lifelines neuro


# R40

EEG System

MADE IN BRITAIN

## USER MANUAL

Imagine EEG Anywhere®

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## Customer Responsibility

The R40 EEG System 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.

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 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 60601-2-26, IEC 60601-1-2 for medical devices.

# 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, Windows and Windows NT 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:** the manufacturer has a policy of continual product improvement; hence the equipment specifications are subject to change without notice.

Check with Lifelines or your distributor if a software update is available.

**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.

## Software and Virus Protection

Lifelines takes all reasonable steps to ensure that its software is virus-free. In line with modern computing practice, it is advisable that continual protection against viruses, Trojans, malware, adware etc. is provided on the PC used for installation and the surrounding systems. Please note the following recommendations which should be supported by your internal IT/Computing department procedures and practices:

1. Virus protection software should be installed on every computer at risk of infection. This software should have a resident (online) shield and provide email scanning if appropriate.
2. Virus scanning should be set to manual mode or automatic if desired but at a time when the system is not being used.
3. All programs offering auto-update features, including Windows, should be set to manual or automatic if desired but at a time when the system is not being used.
4. Adopt formal departmental or organisational procedures to ensure the integrity and safe operation of the medical equipment and supporting systems.

# Contents

## Appendices



## Illustrations

# 1 Overview and Technical Description

## 1.1 General description

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

### Indications for use

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

### General description

The R40 EEG System is a multi-channel electroencephalograph system designed for use in routine EEG and lab monitoring applications.

The R40 system uses either the R40 EEG amplifier or the R40 (24) EEG amplifier. The R40 EEG amplifier is a compact USB 40-channel amplifier which incorporates 32 referential channels and 8 polygraphic channels with built-in calibration and electrode impedance measurement. A Nonin XPOD interface is provided, a Patient Event input, 2 Aux DC inputs and an Electrocap connector.

The R40 (24) EEG Amplifier is a reduced channel variant of the R40 amplifier. The R40 (24) provides 24 referential channels and 4 polygraphic channels. In all other respects the R40 (24) amplifier is identical to the R40.

The system includes a PC and monitor, for control and storage, powered by a medical-grade power supply and an optional USB Photic Stimulator and arm. The system is mounted on a special wheeled cart, which houses all components and allows convenient mobility.

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.

**NOTE:** Unless otherwise specified, throughout this manual the term "R40" refers to both the R40 EEG Amplifier and R40 (24) EEG Amplifier

### 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.

## 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 System 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 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 cart should be positioned in use so that disconnection of the mains plug from the supply socket can be accomplished without difficulty. |
| 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 needs special precautions regarding EMC and needs to be installed and put into service 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 System, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result. |
|  | When in close proximity to the R40 EEG System, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information. |
|  | Before transportation, the system should be put into its transportation position to reduce the risk of overbalancing: disconnect mains supply cable; lower work top to lowest position; fully retract arms; release brakes. |
|  | Do not exceed the Safe Additional Working Load of 4 kg on the worktop. |
|  | 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.

## 1.3 Explanation of symbols

| Symbol | Meaning |
|---|---|
|  | Type BF applied part |
|  | Input/output connection |
|  | Special recycling required* |
|  | Consult warnings in User Manual |
|  | On/Off and patient event switch |
|  | Pushing Prohibited (When not in Transport Position) |
|  | Remote event pushbutton |
|  | Manufacturer |
|  | Equipotentiality |
|   | Internal battery hazard - refer to section **1.7** |

| Symbol | Meaning |
|---|---|
|  | Follow operating instructions |
|  | Input connection |
|  | Bluetooth |
|  | WLAN WiFi |
|   | Nonin Xpod Pulse Oximeter |
|  | Sitting prohibited |
|  | DC power |
|  | Protective earth (ground) |
|  | Electrocap |
|   | European Representative |

* Special recycling required, do not dispose of in landfill. When this equipment has reached the end of its useful life, it must be disposed of in an environmentally-friendly way. Waste electrical and electronic equipment (WEEE) requires special procedures for recycling or disposal. This includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of such equipment. Contact your local distributor for information concerning this.

### Storage and transport symbols

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

## 1.4 The system and its parts

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

The system uses either the R40 EEG amplifier or the R40 (24) EEG amplifier.

The R40 EEG amplifier is a compact USB 40-channel amplifier which incorporates 32 referential channels and 8 polygraphic channels with built-in calibration and electrode impedance measurement. A Nonin XPOD interface is provided, a Patient Event input, 2 Aux DC inputs and an Electrocap connector.

The R40 (24) EEG Amplifier is a reduced channel variant of the R40 amplifier and incorporates 24 referential channels and 4 polygraphic channels. In all other respects the R40 (24) Amplifier is identical to the R40.

The system includes a PC for control and storage, a video monitor, a medical-grade power supply and an optional USB Photic Stimulator and arm. The system is mounted on a special wheeled cart, which houses all components and allows convenient mobility.

The system uses a specific PC and medical grade power supply. Refer section 3.1 for details

| | |
|---|---|
| ⓘ | The PC or laptop must only be powered using the medical-grade mains power supply, as supplied or authorised by Lifelines. |

**The R40 EEG System comprises the following components:**

| Component | Part Number |
|---|---|
| R40 Amplifier | 1326 |
| R40 (24) Amplifier | 1411 |
| Amplifier USB Cable | 1277 |
| Cart, adjustable height | 1296 |
| Arm (for Photic or R40 Amplifier) | 1291 |
| Photic Stimulator | 1290 |
| Photic USB Cable | 1241 |
| Xpod Pulse Oximeter Nonin | 1327 |
| Patient Event Pushbutton | 1353 |

| |
|---|
| **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. |
| **NOTE:** If using the Photic Stimulator refer to the User Manual supplied with it. |

## 1.5 Specifications and safety

Refer to **Appendix 1** for specifications.

The amplifier has been certified and complies with the following standards:

| Standard | Description |
|---|---|
| IEC 60601-1 and<br>IEC 60601-2-26 | Standard for medical electrical equipment, general requirements and particular requirements for EEG systems. |
| IEC 60601-1-6 | Collateral standard for usability. |
| 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** | **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.*

### Classification of system

| Classification | Clinical use |
|---|---|
| Degree of protection against electrical shock | Class I. Type BF applied parts |
| Type of protection against electrical shock | Optically isolated USB amplifier<br>Mains isolation transformer 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 |

## 1.6 Description of the components

### The R40 Amplifier

The R40 USB 40-channel amplifier incorporates 32 referential channels and 8 polygraphic channels with built-in calibration and electrode impedance measurement. A Nonin XPOD interface is provided, a Patient Event input, 2 Aux DC inputs and an Electrocap connector. The Amplifier has built in type-BF patient isolation and has a USB interface to the PC. Optional wireless communication is available (Bluetooth and WLAN WiFi).

The R40 (24) EEG Amplifier is a reduced channel variant of the R40 amplifier. The R40 (24) provides 24 referential channels and 4 polygraphic channels. In all other respects this amplifier is identical to the R40.

#### Applied parts

#### EEG Electrodes

The amplifier connects to standard 1.5mm touchproof EEG recording electrodes arranged in a standard 10-20 pattern, attached to the patient's head.

| | |
|---|---|
|  | Lifelines does not supply EEG electrodes. The Amplifier 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 in Europe or to the relevant local standards outside Europe. |
|  | 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

**Patient Event pushbutton**

The Patient Event Pushbutton is used by the patient to mark the instance of a significant 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 PC

Where EEG studies are conducted within the patient environment the leakage current must be controlled. The PC power supply supplied by Lifelines is a special medical-grade type (with appropriate safety standards), which limits the mains leakage current of the system. It is rated for 90V – 230V input voltage.

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

## The Setup and Recording Software

The R40/Trackit setup software runs under Microsoft Windows XP, Windows Vista, Windows 7, 8 or 10 on the host PC and is used to setup and review the R40 Amplifier and to record on to the PC.

### Functions of the software:

- Setup the input signals.
- Setup and download the recording template.
  This includes which electrodes are used and the recording montage.
- Perform a calibration check of the Amplifier.
- Perform an Impedance check on the Amplifier.
- Perform an EEG recording.
- View on-going EEG traces.
- Review an EEG Recording.

*Refer to the Trackit Plus software manual for more details.*

## 1.7 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.

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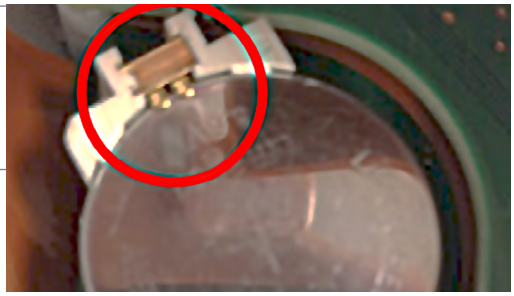
|---|---|
|  | Battery replacement by inadequately trained personnel could result in a hazard. It must be replaced only with the correct type and it must be installed correctly with +ve uppermost. |

1. Remove four screws from the underside of the R40 and remove the bottom of the case.
2. Unclip the wraparound screen to expose the battery beneath.
3. Using a **NON-CONDUCTIVE** tool (for example, a spudger, plastic card or pen lid) place the tool under the coin cell battery and, without exerting any stress on the holder itself, gently prise out the battery at the negative terminal end. The battery should release from the battery holder.
4. Remove the battery from the battery holder.
5. Locate the replacement battery, positive side up, against the POSITIVE terminal of the battery holder.
6. Gently push the battery, at the negative terminal end, into the battery holder. The battery will click into place.

**NOTE:** The positive terminal of the battery holder has a metal tab. The battery must be located UNDER the tab. Take care not to bend the tabs when inserting the battery. The image (right) shows the metal tab.



7. Gently push the battery, at the negative terminal end, into the battery holder. The battery will click into place.
8. Re-clip the wraparound screen and reassemble the case.

| | |
|---|---|
|  | **Battery safety instructions**<br>Do not attempt to open, puncture, disassemble or modify the battery in any way.<br>Do not subject the battery to sudden shock or heat.<br>Do not dispose of battery in fire. |

# 1.8 Installation and Maintenance

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

| | |
|---|---|
| ⚠ | 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. |

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 (details on page ii) for assistance, if 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.

## 1.9 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 Assembly instructions for third-party products will be found in their packing cases. It is recommended that these instructions be filed with the R40 system technical reference materials.

4 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.

## 1.10 Environmental parameters for operation

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

| Operational: R40 Amplifier and Photic | | Storage and transport: R40 Amplifier and Photic | |
|---|---|---|---|
| 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 |

| Operational: All-in-one PC | | Storage and transport: All-in-one PC | |
|---|---|---|---|
| Temperature | +10°C to +40°C (+50°F to +104°F) | Temperature | -40°C to +65°C (-40°F to +149°F) |
| Relative humidity | 20% to 80% non-condensing | Relative humidity | 5% to 95% non-condensing |
| Atmospheric pressure | 700 hPa to 1015 hPa | Atmospheric pressure | 238 hPa to 1015 hPa |
| **NOTE:** Consult the documentation supplied with the PC equipment for additional details. | | | |

| | |
|---|---|
| ⚠ | Do not obstruct any cooling slots.<br>Position the equipment so that air flows freely. |

## 1.11 Power supply connections

### R40 Amplifier and Photic (USB)

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|---|---|
| **Power requirements** | 5VDC (USB Port) |
| **Power consumption** | Maximum power: 2.5W |

### Medical grade AC mains power supply module for Laptop PC

The system operates with a medical-grade mains power supply. The mains input accepts a standard IEC320 three pin mains connection cable.

When the mains plug is designed to hold a fuse, a 3A-rated fuse should be used.

| **Medical grade AC mains power supply module for Laptop PC** | |
|---|---|
| Mains Power input: | 90 – 264 VAC, 47–63 Hz, 1.4 A @ 115 Vac, 0.7 A @ 230 Vac |
| Output: | 20 Vdc, 5.25 A |

| | |
|---|---|
|  | The computer must only be connected to the medical-grade laptop power supply supplied or authorised by Lifelines. Do not use the standard computer power supply.<br>Only use the computer supplied or authorised by Lifelines. |
|  | 1. This equipment must only be connected to a supply mains with protective earth.<br>2. Always use the power lead and connector supplied with the R40 system, or a lead and connector of equivalent standard.<br>3. Do not use adaptor plugs or extension leads unapproved by Lifelines.<br>4. Only appropriately trained and qualified personnel should adjust, maintain or repair this equipment.<br>5. Always disconnect the equipment from the main power supply before removing any covers. |

## 1.12 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, for example a cardiac pacemaker or other electrical stimulator, 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 60950. |

### 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.

## 1.13 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 EN60601-1-2. However, the R40 amplifier records signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. 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.

However, when the equipment is operated with or without its Bluetooth or WiFi on, 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 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix. |

## 1.14 Maintenance and cleaning

The R40 System 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

All the outer surfaces of the individual pieces of equipment of the R40 System may be cleaned using a soft cloth moistened with water and a mild detergent. Each item may also be cleaned using a low-pressure air-line or a vacuum cleaner.

Disinfection of the equipment can be carried out by the use of QAC-based disinfectants. Wipes are recommended in order to prevent the ingress of any liquid into the equipment. Suitable products include Mikrozid Sensitive Wipes (Schülke & Mayr GmbH), Microbac forte (Paul Hartmann AG), Distel Wipes (Tristel Ltd.), Mikro-Kill disinfectant wipes (Medline Industries, Inc.), Sani-Cloth HB Germicidal Wipes (PD International, Inc).

For cleaning instructions for the computer refer to the manufacturer's documentation.

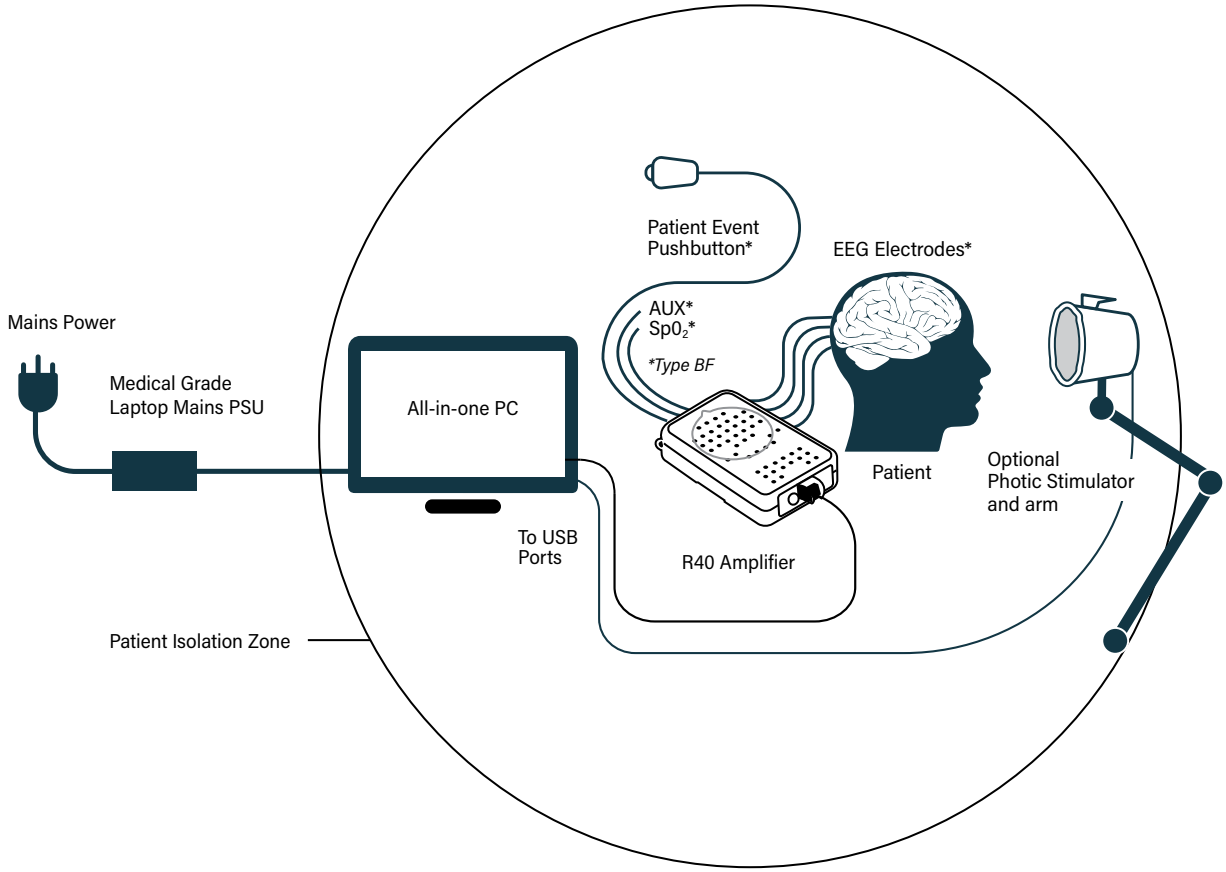
| | |
|---|---|
| ⚠ | Do not allow any liquid to enter the case of the instrument or connector. Do not use acetone on any of the instruments. |

## 1.15 Disposal of equipment

When the device and its parts and accessories has reached the end of its operating life, it should be disposed of in accordance with local waste regulation authority that is typically within the local government office.

# 2 Connections and Usage

## 2.1 Overview




**System Cart**

1. R40 mounted on bracket or flexible arm
2. Lever for height-adjustable cart worktop
3. All-in-one PC
4. VESA mount
5. Photic mounted on medirail and flexible arm

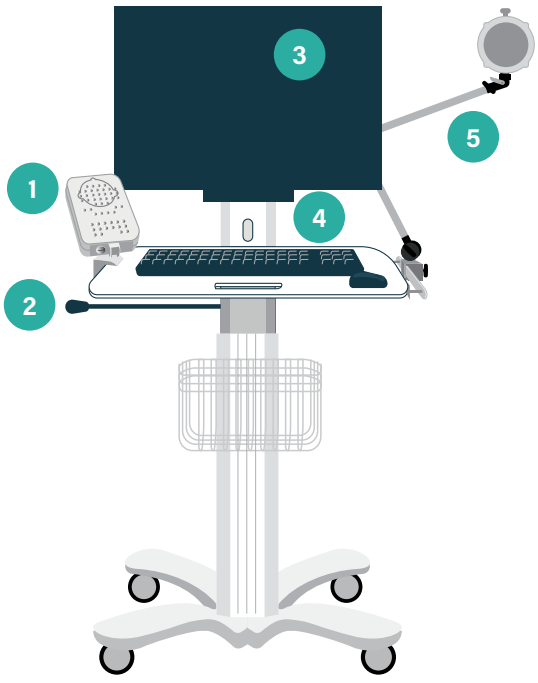



*Figure 1: Connecting the R40 System*

The entire R40 system including the PC can be used within the patient environment. The mains leakage currents and safety and regulatory requirements are met by the use of the medical power supply connected to the PC. The current recommended PC is the Lenovo ThinkCentre Tiny All-In-One system.

### The PC

1. Fit the Lenovo Tiny PC into the Lenovo monitor in accordance with the installation instructions provided with the PC.
2. Fit the monitor to the VESA mount. Route the DC Power cable from the power supply, up inside the VESA mount to the monitor. Connect the DC power cable to the power input of the All-in-one monitor.
3. Connect the mouse and keyboard to the rear of the PC in accordance with the installation instructions provided with the PC. These cables can be neatly routed through the VESA mount pole.
4. Connect the orange power cord to the medical-grade power supply.
5. Connect the country specific power cord to orange mains power cord.

| | |
|---|---|
|  | The laptop must only be connected to the medical-grade laptop power supply supplied or authorised by Lifelines. Do not use a standard laptop power supply.<br>Only use the laptop supplied or authorised by Lifelines. |

### The Cart, Arm and Stand

This allows all the system components to be conveniently located on a custom cart. This cart has a height-adjustable worktop, large lockable wheels, a medirail, VESA display mount and an accessory tray.

| |
|---|
| **NOTE:** The cart is supplied flat-packed - refer to the enclosed instructions for assembly details. |

A single mains input cable to the cart is provided, fitted with an earthed 3-pin IEC plug. A country-specific power cord is provided for different territories. The connector on the cart's mains cable is a locking type.

| | |
|---|---|
|  | The cart should be positioned in use so that disconnection of the mains plug from the supply socket can be accomplished without difficulty. |

The arm will mount on the cart and accommodates either the Photic or the R40 on its bracket. The arm is also supplied with a desk-clamp which allows it to be mounted on any convenient flat surface.

| | |
|---|---|
|  | When the R40 EEG system is in operation, do not push the cart. Place the cart in the transportation position before moving it. |
|  | Before transportation, the system should be put into its transportation position to reduce the risk of overbalancing:<br>• Switch off and disconnect mains cable.<br>• Lower work top to lowest position.<br>• Fully retract arms.<br>• Release brakes.<br>• Push the cart using the handle on the worktop. |

## 2.2 Connecting the R40 System

The R40 Amplifier is plugged into the PC USB port using the cable supplied, part number 1277.

The USB Cable is plugged 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 and R40(24) Amplifier (front face)*

The front face of the Amplifier is laid out in a standard 10-20 format, and accommodates standard touchproof electrode leads fitted with DIN 42802 connectors.

Also on the front face of the Amplifier are the electrode impedance check set-level pushbuttons. Adjacent to each electrode is an LED indicating whether the impedance of the individual electrode is above the set-level.

| | |
|---|---|
| ! | The Amplifier 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 in Europe or to the relevant local standards outside Europe. |
| ! | The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth. |

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

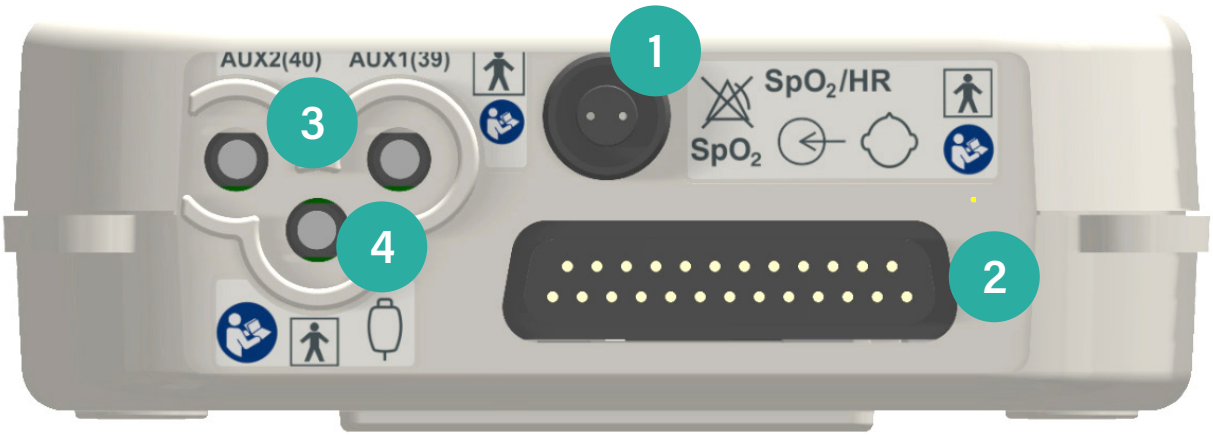



*Figure 3: Connecting the R40 Amplifier (top face)*

1. Nonin Xpod: the circular connector allows for the connection of a Nonin Xpod pulse oximeter for measuring SpO2.
2. Electro-Cap: the 25-way D-type connector allows for the connection of a standard Electro-Cap.
3. Aux1 and Aux2: these two 3.5mm jack connectors allow for the connection of standard transducers like Body Position, Respiration Belts etc.
4. Patient Event: this 3.5mm jack connector allows for the connection of a standard Patient Event Thumb Switch.

| | |
|---|---|
| ⚠ | 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. |

## 2.3 Starting the system

To start the system proceed as follows:

- Plug the PC into the mains supply.
- Switch on the PC and wait for Windows to load.
- Ensure R40 Amplifier is connected via the USB lead.
- Launch the Trackit Plus Software application. Refer to the Trackit Plus Software User Manual for more details.
- These procedures also apply following a mains interruption.

## 2.4 Shutdown of the system

At the completion of a study proceed as follows to shut down the system:

- Stop the recording by pressing the 'Stop Rec' button
- Exit the Trackit program.
- Shut down Windows.
- Switch off the PC and disconnect the mains supply.

# 3 Trackit Software - overview

The Trackit software is available on the included CD/USB disk or on the Lifelines FTP site. A readme file describes installation. The Trackit Software version 2.8.0.0 (or later) supports the R40 EEG Amplifier. Check with your distributor or Lifelines if a newer version of software is available.

The Trackit software is designed to work with both the R40 Amplifier and with the optional Photic Stimulator.

The software is supported on Microsoft Windows XP, Windows Vista and Windows 7, Windows 8 and Windows 10. The USB drivers will be found on the CD. After connecting the Amplifier to the PC for the first time, at the Windows prompt, browse to the folder CD Drive:\USB Drivers. From there Windows will find the correct drivers for the version of Windows being used.

The software has the following functions:

- Define signal types: create labels to attach to inputs
- Attach the desired signal type (label) to the recording input
- Create a recording montage and download it to the amplifier
- Perform a calibration of the inputs
- Perform an impedance check on the inputs
- View ongoing signals and adjust display parameters such as chart speed and display sensitivity
- Start and stop a recording session
- Open and review EEG recordings (EDF and BDF format)

**NOTE:** See separate Trackit Plus software manual for setup and recording details.

# 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.

## R40 Amplifier Specifications

| | |
|---|---|
| **EEG inputs** | |
| Number of EEG channels | R40 : 32 monopolar touchproof inputs<br>R40 (24) : 24 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 | R40: 8 bipolar touchproof inputs<br>R40 (24): 4 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 | R40: 52 Touchproof 1.5mm<br>R40 (24) 34 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 –<br>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<br>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 | |
| **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<br>IEC 60601-2-26 | 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<br>Mains isolation transformer 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 |

| Medical Grade Power Supply Specifications | |
|---|---|
| Input | 90 – 264 VAC, 47–63 Hz, 1.4 A @ 115 Vac, 0.7 A @ 230 Vac. |
| Output | 20VDC, 5.25A |
| Power Rating | 105W |
| Dielectric Strength | > 5kV |
| Earth Leakage Current | < 200uA |
| Safety and Regulatory Approvals | IEC/EN60601-1<br>IEC/EN60601-1-2 |
| Size | 147 x 75 x 39 mm |
| Weight | 1.5 kg |

| Lenovo ThinkCentre All-in-One PC Specifications | |
|---|---|
| Safety and Regulatory Standards | IEC/EN60950-1 |
| EMC | EN55032/CISPR 32 and FCC Part 15 Class B<br>EN55024/CISPR 24<br>EN61000-3-2 and EN61000-3-3<br>EN 62311 |
| Input voltage | 20VDC |
| Power | 90 W |
| Size | 385 x 539 x 251 mm |
| Weight | 6.8 kg |

| Lifelines Photic Stimulator |
|---|
| Refer to the Lifelines Photic Stimulator User Manual for specifications and operational details. |

# Appendix 2: Photic Stimulator and Hyperventilation

## Photic Stimulation

An optional Lifelines Photic Stimulator is available which can be used with the R40 Amplifier to asses patient photosensitivity in EEG studies. For a detailed description of operation, connection and specifications please refer to the separate documentation Lifelines Photic User Manual and the Trackit Plus Software manual.

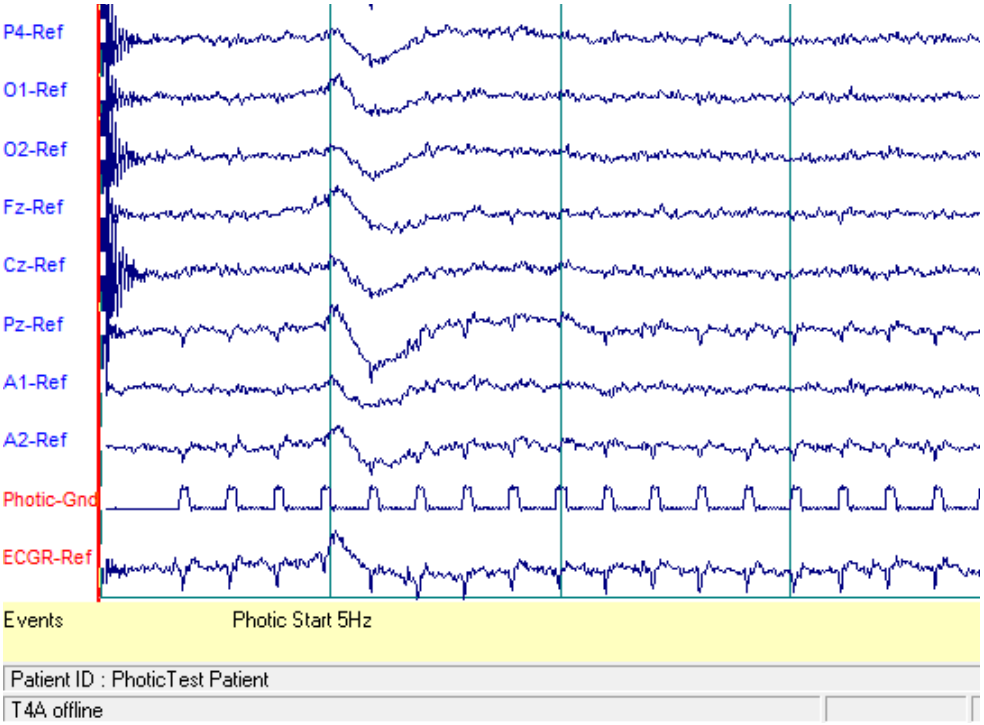



*Figure 4: Photic Stimulation (using Trackit Plus software)*

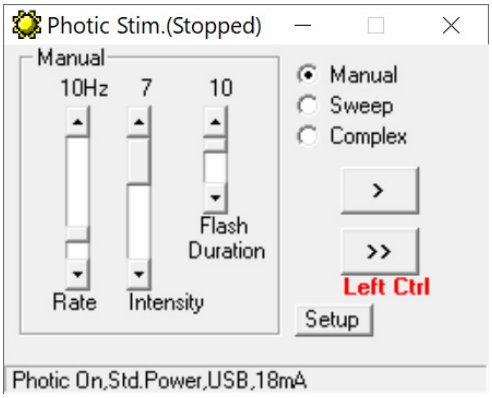



*Figure 5: Photic Stimulation control window*

Click on the Photic Stimulation icon in the top toolbar to bring up the Photic Stimulation control panel, shown (right).

This window allows single, manual, sweep and complex sequences of Photic stimulation to be produced. Photic start/ stop events are recorded as shown above.

## Hyperventilation

A method of timing and marking a Hyperventilation and post-Hyperventilation activation sequence is provided.

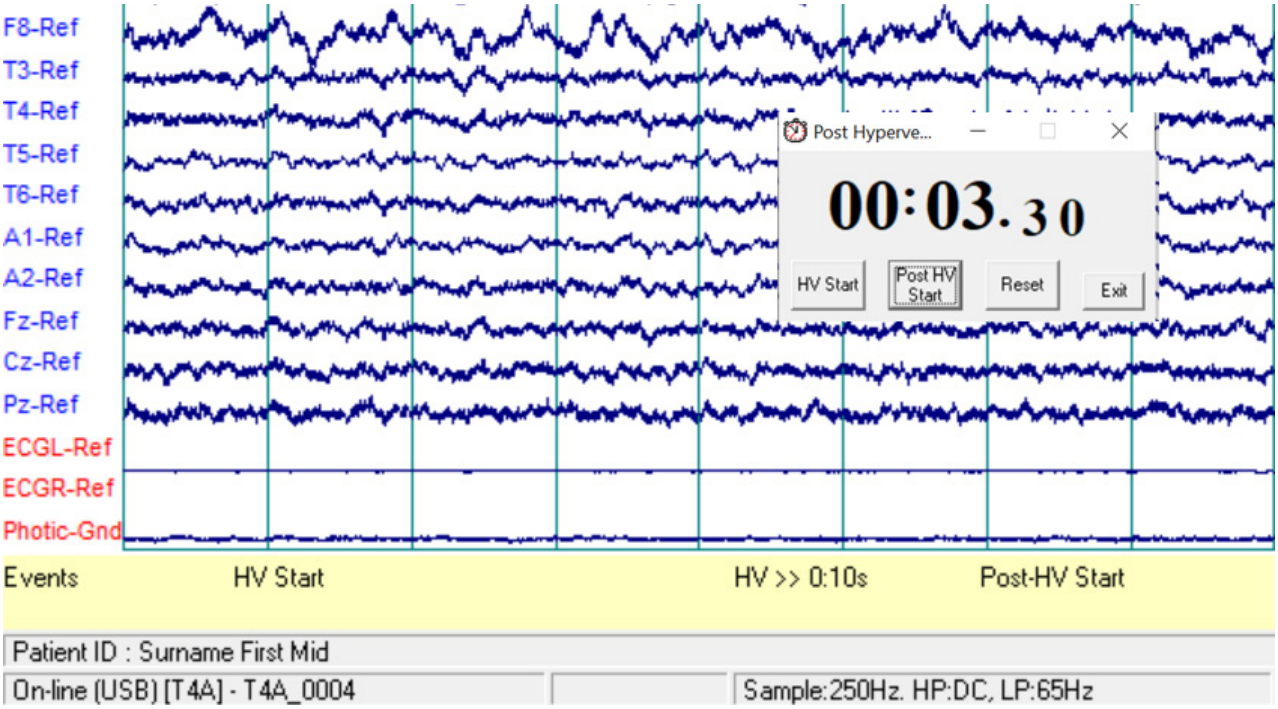



*Figure 6: Hyperventilation*


*Figure 7: Hyperventilation control window*

This provides a digital timer, which is used as follows:

- Click on HV Start to start the HV period and the timer starts running. An 'HV Start' event is recorded.
- Thereafter an 'HV' event is automatically generated every 10 seconds.
- Click on Post HV Start to start the post HV period. A 'Post HV Start' event is recorded.
- Thereafter a 'Post HV' event is automatically generated every 10 seconds.
- Click on Reset or Exit to end the hyperventilate activation.

**NOTE:** The Post HV Start will not work unless HV is in progress. Likewise, HV Start will not work if Post HV is in progress.

# Appendix 3: Additional Events Information

For the R40 EEG Amplifier, events types are as shown below.

- 56 Automatic events (hardware events, photic start/stop, video start/stop etc.)
- 40 user-configurable events
- Free-text events entered during acquisition

*Refer to the Trackit Plus software manual for more information*

| Event List Key | Event No | Contents | Type | Size | Total size | Mapping |
|---|---|---|---|---|---|---|
| 0 | 0 | No event | Fixed | 16x16 | 256 | Auto |
| | 1 | Stop recording | Fixed | | | Auto |
| | 2 | Start recording | Fixed | | | Auto |
| | 3 | Door Open | Fixed | | | Auto |
| | 4 | Door Closed | Fixed | | | Auto |
| | 5 | Host On | Fixed | | | Auto |
| | 6 | Host Off | Fixed | | | Auto |
| | 7 | Low Battery | Fixed | | | Auto |
| | 8 | OK Battery | Fixed | | | Auto |
| | 9 | Imp. Check Mode | Fixed | | | Auto |
| | 10 | Calibrate Mode | Fixed | | | Auto |
| | 11 | Normal Mode | Fixed | | | Auto |
| | 12 | Electrodes On | Fixed | | | Auto |
| | 13 | Electrodes Off | Fixed | | | Auto |
| | 14 | Patient Event | Fixed | | | Auto |
| | 15 | External Event | Fixed | | | Auto |
| 1 | 16 | Awake # | User-config | 16x16 | 256 | F1 |
| | 17 | Asleep # | User-config | | | F2 |
| | 18 | Eyes open # | User-config | | | F3 |
| | 19 | Eyes closed # | User-config | | | F4 |
| | 20 | Lights on # | User-config | | | F5 |
| | 21 | Lights off # | User-config | | | F6 |
| | 22 | Drowsy # | User-config | | | F7 |
| | 23 | # | User-config | | | F8 |
| | 24 | Photic start | Fixed | | | Auto |
| | 25 | Photic stop | Fixed | | | Auto |
| | 26 | HV start | Fixed | | | Auto |
| | 27 | HV >> | Fixed | | | Auto |
| | 28 | HV stop | Fixed | | | Auto |
| | 29 | Post HV start | Fixed | | | Auto |
| | 30 | Post HV >> | Fixed | | | Auto |
| | 31 | Post HV stop | Fixed | | | Auto |
| 2 | 32 | Video start | Fixed | 32x32 | 1024 | Auto |
| | 33 | Video stop | | | | Auto |
| | 34 | Video movement | | | | Auto |
| | 35 | Trackit connect | | | | Auto |
| | 36 | Trackit disconnect | | | | Auto |
| | 37-63 | Reserved | | | | Auto |
| 3 | 64-95 | ? | User-config | 32x32 | 1024 | Shift F1–8<br>Ctrl+Shift F1-8 |
| 4 | 96-159 | ? | User-config (free text) | 64x64 | 4096 | F12 |

# Appendix 4: Wireless

## Introduction

The R40 Amplifier has optional built-in Bluetooth and WiFi capabilities.

Using the internal Bluetooth module in the R40, wireless connections can be established with it from a Bluetooth-enabled PC. Using the internal WiFi module in the R40 wireless connections can be established with it via a Wireless Access Point (WAP). This allows the R40 to be monitored remotely over a secure wireless link up to a range of about 100m or greater (dependent on hardware and environmental factors).

## System overview

The Bluetooth module is Bluetooth Qualified v4.0. The WiFi module is IEEE 802.11 b/g certified. For full specifications, refer below.

Bluetooth is a device to computer wireless connection and will connect to any suitably certified Bluetooth host, like a PC or laptop. The connection process uses authentication and password protection.

The WiFi (wireless LAN Module) is a device to network wireless connection and will connect to a designated network via a Wireless Access Point (WAP). The connection process uses authentication and password protection.

## Connection and use

Both the Bluetooth and WiFi connections require secure passwords to be entered.

During the Bluetooth pairing process, the correct password must be entered to establish the connection. As shown below, a secure password authorization and authentication process takes place during the pairing procedure.

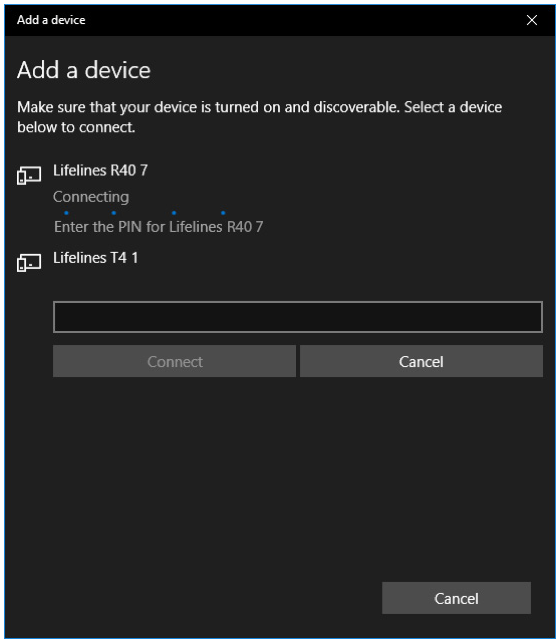



*Figure 8: Bluetooth pairing*

Once established, the R40 acts as the server and provides the SPP service to the PC acting as a client.

During the setup of the WiFi module, the WAP SSID is entered together with its password, as shown below.

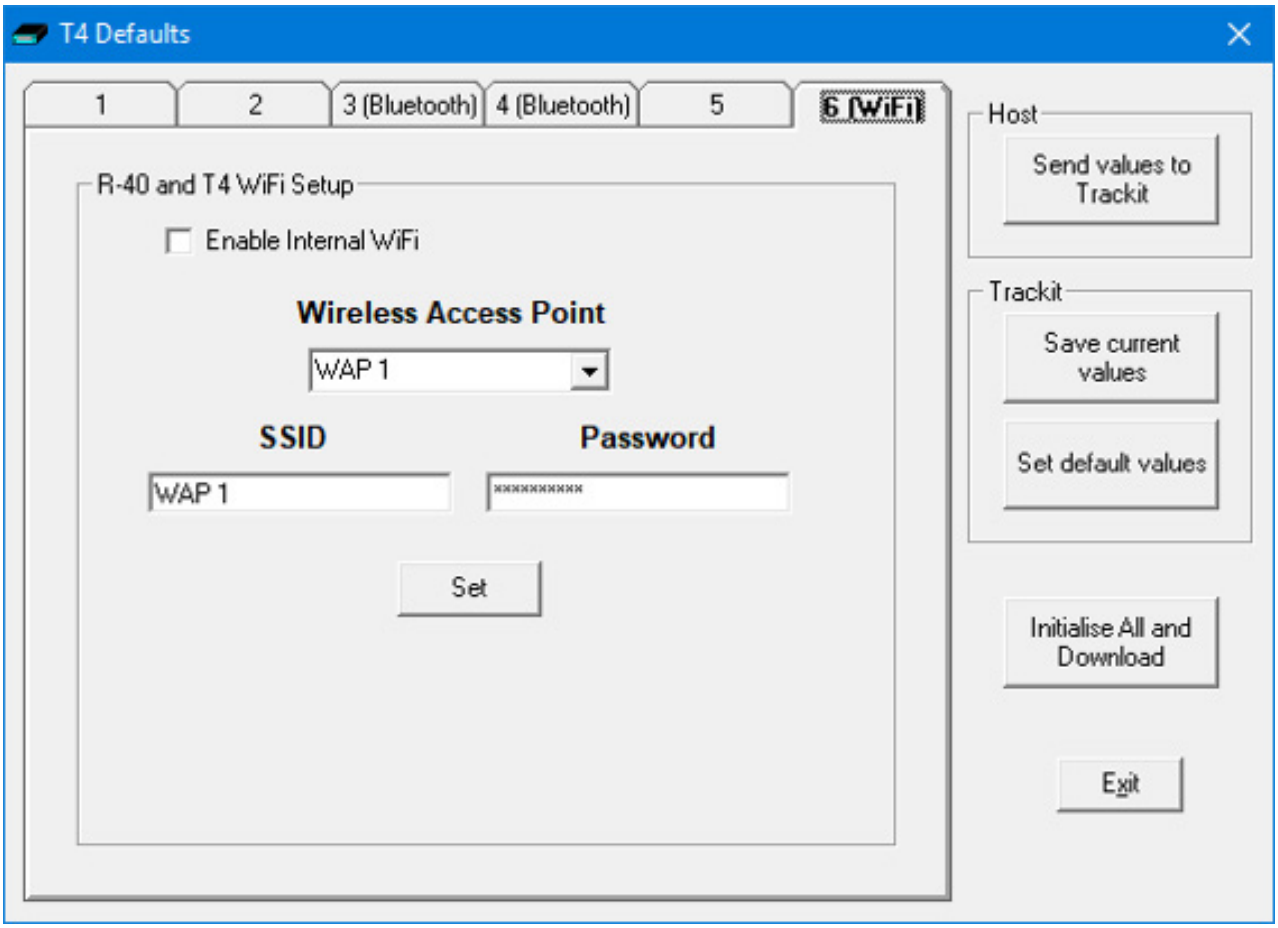



*Figure 9: WiFi setup*

If an attempt is made to connect to an unsecure network without a password, this is prevented and an error displayed as shown below. For maximum security it is recommended that only WPA2 access is allowed.

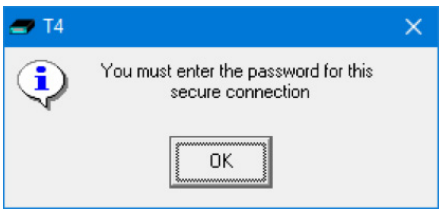



*Figure 10: Unsecure network error message*

When the Trackit application has established the Bluetooth connection, a connection quality monitor labelled "Comms.Q" is displayed in the status bar at the bottom left of the main screen, as shown below.

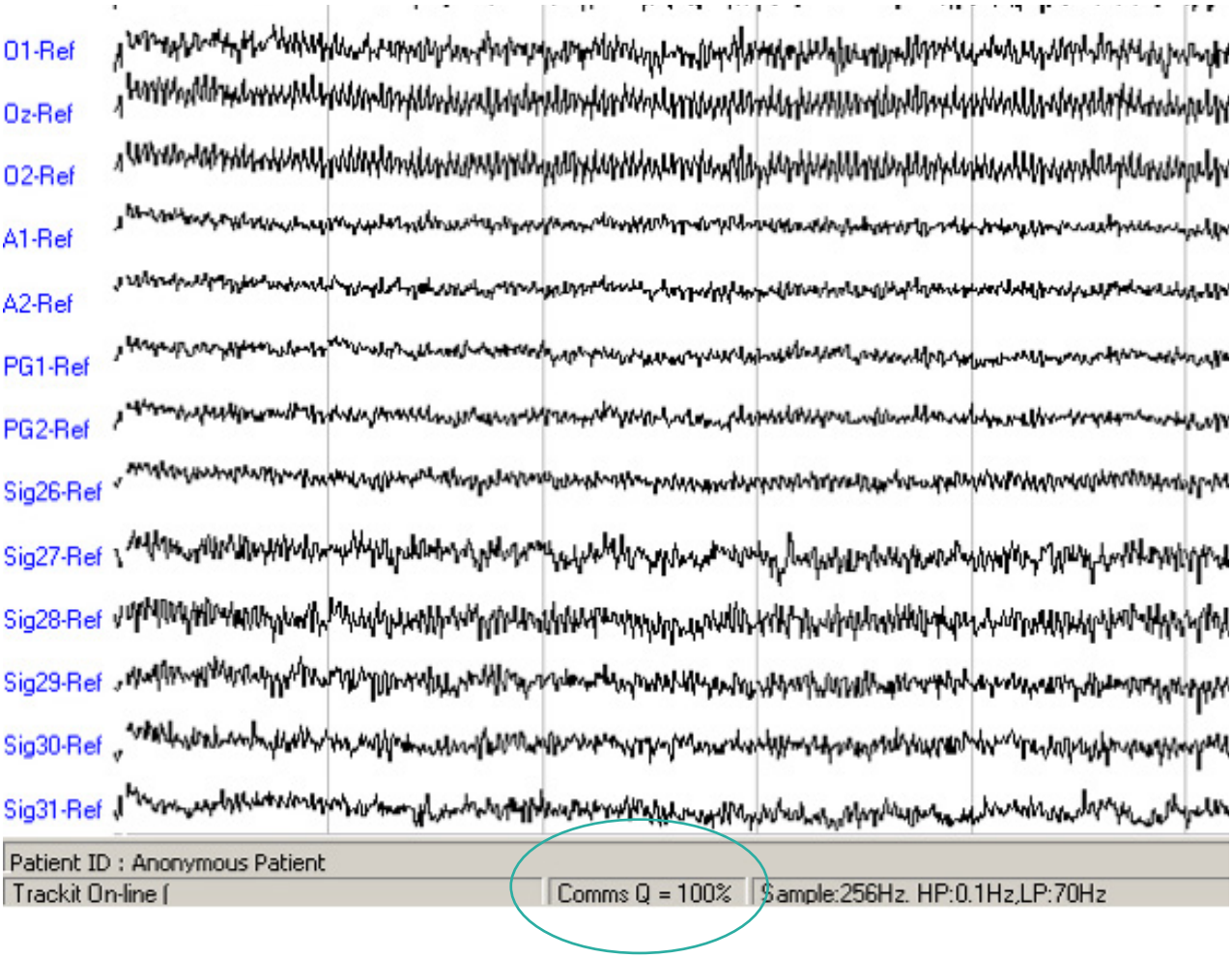



*Figure 11: Bluetooth connection quality monitor.*

This number given as a percentage is an approximate indication of the amount of data received as a ratio to that expected, calculated every second. It is most likely to drop below 100% when either device is at the limit of the transmission range or when either antenna is adversely obscured or under the influence of interference. It will be noticed that the wireless transmission will use its available bandwidth to try to "catch-up" after a drop in signal quality and the indication can read more than 100% momentarily. A reading, therefore, of less than 100% does not necessarily mean a permanent bad connection since data flow can increase shortly afterwards. A sustained low value over several seconds will cause the Trackit application to close the connection. If the Autoconnect feature has been enabled in Options, the application will automatically attempt to reconnect to the R40 every 10 seconds.

## Wireless Communication (general information)

**A wireless link can be subject to interference and disruption to communication.**

Bluetooth is a wireless technology designed for short-range wireless connections between devices in a wireless personal area network (WPAN). Bluetooth is compliant with the IEEE 802.15 standard and operates in the 2.4 GHz band. WiFi is a wireless technology designed to connect devices and an infrastructure in a wireless local area network (WLAN). WiFi is compliant with various IEEE 802.11 standards such as 802.11a, 802.11b, 802.11g, and 802.11n. 802.11b and 802.11g operate in the 2.4 GHz band, 802.11a operates in the 5 GHz band, and 802.11n can operate in both bands

Both WiFi and Bluetooth are based on spread spectrum signal structuring. With this radio transmission technique, a narrowband signal is expanded across a given portion of the radio frequency spectrum to result in a broader or wideband signal. Such a wideband signal provides a very strong immunity to interference compared to a narrow-band signal.

Bluetooth uses Frequency Hopping Spread Spectrum (FHSS), whilst WiFi uses Direct Sequence Spread Spectrum (DSSS). Given that both technologies operate in the same frequency band, this use of differing techniques can result in interference issues. FHSS devices and DSSS devices perceive each other as noise.

Both Bluetooth and WiFi technologies, however, use sophisticated error detection and error correction techniques to deliver correct data. Additionally, if a transmission cannot be decoded due to interference, the transmission is resent. This interference will, of course, increase as the number of coexistent devices in proximity to each other increases. Due to the robust error detection mechanisms, however, as the interference level increases, data continues to be delivered correctly, but the data rate decreases as the number of dropped packets increases.

In terms of security, both system use authentication with encryption and pin codes/pass words. In addition, the R40 itself uses a proprietary Interface Protocol thus preventing a non-authorised user from taking control of the device.

When transmitting wirelessly, data packages are time-stamped when acquired by the amplifier, before being transmitted, and when received by the application they are recorded according to this timestamp. In this way, there is no risk associated with delayed communications or missing data packets over a wireless link since, if the recording software detects missing packages, an event is inserted into the recording to notify the operator. In the extreme case whereby the interference causes the wireless link to be dropped all together, the application automatically reconnects when the interference is removed.

## Quality of Service and Associated Risks

1. The risk of corrupt data due to interference is very small due to error detection, error correction and resend data packet mechanisms. In addition to this error detection and correction, the application provides time-stamped data packages, which enables the detection of corrupt, delayed or missing data.
2. The risk of missing data due to interference is also very small, but at the extreme, the data rate decreases as more and more data packets have to be dropped and resent. Ultimately, in the presence of extreme interference, the data rate will decrease to zero and the wireless link will be dropped. This situation is also adequately handled with the provision of time-coded data packets, which enables the detection of corrupt, delayed or missing data. In the extreme case whereby the interference causes the wireless link to be dropped all together, the application automatically reconnects when the interference is removed. This situation is very similar to being out-of-range and the same mechanisms apply and, again, the application will automatically reconnect when the device comes back into range.

   In the presence of extreme and persistent interference, the cabled USB connection is, of course, available.
3. The risk of unauthorised users is very small due to the authentication requirements of the wireless link and the fact that the R40 Interface Protocol is proprietary.
4. The medical system uses mature, industry-standard hardware and protocols: Bluetooth and WiFi. This ensures that the system utilises all the benefits associated with these mature standards, concerning the authentication, data integrity and interference performance as discussed in this document.
5. The radio modules are tested according to their own EMC emissions and immunity standards: EN 300 328, EN 301 489-1, EN 301 489-17 and IEC 60601-1-2 (Bluetooth).
6. The radio modules are pre-certified and Type Approved.

Considering the medical system function, its indication for use and very low risk associated with a low level of concern, the analysis, evaluation and preventative measures undertaken reveal the low risk associated with wireless communication. In the presence of extreme interference, the rate of delivery of data packets will decrease until ultimately, the wireless link is dropped. Wireless communication problems are identified, prevented and mitigated, as described. The application identifies these wireless problems and automatically reinstates the wireless link if dropped in the presence of extreme interference. Alternatively, the cabled USB connection is available.

## Pre-compliant Wireless Modules

The use of pre-compliant, certified and Type-approved optionally-fitted internal Bluetooth and WiFi wireless modules which comply with applicable national radio regulations ensures best performance, interoperability, coexistence and quality of service is achieved.

## Specifications (taken from Appendix 1).

### Bluetooth Module

**Specifications:**

- 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.

**Conformance:**

- Type Approval: Europe (R&TTE), US (FCC/CFR 47 part 15), Canada (IC RSS).
- 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 60950-1
- Medical Electrical Equipment IEC 60601-1-2
- Bluetooth Qualification v4.0.

### WiFi Module

**Specifications:**

- Type: 2.4 GHz IEEE Std. 802.11 b/g Wireless LAN Module
- Output power: 12dBm max.
- Output frequency: 2.412 to 2.462 GHz, ISM band.
- Data rate: 230kbps max.
- Protocols: TCP, UDP, DHCP, DNS, ICMP, ARP, HTTP Client, and FTP Client.
- Modulation: 802.11b Compatibility: DSSS (CCK-11, CCK-5.5, DQPSK-2, DBPSK-1) - 802.11g: OFDM.
- Error Correction: Forward Error Correction (FEC).
- Security: WEP-128, WPA-PSK (TKIP), WPA2-PSK (AES), proprietary Interface Protocol.

**Conformance:**

- Type Approval: Europe (R&TTE), US (FCC/CFR 47 part 15), Canada (IC RSS).
- R&TTE Directive 1999/5/EC
- Effective use of frequency spectrum: EN 300 328
- EMC: EN 301 489-1, EN 301 489-17
- Health and safety: EN 60950-1, EN50371

## Interference

The R40 Amplifier 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 amplifier records signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. Such interference may cause signal artefacts.

| | |
|---|---|
| ⚠ | 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 Trackit R40, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result. |
| ⚠ | When in close proximity to the amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information. |
| ⚠ | When using the amplifier in close proximity to other devices using Bluetooth or WiFi communication, orientate or position these devices for least interference. If possible separate the devices or turn off their wireless communication. |

**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 Manufacturers Declaration in the Appendix.

# Appendix 5: Troubleshooting Guide

## COM port problems with Bluetooth communication to the R40

### The COM port is available but is being used by another application.

This could well be the case if an application such Microsoft Active Synch is installed and polling the COM port for a Windows CE device. Make sure Connection Mode for Active Synch is set to Only When Device is Connected, and not to Continuous.

Make sure other applications such as virus protection software and personal firewalls (ZoneAlarm) are not accessing the COM port while a connection to Trackit is being made.

## Problems starting the recording

### The setup has not been sent correctly

Under R40 Status, in the Control Panel, check that Acquire Ready shows Yes. If it is not ready, acquisition cannot begin. This could be caused by incomplete transmission of the R40 setup.

Check that all channels in the Recording setup have the same sample rate. The R40 does not support multi-sample rate.

### An incorrect setup has been sent

If an incompatible setup has been sent to the R40 the message; "unable to comply" will indicate that. If an incorrect setup has been sent, the Trackit Control Panel will show 'Acquire Ready: No.'

### The card is not formatted correctly

If the card is not formatted with a correct 32-bit FAT, a recording cannot commence. Format the flash card using the SD Card Formatter PC utility.

### The card is corrupted

Disk corruption can be caused when a SD card is removed from the R40 Amplifier or the Card reader while data is being written or accessed.

R40: always stop a recording and wait for the write LED to go out, before removing the card.

Card reader /PC: Always stop and eject the card using the icon in the Windows system tray before physically ejecting it.

### The card is not inserted correctly

If the flash card is not pushed in far enough, the card will not engage the pins on the card reader. 'No disk present,' in the Status section of the Trackit Control Panel, will confirm this.

# Appendix 6: 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.<br>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<br>+/- 15kV: Air | +/- 8 kV: Contact<br>+/- 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%.<br><br>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<br><br>IEC 61000-4-8 | 3 A/m, 30A/m | 3 A/m<br>See Note e. | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical com-mercial and/or hospital environment. |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>Electromagnetic Fields<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br>6V in ISM Bands<br><br>3 V/m<br>80 MHz to 2.5 GHz<br>10V/m (Home Environment) | 3 Vrms<br><br>3 V/m<br>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.<br><br>**Recommended separation distance**<br><br>$d = [3.5/E] \sqrt{P} = 1.2 \sqrt{P}$<br><br>$d = [3.5/E] \sqrt{P}$ : 80 MHz to 800 MHz = $1.17 \sqrt{P}$<br><br>$d = [7/E] \sqrt{P}$ : 800 MHz to 2.5 GHz = $2.33 \sqrt{P}$<br><br>Note: using unshielded input leads<br><br>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).<br><br>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].<br><br>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<br>$d = 1.17 \sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.17 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \sqrt{P}$ |
| 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.

# Version History

**V1.0 (24th June 2014)**

- Initial release

**V1.1 (7th July 2014)**

**V1.2 (31st July 2014)**

**V1.3 (18th September 2014)**

**V1.4 (29th September 2014)**

- Various amendments for IEC 60601-1 3rd edition
- Amended Appendix 5 compliance levels.

**V1.5 (17th October 2014)**

- Added statements and warnings concerning multiple socket outlets to section 2.4
- Added statement that assembly and modification require evaluation to IEC 60601-1 in section 2.

**V1.6 (27th October 2014)**

- Amended operating temperature for PC in section 2.2

**V1.7 (24th November 2014)**

- Added caution in section 1.2 'Do not touch simultaneously...'
- Updated picture on front page and minor corrections (5/2/2105)

**V1.8 (19th November 2015)**

- Added "CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician" on page 8.
- Added "FDA cleared for use in USA" to EEG electrode warning on page 8.
- Amended "Indications for Use" statement on page 8 and deleted "Intended Use".
- Added "Compliance is provided by the recommended PC equipment" to Electromagnetic Immunity tables in Appendix 5.
- Changed EN references to IEC.
- Amended sampling rate and bandwidth specifications.
- Electromagnetic immunity compliance level amended on pages 39 & 40.

**V1.9 (27th February 2018)**

- Added disinfection information in section 2.6.
- Added device lifetime in section 2.7.
- Change of N.B. to 0086 (BSI).

**V1.10 (19 July 2019)**

- Updated with new cart design and Lenovo PC
- Software section updated
- EMC warnings and information updated

**V1.11 (14 Oct 2019)**

- Notified Body change and EC Rep information added.
- Updated with new Cover page and images.

**V2.0 (5 March 2020)**

- Updated with new design and images
- Trackit Software section moved to separate User manual
- R40 (24) variant added

**V2.1 (07 December 2021)**

- Updated Manufacturer's address
- Updated EC Rep address
- Updated LNC logo
- Updated section 1.7

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# R40

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