embla®

Sandman® Digital 32+™ Amplifier

User Manual

Sandman Digital 32+ Amplifier User Manual

Applies to the Sandman Digital 32+ Amplifier, Sandman elink Adapter, and Sandman DC Expansion (DCX) Box

Issued May 2012. Printed in the USA or The Netherlands.

Document Number: D-1002-001, Revision 3.0

Document Item Number: 4280034

For assistance, please contact Embla Technical Support (support@embla.com).

MANUFACTURER	EUROPEAN REPRESENTATIVE
Embla Systems	Natus Europe GmbH
1 Hines Rd, Suite 202	Robert-Koch-Str. 1
Kanata, ON K2K 3C7	82152 Planegg
Canada	Germany
Tel: +1.613.254.8877	Tel: +49 089 83942-0
Fax: +1.613.270.0627	Fax: +49 089 83942-777

TOLL-FREE IN NORTH AMERICA: 888 NO APNEA (888.662.7632)
www.embla.com support@embla.com sales@embla.com

Disclaimer

This document may contain technical inaccuracies or typographical errors. Embla does not accept any liability for the use or misuse, direct or indirect, of this product. Users must accept all responsibility for any results obtained by or concluded from the products. All clinical conclusions and decisions that are made based on the use of this product are the responsibility of the user. Embla does not accept any liability or responsibility for damages arising out of the use of or inability to use this product.

Copyright

Trademarks

CE 0051	The Sandman Digital 32+ Amplifier is certified to carry the CE mark. The CE mark is a declaration that the Sandman Digital 32+ Amplifier is in compliance with the directive for medical devices set forth by the European Union.
C US	The cCSAus mark is a safety symbol that shows the product has been independently tested and certified to applicable U.S. and Canadian product safety standards.

MANUFACTURED IN ITALY BY:
EBNeuro S.p.A.
via Pietro Fanfani 97/A
50127 Firenze
ITALY
Distributed by Embla Systems.

Table of Contents

List of Figures

List of Tables

1. General Warnings and Cautions

1.1. intended use

The *Sandman® Digital 32+*™ Amplifier ("*SD32+*") is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy, and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

1.2. safety information and document conventions

The following table describes the safety and document conventions found in this manual:

Warning	The **Warning** message appears in this manual before procedures or tasks that must be strictly observed to avoid patient harm, inaccurate measurements, or loss of data.
Caution	The **Caution** message appears in the manual before procedures or tasks that must be strictly observed to avoid damage to the product.
Note	The **Notes** message contains important information to help the operator complete a procedure or task correctly.

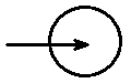
1.3. warnings

1. Do not disassemble the *SD32+* or Headbox.
2. All connections on the Headbox are isolated from the ground of your building's electrical system (AC power ground). This type of insulation is known as "floating isolation". To avoid injury to the patient, *do not* connect input signals to the Headbox from devices that are not equipped with floating isolation.
3. To maintain the *SD32+* electrical isolation ensure that neither the patient nor any conductive part connected to the patient (such as electrodes or sensors) comes into contact with any conductive material.
4. Verify that the building's electrical wiring is in good condition and properly grounded. To ensure the safety of both patient and technician make certain that any AC powered device connected to the *SD32+* is properly grounded.
5. Always follow the safety precautions outlined in chapter 2. Safety on page 6 of this manual.
6. Place the computer outside of the patient area. If this is not possible, power the computer through a dedicated isolation transformer.
7. Carefully route and secure sensor cables to avoid patient entanglement or strangulation.

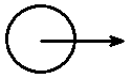
1.4. amplifier casing symbols

This symbol identifies ports or sockets equipped with a Type BF level of electrical isolation in accordance with IEC60601-1.

This symbol prompts the user to refer to this manual for proper usage and safety instructions.



This symbol identifies input connectors.



This symbol identifies output connectors.

This symbol identifies the manufacturing date

REF This symbol identifies the part number of the device

SN This symbol identifies the serial number of the device

1.5. electromagnetic compatibility

This device is designed for use in environments that comply with IEC 60601-1-2:2001 as indicated in the tables shown. You must ensure that the device is used in compliance with the IEC standards.

Emission Test	Compliance	Electromagnetic Environment
Radiated and Conducted RF emission CISPR 11	Class B	The device is suitable for use in domestic and other environments that are connected to a low voltage power supply.
	Group 1	The internal operation uses a low RF. The emission is not likely to cause interference with nearby electronic equipment.
Harmonic emission IEC 61000-3-2	Complies	The device may be connected directly to a low voltage supply using an electrical ground.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The device may be connected directly to a low voltage supply using an electrical ground.

Table 1. electromagnetic emission

Immunity Test	IEC 60601-1-2 Test Level	Compliance	Electromagnetic environment
Electrostatic Discharge (ESD) IEC 61000-4-2	6 kV direct contact 8 kV through air	IEC 60601-1-2 Test Levels	Residential (Note 1)
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply line 1 kV for input/output line >3m	IEC 60601-1-2 Test Levels	Residential (Note 2) (Note 3)
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	IEC 60601-1-2 Test Levels	Residential (Note 2) (Note 3)
Voltage dips, short interruptions and voltage variation on power supply input lines IEC 61000-4-11	0% of rated voltage (voltage dip 100%) for 0.5 cycles 40% of rated voltage (voltage dip 60%) for 5 cycles 70% of rated voltage (voltage dip 30%) for 25 cycles 0% of rated voltage (voltage dip 100%) for 5 cycles		Residential (Note 2) (Note 3)

Immunity Test	IEC 60601-1-2 Test Level	Compliance	Electromagnetic environment
Magnetic fields at ground frequency (50/60Hz) IEC 61000-4-8	3 A/m		
Radiated RF fields IEC 61000-4-3	Non-life-supporting equipment 3 V/m From 80 MHz to 2.5 GHz	IEC 60601-1-2 Test Levels	Residential (Note 4)
Conducted RF fields IEC 61000-4-6	Non-life-supporting equipment 3 V From 150 kHz to 80 MHz		
Measures to observe			
Note 1 – The floor should be antistatic (wood, ceramic, etc.). If carpeted, the relative humidity should be maintained at 30%. Note 2 – The main power supply must be of residential, commercial, or medical grade. Note 3 – If operating for an extended period, a UPS system must be provided in the event of a power outage. Note 4 – Mobile or portable RF communication devices should be used at greater distances than those provided in table 3.			

Table 2. electromagnetic immunity

1.5.1. recommended distance from Radio Frequency systems

It is not recommended to use RF transmitting devices near the *SD32+* digital amplifier. RF transmitting devices can cause interference with the device and impact the quality of the signals being acquired during use.

To prevent RF interference it is recommended to maintain a minimum distance between the *SD32+* digital amplifier and the RF transmitting device being used; such as cell/mobile phones. The following table shows recommended distances that the *SD32+* digital amplifier should remain from some common RF transmitting devices.

RF Source	Typical Rated Power (W)	Distance (m)
Microcellular phone CT1, CT2, CT3	0.01	0.3
DECT cellular phone, Wireless Information Technology equipment (modems, LAN's)	0.25	2
Cellular phone, hand-held (USA)	0.6	2
Cellular phone, hand-held (GSM and NMT, Europe DECS 1800)	2 8	4 7
Walkie-talkie (Rescue, police, fire, maintenance)	5	3
Cellular phone, bag	16	10
Mobile radio (Rescue, police, fire)	100	30

For transmitters, the maximum output power of which is not within the values above, the recommended distance can be estimated by using the following calculations:

For transmitters using a frequency range from 150 kHz to 80 MHz and 80MHz to 800 MHz, the distance can be estimated as follows:

$$D = 1.2\sqrt{P}$$

For transmitters using a frequency range from 800 MHz to 2.5 GHz, the distance can be estimated as follows:

$$D = 2.3\sqrt{P}$$

P = the rated power of the transmitter in Watts (W).

Note: Always use the greater distance provided.

Note: These values are general guidelines as electromagnetic fields can be compromised in the presence of structures, objects, and people.

Table 3. recommended distances

Always remember that the intensity of the electromagnetic field generated by a fixed transmitter (base station for radio, TV, Cell service, etc.) cannot be predicted.

Additional measures may be required if the electromagnetic field exceeds the specified intensity shown in table 3.

2. Safety

Please follow all warnings and cautions listed in this manual to ensure the safety of the patient and the operator.

Warning: Before using the *SD32+* system, ensure that it satisfies all safety requirements. Safety checks should be performed periodically and no less than twice a year.

2.1. operational environment

The *SD32+* amplifier is designed to work in the following environmental conditions:

temperature	5°C to 40°C
relative humidity	30% to 75% RH
atmospheric pressure	700 to 1060 hPa

Avoid condensation.

Use caution when operating the amplifier after moving it between locations with different temperatures. Condensation (slight moisture accumulation or misting over internal or external surfaces of the amplifier) may occur if the amplifier is moved rapidly from a cold location to a warmer location. Wait for the condensation to evaporate completely before supplying power to and using the amplifier.

Avoid flammable vapors or gases.

Do not use the amplifier in atmospheres with high oxygen concentration or in buildings where flammable substances or anesthetic agents are present.

Avoid contact with liquids.

The amplifier and its internal parts are not protected against the inflow of liquids. Avoid exposing the amplifier to moisture or using the amplifier where such a risk is present. Components that have been penetrated by liquids must be cleaned immediately and checked by authorized personnel.

Ensure proper electrical grounding.

The building's electrical wiring must be properly grounded. When the amplifier is connected to other AC powered devices ensure those devices are grounded. This protection is essential for the safety of both the patient and the technician.

Avoid strong magnetic fields.

Keep the amplifier away from sources of induced electromagnetic fields to avoid possible instability or malfunction. The *SD32+* system is compliant with the EMC (Electromagnetic Compatibility) requirements specified by the 89/336/EEC European directive.

Avoid short wave or microwave devices.

Therapeutic short wave or microwave devices may cause instability and interfere with the amplifier's functions. Do not place the amplifier near X-ray or diathermy devices.

2.1.1. electrical safety

Use only the power supply distributed with the *SD32+* system.

The *SD32+* system is specifically designed to function with only the provided AC/DC Adapter. See section *3.7.1. external medical grade ac/dc adapter* on page 20 for more information.

Use caution when operating the amplifier in conjunction with other instruments.

If the patient is connected to several instruments at the same time remember that the sum of leakage currents from all of the equipment must be considered when assessing patient safety.

Avoid switching the amplifier ON while the patient is connected.

To ensure patient safety, it is necessary to connect the patient after the equipment is powered up and working correctly.

Avoid switching the amplifier OFF while the patient is connected.

To ensure patient safety, it is necessary to disconnect the patient before powering down the equipment.

It is not recommended to use the amplifier while using radio-frequency instruments.

In the event the *SD32+* is used in a room at the same time as a Radio-Frequency (RF) instrument, ensure the RF instrument is kept as far as possible from the electrodes as close proximity may increase the risk of RF currents flowing through the electrodes and may result in burns. This risk may be further mitigated by using electrodes with a larger surface area to limit the RF current density. If these mitigations are not possible, it is recommended to disconnect the patient from the *SD32+* before using radio-frequency instruments.

The amplifier is not protected against defibrillator discharges.

If a defibrillator must be used disconnect the patient from the amplifier to avoid the risk of burning the patient along electrode contact areas and damaging the amplifier.

Avoid contacting the patient and the electrodes with conductive metal items.

Do not allow the patient, or any conductive parts connected to the patient such as electrodes or sensors, to contact any other conductive items, especially an electrical ground. The entire input circuit the patient is connected to is electrically isolated (known as "floating isolation") and contact with conductive items could compromise patient safety.

When connecting the *SD32+* amplifier to other instruments, observe the IEC 60601-1-1 and IEC 60601-1-2 safety standards.

Only connect the *SD32+* to devices when the safety of the patient, technologist, and the environment are not compromised. Refer to the device's manual, manufacturer, or authorized servicing centre for information on the possible effects of coupling the device with the *SD32+* amplifier.

Replace damaged parts immediately.

Cables, connectors, accessories, or other parts of the amplifier must be replaced immediately when they show signs of malfunction or damage. In these cases, contact Embla Technical Support.

Use only accessories or peripherals specified by Embla Systems.

Only use accessories and peripherals specified by Embla Systems in this manual as they have been tested with the *SD32+* amplifier for safety. Accessories and consumer goods supplied by other manufacturers do not guarantee the safe or correct operation of the *SD32+* amplifier. Use peripherals in compliance with the standards of the class to which they belong.

There is no increased safety risk for Pacemaker patients with the SD32+ Amplifier.

The Sandman System when used with the SD32+ Amplifier 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.

2.1.2. patient leakage current

The maximum patient leakage current from the *SD32+* amplifier, measured according to the test methods of IEC 60601-1, is less than 100 μA.

Warning: When using the *SD32+* amplifier in conjunction with other instruments the sum of leakage currents from all of the devices may exceed 100μA.

2.1.3. patient connection

Connection between the patient and the *SD32+* amplifier should only be made through the electrode sockets on the Headbox or the Pulse Oximetry Sensor port (using a pulse oximeter cable approved by Embla Systems). Connecting the patient to the amplifier by any other means may constitute an unsafe condition that could result in injury to the patient.

Warnings: **Standard PSG recording guidelines recommend that all patient monitoring devices connected to an electrical outlet be turned on before connection to the patient. Once the device is powered up, you may then connect the patient to the device and begin collection. At the same time, you must disconnect the patient before you power the device down.**

All connections on the Headbox are isolated from the AC power ground. Do not allow these connections to come into contact with earth ground or AC power ground as this constitutes an unsafe condition that could result in serious injury to the patient.

Always use electrodes or sensors cleared for commercial use in your jurisdiction.

It is strongly recommended to check the overall functionality of the system prior to starting a collection. If anomalies or malfunctions are noticed disconnect the patient from the system, switch off the system, and contact Embla Technical Support.

If "flat" traces are observed during a collection and are not rectified by simple corrections (i.e. poor electrode connection, broken lead, etc.) disconnect the patient and contact Embla Technical Support.

If skin irritation occurs during collection discontinue the collection and disconnect the patient. Refer to any directions for use included with the sensor(s) and or paste involved for further information.

2.2. LCD display

Treat the LCD with great care. If the LCD glass should break and spill liquid, avoid coming in contact with the liquid. If anyone is exposed to the liquid, carefully wash the affected area with water for at least 15 minutes. Should the individual experience any irritation, discomfort, or other symptoms after this period, seek medical assistance immediately.

2.3. declaration of conformity

CE 0051

The *SD32+* amplifier meets the requirements of Annex II of the 93/42/EEC Directive on Medical Devices (MDD). For these reasons, the equipment is marked with the CE mark. IMQ S.p.A. (Milan, Italy) issues the approval as the Notified Body notified by the European Commission. The IMQ notified body identifier number is 0051.

The equipment is marked with the cCSAus quality mark. This safety mark is valid for both Canadian and U.S. markets.

2.4. caution for the U.S. market

Federal law restricts this device to sale by or on the order of a physician.

3. Introduction

3.1. *Sandman® Digital 32+™* amplifier (*SD32+*)

The *SD32+* amplifier is a self contained, fully programmable, digital amplifier that is designed specifically for use with the *Sandman Elite®* software (version 7.2 or greater) and the *Sandman Spyder™* software. It collects physiological signals from patients through electrodes/sensors; amplifies and converts them to digital data; converts the data to an optical signal; then sends the data to the *Sandman elink™* Adapter via a fiber optic link (the *Sandman elink* then passes the data to the computer running the *Sandman Elite* software).

The *SD32+* amplifier has the following features; provides electrical references for individual input channels, generates calibration pulses, allows for impedance testing, provides a dynamic range (gain), provides a choice of sampling rate, and is equipped with anti-alias signal filtering.

The *SD32+* system consists of seven key components: the Headbox, Amplifier, Headbox to Amplifier Cable, *Sandman elink* Adapter, pulse oximetry sensor, External Medical Grade AC/DC Adapter, and the DC expansion box. These components can be seen in *Figure 1. the SD32+ system*.

The Headbox provides an electrical connection between the patient and the *SD32+* amplifier using electrodes.

The Headbox to Amplifier Cable allows the Headbox to function without being physically mounted to the *SD32+* amplifier allowing for greater flexibility in lab setups.

The *Sandman elink* Adapter receives optical digital data from the *SD32+* amplifier and converts it for transmission over an Ethernet network to relay it to the computer running the *Sandman Elite* software. The *SD32+* amplifier communicates with the *Sandman elink* Adapter via fiber optic cable.

The External Medical Grade AC/DC Adapter ("AC/DC Adapter") provides an isolated +15V direct current (DC) voltage to the *SD32+* amplifier through the *Sandman elink*. The +15V DC output is electrically isolated from the AC supply mains using methods compliant with the International Electrotechnical Commission's (IEC) safety standard IEC 601-1 for Class I, type B equipment. The AC/DC Adapter is plugged into an Uninterruptible Power Supply (UPS); which, in turn, is plugged into an electrical outlet. The UPS is used to prevent undesirable effects of the electrical system such as electrical noise; power outages, sags, or surges; etc. from adversely affecting the performance of the *SD32+* system.

The *SD32+* amplifier's internal Pulse Oximeter receives data from a finger probe attached to the patient. This data is then sent to the *Sandman elink* Adapter; which passes it on to the computer running the *Sandman Elite* software.

The DC expansion box accepts analog input signals from a variety of DC devices (e.g. CPAP or pressure) and sends their signals directly to the computer running the *Sandman Elite* software.

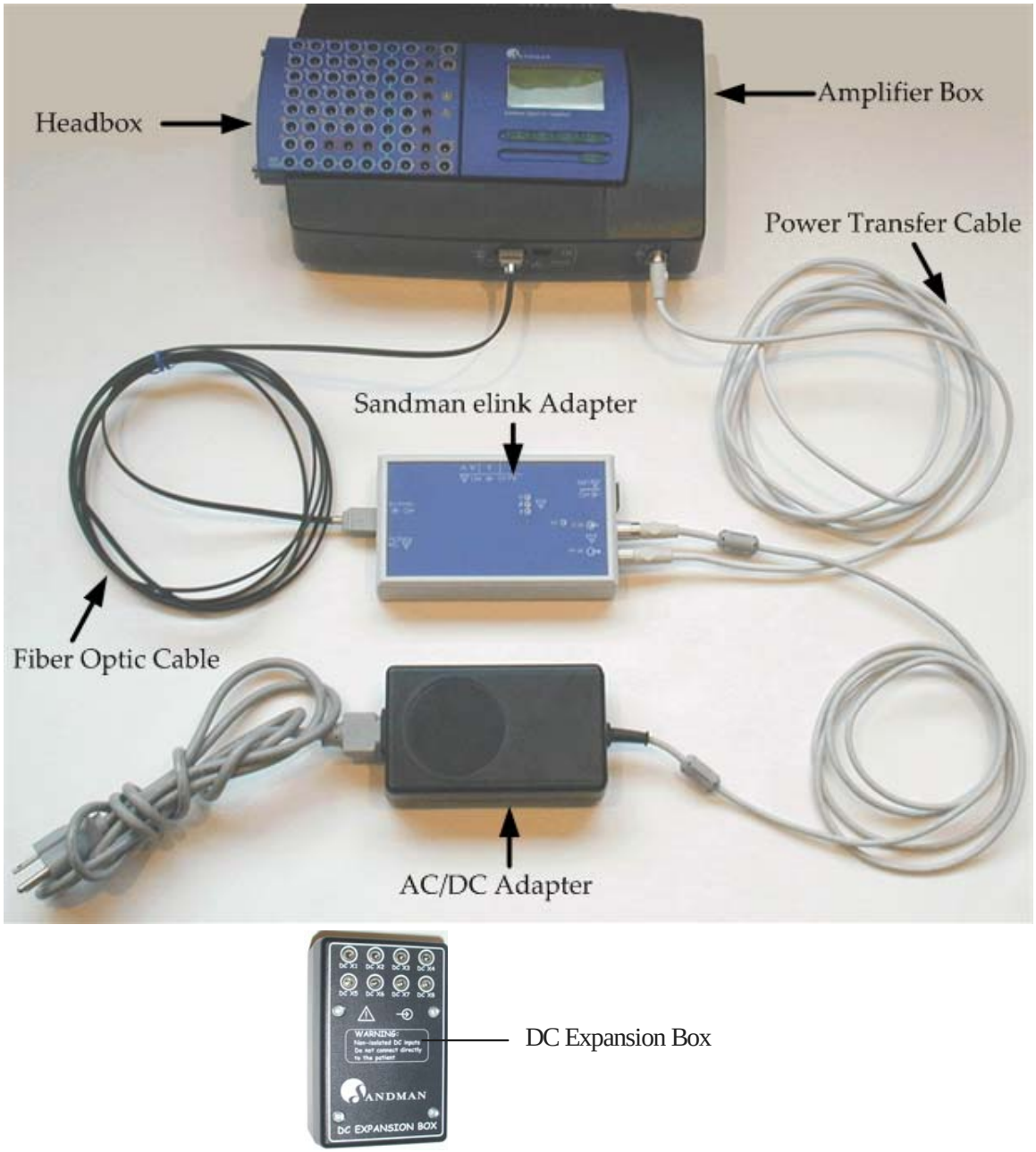


Figure 1. the *SD32+* system

3.2. headbox

Patient electrodes and sensors plug into the *SD32+* amplifier headbox. There are 68 input sockets that accept 1.5-mm electrode safety plugs including 32 AC monopolar input sockets, 8 pairs of AC bipolar input sockets, 3 neutral input sockets, 13 isolated ground input sockets, 2 temperature input sockets, and 2 calibration signal output sockets.

connectors

The Headbox has two different ports that can be used to interface with the *SD32+* amplifier.

Amplifier Connection Port – This port allows the Headbox to be physically connected to the amplifier (this process is referred to as "docking" the Headbox). See *Figure 2. the headbox amplifier connection port* for an illustration of this port.

Figure 2. the headbox amplifier connection port

Removable Patient Box (Headbox) Link Port – This port connects the Headbox to the amplifier using the six-foot Headbox to Amplifier Cable. The cable allows users to place the Headbox near the patient and allows the patient to be easily disconnected from the amplifier without having to remove electrodes from the patient. The cable should be kept clear of other devices or cables in order to achieve the best signal performance. See *Figure 3. removable patient box (headbox) link* for an illustration of this port. See *Figure 4. headbox to amplifier cable* for an illustration of this cable.

Note: When the Headbox's Removable Patient Box Link port is not in use replace the plastic cover provided with the *SD32+* amplifier to prevent dust build-up on this connector.

Figure 3. removable patient box (headbox) link port

Figure 4. headbox to amplifier cable

electrode sockets

The Headbox has six types of electrode sockets: Monopolar, Bipolar, Neutral (NE), Isolated Ground (ISO GND), Temperature, and Calibration. *Figure 5. headbox electrode sockets* displays the Headbox's general appearance and the layout of the electrode sockets.

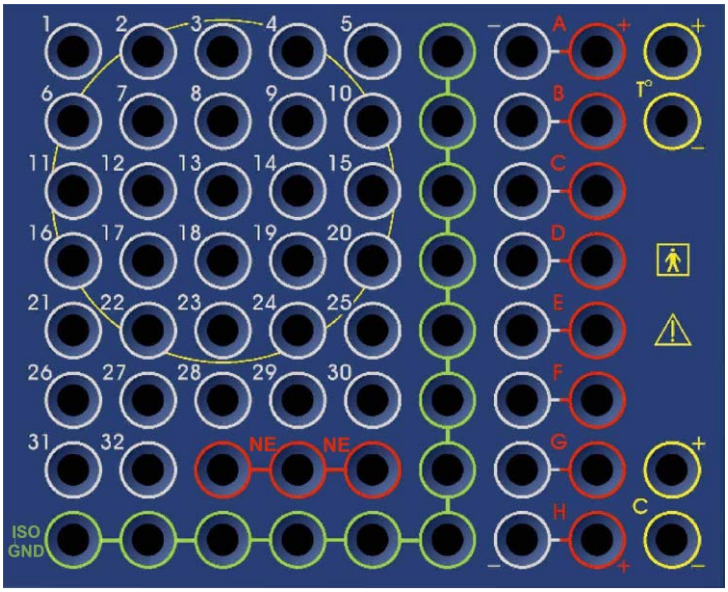


Figure 5. headbox electrode sockets

Monopolar Input Sockets – These input sockets, labeled with numbers ranging from "1" to "32", accept monopolar signals from the patient. The amplified signal is the difference in potential between a monopolar input socket and its reference electrode socket. Channels collected using these input sockets may be referenced to the Neutral (NE) input sockets.

Bipolar Input Sockets – These input sockets, labeled with letters ranging from "A" to "H", accept inputs from bipolar monitoring devices such as a respiratory belt, snore microphone, thermocouple, or any device with a bipolar output. The amplified signal is the difference of potential between the "+" and "–" connection.

Neutral (NE) Sockets – These sockets accept monopolar analog signals and may be used as an input reference for sites plugged into the sockets labeled "1" to "32" (i.e. they may be used to accept a general reference input such as CZ for numbered AC channel inputs). There are three parallel neutral input sockets on the Headbox labeled "NE". This is also used as the reference when impedance testing is done.

Isolated Ground (ISO GND) Sockets – These sockets, labeled "ISO GND", accept and isolate the patient ground to prevent leakage current from making a direct path to the patient. The 13 Isolated Ground input sockets connect the patient to ground.

Warning: The output from any DC device plugged directly into the Headbox must provide an electrically isolated signal. Do not plug a non-isolated DC signal into the Headbox as this compromises patient safety.

Temperature Sockets – These two sockets, labeled "T°", accept input from an external temperature probe. These input sockets are disabled if you have connected the Headbox to the amplifier with the Headbox to Amplifier Cable.

Calibration Sockets – When these two sockets, labeled "C", are enabled, they output the amplifier's calibration signal. You can connect the signal to any input (including the lead used for the connection) for testing. These sockets are disabled if the Headbox is connected to the amplifier with the Headbox to Amplifier Cable.

The following table summarizes the Headbox electrode sockets and their characteristics:

input socket label	socket type	current type	function	Gain setting + resolution	Max. input
A - H	Bi-polar	AC	Accepts channel signal input and reference	'High' 1 µV/8 bits	8mV $_{p-p}$
				'Low' 2 µV/bit	128mV $_{p-p}$
1 - 24	Mono-polar	AC	Accepts channel signal input	'High' 1 µV/8 bits	8mV $_{p-p}$
				'Low' 2 µV/bit	128mV $_{p-p}$
25 - 32	Mono-polar	AC/DC	Accepts channel signal input	'High' 1 µV/8 bits	8mV $_{p-p}$
				'Low' 2 µV/bit	128mV $_{p-p}$ [1]
				'DC1' 10 µV/bit	640mV $_{p-p}$ [2]
				'DC2' 20 µV/bit	1.28 V $_{p-p}$ [3]
				'DC23' 100 µV/bit	6.4 V $_{p-p}$ [4]
Neutral (NE)	N/A	N/A	References mono-polar channel inputs		
Isolated Ground (ISO GND)	N/A	N/A	Connects patient ground		
T^{o} (Temperature)	Bi-polar	DC	Accepts a temperature probe input when the Headbox is docked		
C (Calibration)	Bi-polar	AC	Generates calibration pulse output when the Headbox is docked		

Table 4. *SD32+* amplifier headbox sockets

[1] Includes 28 mV_{p-p} offset

[2] Includes 140 mV_{p-p} offset

[3] Includes 280 mV_{p-p} offset

[4] Includes 1.4 V_{p-p} offset

3.3. amplifier

The *SD32+* amplifier has two sockets, five ports, a graphic LCD display, and five menu control buttons as illustrated in *Figure 6. SD32+ amplifier's external connections (front)* and *Figure 7. SD32+ amplifier's external connections (back).*

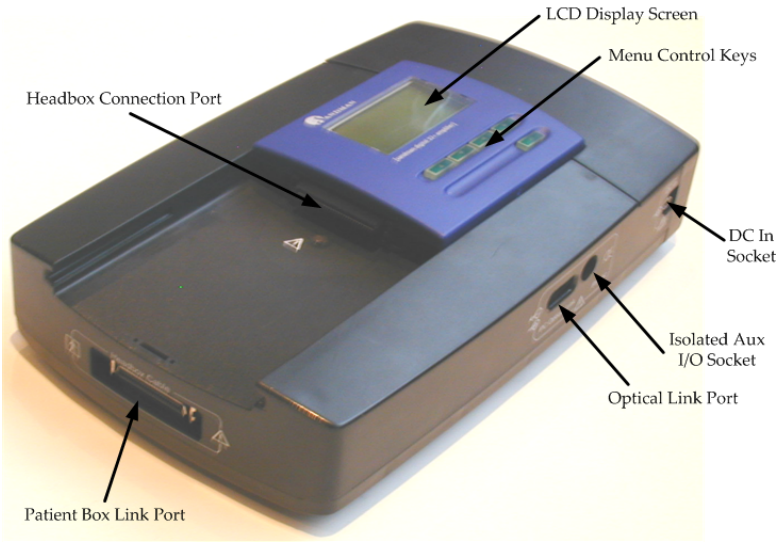


Figure 6. *SD32+* amplifier's external connections (front)

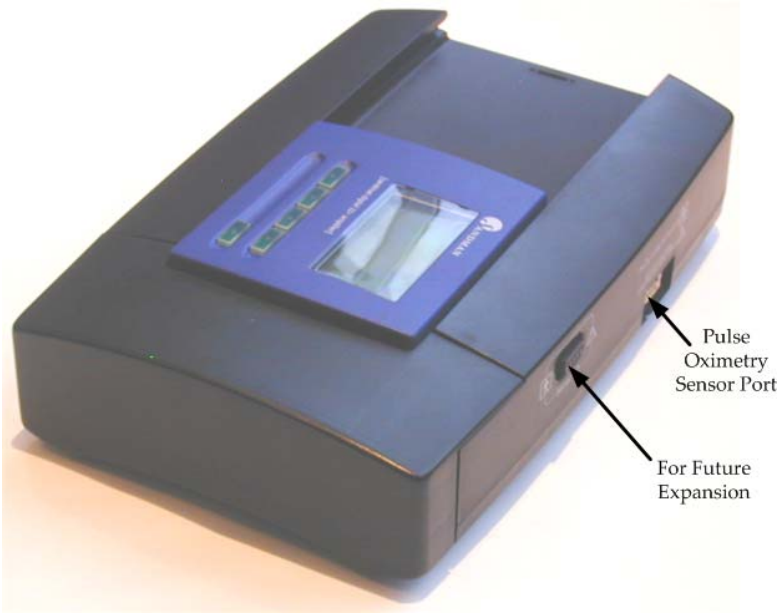


Figure 7. *SD32+* amplifier's external connections (back)

ports

Headbox Connection Port – This port connects the Headbox directly to the amplifier when the Headbox is "docked".

Patient Box Link Port – This port connects the Headbox to the amplifier when using the Headbox to Amplifier Cable.

Note: When the Patient Box Link port is not in use replace the plastic cover provided to prevent dust build up on this connector.

Optical Link Port – This port connects the amplifier to the *Sandman elink* Adapter using a fiber optic cable.

Pulse Oximetry Sensor Port – This port accepts signals from an external finger probe and sends them to the internal pulse oximeter.

Warning: Always use sensors that have been approved by Embla Systems. Sensors must also be cleared for commercial use in your jurisdiction. The oximeter does not possess alarm management capabilities and is not intended for continuous patient monitoring.

Serial I/O Port – This port is reserved for future development.

sockets

DC In Socket – This socket accepts the 15V direct current (DC) voltage from the AC/DC Adapter.

Warning: The DC In socket is only designed for use with the External Medical Grade AC/DC Adapter provided with the *SD32+* amplifier. Do not connect anything else to this socket.

Isolated Aux I/O – This socket is reserved for future development.

Warning: Do not connect any device to the Isolated Aux I/O socket that has not been specified as safe by Embla Systems. Such an action may compromise the safety of the operator and/or patient.

3.4. LCD display

The LCD screen allows the user to assess the patient hook-up without having to view signals in the control room.

The *Sandman Elite* software controls the LCD screen and determines the information that it will display. With the exception of the impedance check, the LCD display does not control any of the amplifier's functions.

The screen initially appears blank, but lights up and displays information when you press one of the Menu Control Keys (see *Figure 6. SD32+ amplifier's external connections (front)* for the location of these buttons). The display then indicates the amplifier's "ON" status and the result of the internal auto test after powering up. The screen powers down again twenty seconds after the last button is pressed.

After a montage in the *Sandman Elite* software has been selected, the LCD screen provides the following menu options: Impedance Check, Montage Setup, Digital Display, and Channel Display.

The LCD's Menu Control Keys allow users to select different menu options and thereby choose the information that will be displayed. Once the screen is activated, the Menu Control Keys function as follows.

The up ▲ and down ▼ buttons allow users to select an option from the main menu. An arrow along the left side of the screen points to the various options. Press the **Enter** button to select an option.

The left ◀ and right ▶ buttons allow users to scroll through the displayed information. For example, during Channel Display, use the right button to skip to the next channel in the montage. Use the left button to go back to the previous channel viewed. Press the **Enter** button to return to the main menu at any time.

impedance check menu option

This menu option sets the amplifier in impedance check mode and displays the channel number, name, and impedance value in kOhms (kΩ) on the LCD screen. Scroll through the channels using the up ▲ and down ▼ buttons. Press the **Enter** button to stop the impedance check at any time.

Note: If the LCD screen has dimmed accurate impedance values will no longer be read.

montage setup menu option

This option allows users to verify channel connections while connecting electrodes. The LCD screen displays the amplifier connector ID and channel name. The information is updated each time the menu control button is pressed.

digital display menu option

This option allows users to navigate through the DC channels and verify their current signal value. Digital Display works with the following channel types: SpO_2, Pulse, Body Position, CPAP, Bi-Level, pH, $EtCO_2$, EtO_2, NPT, $TcpO_2$, $TcpCO_2$, PES, Pulse Amplitude, Pleth, and Other. The *Sandman Elite* software updates the LCD screen every second by sending it the channel ID, name, and current value.

channel display menu option

This option displays the waveform of a channel's signal on the LCD screen. The Channel Display option works with the following channel types: Airflow, Chest, Abdomen, Nasal Cannula, Airflow Sum, $EtCO_2$, PES, Pulse Amplitude, Pleth, and Other. The signal is automatically scaled to fit the 128 by 68 pixel display screen. The waveform "wraps around" the display so that when it reaches the far right side of the display drawing resumes on the left overwriting the previously drawn signal. The channel label initially appears in the background, but is eventually overwritten by the signal as it is drawn. Scroll through the channels using the up ▲ and down ▼ menu control buttons.

Note: The *SD32+* does not store collection data, therefore, the LCD screen can only display signal waveforms during a *Sandman Elite* Collection.

3.5. integrated pulse oximeter

The integrated pulse oximeter calculates oxygen saturation (SpO_2) and heart rate (HR) data collected using an approved sensor. The *Sandman Elite* software receives this data and displays it on the computer monitor.

The pulse oximeter's accuracy depends on the sensor used with the device. For some sensors, the accuracy of neonatal data may differ from that of adult data.

The following conditions can also affect data accuracy.

- Improper sensor application
- Excessive patient movement
- Sensor placement on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line
- Intravascular dye injections
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin in the patient's blood
- Sensor temperature (maintain between 28°C and 42°C for best operation)
- External illumination greater than 5000 lumens/m^2 (typical office lighting)
- Venous pulsation
- High-frequency electrical noise, including electrosurgical equipment and defibrillators
- Interference from magnetic resonance imaging (MRI) procedures

3.6. *Sandman elink™* adapter

The *Sandman elink* adapter serves as a bridge to "link" the *SD32+* amplifier to the computer. This enables the computer to send programming commands to, and receive sleep study data from, the *SD32+* amplifier.

The following figures show the *Sandman elink* adapter:

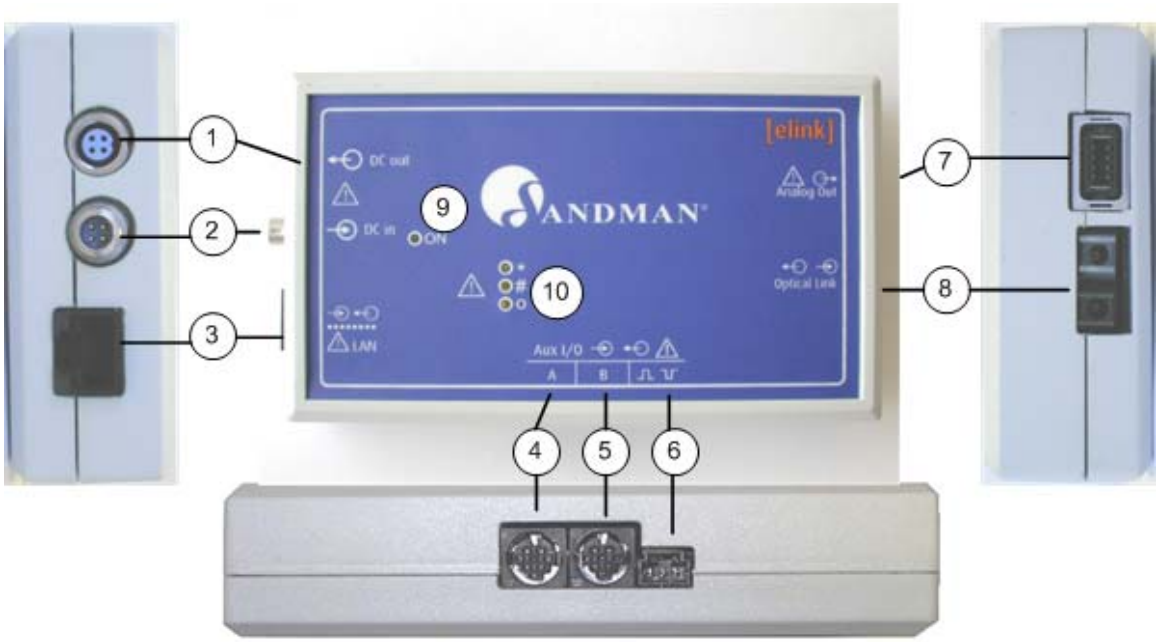


Figure 8. ***Sandman elink*** **adapter**

1. **DC OUT** - (Circular, 4 contact, Female, Triad connector). Supplies the *SD32+* amplifier with DC voltage.
2. **DC IN** - (Circular, 4 contact, Male, Triad connector). Isolated DC input Connector; accepts the DC voltage output from the External Medical Grade AC/DC Adapter.
3. **LAN** - (RJ45 connector) Local Area Network, 10/100 Mbps Ethernet interface.
4. **Serial AUX I/O - (A)** - (Circular, 8 contact, Female, HiRose connector). Connects to peripheral devices using the RS232 communications protocol. Only use devices approved by Embla Systems for use with the *Sandman elink* adapter.
5. **Serial AUX I/O (B)** - Same as "Serial AUX I/O – (A)" above.
6. **Trigger I/O -** Reserved for future use.
7. **Analog out Link** - Reserved for future use.
8. **OPTICAL LINK –** (Dual-strand fiber optic connector) Used to communicate with the *SD32+* amplifier.
9. **Power on LED** - Power status indicator.
10. **LAN activity LEDs** - Indicate various LAN states.

Figure 9. fiber optic cable

Communications between the *SD32+* amplifier and the *Sandman elink* adapter occur using a bi-directional fiber optic cable. This optical link guarantees an absolute level of electrical isolation and offers high quality data transfers that are free of noise and electrical interference.

3.7. power supply

3.7.1. external medical grade ac/dc adapter

Figure 10 shows the AC/DC Adapter that is specified for use with the *Sandman elink* adapter and, in turn, the *SD32+* system. When connected to the *Sandman elink* adapter's "DC In" socket, power from this device is passed to the *SD32+* amplifier via the "DC Out" connector using the Power Transfer Cable (see Figure 11).

Figure 10. external medical grade ac/dc adapter

Figure 11. power transfer cable

3.7.2. amplifier power modes

The *Sandman Elite* software can control the *SD32+* amplifier power modes. When power is applied to the DC In socket of the amplifier, it automatically enters "stand-by" mode. In this mode, all internal circuitry is switched off except for a simple circuit that monitors the state of the Optical Link Port.

When the computer is started, it automatically sends a light signal through the fiber optic connection. This signal causes the amplifier to enter its "active" or "on" mode, immediately perform an auto test, and display the test results on the LCD screen. To completely turn off the amplifier you can either remove the Power Transfer Cable from the DC In socket or unplug the AC/DC Adapter from the wall outlet (this will power down the *elink* causing it to stop providing power to the *SD32+* amplifier).

There is an easy check to test the amplifier without involving the computer. Press and hold one of the five Menu Control Keys until the amplifier enters "active" mode and performs the auto test. See section *3.4. LCD display* on page 17 for more information on these buttons.

3.7.3. surge protection

The AC/DC Adapter used with the *SD32+* system contains an electronic fuse that may automatically turn off the amplifier if a power surge occurs. If the *Sandman elink* Adapter does not power up when connected to the AC/DC Adapter, a surge may have triggered this fuse and it will need to be reset.

To reset the fuse:

1. Unplug the AC/DC Adapter from the wall socket.
2. Wait approximately one minute.
3. Plug the adapter back into the wall socket.

After you reset the fuse the *Sandman elink* Adapter should power up normally, if it does not, reset the fuse again. If after repeated resets the *Sandman elink* still does not power up you should contact Embla Technical Support for assistance.

3.8. DC expansion box

The DC expansion box provides supplemental DC input sockets in addition to the DC-capable input sockets labeled "25" to "32" on the *SD32+* amplifier headbox. To ensure the patient's electrical isolation, the DC expansion box does not connect to the *SD32+* amplifier. Instead, it is located in the control room and sends collected signals directly to the computer. See *Figure 12. dc expansion box input sockets,* for an illustration of the sockets available.

Though the amplifier and the DC expansion box are not directly connected, the *Sandman Elite* software can collect signals from both units at the same time in a single montage and store them

in a single patient file. To add the DC expansion channels to a montage, click the Add button in the Edit Montage window and select the appropriate socket number from the input label drop-down list. The input labels available in the drop-down list correspond to the input socket labels on the expansion box.

Figure 12. dc expansion box input sockets

inputs

DC X Inputs – These inputs, ranging from "DC X1" to "DC X8" accept analog signal inputs from any DC device equipped with an analog output. The connector used to input a DC signal into a DCX socket is a 1/8" male mono connector. The eight input sockets allow the unit to accept DC inputs from multiple beds simultaneously. For example, the *Sandman Elite* software could be programmed so that sockets "DC X1" to "DC X4" accept inputs from bed one DC devices and sockets "DC X5" to "DC X8" accept inputs from bed two DC devices. The socket assignments on your expansion box were set up according to your lab's needs during installation. Only the sockets that have been assigned to the current bed appear in the list of channels that can be added to the montage.

ports

J2 Serial port – This port sends the collected signals to the COM port of the computer running the *Sandman Elite* software.

Warnings: **The DC expansion box may only be used outside of the "Patient Area" (as defined in the IEC 601-1-1 safety standard). The connections on the DC expansion box are not isolated from the ground of your building's electrical system. Do not allow these connections to come into contact with either the patient or any isolated input of the *SD32+* system as this will compromise patient safety.**

All equipment connected to the DC expansion box must be certified under the medical requirements of IEC 60601-1 deemed applicable by local authorities.

Body position sensors should be used with the DC Expansion box and not directly connected to the *SD32+* amplifier.

4. Software Driver Installation

To install the *SD32*+ amplifier, you must have a Microsoft® Windows® operating system installed on your computer that is compatible with the *Sandman Elite* software. For more information about supported operating systems, consult your *Sandman Elite* User Manual.

In most cases, a qualified representative from Embla Systems will install your amplifier and device drivers. If you need assistance, please contact Embla Technical Support.

5. Amplifier System Assembly

5.1. connecting the headbox to the amplifier

You can connect the Headbox to the amplifier either directly or by using the Headbox to amplifier Cable.

Direct Headbox Connection

To connect the Headbox directly to the amplifier:

1. Slide the Headbox firmly into the headbox platform on the top of the amplifier casing.
2. Ensure that the Headbox Connection port on the amplifier and the Headbox Amplifier Connection port on the Headbox are fully connected. The Headbox should be flush against the LCD display and menu control area.

Remote Headbox Connection

To connect the Headbox to the amplifier using the Headbox to Amplifier Cable:

1. Press the release button beneath the portion of the Headbox that extends over the end of the amplifier and slide the Headbox away from the LCD until it is free of the amplifier casing.
2. Connect one end of the Headbox to Amplifier Cable to the Patient Box Link port on the amplifier.
3. Connect the other end of the Headbox to Amplifier Cable to the Removable Patient Box Link port on the Headbox.

5.2. connecting the amplifier to the *sandman elink* adapter

To connect the amplifier to the *Sandman elink* Adapter:

1. Insert one end of the fiber optic cable into the Optical Link port on the amplifier until you hear or feel it click into place; the plug will only fit into the port one way.
2. Insert the opposite end of the fiber optic cable into the Optical Link connector on the *Sandman elink* Adapter until you hear or feel it click into place; the plug will only fit into the port one way.

5.3. connecting the external power supply to the amplifier system

To provide the *SD32+* system with power:

1. Screw the AC/DC Adapter's DC input plug into the DC In socket on the *Sandman elink* Adapter.
2. Screw the appropriate end of the Power Transfer Cable into the DC Out socket on the *Sandman elink* Adapter.
3. Screw the opposite end of the Power Transfer Cable into the DC In socket of the amplifier.
4. Insert the power cord into the three-pronged plug of the AC/DC Adapter.
5. When you are ready to start collecting data, plug the AC/DC power cord into a wall outlet.

5.4. connecting the DC expansion box to the computer (serial connection)

To connect the DC expansion box to the *SD32+* system using the serial connection:

1. Ensure that the computer is off.
2. Insert plug A of the *SD32+* amplifier DC Expansion Box Cable into the J2 Serial port on the DC expansion box. See *Figure 13. SD32+ amplifier dc expansion box* cable for details.

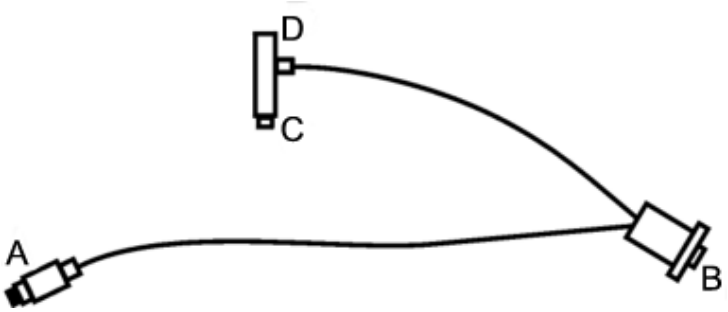


Figure 13. *SD32+* amplifier dc expansion box cable

3. Insert plug B of the *SD32+* amplifier DC Expansion Box Cable into the COM port on the computer.
4. Disconnect the mouse or keyboard from its port on the computer.
5. Insert plug C of the *SD32+* amplifier DC Expansion Box Cable into mouse or keyboard port on the computer.
6. Plug the mouse or keyboard PS2 plug into socket D of the *SD32+* amplifier DC Expansion Box Cable.

Changes must also be made to the *Sandman* software configuration so that the software can detect the DC expansion box. Please contact Embla Technical Support.

5.5. connecting the DC expansion box to the computer (USB connection)

To connect the DC expansion box to the *SD32+* system using the USB connection:

1. Ensure that the computer is off.
2. Plug the small connector of the USB cable into the J2-USB port on the DC expansion box.
3. Plug the large connector of the USB cable into the USB port on the computer.
   When you turn on the computer, the operating system will recognize the DC expansion box.

See *Figure 14. typical SD32+ system set-up* on page 26 for an illustration of a typical lab setup.

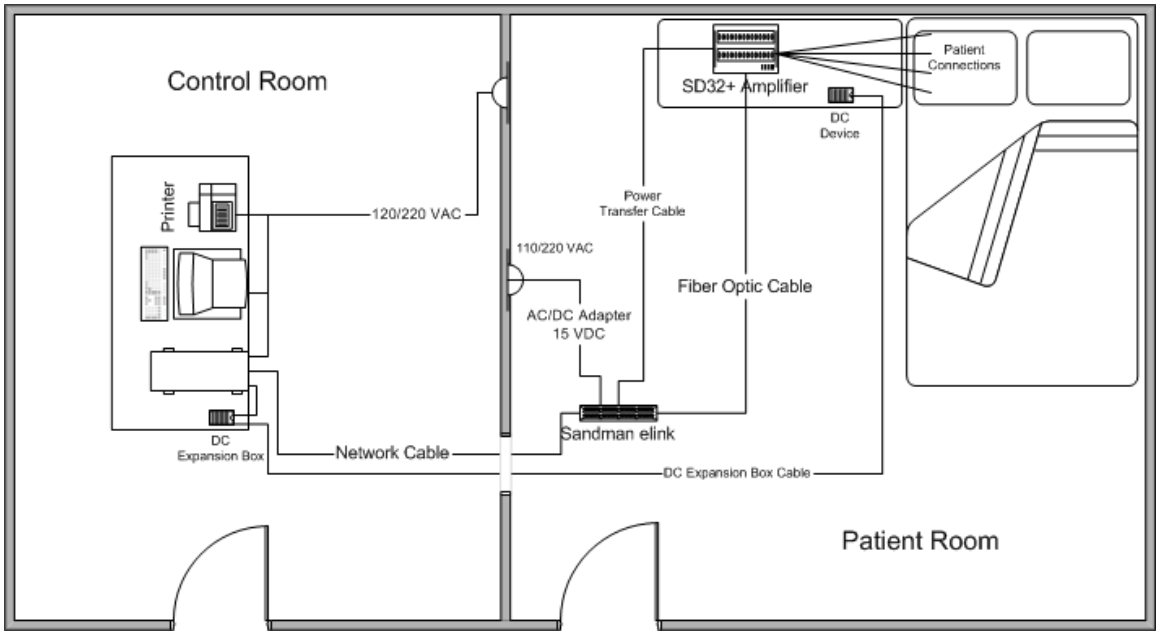


Figure 14. typical *SD32+* system set-up

6. Calibration

6.1. system record calibration

System record calibration is performed at the beginning and at the end of every study. Under the control of the *Sandman Elite* software, the amplifier generates a standard 50µV square-wave signal for calibration. This calibration is important for verifying filter and gain settings and for setting reference levels in a data record.

7. Maintenance

To ensure that the *SD32+* amplifier operates properly and effectively, ensure that the signals are calibrated, the cables and connectors are in good shape, and the equipment is cleaned on a regular basis.

7.1. safety checks

Periodically check the *SD32+* amplifier, and all devices connected to it, to ensure continued efficiency and safety. Testing should include electrical leakage tests and should be performed at least twice yearly by qualified biomedical personnel. Additionally, check the *SD32+* system for any dust deposits.

Perform a visual inspection of all connection cables and power cords for any signs of breakage or improper connection. If such problems exist, contact a qualified representative at Embla Systems.

Note: Safety checks should be performed periodically and no less than twice a year.

7.2. operational environment electrical equipment

Inspection of the electrical wiring of the AC supply mains should be conducted periodically to ensure proper grounding is available in the operating environment of the *SD32+* system.

7.3. amplifier calibration

Semi-annually: Check the amplifier at various gain and filter settings. Verify the amplitude and frequency characteristics of the resulting waveforms. It is recommended that each filter and gain level be tested.

7.4. cables and connectors

Periodically check the integrity of all connection cables used with the *SD32+* system, particularly the fiber optic cable. Remove the cables from their sockets and ports carefully. Twisting or pulling on the cables instead of their connectors may cause breaks or short circuits.

Monthly: Check cables monthly for abrasion and wear. Replace any cable with exposed wires or shielding (wire mesh located just below the outer casing of a cable).

Check the connectors on the ends of the cables for bent or broken pins. Replace any cable that has a damaged connector.

Check the connectors on the amplifier, headbox, and *Sandman elink* Adapter for broken or damaged contacts. If any are found, return the unit to Embla Technical Support for servicing or replacement.

7.5. cleaning

Monthly: Clean the amplifier's external surface with a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

Warnings:	**Before cleaning any part of the amplifier, disconnect it from any source of power and from any external devices.**
	Ensure that no liquid enters the amplifier and that it is completely dry before attempting to apply power to it or before connecting it with other devices.
Caution:	**Do not immerse the amplifier or its parts in liquids. Do not oil any part of the amplifier. Additionally, avoid cleaning the external surface with alcohol-based disinfectants as they may cause discoloration or damage the labeling.**

To obtain maintenance or cleaning information for equipment connected to the *SD32+* that is not produced by Embla Systems, such as sensors, computers, monitors, printers, or other accessories, consult the manual supplied with the equipment.

8. Specifications

8.1. system specifications

Description	Active, non-invasive, medical device.	
Intended Use	Amplifier Module for the acquisition (capture, conditioning, A/D conversion and transferring to a host system) of bioelectric signals produced by the human body	
Classification According to MDD 93/42/EEC	Class II b	
Safety Standard	93/42/EEC	European Medical Device Directive (MDD)
	IEC 60601-1	General safety standard for electromedical equipment
	IEC 60601-1-1	Collateral safety standard for electromedical systems
	IEC 60601-1-2	Collateral safety standard for device EMC test
	IEC 60601-1-4	Safety standard for devices containing programmable systems
	IEC 60601-2-26	Standard on particular safety requirements for electroencephalographs
Type of Protection Against Electric Shocks	Class I equipment powered by specified power supply	
Protection Level Against Direct and Indirect Electrical Contacts	BF type (patient input)	
Protection Level Against Inflow of Solids and Liquids	IPX0	

8.2. environmental operating conditions

Temperature	+5 °C to +40 °C
Relative Humidity	30% to 75% RH
Atmospheric Pressure	700 hPa to1060 hPa

8.3. environmental conditions for storage

Storage Temperature	-30 °C to +60 °C
Relative Humidity	5% to 95% RH (excluding condensation)
Atmospheric Pressure	500 hPa to 1060 hPa

8.4. amplifier specifications

8.4.1. general amplifier specifications

Part Number	4200022
Operating Channels	24/32/40
EEG/Polygraphic Channel	40
DC Channel	up to 8
Impedance Measurement	By means of injected current (20Hz - 0.01μA per electrode)
A/D Conversion	2's complement 24 bit Sigma-Delta A/D (16 bits actually transferred to host)
Amplifier – PC Interface	*Sandman elink* Adapter (by means of a fiber optic link)
Other Interfaces	128x64 graphic LCD display and 5 push buttons
Power Supply	External IEC 601-1 Class 1, type B, AC/DC adapter
Power Consumption	900 mA typical (40 channels)
Case	ABS Plastic
Dimension	250 x 170 x 65 mm
Weight	1.5 kg
Isolation	Fiber optic link

8.4.2. filters

High-Pass Filters	Channels A to H and 1 to 32	Either DC or 0.099 Hz first order filter
Low-Pass Filters (A/D Converter Output)	Frequency cutoff	at -3dB: 0.488 x sampling rate
		at -6dB: 0.500 x sampling rate
	Attenuation	80 dB f ≥ 0.55 x sampling rate

8.4.3. resolution, full scale range, noise

channels A to H and channels 1 to 24

	High	Low
Gain Setting / Resolution	1/8 μV/bit	2 μV/bit
Full Scale Range	8 mV_{p-p}	128 mV_{p-p}
Noise (0.1 Hz - 70 Hz)	1.5 μV_{p-p} max	20 μV_{p-p} max

channels 25 to 32

	High	Low	DC1	DC2	DC3
Gain Setting / Resolution	1/8 μV/bit	2 μV/bit	10 μV/bit	20 μV/bit	100 μV/bit
Full Scale Range	8 mV_{p-p}	128 mV_{p-p} [5]	640 mV_{p-p} [6]	1.28 V_{p-p} [7]	6.4 V_{p-p} [8]
Noise (0.1 Hz - 70 Hz)	≤ 1.5 μV_{p-p} max ≤ 0.5 μVrms	≤ 20 μV_{p-p} max	≤ 200 μV_{p-p} max	≤ 500 μV_{p-p} max	≤ 1 mV_{p-p} max

[5] Includes 28 mV_{p-p} offset

[6] Includes 140 mV_{p-p} offset

[7] Includes 280 mV_{p-p} offset

[8] Includes 1.4 V_{p-p} offset

8.4.4. sampling rate

max sampling rate

Number of Simultaneously Acquired Channels	Maximum Sampling Rate
1 to 16	32768 Hz
16 to 32	16384 Hz
32 to 40	8192 Hz
Selectable Sampling Rate	128,256,512… 32768 Hz (according to the limit of the maximum sampling rate)

sampling skew

All acquired channels will be sampled simultaneously (no sampling skew)

CMRR	>100 dB (>95 dB on polygraphic channels)
IMRR	>120 dB
Max. DC Offset (AC Mode)	± 300 mV

8.5. headbox specifications

Part Number	4200017
Case	ABS Plastic
Dimension	126 x 96 x 25 mm
Electrode Connectors	32 active – one active connection to each input (monopolar) 16 active – two active connections to each input (bipolar) 3 for neutral electrode 13 for isolated ground electrode 2 for temperature probe input 2 for calibration signal output
Connection to Amplifier Extension Cable	50 pin Microcentronics male Shielded cable (max 2m)

8.6. external medical grade AC/DC adapter specifications

You can use either of the following AC/DC power adapters (D.2101) with the Sandman elink Adapter:

8.6.1 AULT SW173

Manufacturer	AULT inc.	
Model	SW173	
Input	100-240VAC - 50/60Hz	
Output	15VDC @ 2.2A	
Safety Standards	IEC 601-1 (CEI 62-5)	
	89/336/EEC (EMC)	
	73/23/EEC (Low Voltage)	
Mark	CE, TUV, CSA, UL	
Electrical protection level	Class I, Type B	
Case	Material:	Plastic
	Dimensions:	129 x 77 x 40 millimeter

8.6.2 SINPRO MPU50-106

Manufacturer	SINPRO Electronics Co., Ltd.	
Model	MPU50-106	
Input	100-240VAC - 47/63Hz	
Output	15VDC @ 3A	
Safety Standards	IEC 601-1 (CEI 62-5)	
	EN 55011	
	EN 60601-1-2	
Mark	CE, TUV, cULus	
Electrical protection level	Class I, Type B	
Case	Material:	Plastic
	Dimensions:	146 x 76 x 43 millimeter

8.7. *Sandman*® *elink*™ adapter

Part Number	4200036	
Case	Materials:	ABS plastic
	Dimensions:	137 x 200 x 8 mm
	Weight:	0.2 Kg
Power supply	AULT SW173 or SINPRO MPU50-106	
Interfaces:	HP 100 Mb fiber-optic Transmitter and Receiver	
	RJ45 for Ethernet 100 bT Network link.	
	Triad F/M 4+1 per external power supply SW173	
	MCH Triad - HiRose HR12-10R-8SDL connector for RS232,	
	Trigger I/O, power supply	
	QM10-8R-PR HiRose connector for analogical output of digital signals.	
Status indicators:	Green LED: 3.3 V power is on.	
	* Yellow LED: Ethernet. Auto-negotiation controller.	
	# Yellow LED: Ethernet. Link 10 /100 Mb controller.	
	o Yellow LED: Ethernet. LAN controller.	
Device rated values	CE0051 mark (93/42/EEC)	
	cCSAus mark	

8.8. DC expansion box specifications

8.8.1. technical characteristics

Part Number	4200024
Supply	5V (± 5%) / 0.5 A max
Case	Plastic
Dimension	115 x 70 x 45 mm (L x W x H)
Weight	250 g
Inputs	8 x 1/8th inch male mono inputs
Maximum Channel Frequency	64 Hz
Connection to Computer	Serial or USB
Number of Analog Inputs	8
Analog Input Signal Range	±5 V (DC to 16 Hz)
Sampling Rate	8, 16, 32, 64 samples/second – host selectable
Input Impedance	> 100 kOhms
A/D Conversion	12 bits

8.8.2. environmental conditions

Usage Temperature	+5 °C to +40 °C
Relative Humidity	30% / 75% RH
Atmospheric Pressure	700 / 1060 hPa
Storage Temperature	-30 °C to +60 °C (relative humidity up to 95% non-condensing Pressure 500 / 1060 hPa) Max 15 weeks

8.9. pulse oximeter performance

Measurement Range	
SpO2	1% to 100%
Pulse Rate	0 and 20 BPM to 250 BPM
Perfusion Range	0.03% to 20%
Accuracy and Motion Tolerance	
Saturation	
Without Motion – Adults[9]	70 to 100% ± 2 digits
Without Motion – Neonate[5]	70 to 100% ± 3 digits
With Motion – Adults and Neonates[10]	70 to 100% ± 2 digits
Low Perfusion[11]	70 to 100% ± 2 digits
Averaging Time	Changes in SpO2 are reported in 2-3 seconds

Except as indicated, all accuracies are expressed as ± "X" digits between saturations of 70%–100%. This variation equals ± one standard deviation (1 SD), which encompasses 68% of the population. Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO_2 range. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry.

The above performance specifications are given for the *Nellcor® OxiMax®* sensors. For further information on *Nellcor* sensors, please visit www.nellcor.com/prod/index.aspx. A full listing of all sensors and descriptions can be found here including ordering information.

[9] Adult specifications are shown for *Nellcor OxiMax MAX-A* and *MAX-N* sensors. Neonate specifications are shown for *Nellcor OxiMax MAX-N* sensors. Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid.

[10] Applicability: *Nellcor OxiMax MAX-A, MAX-AL, MAX-P, MAX-I*, and *MAX-N* sensors.

[11] Specification applies to monitor performance and was validated with Biotek® and *Nellcor* simulators.

Index

R

S

T

REF: 4280034