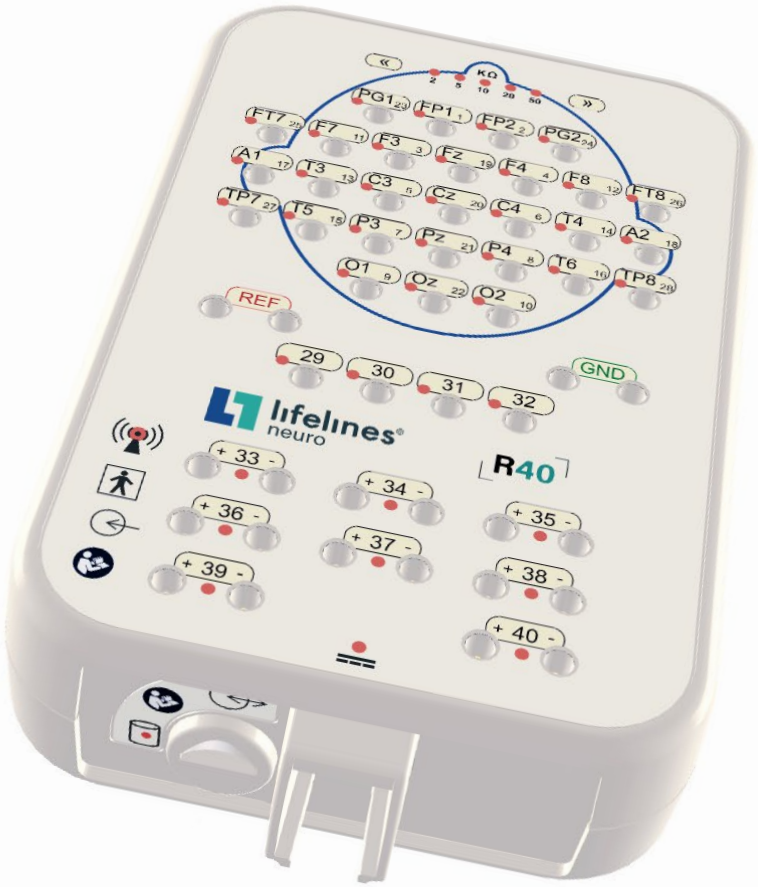

R40 EEG Amplifier

MADE IN BRITAIN

USER MANUAL

lifelines® neuro

Imagine EEG Anywhere

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Customer Responsibility

The R40 amplifier is reliable only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and inserts. A defective system should not be used. Parts that may be broken or missing or those that are clearly worn or contaminated should be replaced immediately with new original replacement parts that have been manufactured by or are available from Lifelines Neuro.

The owner of this system has the sole responsibility for any malfunction resulting from improper use or maintenance, or repair done by anyone other than a qualified Lifelines Neuro representative and for any malfunctions caused by any parts that have been damaged or modified by anyone other than a qualified Lifelines Neuro representative.

The owner of this system has the sole responsibility for the connection of this product to other systems not satisfying the electrical safety requirements class I, type BF, standards IEC 60601-1, IEC 80601-2-26, IEC 60601-1-2 for medical devices.

NOTE: Any serious incident that has occurred in relation to the R40 Amplifier should be reported to the manufacturer and, where applicable, the competent authority of the EU Member State in which the user and/or patient is established.

Disclaimers & Warranties

The information in this section is subject to change without notice.

Except as stated below, Lifelines makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Lifelines shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this material.

Lifelines shall warrant its products against all defects in material and workmanship for one year from the date of delivery.

Misuse, accident, modification, unsuitable physical or operating environment, improper maintenance or damage caused by a product for which Lifelines is not responsible will void the warranty.

Lifelines do not warrant uninterrupted or error-free operation of its products.

Lifelines or its authorised agents will repair or replace any products that prove to be defective during the warranty period, provided that these products are used as prescribed in the operating instructions in the user's and service manuals.

No other party is authorised to make any warranty to assume liability for Lifelines products. Lifelines will not recognise any other warranty, either implied or in writing. In addition, services performed by someone other than Lifelines or its authorised agents or any technical modification or changes of products without Lifelines prior, written consent may be cause for voiding this warranty.

Defective products or parts must be returned to Lifelines or its authorised agents, along with an explanation of the failure. Shipping costs must be prepaid.

Lifelines manufactures hardware and software to be used on or with standard PC-compatible computers and operating software. Lifelines, however, assumes no responsibility for the use or reliability of its software or hardware with equipment that is not furnished by third-party manufacturers accepted by Lifelines at the date of purchase.

All warranties for third-party products used within the R40 system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

Trademarks

Microsoft and Windows are registered trademarks of the Microsoft Corporation. All other trademarks and product names are the property of their relevant owners.

Responsibility of manufacturer

The manufacturer and distributor consider themselves responsible for the equipment's safety, reliability and performance only if:

- any peripheral equipment to be used with the R40 system is supplied by third-party providers recommended by the manufacturer;
- assembly operations, extensions, readjustments, modifications, or repairs are carried out by person authorised by the manufacturer;
- the electrical installation of the relevant room complies with the appropriate requirements;
- the equipment is used by a healthcare professional and in accordance with the instructions for use.

NOTE: Equipment specifications are subject to change without notice.

NOTE: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

General Security Policies

- Prevent physical access to the system from unauthorized persons.
- Make frequent backup of the system. Store the backup on a safely stored device.
- The user should lock the system manually if they leave it unattended.
- Short inactivity timeouts are always active and lock the system when the timeout expires.
- Do not install any 3rd party software which is not intended for use with the application. An unknown software can possess a potential security risk.
- Encrypt system drives which contain local databases and temporarily store data files/reports.

Networked Environments

- Connect the system on secured networks only.
- Using the system on a wide-open network is not recommended.
- Keep the network software updated with latest patches.
- Use encrypted data communication over "less safe" network segments (ipsec, VPN).
- All resources within the network can only be accessed by authenticated users.

Contents

1 Overview

1.1 General description

Indications for use

The R40 EEG Amplifier is used as an aid in the diagnosis of neurophysiological disorders such as epilepsy.

⚠	**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

General Description

The R40 EEG Amplifier is a 40-channel electroencephalograph designed for use in routine EEG and lab monitoring applications.

The R40 Amplifier has the following features:

- Type-BF patient isolation to applied parts.
- 32 EEG inputs and 8 Bipolar polysomnography inputs.
- Two Aux DC inputs and an Electrocap connector.
- Built-in electrode Impedance measurement and Calibration Check.
- Interface to Nonin XPOD module for SpO2, heart rate and Plethysmograph capture.
- Connection for optional remote pushbutton.
- USB or optional wireless interface to the Acquisition PC.
- Powered via USB cable.
- Digital Trigger input .
- Storage on removable microSD card.

The R40 Amplifier is intended to be connected to a PC which is powered from a medical-grade power supply.

This equipment is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. The equipment does not sustain or support life.

Intended Use

The R40 EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

Intended User

The intended user of the equipment is a healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice.

Intended patient population

Pediatric to adult. The patient profile has no influence over the EEG signal acquisition. The patient has no interaction with the device.

Clinical Benefit

The expected clinical benefit for the R40 EEG Amplifier is as an aid in measuring electrical brain activity and in diagnosing brain disorders, such as epilepsy and other seizure disorders.

Recording EEG with the R40 amplifier does not directly affect outcome; the collected EEG activity will allow the physician to decide on diagnosis and treatment. Treatment directed by data recorded with the R40 amplifier may result in better outcomes than treatment informed solely by data from clinical assessment.

Essential Performance

Essential performance of the Lifelines R40 EEG Amplifier is identified in the standard IEC 80601-2-26. Essential performance relates to the quality and accuracy of the signal recorded from the amplifier. Specific essential performances are (1) accuracy of amplitude and rate of variation, (2) dynamic range and differential offset voltage, (3) input noise level, (4) frequency response, and (5) common mode rejection. The definitions of these essential performances can be found in the standard. Refer to the R40 EEG Amplifier specification in *Appendix 1.*

1.2 Warnings and Cautions

	Warning sign indicates a situation or procedures that may be dangerous for the patient and/or user.		**Caution** sign indicates a situation or procedures that may cause equipment damage or its improper usage.

	Do not use the R40 EEG Amplifier in an MRI environment, in an explosive atmosphere or during defibrillation.
	This equipment is intended to be used by a healthcare professional and in accordance with these instructions for use which must be read in their entirety before the device is used.
	This equipment is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. This equipment is not be used for the determination of brain death.
	Lifelines does not supply EEG electrodes. The unit accepts standard 1.5 mm touchproof electrodes using DIN 42802-style connectors. To ensure patient safety, the electrodes used must be approved to the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 in Europe or FDA cleared for use in USA.
	The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth.
	Lifelines does not supply the Nonin sensor. Only use the 'PureLight' sensors specified by Nonin to be used with their Oximeters.
	The function or safety of the equipment could be impaired if it has been subjected to unfavourable conditions in storage or in transit. If at any time function or safety is thought to be impaired, the instrument should be taken out of operation and secured against unintended use.

	Do not open or modify the equipment without the authorization of the manufacturer.
	Do not touch simultaneously any accessible USB or other contacts on the PC and the patient.
	Only use the PC and the medical-grade power supply as supplied or authorised by Lifelines.
	Do not plug the USB connector into any device other than the PC supplied or authorised by Lifelines.
	The conductive part of connectors and transducers should not contact other conductive parts including earth. Always ensure that the transducer fitted is suitable for a connection of Type BF isolation.
	Medical electrical equipment must be installed according to the EMC information provided in the Appendix.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the R40 EEG Amplifier, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the R40 EEG Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
	Only use approved sensors as specified by Lifelines.
	The Amplifier must only be used with the USB cable provided with the unit.
	Do not allow any liquid to enter the case of the instrument or connector. Do not use acetone on any of the instruments.
	Federal (USA) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS: There are no known contraindications to the use of this equipment.

SIDE EFFECTS: There are no known side effects to the use of this equipment.

1.3 Explanation of symbols

Symbol	Meaning
	Type BF applied part
	Input/output connection
	Special recycling required*
	Consult warnings in User Manual
	Internal radio device
	Remote event pushbutton
	Manufacturer
	Internal battery hazard - refer to section **1.5**
	Follow operating instructions

Symbol	Meaning
	Input connection
	Bluetooth
	Nonin Xpod, Pulse Oximeter
	USB Power Indicator
	Electrocap
	European Representative
	Medical Device
	Swiss Representative
	Consult electronic instructions for use (eIFU)

* Do not dispose of in landfill. This product includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. When this equipment has reached the end of its useful life, follow all local laws and regulations for the proper recycling or disposal of such equipment. Contact your local distributor for information.

Storage and transport symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Temperature limits		Fragile		Keep dry
	Relative humidity limits		Atmospheric pressure limits		

1.4 Components and Accessories

The R40 EEG Amplifier Part Numbers:

Component	Part Number
R40 Amplifier	1326
Amplifier USB Cable	1277
Xpod Pulse Oximeter Nonin	1327
Patient event switch	1353
R40 Mounting Bracket	1372

Applied parts

EEG Electrodes

The amplifier connects to EEG electrodes with standard 1.5mm touchproof DIN 42802-style connectors.

ⓘ	Lifelines does not supply EEG electrodes. To ensure patient safety, the electrodes must be approved to the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 in Europe or FDA cleared for use in USA.
ⓘ	The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth.

Oximeter Sensor

An optional oximeter sensor attaches to the patient's finger

NOTE: The Oximeter sensor is a consumable and is not supplied by Lifelines. Only use the 'PureLight' sensors specified by Nonin for use with their Oximeters.

Patient Event pushbutton

The Patient Event Pushbutton is used by the patient to mark an event.

Aux DC Inputs

The Auxiliary DC inputs are intended for the connection of patient-attached transducers which are passive or battery-powered such as sleep sensors. They must be insulated with no accessible conductive parts..

USB Cable

The Amplifier plugs directly into a USB port on the PC.

⚠	The Amplifier must only be used with the USB cable provided with the unit.

Medical grade AC/DC mains power supply module for Acquistion PC

To control the mains power leakage current in the patient environment, the Acquistion PC must use a medical-grade mains power supply.

	Only use the PC and medical-grade power supply as supplied or authorised by Lifelines. Do not use the standard power supply

The Setup and Recording Software

The Trackit setup software runs on the Acquistion PC and is used to set up the R40 Amplifier and to record on to the PC.

Refer to the Trackit Plus software manual.

1.5 Replaceable parts

Lifelines Ltd. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts that are designated by Lifelines Ltd. as repairable by service personnel.

Internal battery replacement – service personnel only

The R40 amplifier contains a replaceable lithium ion rechargeable coin cell, type LIR2450.

	Battery replacement by inadequately trained personnel could result in a hazard. It must be replaced only with the correct type. Refer to the R40 Service Instructions.

2 Installation and Maintenance

The following section must be read and understood before the equipment is switched ON.

⚠	Medical electrical equipment must be installed according to the EMC information provided in the Appendix.

The function or safety of the equipment could be impaired if it has been subjected to unfavourable conditions in storage or in transit. If at any time function or safety is thought to be impaired, the instrument should be taken out of operation and secured against unintended use.

The manufacturer should be contacted if assistance is needed in setting up, using or maintaining the equipment; or to report unexpected operation or events.

The assembly of the system and any modifications during its service life require evaluation to the requirements of IEC 60601-1.

2.1 Checks for completeness and integrity

1. Remove the equipment from the packaging case(s).
2. Use the parts list to check that all ordered items have been received.
3. Check for signs of damage that may have occurred during transit or storage. If any damage is found, do not use the instrument; contact your distributor.

2.2 Environmental parameters for operation

The operational and storage/transportation environmental conditions are as follows:

Operational:		Storage and transport:	
Temperature	+10°C to +40°C (+50°F to +104°F)	Temperature	-10°C to +50°C (14°F to +122°F)
Relative humidity	25% to 95% non-condensing	Relative humidity	10% to 95% non-condensing
Atmospheric pressure	700 hPa to 1060 hPa	Atmospheric pressure	500 hPa to 1060 hPa

2.3 Power supply connections

R40 Amplifier

Power requirements	Standard USB port (5V)
Power consumption	Maximum power from USB port: 2.5W.

⚠	The Amplifier must only be used with the USB cable provided with the unit.

Internal Li-Ion backup battery

The R40 Amplifier includes an internal backup battery, which will enable the unit to continue operating for a short period of time (approx. 30 min) after USB power is removed. It is recharged automatically, while the amplifier is switched on and connected over USB.

The typical service life is 500 charge-discharge cycles. The backup battery is replaceable by service personnel only.

Medical grade AC mains power supply for Acquisition PC

Medical grade AC mains power supply for Acquisition PC	
Mains Power input:	100–240 Vac, 47–63 Hz, 1.4 A @ 115 Vac, 0.7 A @ 230 Vac.
Output:	20 Vdc, 5.25 A.

ⓘ	The PC must only be connected to the medical grade power supply supplied or authorised by Lifelines. Do not use a standard PC power supply.
ⓘ	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2.4 Use with other equipment

Defibrillators and HF surgical equipment

The equipment is not defibrillator proof and should not be used in situations where a defibrillator is likely to be used. The equipment should not be used with, or in the presence of, high frequency surgical equipment.

Other patient-connected equipment

When used simultaneously with other patient-connected equipment, it is unlikely that a safety hazard will arise. However always consult the documentation supplied with the other patient-connected equipment to ensure that all hazards, warnings and cautions are considered before the equipment is used together.

	Non-medical equipment, when used with the system, should comply with IEC/ISO safety standards relevant to that equipment. IT equipment should comply with IEC 62368.

Leakage current

This system is designed to comply with IEC 60601-1, the international standard for medical electronic equipment, which specifies the permissible levels of leakage current. A potential hazard exists in the summation of leakage currents caused by connecting several pieces of equipment together. Because this system can be used in conjunction with standard electronic devices, the total leakage current should be tested whenever the system is modified.

There should be no electrical connections between the system equipment, which is powered via a medical grade power supply, and any other equipment powered from another mains supply.

2.5 Interference

The R40 will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of IEC60601-1-2. However, the R40 amplifier records signals of very low amplitude, and such interference may cause signal artefacts.

The R40 may have internal radios fitted. These are approved industry-standard Bluetooth and WiFi types which present minimal risk of reciprocal interference with other equipment. Other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment.

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the R40, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the R40 Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
	Medical electrical equipment must be installed according to the EMC information provided in the Appendix.

2.6 Maintenance and cleaning

The R40 Amplifier requires no routine testing, calibration or maintenance procedures apart from occasional cleaning and checking for wear and damage to all parts including the accessories.

Cleaning and disinfection

Prior to each re-use of the system, all the outer surfaces of the R40 Amplifier may be cleaned using a soft cloth moistened with water and a mild detergent solution. A low-pressure airline or a vacuum cleaner can also be used.

Disinfection of the equipment can be carried out by the use of QAC-based disinfectants. Wipes are recommended to prevent the ingress of any liquid into the equipment.

⚠	Do not allow any liquid to enter the case of the instrument or connector. Do not use acetone on any of the instruments.

2.7 Disposal of equipment

When the device and its parts and accessories has reached the end of its operating life, follow all local laws and regulations for the proper recycling or disposal of electronic equipment.

3 Connections and Usage

3.1 Overview

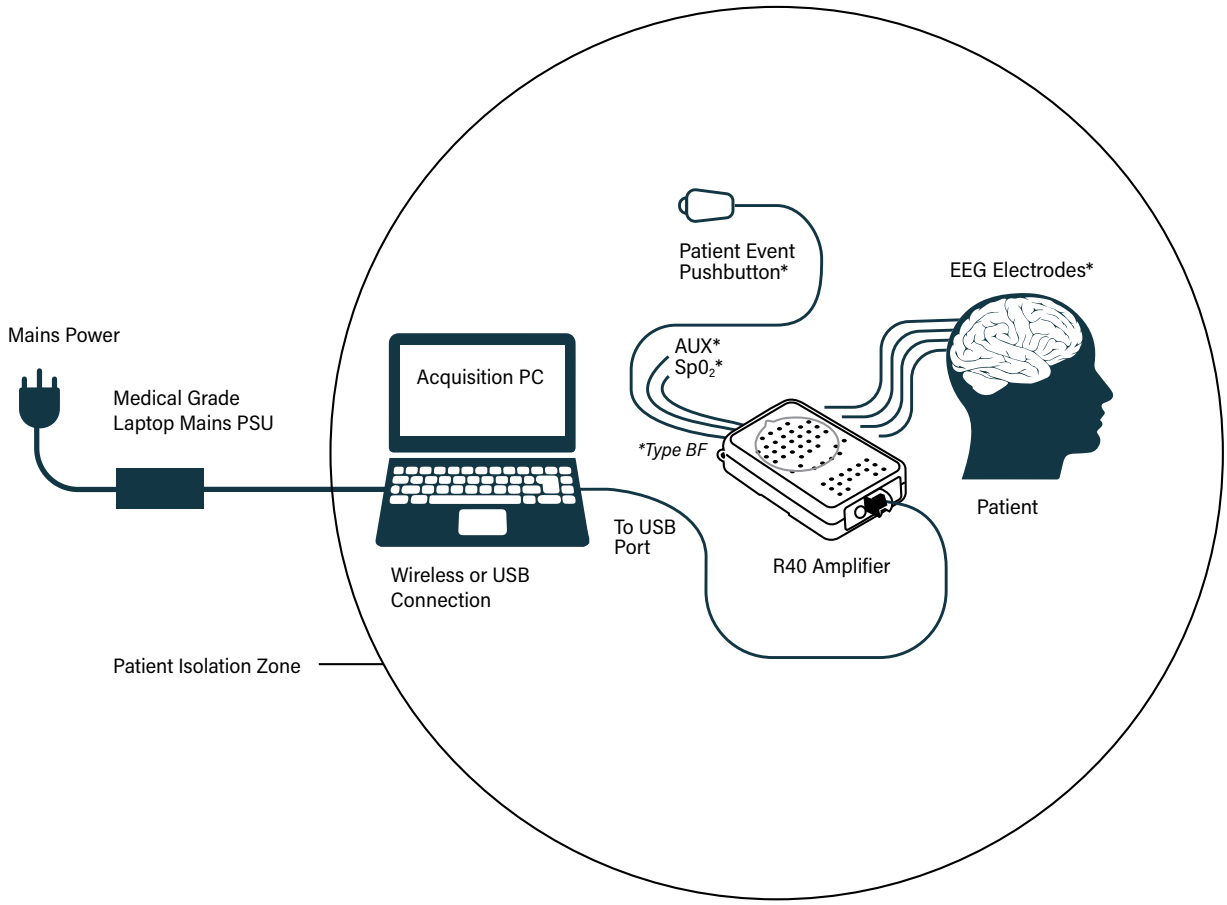

Figure 1: Connecting the R40 Amplifier

⚠	The PC must only be connected to the medical grade power supply supplied or authorised by Lifelines. Do not use a standard PC power supply.

3.2 Connecting the R40 Amplifier

The supplied USB Cable (part number 1277) connects into the bottom housing of the R40 Amplifier as shown below using the RJ45 plug and into any USB port on the PC.

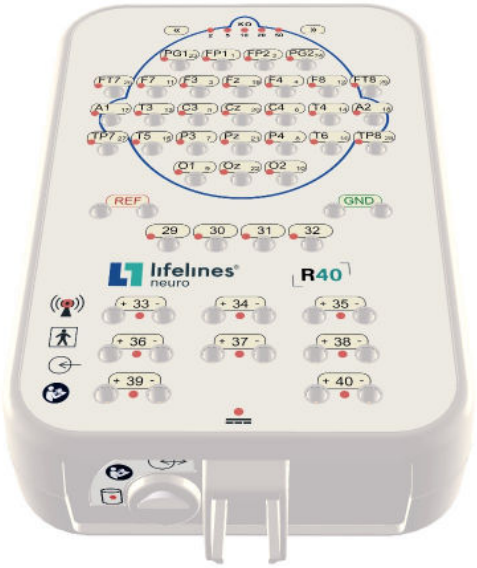

Figure 2 Connecting the R40 EEG Amplifier

The Amplifier electrode inputs are laid out in a standard 10-20 format and accommodates standard EEG Electrodes with touch-proof 1.5mm DIN 42802 connectors.

ⓘ	To ensure patient safety, the electrodes used must be approved to the Medical Device Directive 93/42/ EEC or Medical Device Regulation 2017/745 in Europe or FDA cleared for use in the USA.
ⓘ	The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth.

Adjacent to each electrode is an LED indicating whether the impedance of the individual electrode is above the set-level. Two buttons, located on the top of the front face, set the electrode impedance threshold level, and is indicated by five LED indicators.

The top edge of the Amplifier provides for several other connections, as shown below.

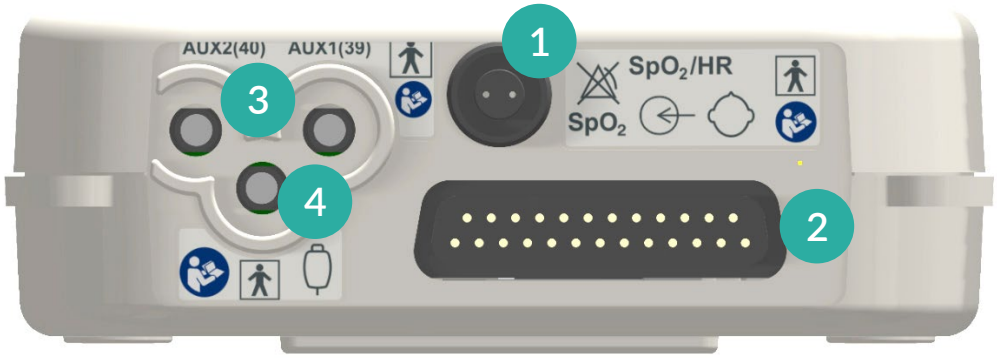

Figure 3 Connecting the R40 Amplifier (top face)

1. SpO2/HR: the circular connector allows for the connection of a Nonin Xpod pulse oximeter for measuring SpO2.
2. 25-way D-type connector allows for the connection of a standard Electro-Cap or Incereb array.
3. Aux1 and Aux2: 3.5mm jack connectors for the connection of transducers like Body Position, Respiration Belts etc.
4. Patient Event: 3.5mm jack connector for the connection to Patient Event pushbutton (part number 1353).

ⓘ	All these connections are Type BF isolated. The conductive part of connectors and transducers should not contact other conductive parts including earth. Always ensure that the transducer fitted is suitable for a connection of this type.

3.3 Switching the R40 On & Off

Switching On

- Power on the PC and start the EEG software as per the software instructions.
- Connect the R40 to the PC using the supplied USB cable

The amplifier will switch on when connected to a PC with the USB cable. The power indicator (⎓) will be illuminated when the R40 is powered on.

Switching Off

The R40 amplifier will automatically switch off (after a period of inactivity) after disconnection from the PC or after the PC has been switched off.

3.4 Connection Checks

Calibration Check

The Calibration Check performs a channel test on all inputs to verify the integrity of the signal processing from the R40 input to the display on the PC. This allows the user to examine the waveforms on the screen to see if all the channels are functioning correctly. The calibration check waveform for the R40 is configurable. The default waveform is an 8mVp-p square wave @ 1 Hz.

> **NOTE:** The Calibration Check does not validate the connection from the patient electrode to the R40 Electrode input.

Impedance Check

An Impedance Check can be performed to ensure the electrode contact with the patient is satisfactory. The Impedance check can be performed any time during a study, regardless of whether the R40 is recording or not.

The R40 can perform an impedance check on all the referential EEG channels and the REF input.

> **NOTE:** Impedance check cannot be performed on channels configured as Poly / Bipolar channels.

An LED adjacent to each electrode input indicates if the measured impedance is above the set threshold. The LED is off if the impedance is below the set threshold. The set threshold is indicated by five LED indicators (2kΩ, 5kΩ, 10kΩ, 20kΩ, 50kΩ).

The threshold can be set with the << and >> buttons on the R40, or through the acquisition software.

Appendix 1: R40 Amplifier Specifications

Lifelines reserves the right to change product specifications at any time without notice. This is in line with the company's policy of continual product development.

EEG inputs	
Number of EEG channels	32 monopolar touchproof inputs
ADC Resolution	24 bits
Sampling	250 – 16000 Hz
Input impedance	>20 Mohms
Common mode rejection ratio	>100dB @ 50 and 60 Hz
Equivalent input noise	<1.5µVpp, <0.2µV rms
Gain	12 ±0.5%
Max Input Vdiff	750mVpp (including DC)
Quantisation	0.17µV/bit @ Gain = 12 and Bits = 22
Bandwidth (-3dB)	DC to 4193Hz
Max common mode input voltage	0.4Vpp
Input bias current	< ±0.3 nA
Front-end Calibration	8mVpp ±5% at 0.98Hz
Impedance Check current	24nA ±20% at 7.8Hz
Polygraphy inputs	
Number of polygraphy inputs	8 bipolar touchproof inputs
ADC Resolution	24 bits
Sampling	250 - 16000 Hz
Input impedance	>20 Mohms
Common mode rejection ratio	>100dB @ 50 and 60 Hz
Equivalent input noise	<1.5µVpp, <0.2µV rms
Gain	12 ±0.5% (AC), 4 ±0.5% (DC)
Max Input Vdiff	750mVpp AC setting (including DC), 2.25Vpp DC setting
Bandwidth (-3dB)	DC to 4193Hz
Quantisation	0.17µV/bit @ Gain = 12 and Bits = 22
Max common mode input voltage	0.4Vpp
Input bias current	< ±0.3 nA
Front-end Calibration	8mVpp ±5% at 0.98Hz
Impedance Check current	24nA ±20% at 7.8Hz
Aux. high-level DC Inputs	
Number of Aux channels	2 (channels 39 and 40)
ADC Resolution	24 bits
Sampling	250 - 16000 Hz
Input impedance	100 Kohms
Gain	4 ±0.5%
Max Input Vdiff	2.25Vpp
Bandwidth (-3dB)	DC to 4193Hz max.

Connections, ports and controls	
Electrode Input connectors	52 Touchproof 1.5mm
E-cap connector	1 Standard 25-pin D socket
Aux DC Inputs	2 Jack socket 3.5mm (Channels 39 and 40)
Patient Event Input	1 Jack socket 3.5mm
Front-panel push-buttons	1 push-button Impedance Check – 1 push-button Impedance Check +
Host PC Connector	1 RJ45 socket providing USB port (isolated from patient)
Nonin Xpod (SaO2)	1 Binder 710 series 3-pin socket
LED indicators	Impedance Check Indication (1 per channel). R40: 40 LEDs, R40 (24): 28 LEDs 5 LEDs for Impedance Check Level, 1 LED for Power On, 1 LED for Wireless operation
Micro-SD card port	1 Micro-SD socket
Internal Battery	1 type LIR2450 Lithium-ion rechargeable Coin cell
Internal beeper	
Bluetooth Wireless	
Type	Bluetooth 4.0
Output power	11dBm max.
Output frequency	2.402 - 2.480 GHz, ISM band
Data rate	1.3 Mbps max.
Protocols	Standard Bluetooth - SPP, GATT, DUN, PAN
Modulation	GFSK, DQPSK. Frequency Hopping Spread-Spectrum (FHSS)
Error correction	Forward Error Correction (FEC), Automatic repeat request (ARQ).
Security	Authorization and authentication of devices, proprietary Interface Protocol
Type Approvals	Europe (ETSI R&TTE); US (FCC/CFR 47 part 15 unlicensed modular transmitter approval) Canada (IC RSS); Japan (MIC - formerly TELEC)
R&TTE Directive 1999/5/EC	Effective use of frequency spectrum: EN 300 328 EMC: EN 301 489-1, EN 301 489-17, EN 61000-6-2 Health and safety: EN 62479, EN 60950-1, IEC 609501
Medical Electrical Equipment	IEC 60601-1-2
Bluetooth Qualification	V4.0
Physical characteristics	
Weight	400g
Size	17cm x 11cm x 4cm

Safety and EMC standards	
The system has been certified and complies with the following standards:	
IEC 60601-1 and IEC 80601-2-26	International standard for medical electrical equipment, general requirements and particular requirements for EEG systems.
ANSI/AAMI ES 60601-1	AAMI Deviations from IEC 60601-1 (USA).
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	International standard for medical electrical equipment, EMC requirements, calling:
*CISPR11	Conducted Emissions, Group 1, Class B
CISPR11	Radiated Emissions, Group 1, Class B
IEC61000-4-2	Electrostatic Discharges
IEC61000-4-3	Immunity - Radiated RF Field
*IEC61000-4-4	Immunity - Transients Bursts
*IEC61000-4-5	Immunity – Surges
IEC61000-4-6	Immunity – Conducted
IEC61000-4-8	Immunity – Power frequency fields
*IEC61000-4-11	Immunity – Voltage dips, interruptions
*IEC61000-3-2	Harmonic Emissions
*IEC61000-3-3	Voltage Fluctuations/flicker
*Note: Compliance is provided by the PC	

R40 Amplifier Classification	
Classification	**Clinical use**
Degree of protection against electrical shock (when connected to host system)	Type BF
Type of protection against electrical shock (when connected to host system)	Optically isolated USB amplifier Medical grade Class I Power supply for PC
Degree of protection against harmful ingress of water	Ordinary (no protection)
Mode of operation	Continuous
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Appendix 2: Manufacturer's Declaration

EMC Compatibility

This section contains specific information regarding the device's compliance with IEC 60601-1-2 and EN 60601-1-2.

	The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.
	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here.
	The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the R40, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the R40 Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.

Accessory name	Type	Length	Description
USB Interface Cable	USB	2.8 m	USB shielded cable
Input electrodes	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Input electrodes (E-cap)	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Nonin XPOD	Shielded	2 m	Nonin
Aux. Connector cable	Shielded	1 m	Shielded cable
Patient Event Switch	CM-5	2 m	Two-core unshielded cable

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

IEC 60601-1-2 / EN 60601-1-2

The R40 is intended for use in the electromagnetic environment specified below. The customer or user of the R40 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The R40 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11/EN55011	Class B	The R40 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. Note: Only the recommended or supplied PC must be used in the system to ensure compliance.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

IEC 60601-1-2 / EN 60601-1-2

The R40 is intended for use in the electromagnetic environment specified below. The customer or user of the R40 should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	+/- 8 kV: Contact +/- 15kV: Air	+/- 8 kV: Contact +/- 8kV :Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. While in use, the patient should be stationery and not touch the R40 amplifier
Electrical fast Transients/ burst IEC 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment. If the user of the R40 system requires continued operation during power mains interruptions, it is recommended that the R40 system be powered from an uninterruptible power supply or a battery

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m, 30A/m	3 A/m See Note e.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF Electromagnetic Fields IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6V in ISM Bands 3 V/m 80 MHz to 2.5 GHz 10V/m (Home Environment)	3 Vrms 3 V/m See Note f.	Portable and mobile RF communications equipment should be used no closer to any part of the R40, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [3.5/E]\sqrt{P} = 1.2\sqrt{P}$ $d = [3.5/E]\sqrt{P}$: 80 MHz to 800 MHz = $1.17\sqrt{P}$ $d = [7/E]\sqrt{P}$: 800 MHz to 2.5 GHz = $2.33\sqrt{P}$ Note: using unshielded input leads Where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the R40 is used exceeds the applicable RF compliance level above, the R40 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the R40.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c The immunity levels for conducted RF are for unscreened input electrode leads 1 m in length and worse-case coupling, including any resonances across the frequency band. The interference is less when the coupling plane of the interference source is not in the same plane as the electrode leads.

d The immunity levels for radiated RF are for unscreened input electrode leads 1 m in length and worse-case coupling, including any resonances across the frequency band. The interference is less when the polarisation plane of the interference source is not in the same plane as the electrode leads.

e The R40 does not contain magnetic components and is not susceptible to power frequency magnetic field interference.

f The conditions of intended use justify lower immunity test levels. The hazards and risk analysis associated with these lower limits have been documented in the Risk Management file.

Recommended separation distance between portable and mobile RF communications equipment and the R40 EEG System

IEC 60601-1-2 / EN 60601-1-2

The R40 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the R40 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the R40 as recommended below, according to the maximum output power of the communications equipment.

If any electromagnetic interference is encountered, the patient and equipment should move to an area without interference. In any case, the electromagnetic interference does not pose any risks to the patient, as the R40 is a non-invasive recording device that does not modify or interact with the patient.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
W	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

R40 EEG Amplifier

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