
5. Reposition the measuring tape at the mid-line through Cz and mark the points 10% up from the inion (Oz) and nasion (Fpz).
6. Reposition the measuring tape in the transverse plane through Cz and mark 10% (T3) and 30% (C3) up from the left preauricular point and 10% (T4) and 30% (C4) up from the right preauricular point.
7. Position the tape around the head through Fpz, T3, Oz, and T4. Ten percent of this circumference distance is the distance between Fp1 and Fp2 and between 01 and 02. Mark these four locations on either side of the mid-line.

8. The second marks for O1 and O2 are made by continuing the horizontal mark for Oz. Do this by holding the tape at T3 and T4 through Oz, and extend the horizontal mark to intersect the previous O1 and O2 marks.

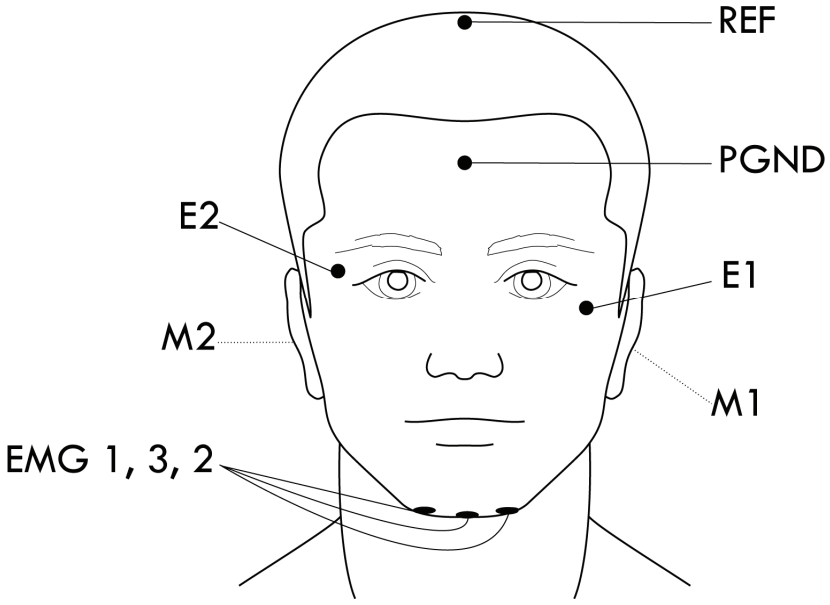
9. To establish the final marks for C3 place the tape from O1 to Fp1 and make a mark at the midpoint of this line. When extended, this mark will intersect the previous C3 mark. Repeat on the right side for C4.

10. Secure the electrode leads in Cable Wraps above the patient's head:



Securing the cable wraps

A standard polysomnographic recording uses the electrode locations displayed in the following figure:



Example of electrode locations for a standard PSG recording. Not shown is this figure are electrode placements F3, F4, C3, C4, O1 and O2e.

Conditions for use of electrodes

The conductive part of electrodes and their connectors, including the ground electrode, should not contact other conductive parts including earth.

To prevent the hazard of burns, all electrodes should be removed from the patient before using high frequency (HF) surgical equipment.

The interconnection of several equipments can cause a summation of leakage currents that may be dangerous to the patient.

To protect the patient against the effect of discharge, all electrodes should be removed from the patient before using a cardiac defibrillator.

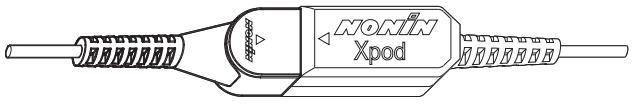
There are no means of indicating an inoperative electrocardiograph.

Avoid accidental contact between the connected but unapplied applied parts and other conductive parts including those connected to protective earth.

Attaching the Oximeter and Oximeter Flex Sensor

The Nonin oximeter is external and can accommodate a wide range of pulse oximeter sensors from which it receives information. The oximeter, by shining light through the finger, detects the amount of light that travels through, thereby providing an indirect measure of the oxygen saturation.

The oximeter is calibrated to closely approximate functional oxygen saturation values. Re-calibration is not required as the oximeter performs all computations from the internal software and there are no critical parts to drift.



Nonin Xpod Oximeter

Warning:

The pulse oximeter alone should not be used for continuous monitoring as no low alarm SpO2 is provided.

The Oximeter Sensor

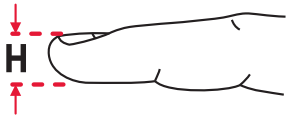
The Bedside Unit and the oximeter transform the information received from the Oximeter Sensor into four signals: oxygen saturation, pulse, pulse plethysmograph waveform, and Beat-to-beat SpO2.

Table 5: Signals Received from the Oximeter Sensor

Signal	Description
Oxygen Saturation	The arterial hemoglobin oxygen saturation is displayed in units of percentage SpO2 over a fixed number of heartbeats.
Pulse	The pulse detected indicates the heart rate of the patient.
Pulse Plethysmograph Waveform	The pulse waveform measured by the oximeter is an indicator for peripheral blood flow. It may be used to indicate heart rate. It is possible to use pulse waveform as a visual aid in the manual scoring of brady- and tachycardias. Furthermore, the pulse waveform is an indicator of the signal quality of the oximeter sensor. A clear pulse waveform signal tells the clinician that the oximeter signal is reliable. *Note that the plethysmograph waveform displayed is not proportional to the pulse volume.*
Beat-to-beat SpO2	The beat-to-beat SpO2 shows the saturation level on a given heart beat, without averaging, and is therefore, faster and more receptive than the averaged SpO2. This signal is sensitive to movement artifacts. The manufacturer of the oximeter, Nonin Medical Inc., has validated the oximeter. For more information, see *Technical Specifications,* or consult the Embla web site (www.embla.com).

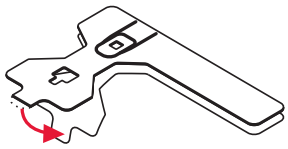
Attaching the Oximeter Flex Sensor

The Oximeter Flex Sensor records oxygen saturation and pulse. The preferred application site for the oximeter flex sensor on adults is the index finger. However, other fingers may be used where the finger thickness is between 5mm and 21mm (0.2" and 0.8"): dimension "H" in the following figure.

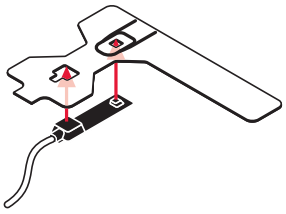


To apply the oximeter:

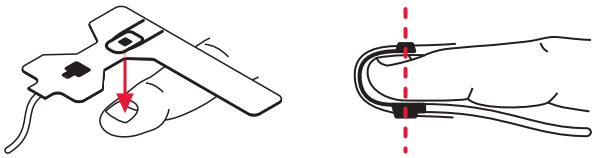
1. Grasp the blue tab on the FlexiWrap™. Peel the paper backing away.



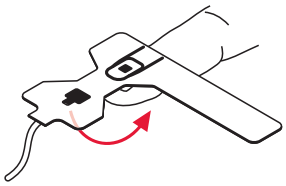
2. Firmly press the sensor against the adhesive side of the FlexiWrap.



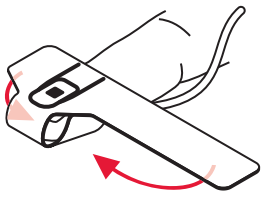
3. Carefully position the adhesive side of the FlexiWrap on the finger as shown in the figure below. Make sure that the dotted line is at the tip of the finger. (This positioning helps line up the light emitter and the light detector).



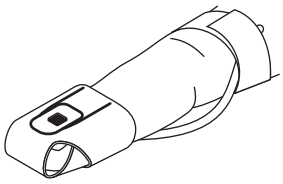
4. Carefully fold the flap of the FlexiWrap over the fingertip. Make sure that the light emitter and the light detector are vertically aligned.



5. Wrap the side flaps of the FlexiWrap around the sides of the finger as indicated by the arrows in the figure.



6. For best results secure the sensor wire with medical tape, preferably around the base of the finger. Make sure that the tape securing the wire does not restrict the blood flow.



Dispose of the FlexiWrap after each application.

Other Oximeter Sensors

It is possible to use other Nonin standard oximeter sensors certified to carry the CE mark with the Bedside Unit such as: pediatric sensor, disposable sensor and finger-clip sensor. These have to be ordered separately. The various sensors are either intended for short term continuous monitoring or extended duration. The operator should consult the documents that come with the sensors for information on the correct usage.

Caution: Conditions for use of an oximeter

An oximeter alone should not be used to reach important clinical conclusions. Clinical caution must always be exercised, and other means should be used for confirmation whenever possible.

Misuse or improper handling of the sensors can result in damage of the sensor or the cable. This may cause inaccurate measurements and readings.

Remove fingernail polish or artificial fingernails before applying the sensors. Fingernail polish or artificial fingernails may cause inaccurate readings.

Do not autoclave, ethylene oxide sterilize or immerse the sensors in liquid. Unplug the sensors from the Bedside Unit before cleaning or disinfecting.

Operation of oximeter sensors can be affected by the presence of strong ambient light. Shield the sensor area (with a medical tape, for example) if necessary.

Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patients may react differently to the sensors depending on their medical status and skin condition. Do not use adhesive material if the patient exhibits an allergic reaction to it.

The oximeter may be unable to detect lower saturation values with the same degree of accuracy and precision as higher saturation values. It may also be unable

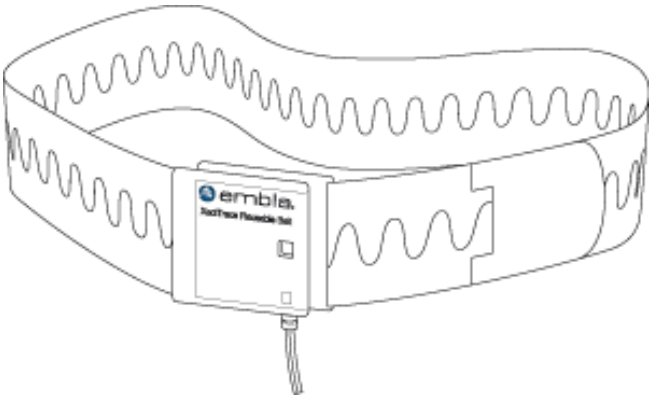
to quantify the degree of hyperoxemia present.

Interferences such as movement, abnormal hemoglobins, intravascular dyes, low perfusion states and skin pigmentation may influence the function of the pulse oximeter.

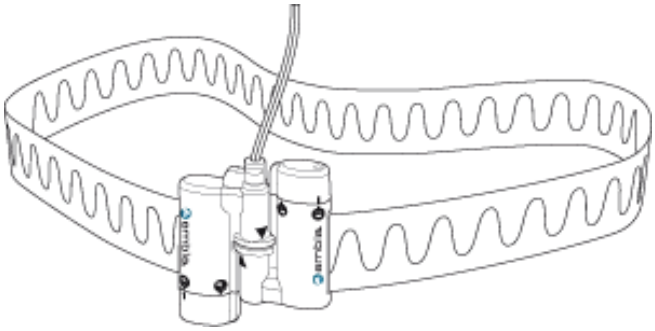
Note that the temperature of the SpO2 probe may reach up to 42°C.

Attaching XactTrace™ Respiratory Effort Sensors

The Bedside Unit accommodates two respiratory effort sensors: one around the thoracic region and the other around the abdominal region. The XactTrace sensor uses a Respiratory Inductive Plethysmograph (RIP) and is much more sensitive and reliable than typical respiratory effort sensors, especially in cases of paradoxical breathing. The XactTrace sensor generates a high quality signal that is a measure of the chest/abdomen circumference. These sensors help to distinguish between obstructive, central or mixed apnea and give an indirect measure of the respiratory tidal volume. The XactTrace belts are available in single-use and reusable types.



XactTrace Reusable Belt



XactTrace Single Use Belt

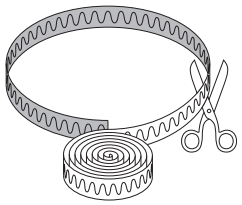
Fitting the Single-Use XactTrace Belts

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

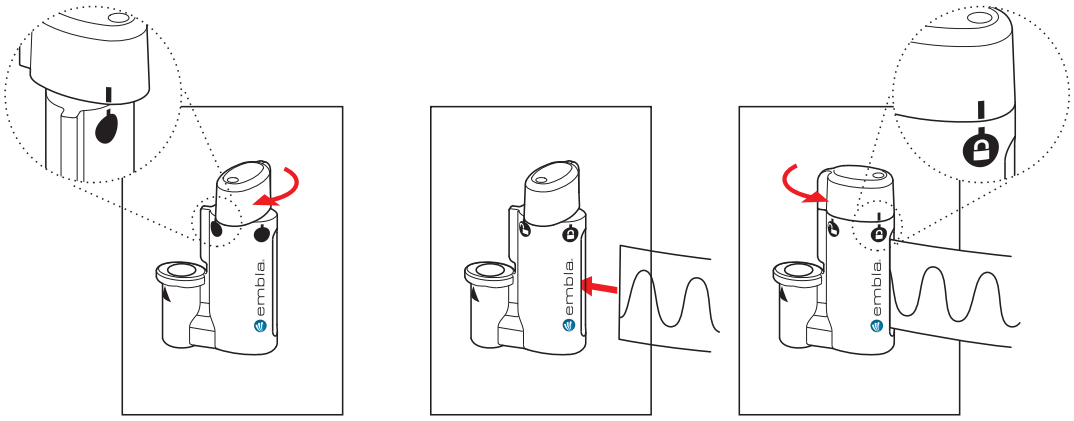
To prepare the single use belt for the study:

1. Encircle the belt around the patient's chest to approximate the circumference for the thoracic belt.

2. When cutting the belt, reduce its circumference by 10-15cm (4-6") so that it will stretch around the thorax. The belt should fit snugly to prevent slippage during the night. 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:



   i. Turn 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.

   ii. 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.

   iii. 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 fitting the belt around the patient's stomach at the navel and using the Belt Lock with the yellow connector.

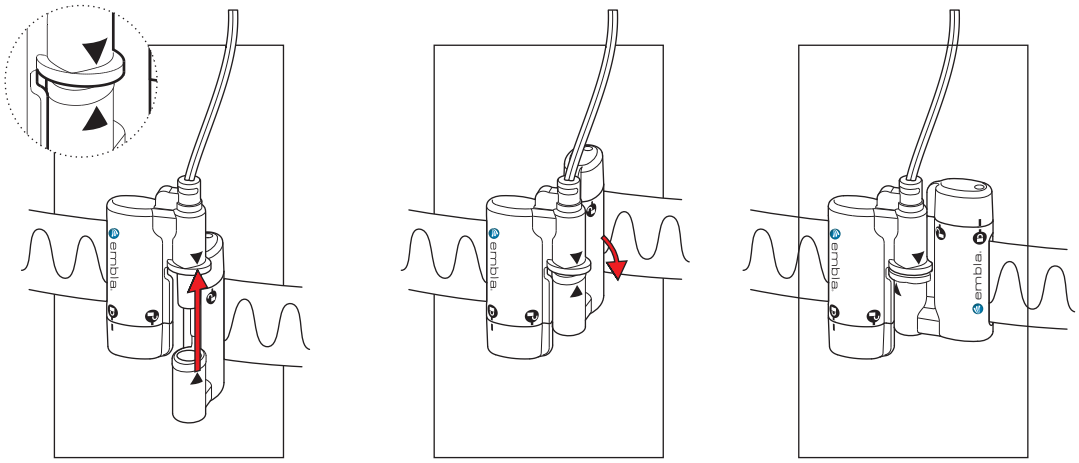
Attaching the XactTrace Single-Use Belts to the Patient

XactTrace belts are attached to the patient and are used to measure respiratory effort. The XactTrace sensor generates a high quality signal that is a measure of the thoracic (chest) and abdominal circumference. This signal provides a qualitative measure of ventilation and flow.

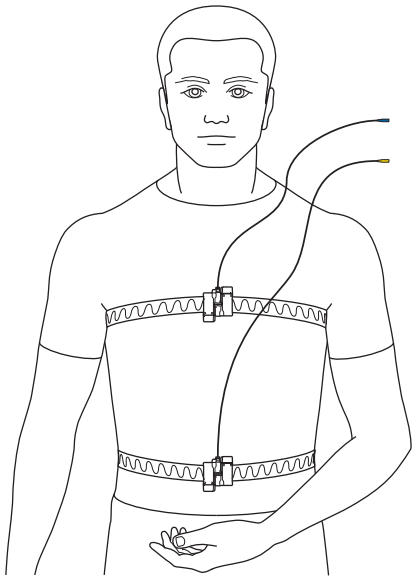
The XactTrace belts are intended to be worn over the patient's nightclothes.

To attach the belts to the patient:

1. Place the abdominal belt with the yellow sensor plug around the patient's stomach at the navel.
2. Take the two components of the black Belt Lock and connect them as shown below:



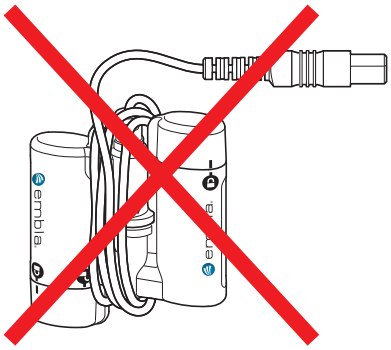
3. Place the thoracic belt with the blue connector around the patient’s chest under both arms.
4. Connect the second belt lock.



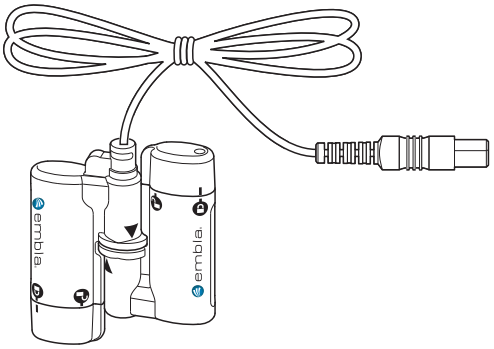
Thoracic and abdominal XactTrace belts attached to the patient.

Storing the Belt Lock

Proper storage of the XactTrace belt locks between recordings will increase their lifetime. To protect the sensor cable from damage, do not wrap it tightly around the Belt Lock as it may cause the cable to break where it connects to the Lock.



Incorrect



Correct

Considerations for Use

- Avoid all unnecessary contact with moisture.
- The belts are intended to be worn over nightclothes.
- Do not stretch the belts too tightly around the patient as this may cause discomfort. To prevent the belt from slipping during the night, the position can be fixed with medical tape.
- Care must be taken not to cut any cables when cutting the belts.
- If the top end of the lock is not properly secured, the signal will be affected.
- The belt is intended for single use only.

Fitting the XactTrace Reusable Belts

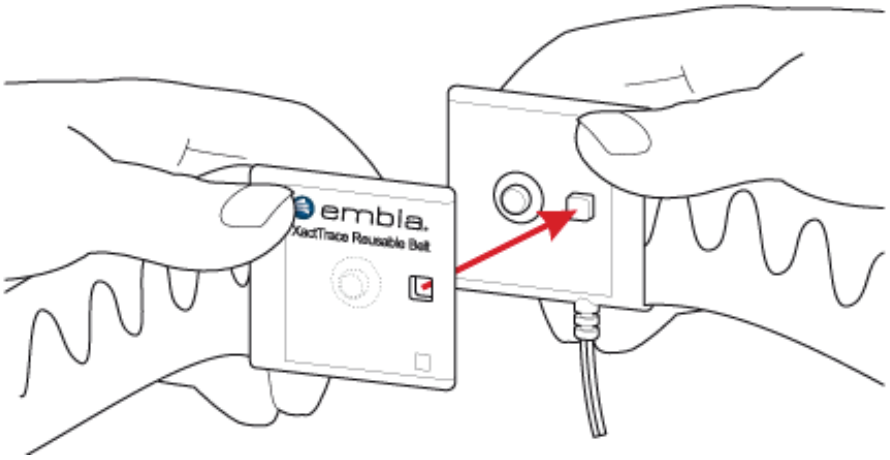
The XactTrace reusable sensor belts come in three sizes that should fit all adult patients. The length of each belt can be adjusted to ensure a good fit using the Velcro patches provided (see below for details). The belts should fit the patient snugly without being uncomfortably tight. Measure the patient's circumference and use the following table as a guide to choose the appropriate belt size.

	Full Size		Reduced Size	
	Cm	**inches**	**cm**	**inches**
Large	141-194	56-76	120-167	47-66
Medium	104-142	41-56	83-114	33-45
Small	78-104	31-41	57-77	22-30

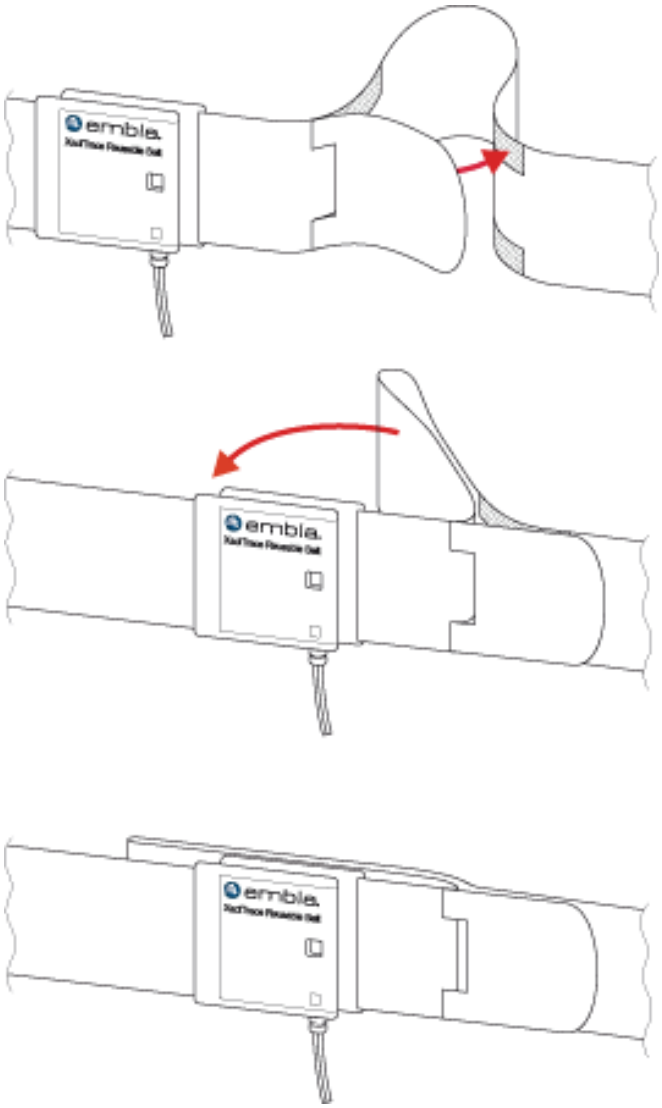
Attaching the XactTrace Reusable Belts:

When using the XactTrace belts, it is advised to avoid all unnecessary contact with moisture. The belts are intended to be worn over nightclothes.

1. Place the belt with the yellow connector around the patient's abdomen at the navel.
2. Snap the two components of the snap lock together as shown below:



3. If the belt is too loose, use the Velcro patches to reduce the circumference according to the following steps:



4. Place the belt with the blue connector around the patient's chest under the arm and snap the snap lock together.
5. Insert the blue and yellow sensor plugs into the appropriate color-coded inputs.

Storing the Reusable Belt

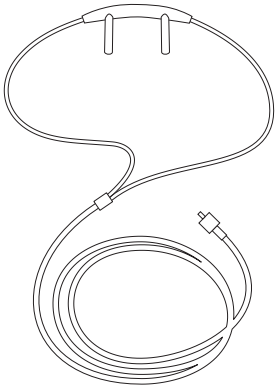
Proper storage of the XactTrace belts will increase the lifetime of the belts. To protect the belt and the sensor cable from damage, keep the following in mind when storing the belts between studies:

- Do not wrap the belt tightly around the belt lock because it will cause strain on the wire where it connects to the lock. Rather fold it loosely together.

- Do not wrap the sensor cable tightly around the belt lock as it may cause the cable to break where it connects to the lock.

Attaching the Nasal Pressure Sensor

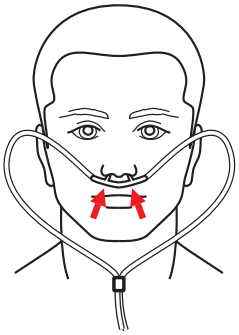
The Bedside Unit has a built-in pressure sensor. The pressure is measured via a nasal cannula connected to the Luer Lock on top of the Bedside Unit. The pressure sensor can be used for measuring both nasal flow and mask pressure. With the appropriate software support the signal from the nasal cannula can be used to detect snoring.



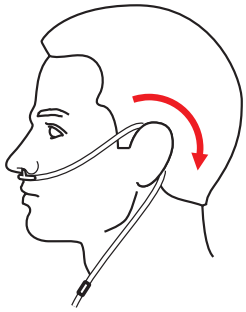
Nasal pressure sensor

To apply the nasal cannula:

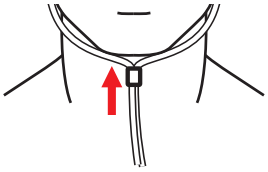
1. Place the nasal prongs in the nostrils. The prongs should bend downwards in the nostrils to effectively measure nasal breathing.



2. Loop the air cannula tube over the ears and then position it under the chin.



3. Tighten the loop by pushing the toggle towards the chin.



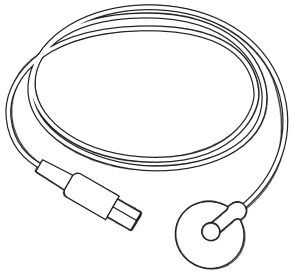
4. Secure the nasal cannula to the Luer Lock on the Bedside Unit and twist clockwise to tighten.

Medical tape can be used to fasten the cannula tube to the patient's cheeks.

The use of oral/nasal cannula is NOT recommended. Dispose of the nasal cannula after each use.

Attaching the Snoring Sensor

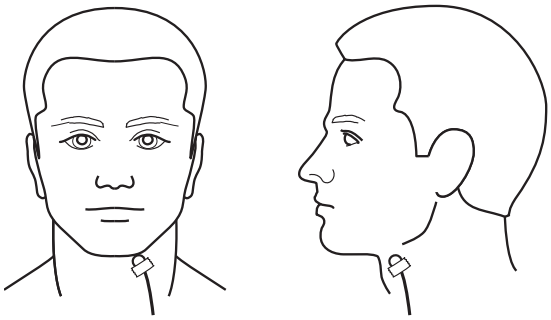
An external piezo-electric snoring sensor can optionally be used with the system. When the snoring sensor is attached to a patient's throat, it generates a signal in response to vibration during snoring. Relying on vibrations rather than actual sounds eliminates all artifacts associated with external noises. The snoring signal is converted to an analog voltage that can be measured.



Snoring sensor

To attach the snoring sensor:

1. Have the patient simulate a snore while the clinician gently places his fingers on his or her neck to find the best position for the sensor. The spot that exhibits the most vibration should be selected. The snoring sensor should not be placed directly on the larynx.
2. Place the side of the sensor with the raised bump next to the skin.
3. Fasten with medical tape.



A second piece of medical tape can be placed about 15cm (6in) away from the sensor in order to relieve tension on the sensor wire.

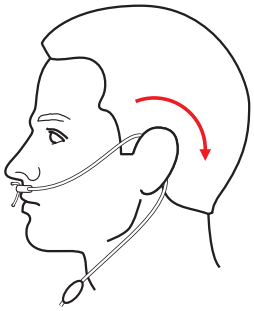
Attaching the Thermistor

Airflow may be measured with a thermistor that connects to the Bedside Unit. When the thermistor is used alongside a nasal cannula it can help distinguish between apneas and mouth breathing. The quality of the recorded signal depends on variables such as filters, placement, patient's respiration, room temperature and CPAP pressure.

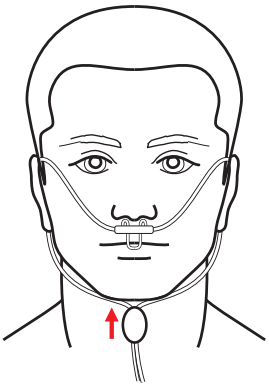
The thermistor should be attached after the nasal cannula has been attached.

To attach the thermistor:

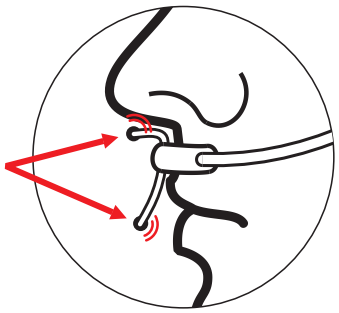
1. Bend the nose sensor forward in a rounded angle, slightly away from the sensor body.
2. Position the thermistor on the upper lip. Position the nasal probes right under the nostrils so that they are exposed to the maximum available airflow. The probes should not touch the skin or enter the nose.
3. Loop the sensor wire over the ears (as with the cannula tube), and then position it under the chin.



3. Tighten the sensor wire loop, if necessary, by pushing the toggle towards the chin.



4. Secure the sensor wire to the cheeks with a medical tape. *The sensor tips should not touch the skin as skin contact will significantly attenuate the signal amplitude.*

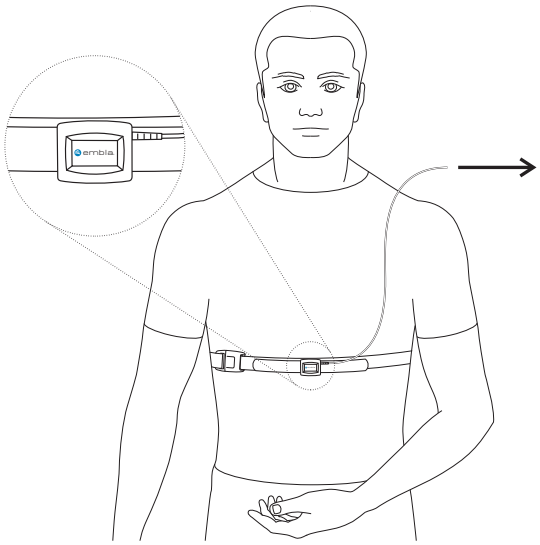


Attaching the Body Position Sensor

Body position may be measured with a position sensor that connects to the Beside Unit. When the sensor is attached to a patient, it generates a signal in response to body position changes.

To attach the body position sensor:

1. To achieve correct position output, secure the elastic strap firmly around the centerline of the chest or abdomen.
2. Attach the sensor to the strap by using the hook Velcro on the sensor's back. To ensure proper placement, the Embla logo should be turned correctly.
3. Plug the 2 pin touch-proof connector in the Bedside Unit. No external interface or power supply is necessary.



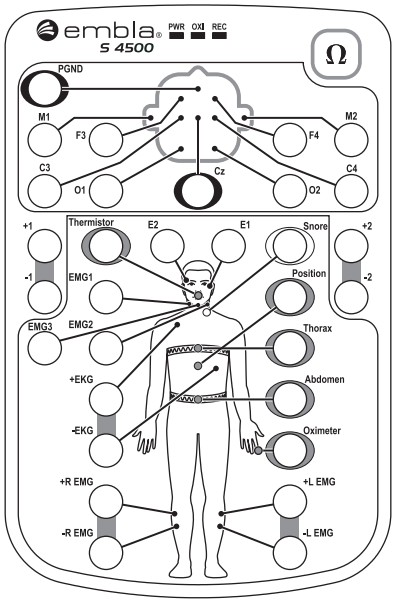
Insert the connector in the appropriate input on the Bedside Unit

Connecting Sensors to the Bedside Unit

Once the sensors are attached to the patient, you must connect these inputs to the Bedside Unit Input Panel. The clinician can prepare the patient and the system in whatever order is most convenient. See Table 6 for sensor color code references and connector types.

To connect the sensor to the Bedside Unit:

1. Connect the electrodes to the appropriate marked channel inputs.



2. Make sure to connect other sensors to the bipolar channels as specified in the acquisition application.
3. Insert the sensor connectors into the color-coded inputs on the Bedside Unit.
4. Connect the nasal cannula to the Luer Lock. Twist clockwise to tighten.

Table 6: Sensor Input Color Code

Color	Sensor	Connector Type
Yellow	Abdominal Respiratory Effort	2 pin touch-proof
Blue	Thoracic Respiratory Effort	2 pin touch-proof
White	Snoring	2 pin touch-proof
Gray	Thermistor	2 pin touch-proof
Brown	Oximeter	3 pin touch-proof

Color	Sensor	Connector Type
Purple	Position	2 pin touch-proof

Caution:

Before the patient leaves the bed, ensure that all cables have been safely secured and the patient has no risk of falling. The operator should assist the patient and check the equipment. Secure the cables and electrode leads in a cable wrap above the patient's head.

Caution: Conditions for use of sensors

Misuse or improper handling of any sensor can result in damage of the sensor or the sensor cable. This may cause inaccurate measurements and readings.

Do not use damaged sensors, cables or accessories.

Ensure that cables do not encircle the patient's neck. Special attention is required in the case of children.

Testing the Electrode Impedance

Electrode impedance testing is built into the system. Electrode impedance may be tested in two ways: by pushing the impedance test button on the Bedside Unit, and in the software during a recording. Consult your sleep acquisition Embla PSG software user manual for further information on how to manipulate the electrode impedance testing in the acquisition software.

Although it is possible to test impedance using the test button on the input panel of the Bedside Unit, using your Embla PSG software to test impedance is recommended. If you require a specific impedance threshold, for example, 5kOhms (to meet AASM guidelines), you must perform impedance testing using your Embla PSG software.

When an impedance test is started, the system sends a very small current for a fixed period of time to the appropriate channels on the bedside Unit. No signals are received from the electrodes during that time.

During an impedance test, the REF channel is used as a reference, and the actual values of impedance are displayed in the Embla PSG software. The impedance of the electrode connected to the REF channel will not be tested. However, if any of the other channel inputs

being tested have acceptable impedance, the electrode connected to the reference channel should also have acceptable impedance.

- **Performing an Impedance Test When Not Recording**

  If an impedance test is performed when not recording, the impedance is tested on all unipolar and bipolar inputs of the Bedside Unit. The test is started by pushing the impedance test button Ω on the Bedside Unit. When an impedance test is started, all the electrode inputs on the Bedside Unit flash orange. The lights then turn green, indicating that they are working. After that, the impedance test scans start. Electrodes that have impedances higher than 10kOhm light up in orange while electrode inputs that have impedance lower than 10kOhm light up in green. When the impedance test is complete, the electrodes with too high impedance will continue to display an orange light while electrodes with acceptable impedance display since no recording is taking place.

- **Performing an Impedance Test During a Recording**

  If an impedance test is started during a recording, the test is performed on the channels selected in the Embla PSG software, and is started from within the software application. Consult your PSG software user manual for details on how to start and stop the impedance test in the software. The results of the impedance test are stored with the recording.

- Stopping an Impedance Test

  An impedance test that has been started can be stopped before it has finished.

  To stop the impedance test:

  - Push the impedance test button Ω on the Bedside Unit.

For information on how to stop the impedance test in the acquisition software, consult your PSG software user manual.

If the impedance test results in an error, check the reference electrode (REF) connection. The impedance test may also result in an error if the impedance of all electrodes is too high.

Activating the Calibration Test Signal

The S4500 recorder, together with the Embla PSG software, allows you to verify the gain for the Bedside Unit. When you activate the calibration test signal from the Embla PSG software, the system sends a calibration signal for 30 seconds to all channels on the Bedside Unit. The signal has an amplitude of +/- 50µV and a frequency of 0.1Hz. See your Embla PSG software manual for calibration instructions.

During Use

If the patient needs to leave the bed during a recording, the clinician or technician is responsible for properly disconnecting the equipment.

The patient should be advised against placing the Bedside Unit on the floor when going to the bathroom. The unit must be hung on a hook or other similar fastener mounted on the wall close to the toilet for that purpose. The Bedside Unit should not be placed under a comforter or a blanket.

Caution:

⚠ To prevent the sling from encircling the patient's neck, the Bedside Unit shoulder strap should not be used when the patient is in bed. Special caution must be taken with children.

System Maintenance

Cleaning the System Units

The Embla S4500 bedside unit is covered with plastic coating and does not require cleaning after each use. When necessary, clean with a damp cloth. Isopropyl alcohol may also be used for disinfecting the exterior of the unit. The contact of liquid to the inner parts and the connectors of the units should be avoided at all times. The bedside unit plastic coating does not withstand cleaning with substances such as acetone.

Cleaning Sensors

The sensors that come in contact with the patient should be cleaned before reuse. Table 7 describes the cleaning procedure associated with each sensor.

Table 7: Sensor Cleaning Instructions

Sensor	Instructions
Oximeter Flex Sensor	This sensor can be cleaned with Isopropyl alcohol or sterilized with ethylene oxide (cold cycle).
Oximeter, Thermistor, and Snoring Sensor	These sensors should be cleaned with Isopropyl alcohol.
XactTrace Belt Lock, Snoring Sensor, and Thermistor	These sensors may be safely wiped clean with hospital grade cleaner that is not corrosive to plastic or metal, and then dried with a clean, dry cloth. Care should be taken to avoid cleaning solution coming into contact with the sensor connectors For sterilization, a standard procedure for gas sterilization should be implemented. Do not autoclave.

Sensor	Instructions
Body Position Sensor	This sensor may be wiped clean with hospital grade cleaner that is not corrosive to plastic or metal and then dried with a clean, dry cloth. Care should be taken to avoid contact of the cleaning solutions with the connectors. For sterilization, a standard procedure for gas sterilization should be implemented. Do not autoclave. The elastic strap may be machine washed in gentle cycle at 40°C or hand washed in warm (not hot) solution of hospital grade laundry detergent and then air dried.

To ensure patient safety, the entire assembly must be completely dry before each use.

Single Use Sensors

The following items are disposable and intended for single use only:

- Nasal cannula
- XactTrace Single-Use belts

Environment

The following limitations apply to both storage and shipment of the Embla S4500:

- The Embla should be stored in a clean, dry environment with a temperature range between -20°C (-4°F) and +60°C (140°F).
- The operating temperature range is between +5°C (41°F) and +45°C (113°F).
- Avoid using the Embla in high humidity, where there is a danger of water condensing inside the recorder.
- The warranty is void if the system is opened.
- Handle the Embla system with care. Despite its rugged design, the unit is not waterproof, splash-proof or dirt-proof.
- Keep connectors free of dust and dirt.

Factory Calibration

The Embla system is calibrated in production and no further calibration is needed.

Disposal

The units in the Embla system are to be disposed of like other electronic equipment.

The Communication Unit contains Nickel Metal Hydride (NIMH) batteries that should be disposed of as such.

Troubleshooting

This section provides some steps that can be taken to quickly troubleshoot the Embla S4500 system. If the system does not operate correctly after troubleshooting, contact your local representative.

- No part of the system is serviceable by third party technical personnel.
- All service on the system (including fuse replacement) shall be performed by Embla or authorized parties only.
- In case of a system failure, the system should be sent in for repair or replacement depending on the warranty agreement.

Problems Starting a Recording

Problems encountered when starting a recording may be caused by the connections.

To correct the problem:

1. Check the voltage setting.
2. Ensure the Communication Unit is connected to a power source. The power indicator light should be green.
3. Check that the Ethernet cable is firmly connected to the rear panel of the Communication Unit.
4. Ensure the cable from the Bedside Unit is firmly connected to the rear panel of the Communication Unit. The power indicator light on the Bedside Unit should be yellow.
5. Try starting a recording. The recording light on the Bedside Unit should be yellow if the system is recording data.

Unclear Signals

A flat signal may simply indicate that an electrode has fallen off or become partially detached. Double-check all electrode connections and sensors.

An unclear respiratory effort signal may be caused by the incorrect preparation of the XactTrace belts. If the crimping of the XactTrace belts is not properly done, the respiratory effort tracing may be incomplete or unclear. Crimping refers to the process of inserting the cut end of the belt into the catch of the Belt Lock and tightening until the white mark on the top matches the closed lock symbol on the catch.

Technical Specifications

Communication Unit

Table 8: Communication Unit Technical Specifications

Description	Properties
LAN (Ethernet)	10Base-T (10 Mbps)
RS232 port speed (COM A & B)	Up to 115.2 kbits per second
Input AC voltage, non-isolated	115 V/ 230 V
Input AC current, non-isolated	100/50 mA
Input DC voltage to 8 AUX channels	±5V
Bandwidth of AUX channels	Max. 0-80 Hz, depending on the sampling rate
Voltage selector	115/230 V
Internal replaceable fuses	2 x 315 mA
Mains power supply	Class II protection (reinforced isolation, no ground lead), frequency 50/60 Hz, isolation voltage 4000 Vac.
Maximum patient leakage current	Complying with IEC 60601-1/UL60601-1
Dimension	• Height 75 mm (2.95 in) • Width 200 mm (7.87 in) • Length 290 mm (11.42 in)
Weight	2300 g (4.41 lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)

Description	Properties
Storage and transport temperature	-20°C (-4°F) to +60°C (140°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% (non-condensing)
COM A & B Serial Ports	RS-232 signal level serial ports. In addition to the RX and TX signals, the port also includes a 5V power source, from which a total of 120mA can be drawn. **Note:** 120mA is the maximum current that can be drawn from both COM A and COM B connectors.
Auxiliary Inputs	Auxiliary devices must meet the following requirements: • Maximum Output Voltage Range: -5 to +5 V • Minimal Dynamic Range: 0.1 V Maximum Bandwidth: 80Hz • Maximum Output Impedance: 1 kOhm

Bedside Unit

Table 9: Bedside Unit Technical Specifications

Description	Properties
ADC bandwidth	DC to 512Hz (-6dB)
Maximum bandwidth	Referential channels: 400Hz Bipolar channels: 400Hz Down-sampled channels: ≥0.45*fs (except for 2kHz sampling)
Signal acquisition channels	• 13 referential channels • 5 bipolar channels

Description	Properties
External channels	Signals supported: Nonin oximeter, Thermistor, Snoring Sensor, Abdominal belt (XactTrace), Thoracic belt (XactTrace), Body Position Sensor
Internal channels	Pressure input Pressure range • ± 50 mbar
Sampling rates (base 10)	Referential channels: Fs = 50, 100, 200 and 500 Hz Bipolar channels: Fs = 2, 10, 20, 50, 100, 200 and 500 Hz. Software selectable for each channel.
Input range	Referential channels: Vin = ±8 mV dynamic range Bipolar channels: Vin = ±350 mV
Input noise	Referential channels: < 2µVrms @ 0.3 to 90Hz (base 10) / 0.3-115Hz (base 2) Bipolar channels: < 2µVrms @ 0.2 to 90Hz (base 10) / 0.3-115Hz (base 2)
Maximum patient leakage current	Complying with IEC 60601-1/UL60601-1
ESD protection	Complies with IEC 60601-1-2
Impedance test output waveform	0.25 µA square wave, 20-30 Hz
Frequency response	Bipolar channels: Max. 0 Hz - 400 Hz, depending on the sampling rate Referential channels: Max. 0.3 Hz - 400 Hz, depending on the sampling rate
Power-line notch filters	Software selectable for each channel. If activated, a notch filter will reject the 50 or 60 Hz power line frequencies when sampling at a higher sampling rate than 200 Hz
Signal noise	Referential channels: Noise levels when sampling at 200Hz is less than 1µVrms Bipolar channels: Noise levels when sampling at 200Hz is less than 2µVrms

Description	Properties
Dimension	Height: 27 mm (1.06 in) Width: 130 mm (5.12 in) Length: 190 mm (7.48 in)
Weight	620 g (1.37 lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-20°C (-4°F) to +60°C (140°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% (non-condensing)

Bedside Unit Bracket

Table 10: Bedside Unit Bracket Technical Specifications

Description	Properties
Dimension	Height 50 mm (1.97 in) Width 140 mm (5.51 in) Length 200 mm (7.87 in)
Weight	370 g (0.82lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-20°C (-4°F) to +60°C (140°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% non-condensing

Oximeter Accuracy for Type Nonin Xpod

Table 11: Oximeter Accuracy for Type Nonin Xpod

Signal	Properties	Accuracy
SpO2 averaged (±1 Standard Deviation)	70 - 100%	±2% for adults using the Finger Clip Sensor
	70 - 100%	±3% for adults using the Flex or Reflectance Sensors
	70 - 100%	±4% for adults using the Ear Clip Sensor
	70 - 95%	±3% for neonates using the infant or neonatal sensors
	Below 70%	Not specified for all sensors
Plethysmograph	75Hz	n/a
Pulse/HR value	18- 300bpm (3Hz)	±3% ±1bpm

Signal	Properties
Oxygen saturation range	Range 0 - 100% (3Hz)
SpO2 beat-to-beat value	0-100% (3Hz)

For more information on oximeters consult the Embla Web site products page (www.embla.com/products).

Materials List

The following table details the Embla S4500 System component materials.

Table 12: Embla S4500 System Materials List

Component	Material
Communication Unit	ABS/PC
Bedside Unit	ABS/PC
System Cables	PVC
Mounting Bracket	Nylon
Shoulder Strap	Nylon
Elastic Strap	Nylon, Velcro®
Electrodes	silver, silver-silverchloride, gold
Leads	RiteFlex® , PVC
XactTrace Respiratory Effort Sensor (Belt Lock)	Polyamide
XactTrace Respiratory Effort Sensor (Belt)	Lycra® and Polyester Elastomer
Nasal Cannula	Polyvinylchloride, Polyethylene
Oximeter	ABS plastic
Oximeter Seal	PVC
Oximeter Flex Sensor	Does not contain natural rubber latex
Oximeter Sensor FlexiWrap	Does not contain natural rubber latex
Medical Tape	Hypoallergenic non-woven tape
Body Position Sensor	ABS plastic
Thermistor	PVC Plastic, C-Flex plastic, lead wire
Snoring Sensor	C-Flex® Thermoplastic Elastomer

Further Readings

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List of Tables

Glossary

A

AHI: Apnea-Hypopnea Index

AI: Apnea Index

ASDA: American Sleep Disorder Association

C

CPAP: Continuous Positive Airway Pressure

E

EEG: Electroencephalogram

EKG/ECG: Electrocardiogram

EMG: Electromyogram

EOG: Electro-Oculogram

ESD: Electrostatic Discharges

H

HI: Hypopnea Index

I

IP: Internet Protocol

IT: Information Technology

L

LAN: Local Area Network

LED: Light Emitting Diode

M

MRI: Magnetic Resonance Imaging

P

PGND: Patient Ground

PSG: Polysomnography

R

RDI: Respiratory Disturbance Index

RF: Radio Frequency

RIP: Respiratory Inductive Plethysmograph

T

TCP: Transmission Control Protocol

TP: Twisted-pair

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