Service Manual

Embla

N7000
S7000

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Embla N7000 and S7000 Service Manual

Draft

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Contents

Introduction

This manual is a service manual for the Embla N7000 and S7000 systems from Medcare. The manual is a supplement to the Embla N7000 and S7000 clinical manual and is intended to assist qualified service technicians when performing maintenance on the systems.

Medical Information

Intended Use

The Embla N7000 and S7000 systems are intended for use by a physician or trained technician for the acquisition of EEG and polysomnography (PSG) signals and transmission of these signals 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 systems does not involve any patient monitoring or diagnosis.

Warnings and Cautions

- Embla is NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING where failure to operate can cause injuries or death of the patient. The term CONTINUOUS MONITORING is specified in the standard EN60601-1. The system is classified as a Class IIa medical device according to the Medical Device Directive (MDD) of the European Union.
- The system may NOT be used for direct cardiac application.
- In the USA, Federal law restricts this system to sale by, or on the order of, a physician.
- No user serviceable parts inside. Serviced by Medcare Flaga and authorized parties only.
- 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 system in an MRI environment.
- The system is not designed to operate in an explosive environment.
- The system is not defibrillator proof.
- While the Embla is recording, it is not advisable to use mobile phones, transmitters and similar equipment that generate RF field in close proximity to the system.
- Signal artifacts may be expected as a result of ESD. A trained operator should

be able to recognize these artifacts easily.

- 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.
- 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 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.

Certifications

Embla is certified to carry the CE mark (CE 0413). The CE mark is a declaration that Embla is in compliance with the directive set forth by the European Union for medical devices.

Embla is manufactured by Medcare Flaga and the system conforms to the following standards and regulations:

- Class IIa, Medical Device Directive (MDD), Annex V, "EC Directive" 93/42/EEC
- EN60601-1:1990 with A1 and A12:1993, A2:1995 and A13:1996. (IEC 60601-1, 2nd ed., 1988 with A1,1991 and A2, 1995) : MEDICAL ELECTRICAL EQUIPMENT –PART 1: GENERAL REQUIREMENTS FOR SAFETY
- EN60601-1-2:2001 MEDICAL ELECTRICAL EQUIPMENT –PART 1: GENERAL REQUIREMENTS FOR SAFETY - 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY – REQUIREMENTS AND TESTS
- EN 61000-3-2:1995 and A14:2000. ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-2: LIMITS - LIMITS FOR HARMONIC CURRENTS EMISSIONS (EQUIPMENT INPUT CURRENT UP TO AND INCLUDING16 A PER PHASE)
- EN 61000-3-3:1995, ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-3: LIMITS - LIMITATION OF VOLTAGE FLUCTUATIONS AND FLICKER IN LOW-VOLTAGE SUPPLY SYSTEMS FOR EQUIPMENT WITH RATED VOLTAGE UP TO 16 A
- EN865:1997 PULSE OXIMETERS – PARTICULAR REQUIREMENTS
- IEC 60601-2-25:1993 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS
- IEC 60601-2-26:1994 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS
- IEC-60601-2-40:1998 PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROMYOGRAPHS AND EVOKED RESPONSE

EQUIPMENT

- EN60601-1-4 MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY - 4. COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS
- UL 2601-1: MEDICAL ELECTRICAL EQUIPMENT, PART 1:GENERAL REQUIREMENTS FOR SAFETY, 2nd ed.1997
- CAN/CSA C22.2 No.601.1-M90 MEDICAL ELECTRICAL EQUIPMENT PART 1: GENERAL REQUIREMENTS FOR SAFETY
- AS/NZS 3200.1.0: 1998 MEDICAL ELECTRICAL EQUIPMENT – GENERAL REQUIREMENTS FOR SAFETY – PARENT STANDARD

System Components

The Embla system consists of three main components: Communication Unit, Bedside Unit and Patient Unit.

The Embla system comes with the following cables: Communication Unit Cables, Bedside Unit Cable, and Patient Unit Cable.

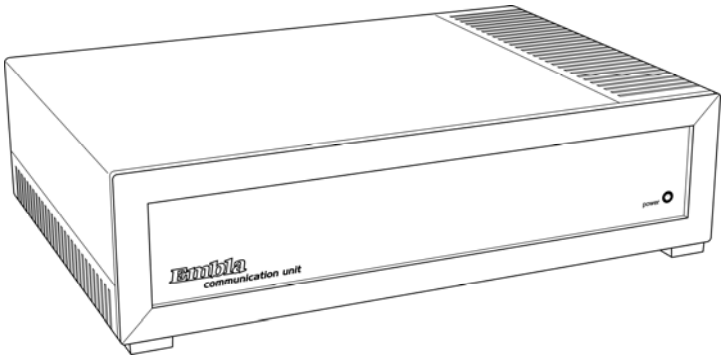
Communication Unit

The Communication Unit communicates between the Embla and an acquisition computer over a Local Area Network (LAN). It supplies the power to the other units of the system, features additional inputs for external devices (such as a CPAP) and provides isolation for patient protection. The Communication Unit functions in part as a patient isolation unit that prevents a direct electrical connection between the patient and the external devices connected to the system.

Explanation of labels and lights

This section gives an overview of the labels and lights on the Communication Unit.

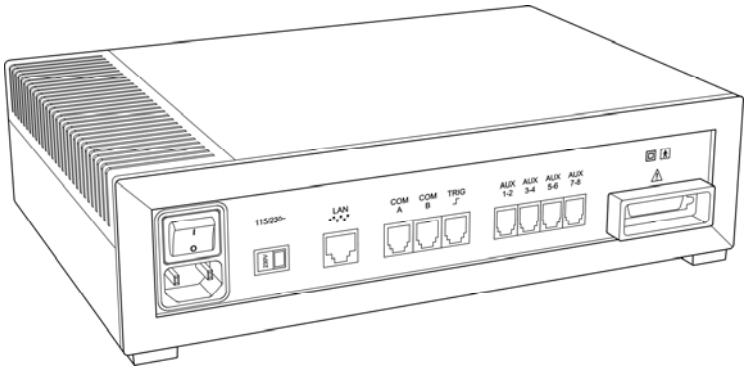
Front Panel



The front panel of the Communication Unit

SYMBOL	DESCRIPTION
Green LED	Power indicator light ON: The unit is turned on OFF: no power to the unit

Rear Panel



The rear panel of the Communication Unit

SYMBOL	DESCRIPTION
115/230V~	Voltage selector switch
LAN	Communication port to the LAN
COM A	Serial port for digital output devices

COM B	Serial port for digital output devices
TRIG ⌐	Trigger input/output port
AUX 1-2	Auxiliary input for devices with analog output signals, up to 2 channels
AUX 3-4	Auxiliary input for devices with analog output signals, up to 2 channels
AUX 5-6	Auxiliary input for devices with analog output signals, up to 2 channels
AUX 7-8	Auxiliary input for devices with analog output signals, up to 2 channels
	Class II power supply. Double isolation
	Type BF applied part
	Attention: consult accompanying documents

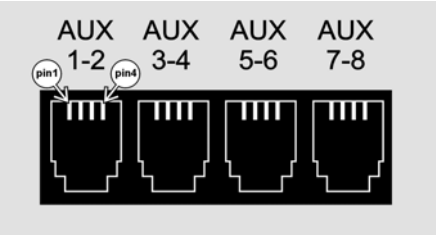
Detailed Interfaces Description

This section includes description and pin-outs of the interfaces of the Communication Unit.

Interfaces description

SYMBOL	TYPE	DESCRIPTION
Internal Mains power supply	Transformer is manufactured by ECU Electronics 24VA, ECU part number RENQ279. Power supply designed by Medcare.	24VA power transformer. Class II protection (double isolation and no ground lead). ON/OFF switch and 115/230V voltage selector. Two internal fuses. Fuse type 315mA “slow blow”. Primary voltage 115/230V, secondary 2x12V/1A
Voltage selector switch	Voltage selector switch from ITW Switches, part no. 18-000-0019.	A voltage selector that determines which voltage is used. The Communication Unit is delivered with the appropriate default voltage setting.
LAN Port	A standard RJ45 connector intended for a twisted pair wire.	Connects the Communication Unit to a network. The required network connection is twisted-pair (TP) Ethernet.
Digital Serial Ports	Modular 6/6	The two digital serial ports inputs are intended for use with supported devices with digital outputs, such as a CPAP or CO_2 device. These connectors host the RS-232 signal level serial ports. In

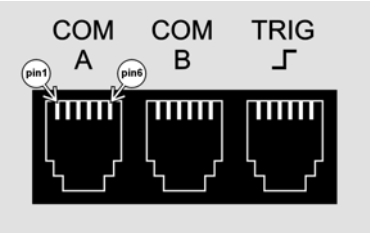
		addition to the RX and TX signals, the port also includes a 5V power source, from which a total of 120mA can be drawn. Note that 120mA is the maximum current that can be drawn from both COM A and COM B connectors. Contact Medcare Flaga at support@medcare.com for information on which external devices can be connected to these ports.
Trigger input/output port	Modular 6/6	A digital 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 N7000 system. Contact Medcare at support@medcare.com for information on which external devices can be connected to this input.
Auxiliary inputs	Modular 4/4	These four dual channel auxiliary inputs can each read 2 channels (8 total) and support devices that output analog signals. See *Technical Specifications* for more detailed information on the auxiliary inputs.
Unit Interface	Centronics half pitch 36	This connection communicates with and supplies power to the other units in the system and is marked with a ⚠



Pin placement of the auxiliary inputs

AUX 1-2		AUX 3-4		AUX 5-6		AUX 7-8	
Pin	**Signal**	**Pin**	**Signal**	**Pin**	**Signal**	**Pin**	**Signal**
1	AUX1+	1	AUX3+	1	AUX5+	1	AUX7+
2	AUX2+	2	AUX4+	2	AUX6+	2	AUX8+
3	AUX2-	3	AUX4-	3	AUX6-	3	AUX8-
4	AUX1-	4	AUX3-	4	AUX5-	4	AUX7-

Pin-outs of the auxiliary inputs



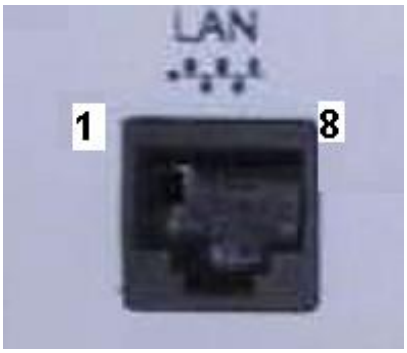
Pin placement of the COM and Trigger ports

COM A		COM B	
Pin	**Signal**	**Pin**	**Signal**
1	TX1	1	TX2
2	RX1	2	RX2
3	NC	3	NC
4	NC	4	NC
5	5V	5	5V
6	GND	6	GND

Pin-outs of the COM Serial ports

TRIG Port	
Pin	**Signal**
1	EXT0
2	EXT1
3	EXT2
4	EXT3
5	EXT4
6	GND

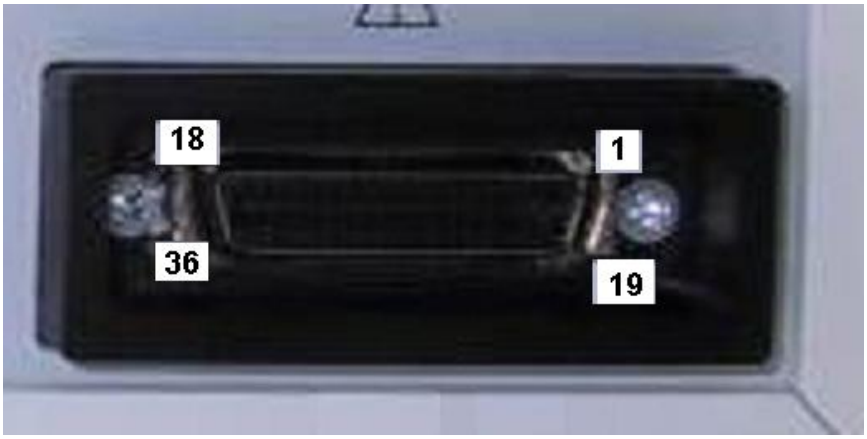
Pin-outs of the TRIG port



Pin placement of the LAN port

LAN	
Pin	**Signal**
1	RC+
2	RC-
3	TX+
4	NC
5	NC
6	TX-
7	NC
8	NC

Pin-outs of the LAN port



Pin placement of the Unit Interface

Unit Interface			
Pin	**Signal**	**Pin**	**Signal**
1	PU_PWR	19	NC
2	GND	20	NC
3	NC	21	Not used
4	NC	22	Not used
5	DR_H	23	Not used
6	RX_L (RU	24	Not used
7	DR_L	25	Not used
8	RX_H (RU	26	TX_L (RU
9	DRDY_L (IRQ)	27	Not used
10	Not used	28	TX_H (RU
11	DRDY_H (IRQ)	29	Not used
12	Not used	30	I2C_SCL
13	RFS_H	31	Not used
14	SCLK_L	32	I2C_SDA
15	RFS_L	33	GND_SENSE
16	SCLK_H	34	NC
17	NC	35	PU_PWR
18	NC	36	NC

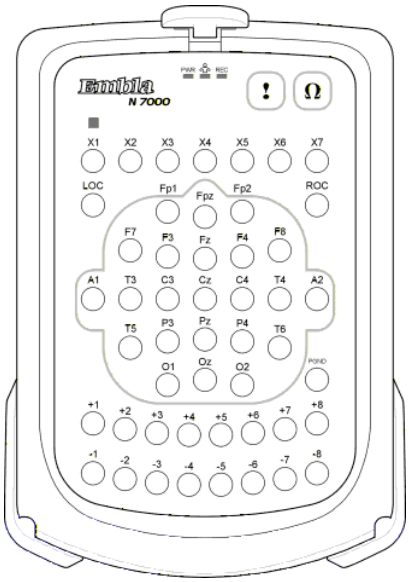
Pin-outs of the Unit Interface

Hardware Version

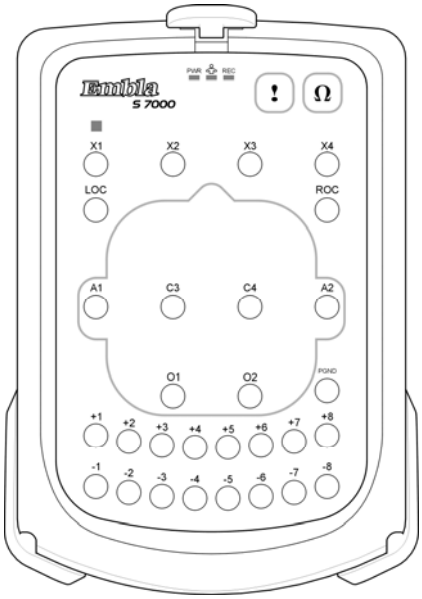
There is only one version in use for the Communication Unit, and thus no version history is available.

Bedside Unit

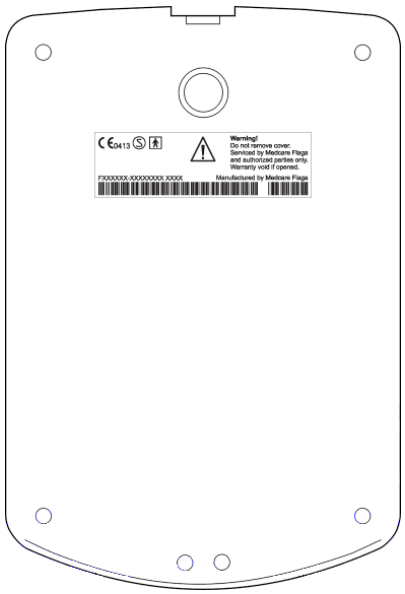
The Bedside Unit reads and transmits the physiological channels used during the study, such as EEG, EOG, EKG/ECG and EMG.



The Input Panel of the N7000 Bedside Unit



The Input Panel of the S7000 Bedside Unit

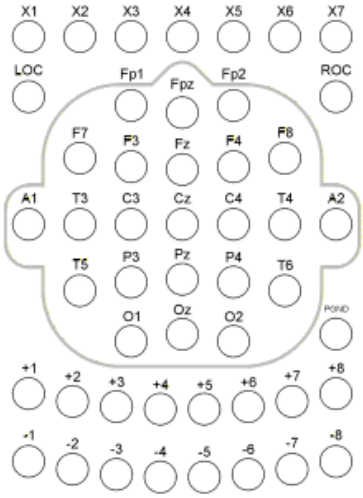
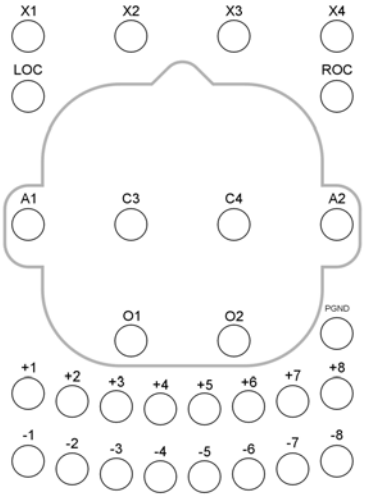


The rear panel of the Bedside Unit

Explanation of labels and lights

This section gives an overview of the labels and lights on the Bedside Unit. The Input Panel of the Bedside Unit features the channel inputs, an event button, an impedance test button, a light detector and status lights. The N7000 and S7000 display different Input Panels.

SYMBOL	DESCRIPTION
PWR	Power Supply Yellow: power connected No light: no power to the unit
	Connection to the Patient Unit Yellow: connection No light: no connection
REC	Recording Status Yellow: recording No light: not recording
Ω	Impedance test button When the impedance test button is pressed the electrode inputs flash orange. The lights then turn green for a short while, indicating that they are working. After that a timed switch starts the impedance test scans. Electrode inputs with

	acceptable impedance display a green light while inputs with high impedance display an orange light.
	Event button, allows the user to time stamp events.
	The Light Detector allows the system to register ambient light information in the patient room
	**N7000** 32 Referential channel inputs - 23 channels are intended for EEG and labeled according to the 10-20 system. - 2 are labeled LOC and ROC and intended for EOG. - 7 are labeled X1 through X7 and are extra referential channels. PGND: label for patient ground electrode 8 Bipolar channel inputs labeled with numbers and "+" and "-" symbols.
	**S7000** 12 Referential channel inputs - 6 channels are intended for EEG - 2 are labeled ROC and LOC and intended for EOG - 4 are labeled X1 through X4 and are extra referential channels. PGND: label for patient ground electrode Bipolar channel inputs labeled with numbers and "+" and "-" symbols.
PGND	Patient ground electrode
	Interface to the Patient Unit
	Attention: consult accompanying documents

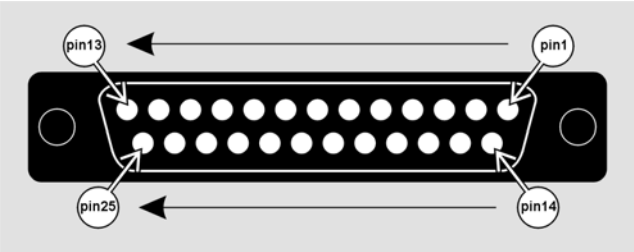
Detailed Interfaces Description

This section includes description and pin-outs of the interfaces of the Bedside Unit.

Interfaces Description

INPUT/INTERFACES	TYPE	DESCRIPTION
Referential channel inputs	Touch proof (DIN 32-802,1,5mm)	32 referential inputs for Embla N7000 12 referential inputs for Embla S7000 The connectors are transparent and labelled according to the 10/20 system
Bipolar channel inputs	Touch proof (DIN 32-802,1,5mm)	8 bipolar inputs for Embla S/N7000 Each of the 8 bipolar channels has two touch proof connectors for the active signal and a reference signal input
PGND	Touch proof (DIN 32-802,1,5mm)	Input for patient ground
Electrocap located on the side of the Bedside Unit	D25	This interface is used with Electrocap technology The Electrocap interface is protected with a cover that should always be in place when the connection is not in use. Do not touch the Electrocap interface when the system is connected to the patient The Electrocap connection should only be used for Electrocap or equipment recommended by Medcare Flaga. The operator is responsible for ensuring patient safety with any other 3rd party equipment that is connected to this port. The attached equipment must fulfill the requirements for electrical safety set forth by the EN60601-1 and UL2601 standards.
Communication Unit Interface on the underside of the Bedsice Unit	Fischer circular female connector 19 pins	This interface is connected to the mounting bracket The interface on the underside of the Bedside Unit should not be touched when the system is connected to the patient
Patient Unit Interface at the bottom end of the Bedside Unit	REDEL 4 pin, plastic black female	This connection communicates with and supplies power to the Patient Unit

Pin placement of the Electrocap connector receptacle



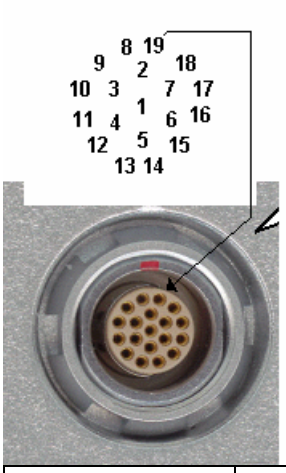
Pin-out of the Electrocap connector for the S7000 Bedside Unit

Pin	Signal	Pin	Signal	Pin	Signal
1	X1	10	+5	19	+3
2	X2	11	A1	20	-3
3	C3	12	LOC	21	+4
4	X3	13	+2	22	-4
5	O1	14	-2	23	-6
6	X4	15	-5	24	A2
7	+1	16	C4	25	ROC
8	-1	17	+6		
9	PGND	18	O2		

Pin-out of the Electrocap connector for the N7000 Bedside Unit

Pin	Signal	Pin	Signal	Pin	Signal
1	Fp1	10	Fz	19	F8
2	F3	11	A1	20	T4
3	C3	12	LOC	21	T6
4	P3	13	NC	22	Cz
5	O1	14	Fp2	23	Pz
6	F7	15	F4	24	A2
7	T3	16	C4	25	ROC
8	T5	17	P4		
9	PGND	18	O2		

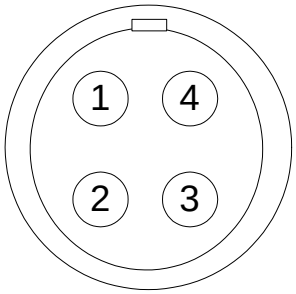
Pin- placement of the Communication Unit Interface on the rear side of the Bedside Unit (Fischer connector).



Pin-out of the Communication Unit Interface (Fischer connector)

Pin number	Signal	Pin number	Signal
1	12C_SDA	11	VCC1
2	PGND1	12	TX_H
3	TX_L	13	RFS_H
4	RFS_L	14	PGND2
5	DRDY_H	15	VCC2
6	SCLK_H	16	DRDY_L
7	DR_L	17	SCLK_L
8	DR_H	18	RX_H
9	12C_SCL	19	RX_L
10	PGND1		

Pin- placement of the Patient Unit Interface (Redel Connector)



Front view on 4 pin Redel connector.

Pin- out of the Patient Unit Interface

Redel 4 pin – pin number	Signal
1	3V3
2	TX
3	RX
4	GND

Hardware Versions

There is only one version in use for each system type of the Bedside Unit, and thus no version history is available.

Patient Unit

The Patient Unit reads and transmits the respiratory data.

The Patient Unit

In addition to an internal pressure transducer and a position sensor, external respiratory sensors are connected to the Patient Unit.

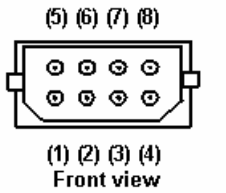
Symbols on the Patient Unit

The only symbol on the Patient Unit is the ! symbol that marks the event button. The RU shall “beep” when the event button is pushed. There are no lights on the unit.

Detailed Interfaces Description

Interfaces Description

SYMBOL	TYPE	DESCRIPTION
A top multipole port	JAE "TX20A-26R D 2GF1-A1L"	Connects to the desired proxy
Bedside Unit Interface	Micronector 8 pole male	Interfaces with the Bedside Unit
A top Luer Lock	Luer	Connects to a nasal cannula for measuring nasal pressure A flow generator with pressure tubing can also be connected to the Luer Lock to record mask pressure



Pin placement of the Bedside Unit Interface

Micronector male pin	Signal
2	3V3
3	TX
6	RX
7	GND

Pin out of the Bedside Unit Interface

Pin placement of the Bedside Unit Interface

Proxies

A proxy is an interface containing electronics. External sensors connect to the proxy inputs.

Front view of a proxy

Top view of a proxy

Z10 and X10 Proxy 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

Inserting a Proxy

1. Insert the desired proxy and push firmly.
2. The Patient Unit will beep if the power is on.

Hardware Version

There is only one version in use for the Patient Unit, and thus no version history is available.

Communication Unit Cables

Power Cable

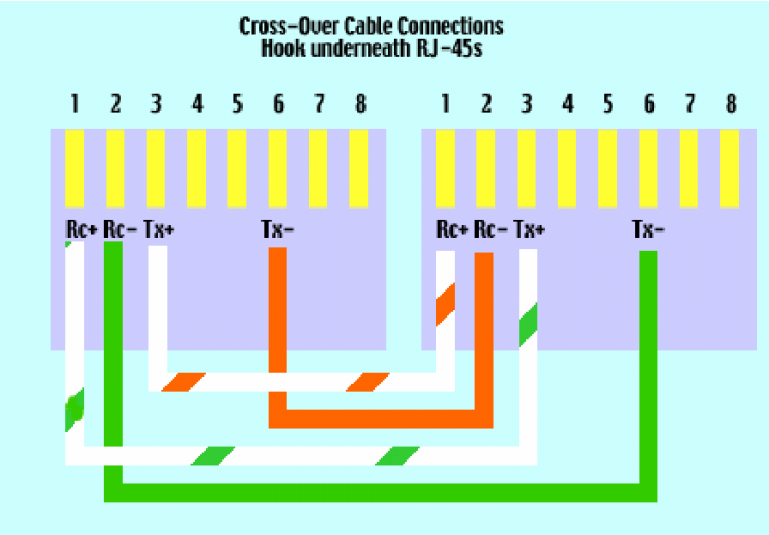
This cable plugs into the mains power input on the back of the Communication Unit and to a standard wall outlet. This cable is delivered to the customer either with an European plug or US plug.

Standard Ethernet Cable

This cable plugs into the LAN port on the rear panel of the Communication Unit and to an Ethernet wall outlet. The cable is gray and 5m (197") long. It is used to connect the system to an already installed network.

Crossover Ethernet Cable

This 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 (98") long. The crossover cable is used, e.g., when testing the system and it cannot be used to connect to an Ethernet wall outlet.



Pin-out for the Cross Over cable

Serial Communication Unit Cable

This 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.

Bedside Unit Cable

This cable connects the Bedside Unit to the Communication Unit. It connects to the Interface marked ⚠ on the rear panel of the Communication Unit through a Centronics half pitch 36-pin connector. This cable is permanently fastened to the mounting bracket and should not be removed unless it needs to be replaced.

Regarding the pin-out for the Centronics half pitch 36-pin connector see the section about the Communication Unit.

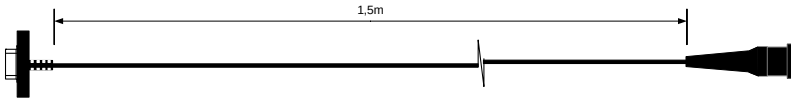
The Bedside Unit is designed to be easily connected and disconnected, rugged and mountable anywhere. Therefore, a special mounting bracket with a quick release feature is included in the system that can be mounted, for example, on a wall or a bedside table.

A handle is attached to the Bedside Unit to simplify mounting and dismounting from the mounting bracket.

Dismounting the Bedside Unit using the handle

Patient Unit Cable

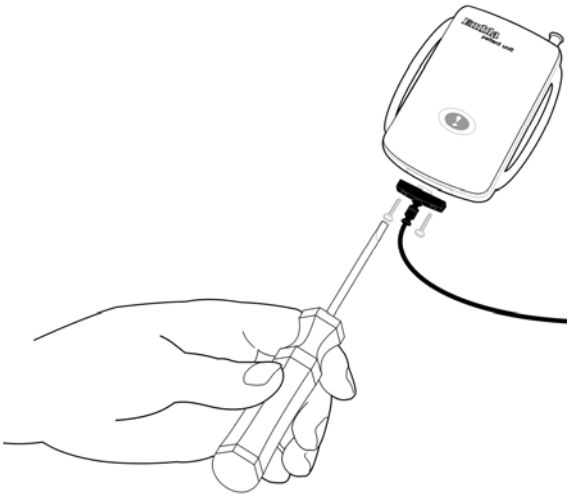
This cable connects the Patient Unit to the Bedside Unit. The system comes with the cable already connected to the Patient Unit. The one end that connects to the Patient Unit is of type Micronector 8 pole female. The other end of the cable is of type Redel 4 pin male and plugs into the Patient Unit Interface on the bottom end of the Bedside Unit.



The Patient Unit cable

This cable should not be disconnected from the Patient Unit during daily use. However, if the cable needs to be replaced (for example with a 3m long cable also available), it can be detached from the Patient Unit by unscrewing the two screws (2mm) that secure it to the unit, see picture.

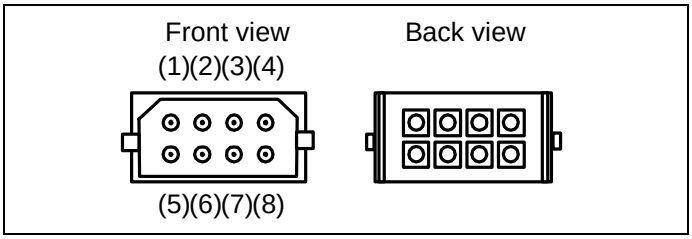
Changing the Patient Unit cable



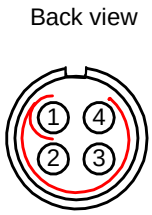
Connection table for the Patient Unit Cable

Micronector female	Lemo (REDEL) connector	Color
2	1	RED
7	2	BLUE
3	3	YELLOW
6	4	BLACK

Pin-placement for the Micronector 8 pole female connector



Pin-placement for the Redel 4pin male connector

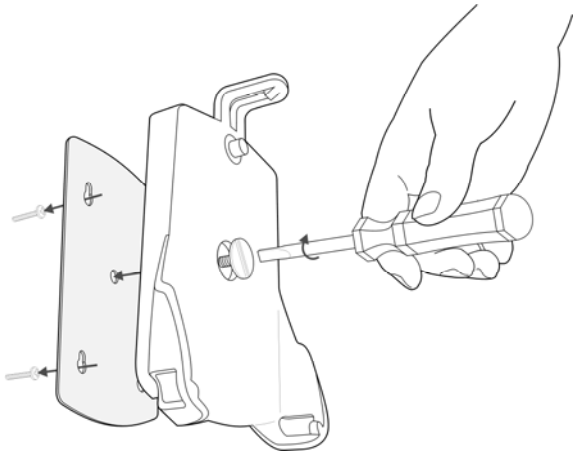


Assembling the System

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 and requires no setup. To mount the bracket:

1. Unscrew the metal plate from the bracket.
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.



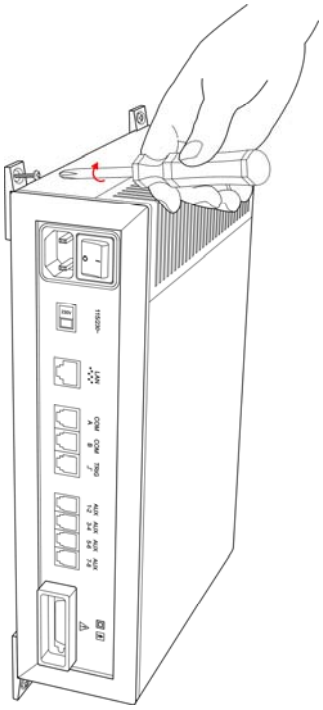
Mounting the Bedside Unit bracket

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

Mounting the Communication Unit

It is possible to secure the Communication Unit by mounting it, for example, on a wall.

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

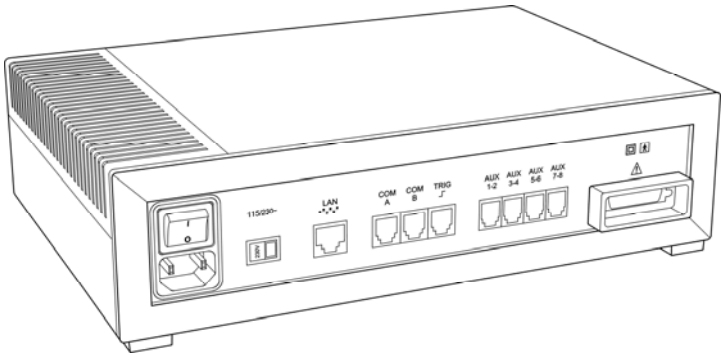
Connecting the Units

This section details the connection of the system units. This should only be done by a trained technician.

Connecting the Communication Unit

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

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



Inputs on 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.
4. Connect the cable to the Ethernet outlet on the wall.

Note: It is recommended that the network being used for collecting sleep studies be isolated from other net traffic.

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.

Note: Check the input/output ranges before connecting external devices. The COM connectors on the Communication Unit are type RJ-12 6/6 modular plugs and the AUX connectors are type 4/4 modular plugs.

6. Connect the Bedside Unit cable to the interface labeled ⚠.

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

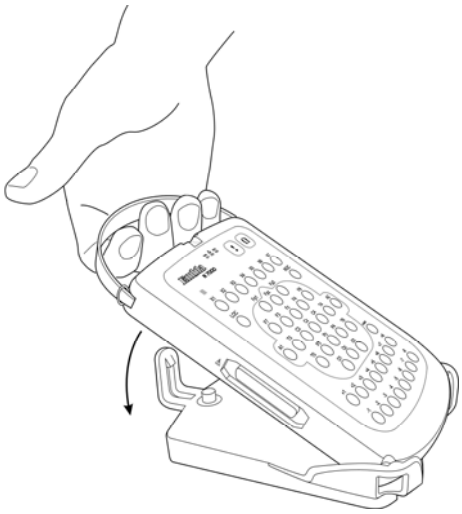
The cable from the Communication Unit is already locked into the mounting bracket and requires no setup.

Connecting 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.

For precautionary reasons, the interface on the rear panel of the Bedside Unit and the Electrocap interface must not be touched when the system is connected to the patient.

3. Press the top end of the Bedside Unit down into the bracket until it clicks into place.



Connecting the Bedside Unit to the bracket

Disconnecting from the Bracket

1. Push the quick-release clip away from the unit.

Opening the quick-release clip

2. Hold the handle and pull the Bedside Unit out of the bracket.

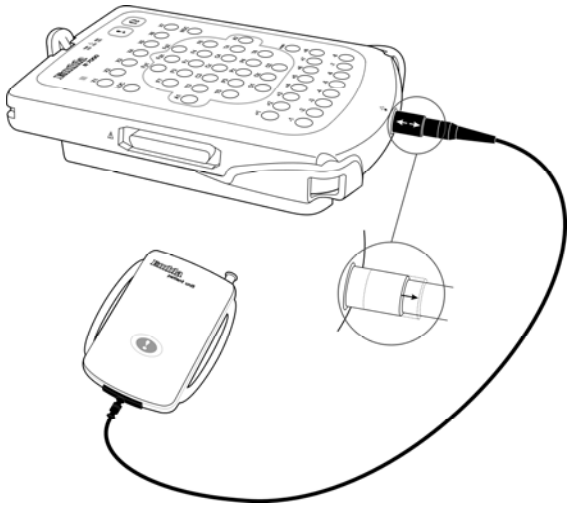
Releasing the Bedside Unit

Connecting the Patient Unit

The end of the Patient Unit cable that interfaces with the Patient Unit is already connected. This end of the cable should not be disconnected unless the cable needs to be replaced.

Connecting to the Bedside Unit

The connector on the Patient Unit cable has a lock-release mechanism that locks into place when it is pushed into the interface on the Bedside Unit.



Connecting and disconnecting the Patient Unit cable

Disconnecting from the Bedside Unit

1. Slide down the lock-release mechanism as shown with the arrows above.

Cautions for 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.

Installing the System on the Network

Overview

This section gives a brief introduction on how to install the Embla N7000 and S7000 systems on the network. This should only be done by a trained technician. For more detailed instructions see the Medcare knowledge base on www.medcare.com or contact support@medcare.com.

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 acquisition 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.

TCP/IP and Ethernet are industry standard solutions for networking devices. A wide variety of equipment is available for implementing this kind of network.

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 in the following:

A Networked

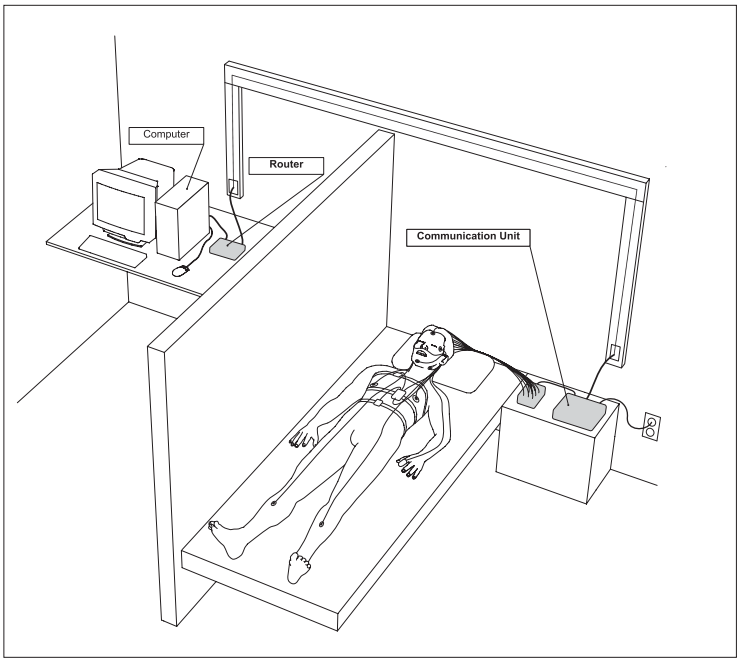
The conventional way to set up an Ethernet network is to use a star topology with one central unit, which can be a router, hub or switch. For more detailed instructions, such as which router Medcare recommends, see the Medcare knowledge base on www.medcare.com.

1) 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.

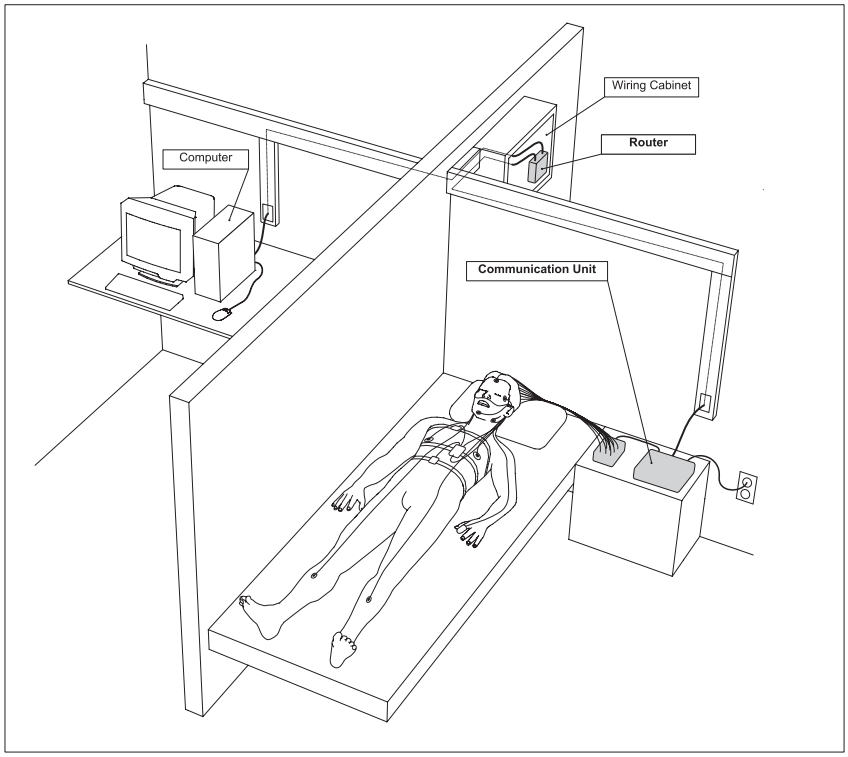
The network can be installed by placing a router with a built-in DHCP server in the control room and connecting all the devices, both Emblas and computers, to the router with standard Category 5 twisted-pair Ethernet cables.

If the Embla N/S7000 is replacing an Embla A10, the Ethernet cable that is connected from the Isolation Unit to the computer can be used to connect the Embla N/S7000 Communication Unit with the router.



Network connection with one Embla, one Computer and a router

It is also possible to place the router in a central wiring cabinet and connect both the computer and the Embla to that cabinet as shown.



Network connection with one Embla, one Computer and the router placed in a Wiring Cabinet

Most routers 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 router. In case the acquisition computer needs to be connected to a larger network, a second Ethernet adapter may be added to the computer.

2) 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.

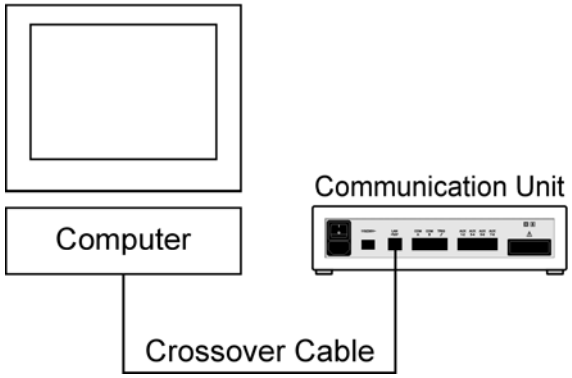
B Direct

The Embla system can be connected directly to the acquisition computer with a Crossover Cable. This is a special kind of Ethernet cable that allows a connection without any central unit such as a router, switch or a hub.

To establish a direct connection, plug one end of the cable into the LAN port on the Communication Unit and the other end into the Ethernet port on the computer. No further connections should be necessary. Only one Embla can be connected to each computer in this way.

This method is effective, for example, when using a portable computer to record in a remote location.

Note: The direct configuration is not possible in networks with more than one system.

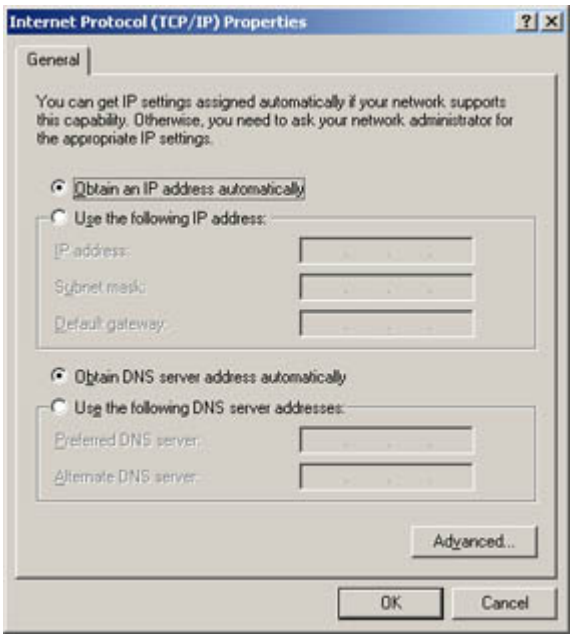


Direct connection

Computer Setup

The following computer setup instructions refer only to setup with router. Regarding setup with crossover cable, the IP Address must be manually set, see "*Troubleshooting*" for further instructions.

Both the Embla and the computer should come preconfigured to "*Obtain IP Address Automatically"*. To verify this setting on the computer, open the Control Panel and Network connections. Double click on the LAN connection and click "*Properties***"**. Then select "*TCP/IP*" and click "*Properties*". The settings should look like this:



Internet Protocol Properties

Installing the Embla for Somnologica

Somnologica should be installed on the computer.

1. Open Somnologica and choose "*Add Device*" from the Device menu
2. Select "*Automatically Scan for Devices"* and click *"Next"*.
3. If the Embla is turned on and connected to the router, it should appear in the wizard. Select the device and click "*Next"*.
4. Give the Embla a representative name and click "*Next"*.
5. Click "*Finish"* to complete the installation and the Embla will show up in the list of devices in the Device Manager
6. If all communications are working properly, the small red X will disappear in few seconds and the Embla can be used for recordings

New device wizard

Refer to the "*Troubleshooting*" section if Somnologica does not find the Embla, or if the red cross remains on the device icon in the Somnologica device manager listing.

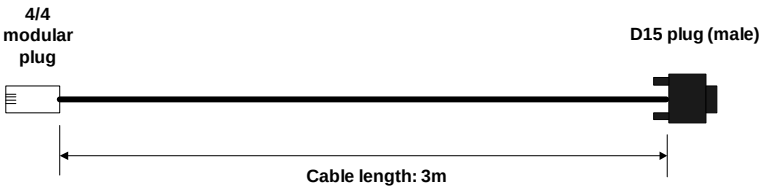
System Accessories

Overview

The Embla S/N7000 system accessories include cables to connect analog outputs from the following devices to the Communication Unit. The system accessories are described in detail in the following section.

Embla Masimo Radical™ Oximeter Cable

This cable is used to connect Analog outputs of the Masimo Radical oximeter to the Auxiliary channels of the Communication Unit.



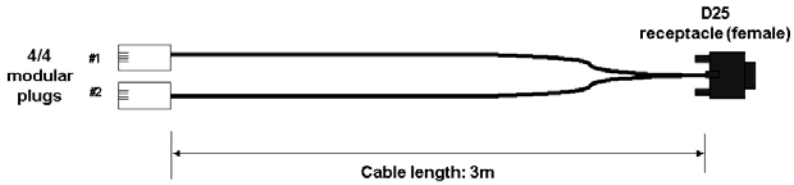
Schematic of the Embla Masimo Oximeter Cable

Modular Plug Signal Name	4/4 Modular Plug pin number	D15 Signal Name	D15 Plug pin number
AUX1	1	$\%SpO_2$	9
AUX2	2	Pulse rate	15
GND	3	GND	14
GND	4	GND	8

Pin-out table for the Embla Masimo Oximeter Cable

Embla BCI Capnocheck™ CO_2 Cable

This cable is used to connect Analog outputs of the Capnocheck CO_2 monitor Capnocheck Plus from BCI to the Auxiliary channels of the Communication Unit.



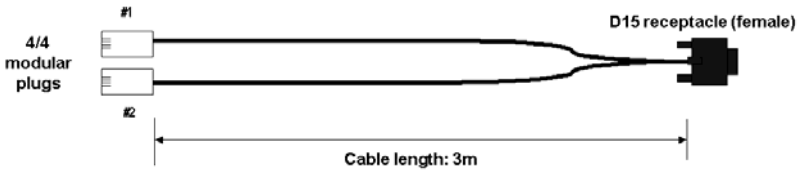
Schematic of the Embla Capnocheck CO2 Cable

Modular Plug Signal Names	4/4 Modular Plug #1 pin numbers	D25 Receptacle Signal Names	D25 Receptacle Pin numbers
AUX1	1	Analog 1	21
AUX2	2	Analog 2	23
GND	3	GND	7
GND	4	GND	7
	4/4 Modular Plug #2 pin numbers		
AUX1	1	Analog 3	24
AUX2	2	Analog 4	19
GND	3	GND	7
GND	4	GND	7

Pin-out table for the Embla Capnocheck CO2 Cable

Embla to Radiometer TCM3™ CO_2 Monitor Cable

This cable is used to connect Analog outputs of the Radiometer TCM3 CO_2 monitor to the Auxiliary channels of the Communication Unit.



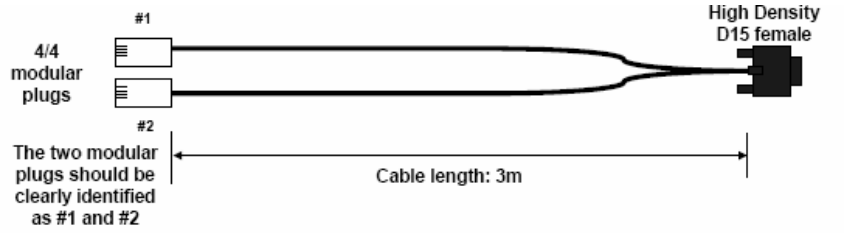
Schematic of the Embla to TCM3 CO2 Monitor Cable

Modular Plug Signal Names	4/4 Modular Plug #1pin numbers	D15 Receptacle Signal Names	D15 Receptacle Pin numbers
AUX1	1	PO_2	9
AUX2	2	PCO_2	10
GND	3	GND	15
GND	4	GND	15
	4/4 Modular Plug #2pin numbers		
AUX1	1	TEMP	8
AUX2	2	ALARM	5
GND	3	GND	15
GND	4	GND	15

Pin-out table for the Embla to TCM3 CO2 Monitor Cable

Embla to Radiometer TCM4™ CO_2 Monitor Cable

This cable is used to connect Analog outputs of the Radiometer TCM4 CO_2 monitor to the Auxiliary channels of the Communication Unit.



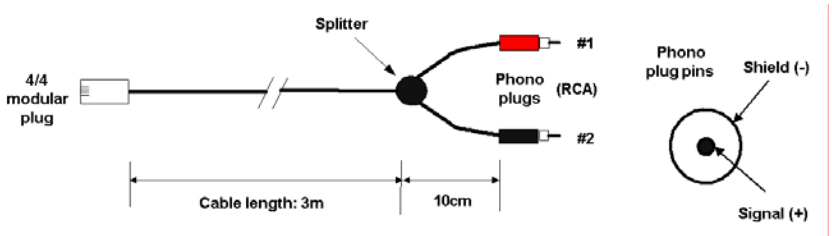
Schematic of the Embla to TCM4 CO2 Monitor Cable

Modular Plug Signal Names	Modular Plug #1pin numbers	D15 Receptacle Signal Names	D15 Receptacle Pin numbers
AUX1	1	PO_2	13
AUX2	2	PCO_2	14
GND	3	GND	5
GND	4	GND	5
	4/4 Modular Plug #2 pin numbers		
AUX1	1	TEMP	12
AUX2	2	HEAT	11
GND	3	GND	5
GND	4	GND	5

Pin-out table for the Embla to TCM4 CO2 Monitor Cable

Embla to ResMed ResControl™ Cable

This cable is used to connect Analog outputs of the ResMed ResControl Unit to the Auxiliary channels of the Communication Unit.



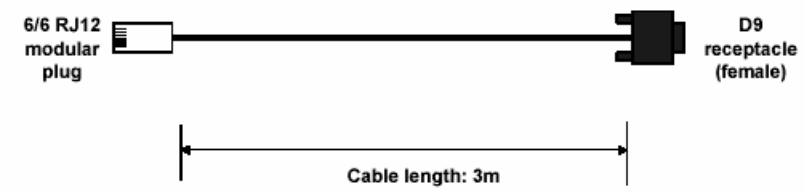
Schematic of the Embla to ResMed ResControl Cable

Modular plug Signal Names	4/4 Modular Plug	Phono Plugs/RCA Signal Names
AUX1	1	Phono plug 1 (red) Signal (+)
AUX2	2	Phono plug 2 (black) Signal (+)
GND	3	Phono plug 2 (black) Shieldl (-)
GND	4	Phono plug 1 (red) Shieldl (-)

Pin-out table for the Embla to ResMed ResControl Cable

Embla Serial Cable

This cable is used to connect RS232 serial port of the AutoSet to COM port on the Communication Unit. It can also be used to communicate directly with a serial port on a PC for troubleshooting purposes.



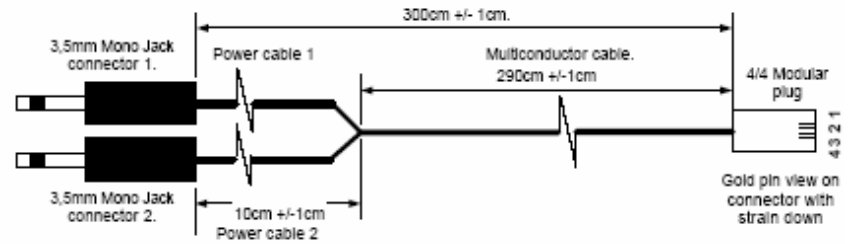
Schematic of the Embla Serial Cable

Modular plug Signal Names	Modular Plug	D9 Receptacle (female) Signal Names	D9 Receptacle (female) pin no
TX	1	RX	2
RX	2	TX	3
5V	5	DTR	4
GND	6	GND	5

Pin-out table for the Embla Serial Cable

Embla to DMDavis NPT Cable

This cable is used to connect Analog outputs of the DMDavis NPT Unit to the Auxiliary channels of the Communication Unit.



Schematic of the Embla to DMDavis Cable

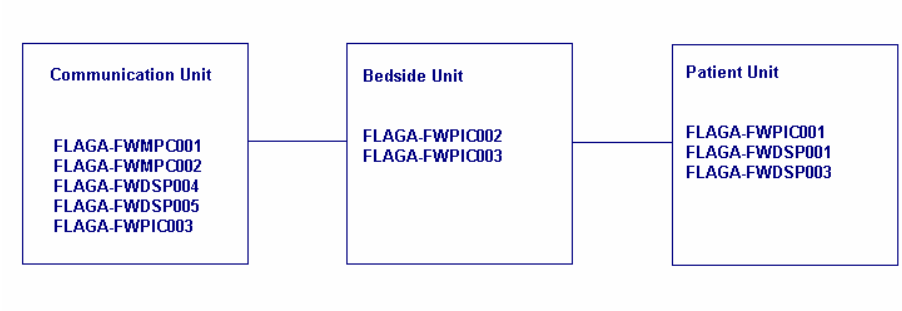
4/4 Modular plug	Multicond. Cable	Jack Connector 1	Power Cable 1	Jack Connector 2	Power Cable 2
1	Black	Center	White		
2	Red			Center	White
3	Green	Shield	Brown		
4	Yellow			Shield	Brown

Pin-out table for the Embla to DMDavis Cable

Firmware

Overview

The Embla S/N7000 is composed of several firmware modules, which run on several processors, which are distributed through the system.



Overview of firmware components

For easier handling of the firmware components, they were combined into four firmware packages according to the table below:

Overview of firmware components

Firmware packet	Modules included	Description
FLAGA-FWCOM002	FLAGA-FWPIC001 FLAGA-FWDSP001 FLAGA-FWDSP003	Firmware modules for the Patient Unit Can be upgraded in the field
FLAGA-FWCOM004	FLAGA-FWPIC002 FLAGA-FWPIC003	Firmware modules for the Bedside Unit Can be upgraded in the field
FLAGA-FWCOM006	FLAGA-FWMPC001 FLAGA-FWDSP004 FLAGA-FWDSP005 FLAGA-FWMPC002	Firmware modules for the Communication Unit (except the PIC firmware) Can be upgraded in the field
FLAGA-FWCOM007	FLAGA-FWPIC003	Firmware module for the PIC processor in the Communication Unit Cannot be upgraded in the field. The Unit must be serviced by Medcare if an update is required

The latest firmware version can be found on the Medcare software download site at http://www.medcare.com.

Firmware Versions

The following tables show the Version Log File of the firmware packages and the compatibility between these.

Versions Log File of the FLAGA-FWCOM002 firmware

Firmware Version	Release date	Compatibility
FLAGA-FWCOM002-0100	7.11.2002	First Version
FLAGA-FWCOM002-0101	7.11.2002	Compatibility not guarantied for FWCOM006-0102 but to all versions of FWCOM004 and to FWCOM006-0101 and earlier and FWCOM007-0100
FLAGA-FWCOM002-0102	3.1.2003	Compatible with FWCOM004-0101, FWCOM006-0102 and FWCOM002-0100

Versions Log File of the FLAGA-FWCOM004 firmware

Firmware Version	Release date	Compatibility
FLAGA-FWCOM004-0100	8.11.2002	First Version
FLAGA-FWCOM004-0101	8.11.2002	Compatible with FWCOM002-0102, FWCOM007-0100 and all versions of FWCOM006 released until 3.1.2003

Versions Log File of the FLAGA-FWCOM006 firmware

Firmware Version	Release date	Compatibility
FLAGA-FWCOM006-0100	8.11.2002	First Version
FLAGA-FWCOM006-0101	14.11.2002	Compatible with FWCOM002-0102, FWCOM007-0100 and all versions of FWCOM004 released until 3.1.2003
FLAGA-FWCOM006-0102	14.11.2002	Compatible with FWCOM002-0102, FWCOM007-0100 and all versions of FWCOM004 released until 3.1.2003

Versions Log File of the FLAGA-FWCOM007 firmware

Firmware Version	Release date	Compatibility
FLAGA-FWCOM007-0100	8.11.2002	First Version Compatible with FWCOM002-0102 and all versions of FWCOM004 and FWCOM006 released until 3.1.2003

Checking the Versions

Information about each unit can be derived from the homepage of the device. To access the homepage do the following steps (the instruction are only given for the Somnologica application from Medcare):

1. Open Somnologica
2. Open Device Manager: View->Workspace->Devices
3. From the Device menu right click on each device at a time. You will see a drop down list
4. From the drop down list select Properties and simultaneously press

the Ctrl. key on the keyboard

5. A Device Properties window is displayed which has a button "Configure"
6. Press the "Configure" button. Then you have accessed the homepage of the device
7. Select the System Information tab

Note: Depending on network setup, it may not be able to access the device homepage through a proxy server. If the device homepage does not appear after step 6, disable any proxy servers you may be using. The proxy settings are accessed through the "Connections" tab under Tools->Options in Microsoft Internet Explorer.

Upgrading the firmware

The following instruction steps for upgrading the firmware are only given for the Somnologica application from Medcare.

Communication Unit

The steps involved in updating the firmware version of the Communication Unit are:

1. Save the FLAGA-FWCOM-006-APPLICATION file to your Desktop
2. Go the device homepage (see above)
3. Select the Firmware Update tab
8. Check by Communication Unit
9. Select the Browse button and browse for the newest FLAGA-FWCOM-006-APPLICATION file
10. Select Upload
11. You will be asked for a password. This password may be changed by the user but the factory default password is “Embla” with a capital E
12. After this is done go into the patient room and reboot the device by turning the power off for 10 seconds and on again
13. Confirm that the correct build has been installed by going into the device properties

Bedside Unit

The steps involved in updating the firmware version of the Communication Unit are:

1. Save the FLAGA-FWCOM-004-APPLICATION file to your Desktop
2. Go the device homepage (see above)
3. Select the Firmware Update tab
4. Check by Bedside Unit
5. Select the Browse button and browse for the newest FLAGA- FWCOM-004-APPLICATION file from your Desktop
6. Select Upload
7. You will be asked for a password. This password may be changed by the user but the factory default password is “Embla” with a capital E
8. During the uploading the Power light on the Bedside Unit blinks
9. After this is done go into the patient room. The light should stop to blink after about 2 minutes from the update start. If it is still blinking something went wrong. Then you should repeat the update procedure.
10. Confirm that the correct build has been installed by going into the device properties

Patient Unit

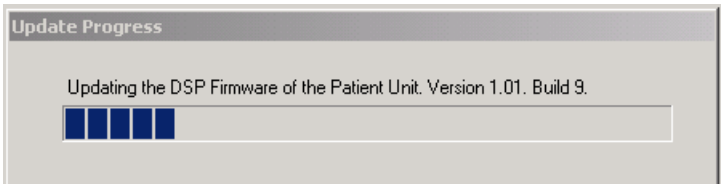
To update the FWCOM002 firmware the user must use a special cable that is delivered to the customer and a special port application program.

The steps involved in updating the firmware version of the Patient Unit are:

1. Run the Embla Patient Unit Firmware Update Program (FWCOM002xxx.exe). This program updates the software running inside the Embla Patient Unit
2. Exit Somnologica
3. Disconnect the Patient Unit from the Bedside Unit
4. Connect the Patient Unit via the Embletta Download Cable to a COM port on the PC as shown on the picture

5. Press the button “Update Firmware”
6. A dialog box shows the current firmware for the Patient Unit and what firmware is going to replace it

7. Press Yes if you want to proceed. During the upgrading of the firmware a dialog is shown with a progress bar



8. First the DSP firmware is updated after that the device beeps and proceeds with updating the PIC firmware. After that the device beeps again.
9. When the update is finished a dialog box is shown. Press the “OK” button

Note: The firmware file can be downloaded to any convenient location on the computer, such as the desktop.

System Maintenance

Cleaning

System Units

Embla system units are covered with plastic coating. The units do not require cleaning after each use but when necessary, clean with a damp cloth. Ethanol may also be used for disinfecting the exterior of the system units. The contact of liquid to the inner parts and the connectors of the units should be avoided at all times. The coating does not withstand cleaning with substances such as acetone.

Reusable Sensors

The Velcro Straps may be washed in a washing machine at 40ºC.

The sensors that come in contact with the patient should be cleaned before reuse:

- Oximeter Flex Sensor – This sensor can be cleaned with ethanol or sterilized with ethylene oxide (cold cycle).
- Oximeter, Thermistor and Snoring Sensor – These sensors should be cleaned with ethanol.
- Piezo Respiratory Effort Sensors – These sensors may be safely soaked clean in a warm (not hot) solution of hospital grade laundry detergent and then air-dried. Care should be taken to avoid cleaning solution coming into contact with the sensor plugs.
- XactTrace Belt Lock – This sensor may be cleaned with a moist cloth in hospital grade laundry detergent and dried with a clean, dry cloth. Care should be taken to avoid cleaning solution coming into contact with the sensor connector and plug of the Belt Lock.

Single Use Sensors

The following items are intended for single use only:

- Nasal cannula.
- XactTrace sensor belts.

Environment

The Embla should be stored in a clean, dry place and it tolerates temperature in the range between -20°C and +60°C. The warranty is void if the system is opened. Handle the Embla system with care. Despite its rugged design, it is not waterproof, splash proof or dirt proof.

The operating temperature range is between +5°C and +45°C. Avoid using the Embla in high humidity, where there is a danger of water condensing inside the recorder. 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 Hydrid (NIMH) batteries that should be disposed of as such.

Troubleshooting

Overview

This section provides some steps that can be taken to quickly troubleshoot the system. If the system does not operate correctly after troubleshooting, contact your local representative. No parts of the system are serviceable by third party technical personnel. All service on the system (including fuse replacement) shall be performed by Medcare 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.

Troubleshooting network connections

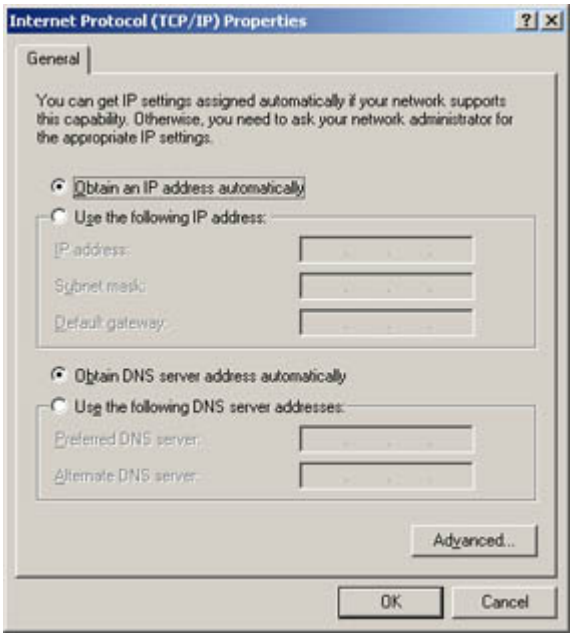
If an acquisition computer fails to communicate with an Embla after all connections have been made, the following steps should be checked.

Cabling

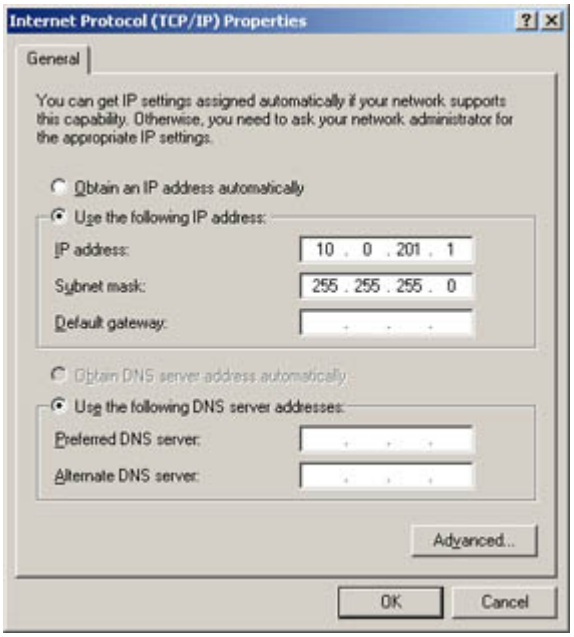
It is vital that good quality cables are used throughout. If all cables are rightly connected, a Link LED will light up on the router and usually also next to the network connector on the back of the acquisition computer. If a Link LED does not light, the cabling must be checked.

TCP Setup on Computer

a) The simplest way to connect the Embla to a computer is by using a router with a built-in DHCP server as described in the section "*Installing the system on the network*"http://www.medcare.com/support/knowBase/show.asp?ID=293. In this setup, the computer should be set to "*Obtain an IP Address Automatically*".

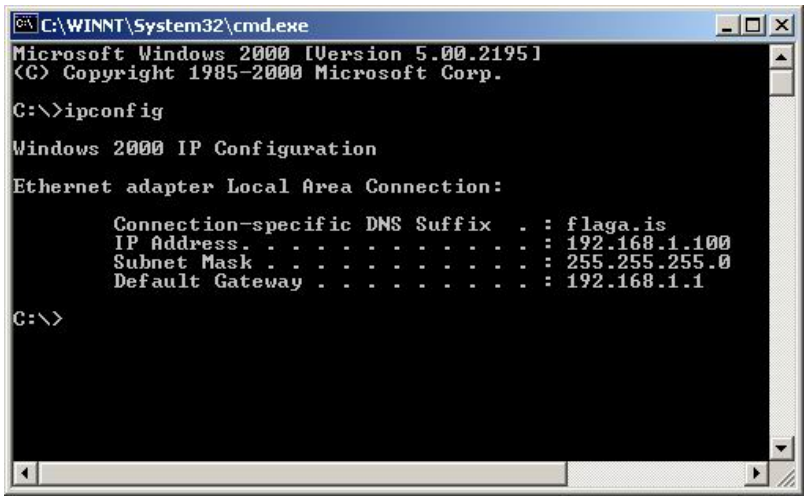


b) If a crossover cable is used to connect the Embla directly to an acquisition computer, both the Embla and the computer should be set to use manually assigned IP addresses from the same address range (the same subnet). An Embla that does not find a server for automatically assigned addresses (DHCP) will default to the address 10.0.201.4. A good address in the same range is 10.0.201.1. Set the TCP/IP for the computer as shown.



c) If the Embla and the acquisition computer are both connected to a larger network, the administrator for that network should be consulted to determine appropriate settings.

To verify that the computer is correctly configured, open the Command Prompt from Programs->Accessories under the Start menu. Type in the command: *ipconfig*. It should give you a listing similar to the following.



Communication

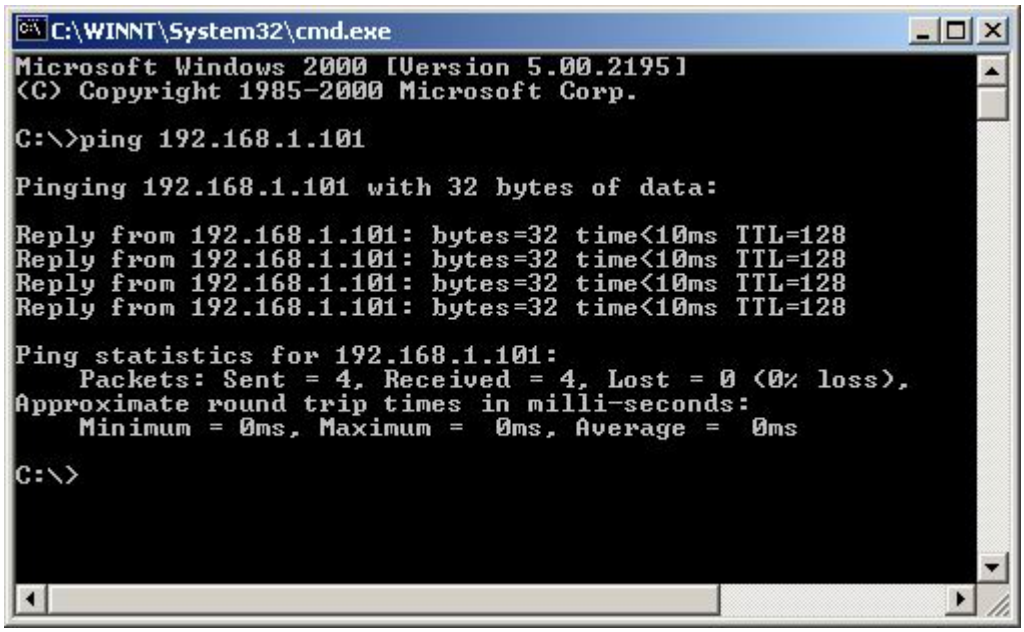
The next step is to verify that the computer can communicate with the Embla. First the IP address of the Embla must be determined.

If the Embla is found when you scan for devices in Somnologica, the IP address will be displayed next to the serial number.

If you are using a router with a built-in DHCP server, the router determines the IP addresses. The computer and the Embla will have different IP addresses. Refer to the documentation for the router to determine the IP addresses.

If you are using a crossover cable, the default address for the Embla will be 10.0.201.4.

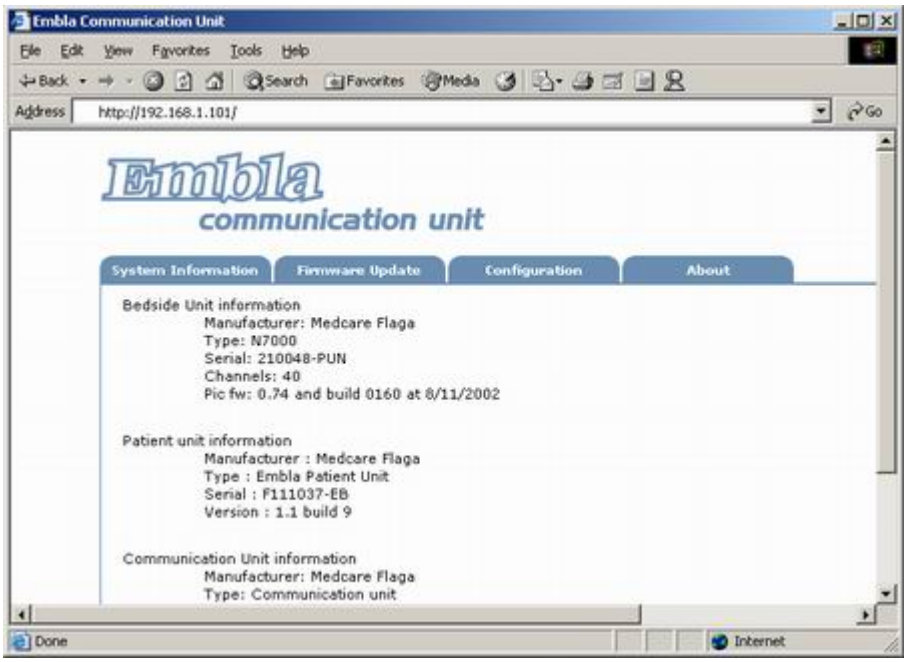
Using the Command Prompt, type in the command ping <ip address>, where <ip adress> is the IP address of the Embla. If basic communications are working, you should get a screen similar to the following:



If you get no reply from the Embla, you need to verify the IP address of the Embla and the computer and make sure that they are both in the same range and that they are not using the same address.

Embla Setup

Once communication has been established, Internet Explorer can be used to review and edit the settings of the Embla. Open Internet Explorer and make sure that a proxy is not being used. To access proxy settings; click on "*LAN Settings*" under the "Connections" tab in the "Options" dialog. Type in the address of the Embla on the form http://192.168.1.101/. You should get the main window for the Embla as shown.



In the web interface you can verify that firmware versions and IP settings for the Embla are as they should be. Contact support@medcare.com - to establish current firmware versions.

If you have got this far, you should be able to add the Embla by using the New Device Wizard in Somnologica.

If the Embla can be added manually (by entering the IP address) but is not found when Somnologica automatically scans for devices, something may be blocking UDP traffic on the network. Make sure that the Embla and the computer is plugged into the same switch or router, and that the router is not blocking out any traffic.

Using the Embla Serial Cable for troubleshooting

By using the Embla Serial Cable and the program HyperTerminal it is possible to show the desired and current network configuration and to change it.

Connection description

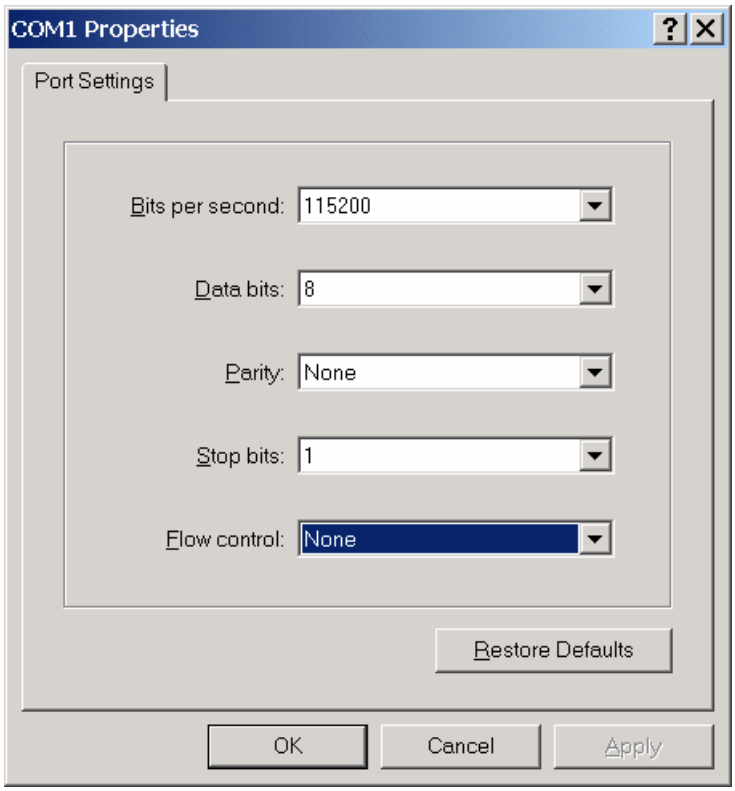
To connect to the Communication Unit with the Embla Serial Cable do the following steps:

1. Connect the RJ12 cable end of the Embla Serial Cable to COM A port on the Communication Unit and the other end with the DSUB9 connector to a COM port on the PC, for example COM1.

2. Run the program HyperTerminal on your PC: (Programs/Accessories/Communication/HyperTerminal)
3. Enter a name for the connection, see dialog "*Connection Description*" below, and press OK.

4. Next a dialog "Connect To" is shown. It doesn't matter what information you enter for the country, area code and phone number entries because they will not be used. Select the appropriate COM port, for example COM1, for the connection used. Then press OK.

5. Then another dialog pops up. Enter the information shown in the picture below. Then press OK. **Note**: It is possible to save this connection by selecting File/Save from the menu bar. The next time HyperTerminal is entered it is possible to select the saved connection.

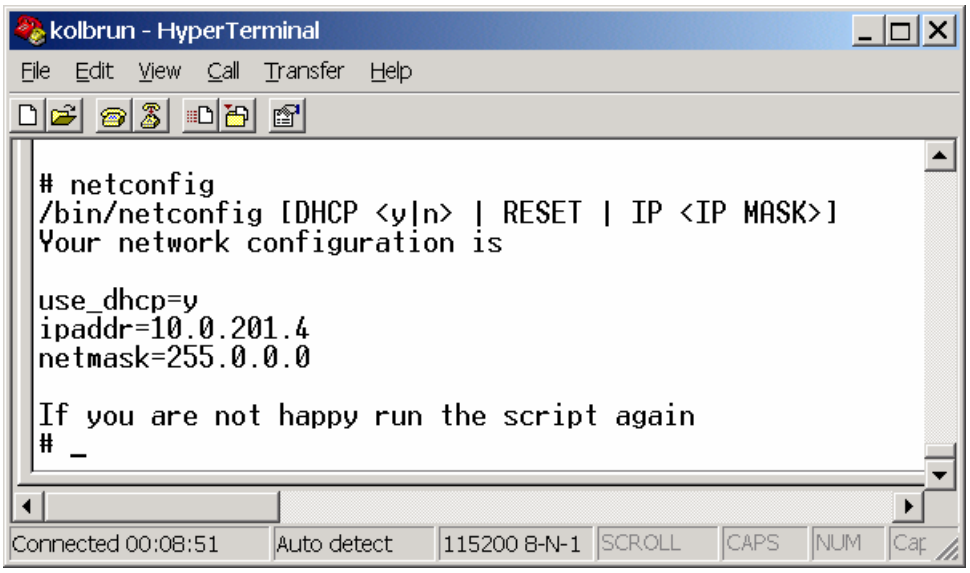


6. Turn on the power on the Embla Communication Unit. You will then see a lot of information flow over the HyperTerminal window.
7. When the text stops flowing press enter and you should get the hash (#) symbol on the screen. This is the **command line**.

Using the command netconfig

The command **netconfig** is used to get (and set) information about the desired configuration of the network. The device will use this information during boot up to adjust the network according to the desired configuration. To modify the network configuration do the following:

1. Enter the **netconfig** command in the command line and press Enter.
2. Then information about the desired network configuration is shown. As an example the picture below shows that for the device connected in this case the DHCP server is first given a chance to assign the device an IP number (use DHCP server = yes), but if that fails the device gets a default IP address listed in line 2 (ipaddr) and a default netmask listed in line 3 (netmask).



3. To desired network configuration of the device choose between the following 3 modes

    a) **DHCP <y | n>**: If the user has DHCP server we recommend this mode. When entering netconfig DHCP y in the command line the device is configured with a default IP number allocated by the DHCP server if that is possible. When entering netconfig DHCP n, no attempt is made to allocate an IP address by a DHCP server. For example:
    #netconfig DHCP y

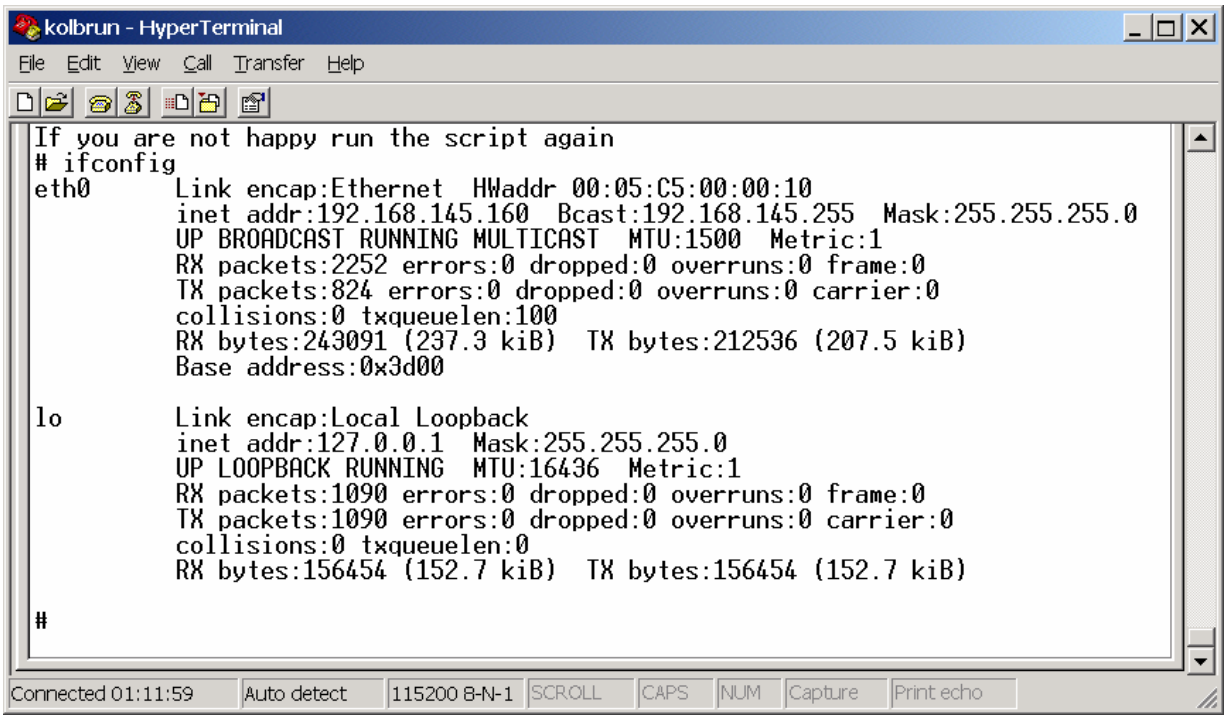
    b) **RESET**: If the user enters: RESET in the command line then the device is configured with the same IP default 10.0.201.4 address and netmask as it had when leaving Medcare manufacturing facilities. For example:
    #netconfig RESET

    c) **IP <IP MASK>**: By entering IP number and MASK the device is configured with that IP number and mask. For example:
    #netconfig IP 192.168.145.100 255.255.255.0

Using the command ifconfig

The **ifconfig** (ifconfig stands for interface configuration) command gives information about the actual IP number and IP mask of the device connected. This can for example be useful when DHCP option is used to see the actual ip address and netmask assigned to the device from the DHCP server.

1. Enter the **ifconfig** command in the command line and press Enter
2. For the device connected the IP number is shown as the **inet addr** (internet address) and the IP mask as **Mask**, see the picture below
3. Use this information about the IP configuration of the device when entering the homepage of the device



Problems Starting a Recording

Problems starting a recording may be caused by the cable connections:

1. Check the voltage setting.
2. Make sure the Communication Unit is connected to power. 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. The cable from the Bedside Unit should be firmly connected to the rear panel of the Communication Unit and the power indicator light on the Bedside Unit should be yellow.
5. Make sure that the cable from the Patient Unit is firmly connected to the Bedside Unit. The connection to the Patient Unit indicator light on the Bedside Unit should be yellow.

6. Try starting a recording.
7. 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 attached. Double-check all electrodes, 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 pin is partly covered.

A lot of artifacts in the oximeter signal could indicate that the finger probe used is bad. Try to change the finger probe.

Signals are missing

If you do not see one or more of your respiratory signals (signals recorded with the patient unit), in the sense that there is no pane with the name of the signal, check the following:

1. Confirm that the signal was recorded by looking into the Raw Data Folder that should contain all recorded data, including the missing signals.
2. The signal may not be included in the sheet currently being displayed. A recording template determines what signals are recorded but a sheet determines what is displayed
3. If both of the above listened steps seem to be okay this could indicate bad connection of the oximeter with the patient unit. Check the oximeter connection
4. If you still have no pane this could indicate a failure in the oximeter. Change the oximeter.

Flat or empty traces

If you do not see one or more of your respiratory signals (signals recorded with the patient unit), in the sense that there is a pane with the name of the signal but no trace in the pane, check the following:

1. Move further into the recording and check if the signal seems lost during the whole recording
2. Try using the ***scale to fit*** option.
3. If you still have no trace in the pane this could indicate bad

connection of the oximeter with the patient unit. Check the oximeter connection

4. If you still have no pane this could indicate a failure in the oximeter. Change the oximeter.

Bad electrode impedances

If the electrode impedances are bad try the following:

1. Check the connection of the electrodes to the Bedside Unit. Run the impedance test.
2. If the impedances are still unacceptable: Check the electrodes on the patient. Run the impedance test.
3. If the impedances are still unacceptable: Try to lower the impedance values by cleaning the electrode sites properly and then reconnect the electrodes. Run the impedance test.
4. If the impedances are still bad this could indicate bad electrodes. Change the electrodes and run the impedance test.

Performing a Calibration Test

The system allows the user to verify the gain for the Bedside Unit channels at the start of each recording. The system sends a calibration signal for 30 seconds to all channels on the Bedside Unit. The signal has amplitude of 100µV and a frequency of 0.1Hz. The calibration is performed by default at the start of each recording, but this feature can be deactivated in the software.

Technical Specifications

Embla System Properties

Technical Specifications for the Communication Unit

Properties	Description
RS232 port speed	Up to 115.2 k bits per second
Input AC voltage, non-isolated	115V/ 230V
Input AC current, non-isolated	100/50mA
Input DC voltage to 8 AUX channels	±5V
Bandwidth of AUX channels	Max. 0-80Hz, depending on the sampling rate
Voltage selector	115/230V
Internal replaceable fuses	2 x 315mA "slow blow"
Mains power supply	Class II protection (reinforced isolation, no ground lead), frequency 50/60Hz, isolation voltage 4000Vac.
Maximum patient leakage current	Complying with EN60601-1/UL2601
Dimension	Height 80mm (3.15") Width 200mm (7.87") Length 290mm (11.42")
Weight	2300g (4.41lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-40°C to +70°C (-40°F to +158°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar

Humidity	0-95% (non-condensing)

Technical Specifications for the N7000 Bedside Unit

Properties	Description
Signal acquisition channels	32 referential channels 8 bipolar channels 1 light sensor channel
Sampling rates base 10	Referential channels: Fs = 50, 100, 200 and 500Hz Bipolar channels: Fs = 2, 10, 20, 50, 100, 200 and 500Hz. Software selectable for each channel. 2 channels can be sampled at 2000Hz
Sampling rates base 2 Note: To use base 2 sampling rates, a firmware/software upgrade is needed	Referential channels: Fs = 64, 128, 256 and 512Hz Bipolar channels: Fs = 2, 16, 32, 64, 128, 256 and 512Hz. Software selectable for each channel. 2 channels can be sampled at 2048Hz
Input range	Vin = ±350mV on bipolar channels, Vin = ±75mV dynamic range on referential channels
Maximum patient leakage current	Complies with EN60601-1/UL2601
ESD protection	Complies with EN60601-1/UL2601
Impedance test output waveform	0.25 µA square wave, 20-30Hz
Bipolar channels: Frequency response:	Max. 0Hz-400Hz, depending on the sampling rate
Referential channels: Frequency response:	Max. 0.3Hz-400Hz, depending on the sampling rate
Power-line notch filters	Software selectable for each channel. If activated a notch filter will reject the 50 or 60Hz power line frequencies when sampling at a higher sampling rate than 100Hz
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
Dimension	Height 27mm (1.06") Width 130mm (5.12") Length 190mm (7.48")
Weight	620g (1.37lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-40°C to +70°C (-40°F to +158°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% (non-condensing)

Technical Specifications for the S7000 Bedside Unit

Properties	Description
Signal acquisition channels	12 referential channels 8 bipolar channels 1 light sensor channel
Sampling rates base 10	Referential channels: Fs = 50, 100 and 200Hz Bipolar channels: Fs = 2, 10, 20, 50, 100 and 200Hz. Software selectable for each channel.
Sampling rates base 2 Note: To use base 2 sampling rates, a firmware/software upgrade is needed	Referential channels: Fs = 64, 128 and 256Hz Bipolar channels: Fs = 2, 16, 32, 64, 128 and 256Hz. Software selectable for each channel.
Input range	Vin = ±350mV on bipolar channels, Vin = ±75mV dynamic range on referential channels
Maximum patient leakage current	Complies with EN60601-1/UL2601
ESD protection	Complies with EN60601-1/UL2601
Impedance test output waveform	0.25 µA square wave, 20-30Hz
Bipolar channels: Frequency response:	Max. 0Hz-90Hz, depending on the sampling rate
Referential channels:	Max. 0.3Hz-90Hz, depending on the

Frequency response:	sampling rate
Power-line notch filters	Software selectable for each channel. If activated a notch filter will reject the 50 or 60Hz power line frequencies when sampling at a higher sampling rate than 100Hz
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
Dimension	Height 27mm (1.06") Width 130mm (5.12") Length 190mm (7.48")
Weight	620g (1.37lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-40°C to +70°C (-40°F to +158°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% (non-condensing)

Technical Specifications for the Patient Unit

Description	Properties
External channels	The external channels that are supported depend on the proxy that is installed. Currently two proxies are supported, Z10 and X10. Signals supported by X10 proxy: ▪ Nonin oximeter ▪ Thermistor ▪ Snore sensor ▪ Abdomen belt (XactTrace belts) ▪ Thorax belt (XactTrace belts) Signals supported by Z10 proxy: ▪ Nonin oximeter ▪ Thermistor ▪ Snore sensor ▪ Abdomen belt (piezo belts)

	▪ Thorax belt (piezo belts) Max. Bandwidth 0-90Hz, depending on the sensor signal type.
Internal channels:	Pressure input (cannula or mask pressure) Pressure range ▪ +/- 5mbar (Nasal cannula setting) ▪ +/- 22mbar (Mask pressure setting) 2-dimensional gravity sensor
Maximum patient leakage current	Complies with EN60601-1/UL2601
Output waveforms: DC component Maximum AC component	 0uA square, 5-15Hz, 25nA, 2.5V at infinite impedance
Dimension	Height 18.5mm (0.73") Width 80mm (3.15") Length 110mm (4.33")
Weight	280g (0.62lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-40°C to +70°C (-40°F to +158°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% non-condensing

Technical Specifications for the Bracket

Description	Properties
Dimension	Height 50mm (1.97") Width 140mm (5.51") Length 200mm (7.87")
Weight	370g (0.82lbs)
Operating temperature	+5°C to +45°C (40°F to +113°F)
Storage and transport temperature	-40°C to +70°C (-40°F to +158°F)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
Humidity	0-95% non-condensing

Technical Specifications for Oximeter Type Nonin XPOD

Signal	Properties	Accuracy
Oxygen saturation range	Range 0 - 100% 3Hz	
SpO_2 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	
Pulse/HR value	18- 300bpm 3Hz	±3% ±1bpm
SpO_2 beat-to-beat value	0-100% 3Hz	

For further information regarding oximeters, please refer to www.medcare.com/products/

Materials List

The following table lists all of the materials used in the system:

List of Materials in the Embla System

Description	Properties
Communication Unit	ABS/PC
Bedside Unit	ABS/PC
Patient Unit	ABS/PC
Proxies	Polyamide
System Cables	PVC
Mounting Bracket	Nylon

Shoulder Strap	Nylon
Velcro Strap	Nylon, Velcro®
Electrodes	silver, silver-silver chloride, gold
Leads	RiteFlex® , PVC
Piezo Respiratory Effort Sensor	Nylon Velcro®, latex
XactTrace Respiratory Effort Sensor (Belt Lock)	Polyamide
XactTrace Respiratory Effort Sensor (Belt)	Dry natural rubber, Nylon
Nasal Cannula	PVC, PC
Oximeter	ABS
Oximeter Seal	PVC
Oximeter Flex Sensor	Silicone
Oximeter Sensor FlexiWrap	Polyethylene foam coated with medical-grade acrylic pressure-sensitive hypoallergenic adhesive
Medical Tape	Hypoallergenic non-woven tape
Thermistor	PVC Plastic, C-Flex plastic, lead wire
Snoring Sensor	C-Flex® Thermoplastic Elastomer