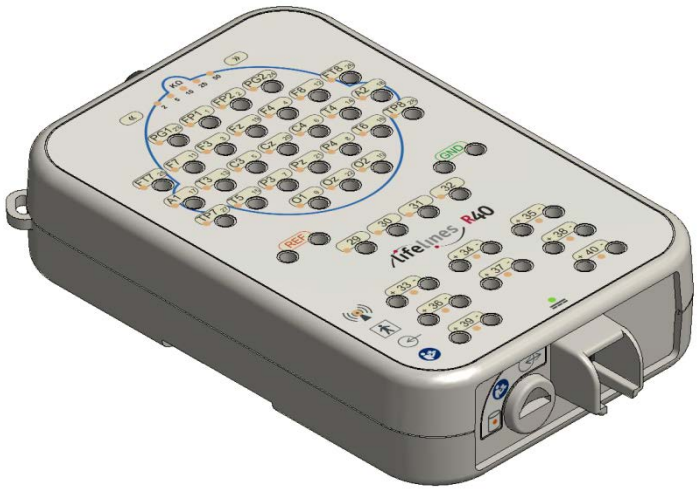
R40 EEG System

User Manual



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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).

Lifelines Ltd, 7 Clarendon Court,
Over Wallop, near Stockbridge,
Hampshire SO20 8HU, UK
Telephone +44 (0)1264 782226
www.LLines.com
sales@LLines.com

CE 0086

Disclaimers & Warranties

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

Except as stated below, Lifelines Ltd 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 Ltd. 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 R-40 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 R-40 system is supplied by third-party providers recommended by the manufacturer;
- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by the manufacturer;
- the electrical installation of the relevant room complies with the appropriate requirements;
- the equipment is used by a health-care 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 it's 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

Illustrations

1 System Overview and Technical Description

1.1 General description

Indications for use

The R-40 EEG System is intended to measure and record EEG signals and is used as an aid in the diagnosis of neurophysiological disorders.

General description

The R-40 EEG System is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications.

The system uses the compact R-40 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 system includes a PC for control and storage, a video monitor, a medical-grade mains isolation transformer 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.

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 Cautions and Warnings

CONTRAINDICATIONS: Do not use the R-40 EEG System in an MRI environment, in an explosive atmosphere or during defibrillation.

WARNING: 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.

WARNING: This equipment in 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.

WARNING: 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.

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

WARNING: Lifelines does not supply the Nonin sensor. Only use the 'PureLight' sensors specified by Nonin to be used with their Oximeters.

CAUTION: When in close proximity to the recorder, 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.

WARNING: 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.

WARNING: Do not open or modify the equipment without the authorization of the manufacturer.

CAUTION: 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; close and lock drawer; fully retract arms; release brakes.

CAUTION: Do not exceed the Safe Additional Working Load of 4 kg on the work-top.

CAUTION: Do not touch simultaneously any accessible USB or other contacts on the PC or monitor and the patient.

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

1.3 Explanation of symbols

Type BF equipment

Follow operating instructions

Input/output connection

Input connection

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.

Consult warnings in User Manual

Bluetooth

Internal radio device

WLAN WiFi

Pushing prohibited

Sitting prohibited

Pushbutton

Nonin Xpod Pulse Oximeter

Manufacturer

DC power

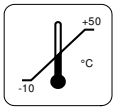
Protective earth (ground)

Equipotentiality

Internal battery hazard – refer to section 1.7

Electrocap

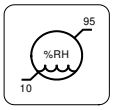
Storage and transport symbols



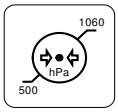
Temperature limits

Fragile

Keep dry



Relative humidity limits



Barometric pressure limits

1.4 The system and its parts

The R-40 EEG System is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications.

The system uses the compact R-40 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 system includes a PC for control and storage, a video monitor, a medical-grade mains isolation transformer 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 a special mains isolation transformer. Refer section 3.1 for details.

Caution:
Only use the PC supplied or authorised by Lifelines
Only use the medical-grade mains power supply with it as supplied or authorised by Lifelines

The R-40 EEG System comprises the following components:

R-40 Amplifier	part number 1326
Amplifier USB Cable	part number 1277
Dell Optiplex 7010 SFF PC	part number 1336
Dell Monitor LED 19.5”	part number 1337
Cart, adjustable height	part number 1296
Reomed mains isolation transformer, 600VA	
• 230V Input/230V Output	part number 1288
• 115V Input/115V Output	part number 1289
Arm (for Photic or R-40 Amplifier)	part number 1291
Photic Stimulator	part number 1290
Photic USB Cable	part number 1241
Xpod Pulse Oximeter Nonin	part number 1327
Patient Event Pushbutton	part number 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 system has been certified and complies with the following standards:

IEC 60601-1 and IEC 60601-2-26	European 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	European 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

Degree of protection against electrical shock	Class I. Type BF applied parts
Type of protection against electrical shock	Optically isolated USB amplifier 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 R-40 Amplifier

The R-40 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.

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.

WARNING: 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.

CAUTION: 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 record 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.

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

Reomed mains Isolation Transformer for Desktop PC

The mains power supply limits the mains leakage current of the system and is a special medical-grade isolation type supplied by Lifelines with appropriate safety standards. It is rated at 600VA and available as 230V input/output or 115V input/output.

The isolation transformer incorporates a mains ON/OFF switch which is used to isolate the system from the mains.

There is a potential equalisation terminal on the isolation transformer which is not intended to be utilised.

WARNING: The PC, video monitor and any other mains-powered equipment in the vicinity must only be connected to the medical-grade mains isolation transformer supplied by or authorised by Lifelines. Ensure that the voltage rating of the isolation transformer matches the local mains supply voltage and do not exceed the maximum power output rating of 600VA.

The Setup and Recording Software
The R-40/Trackit setup software runs under Microsoft Windows 2000 (with SP2), Windows XP, Windows Vista, Windows 7 or Windows 8 on the host PC and is used to setup and review the R-40 Amplifier and to record on to the PC.

Functions of the software:

- Download the recording template. This includes which electrodes are used and the recording montage. See section 4.2, step 2.
- Perform a calibration check of the Amplifier. See section 4.2, step 8.
- Perform an EEG recording. See section 4.2, step 8.
- View on-going EEG traces. See section 4.2, step 9.

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.

Fuse replacement – service personnel only
The system will have been supplied with one of two isolation transformers to suit mains supplies of 115 V or 230 V. The ratings of the fuses on the isolation transformer are:

Mains supply	Fuse (IEC 60127)
115 V a.c.	T6.3A, HBC, 5 x 20 mm
230 V a.c.	T3.15A, HBC, 5 x 20 mm

Ensure the equipment is switched off and the mains cable disconnected before replacing fuses.

Remove the fuse-holder on the isolation transformer using a small flat-bladed screwdriver.

Replace the fuses with the correctly rated part, as in the table above.

Internal battery replacement – service personnel only
The R-40 amplifier contains a replaceable lithium ion rechargeable coin cell, type LIR2450.

WARNING: 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 underside of instrument and remove bottom of case.
2. Un-clip the wrap-around screen to expose the battery beneath.
3. Grasp battery between thumb and forefinger and pull it from the socket.
4. Push replacement battery into the socket ensuring +ve is uppermost.
5. Re-clip the wrap-around screen and reassemble the case.

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

Power supply cord replacement – service personnel only
Replacement power supply cord and gland assembly should be obtained from Lifelines Ltd.

1. Disconnect system from supply mains.
2. Disconnect green/yellow wire from earth terminal and remove plug from the isolation transformer.
3. Remove cable gland using suitable assembly tool[1] and discard. Cable assembly can now be removed.
4. Fit replacement cable and gland by reversing the instructions above. Ensure new cable gland is fitted.
5. Check earth continuity.

[1] A suitable assembly tool is DURATOOL part number KT-1.

2 Installation and Maintenance

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

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.

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 3) 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.

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 Ensure that the voltage rating of the isolation transformer matches the local mains supply voltage.
4 Assembly instructions for third-party products will be found in their packing cases. It is recommended that these instructions be filed with the R-40 system technical reference materials.
5 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: R-40 Amplifier and Photic

Temperature	+10°C to +40°C
Relative humidity	25% to 95% non-condensing
Atmospheric pressure	700mB to 1060mB

Operational: Dell Optiplex PC

Temperature	+10°C to +40°C
Relative humidity	20% to 80% non-condensing
Atmospheric pressure	700mB to 1015mB

Consult the documentation supplied with the PC equipment for additional details.

WARNING:
Do not obstruct any cooling slots.
Position the equipment so that air flows freely.

Storage and transport: R-40 Amplifier and Photic

Temperature	-10°C to +50°C
Relative humidity	10% to 95% non-condensing
Atmospheric pressure	500mB to 1060mB

Storage and transport: Dell Optiplex PC

Temperature	-40°C to +65°C
Relative humidity	5% to 95% non-condensing
Atmospheric pressure	238mB to 1015mB

2.3 Power supply connections

Power requirements

115 or 230 V a.c., 50/60 Hz.

Power consumption

Maximum power for Reomed mains isolation transformer: 600W maximum (comprising PC: 240W and Monitor: 36W.
Maximum power from USB port: 2.5W.

Mains power connections

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.

WARNING:

1. **This equipment must only be connected to a supply mains with protective earth.**
2. **Ensure that the voltage rating of the isolation transformer matches the local mains supply voltage.**
3. **Always use the power lead and connector supplied with the R-40 system, or a lead and connector of equivalent standard.**
4. **Do not use adaptor plugs or extension leads unapproved by Lifelines.**
5. **Only appropriately trained and qualified personnel should adjust, maintain or repair this equipment.**
6. **Always disconnect the equipment from the main power supply before removing any covers.**

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 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.

Connecting to the multiple socket outlets

The multiple socket outputs provided on the isolating transformer shall only be used for supplying power to equipment that is intended to form part of the system.

WARNING: Additional multiple socket outlets or extension cords shall not be connected to the system.

Equipment that has not been supplied but is intended to form part of the system can be connected to the multiple socket outlets on the isolating transformer as long as the maximum total extra load does not exceed 350 VA.

WARNING: Connecting equipment to the multiple socket outlets effectively modifies the system and can result in a reduced level of safety. 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 the isolation transformer, and any other equipment powered from a non-isolated mains supply.

2.5 Interference

The R-40 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 R-40 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 R-40 may have internal radios fitted. These are approved industry-standard Bluetooth and Wi-Fi types which present minimal risk of reciprocal interference with other equipment.

Caution: 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.

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.

2.6 Maintenance and cleaning

The R-40 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 R-40 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.

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

2.7 Disposal of equipment

The expected service life of the equipment, parts and accessories is three years. When the equipment 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

3 Connections and usage

3.1 Overview

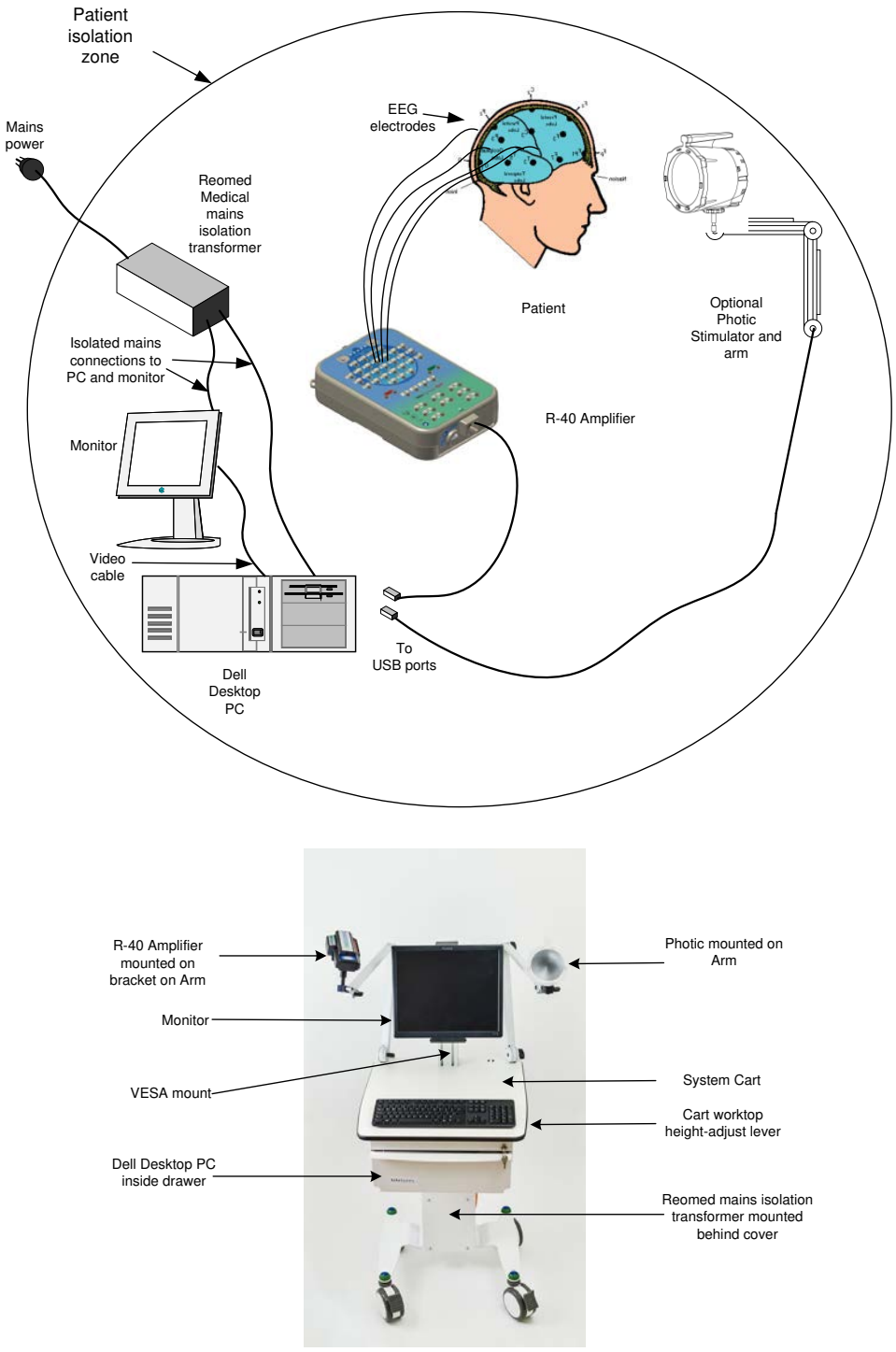


Figure 1 Connecting the R-40 System

The entire R-40 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 special Reomed medical mains isolation transformer connected to the PC and video monitor. The current recommended Dell desktop is the Optiplex SFF.

The PC

1. Fit the PC inside the lockable drawer of the Cart oriented so that the ON/OFF switch and CD drawer are accessible through the aperture at the side. Connect to the mains output cable which is provided there coming from the Reomed isolation transformer.
2. Fit the monitor to the Vesa mount. Route the mains and video data cable up inside the Vesa mount and through the rear of the drawer. Connect the mains to the output cable from the Reomed isolation transformer.
3. Connect the mouse, keyboard and monitor to the rear of the PC in accordance with the installation instructions provided with the PC.

WARNING: The desktop PC, its monitor and any other mains-powered equipment in the vicinity must only be connected to the medical-grade mains isolation transformer supplied by or authorised by Lifelines. Ensure that the voltage rating of the isolation transformer matches the local mains supply voltage. Do not exceed the maximum power rating of 600VA.
Only use the PC 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, dual arm-mounting holes, lockable drawer, Vesa display mount. It also conveniently houses the Reomed medical mains isolation transformer in the base and the mains input power cord. The Reomed provides 600VA of power and has multiple output connectors. It has an ON/OFF switch to provide isolation from the mains supply.

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 Schuko Europe plug. A Euro-US and Euro-UK adapter plug is provided for different territories. These are firmly screwed onto the Euro plug.

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

The Vesa mount will accommodate a monitor equipped with a standard Vesa mount. Alternatively, the monitor can be mounted on its stand on the worktop.

The arm will mount on the cart and accommodates either the Photic or the R-40 on its bracket. The arm is also supplied with a desk-clamp which allows it to be mounted on any convenient flat surface.

CAUTION: Before transportation, the system should be put into its **transportation position** to reduce the risk of overbalancing:

- Switch off and disconnect mains cable.
- Lower work top to lowest position.
- Close and lock drawer.
- Fully retract arms.
- Release brakes.

3.2 Connecting the R-40 System

The R-40 Amplifier is plugged into the PC USB port using the cable supplied, part number 1277 as shown below:

Figure 2 Connecting the R-40 Amplifier (top face)

The USB Cable is plugged into the bottom housing of the R-40 Amplifier as shown above using the RJ45 plug and into any USB port on the PC.

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

WARNING: 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.

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

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

Figure 3 Connecting the R-40 Amplifier (front 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.

CAUTION: All these connections are 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 Starting the system

To start the system proceed as follows:

- Plug the system into the mains supply and switch on using the switch on the isolation transformer.
- Switch on the PC at the left hand side of the drawer and wait for Windows to load.
- Ensure R-40 Amplifier is connected.
- Launch Trackit application and continue as detailed in section 4.
- These procedures also apply following a mains interruption.

3.4 Shutdown of the system

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

- Stop the recording by pressing the 'PC Record Off' button 

- Exit the Trackit program.
- Shut down Windows.
- Switch off using the switch on the isolation transformer and disconnect the mains supply.

4 The setup and recording software

The software is available on CD. A readme file describes installation. Check with your distributor or Lifelines if a newer version of software is available.
The Trackit software is designed to work with both the Trackit recorder and the R-40 Amplifier and with the optional Photic Stimulator.
The software is supported on Microsoft Windows 2000 (with SP2), Windows XP, Windows Vista and Windows 7 and Windows 8.

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
- Start and stop a recording session

4.1 Setting up a recording protocol

Summary

Step 1 Define the patient ID
Step 2 Define the signals – if required [1]
Step 3 Define the inputs – if required [2]
Step 4 Define the recording channels – if required [2]
Step 5 Activate the recording control
Step 6 Connect the R-40 for setup
Step 7 Check R-40 status
Step 8 Start a recording
Step 9 View the ongoing EEG traces

Notes:

1. Defining signals is usually done once only or very occasionally. The R-40 Amplifier arrives with a default set of signals that should suffice for most applications, hence it may only necessary to add signal types for polygraphic recordings (airflow, respiration etc).
2. Defining inputs, recording channels and montage is usually only done once per setup type. This entire setup can then be saved and recalled for future use.

Step 1 Define the patient ID

1 Select the New patient icon on the toolbar.

New Patient icon

2 Enter the patent name and Recording ID into the New Patient dialog.
This information is saved with the recording setup for download to the recorder in a future recording.

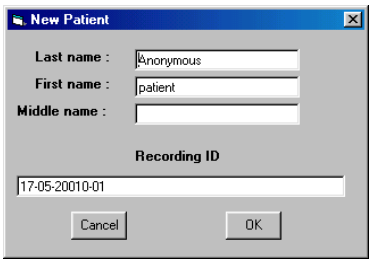


Figure 4 New Patient dialog

It is possible to configure the system to use a patient database instead of the simple dialog shown above.

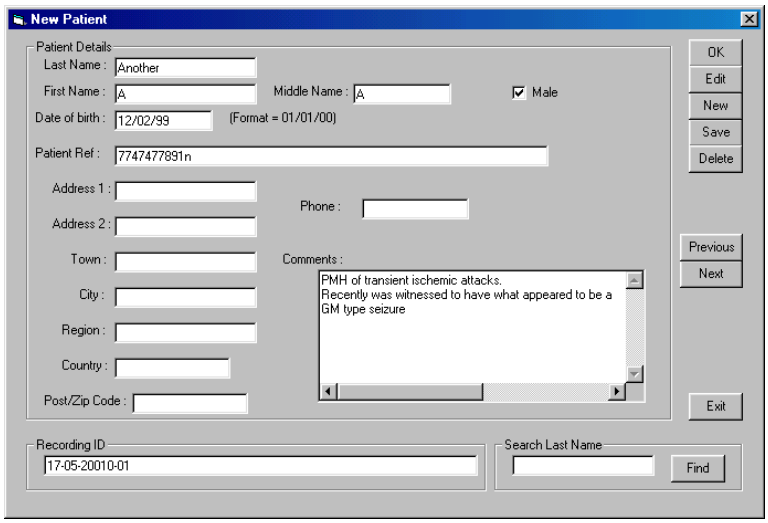


Figure 5 New Patient database

The database allows you to enter more extensive information about the patient and recording, and save it for future reference. See the section entitled 'Advanced options'.

Step 2 Define the signals – if required

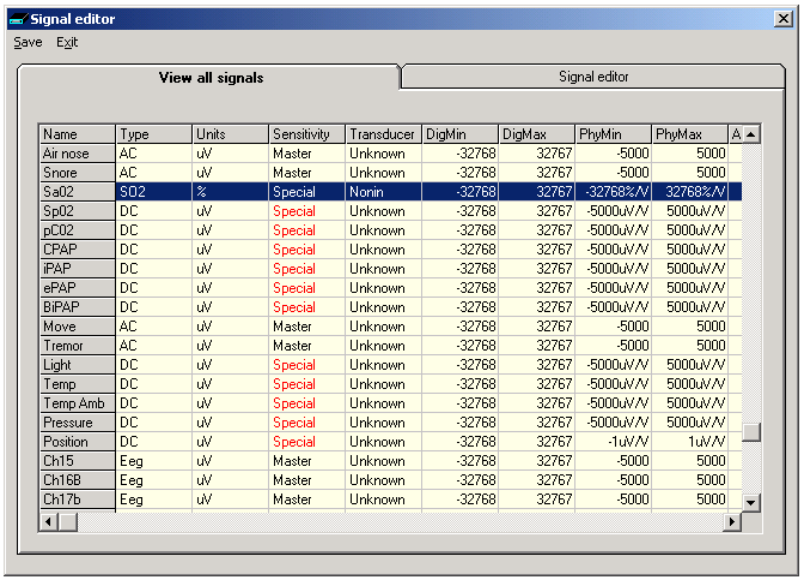
Defining signals is usually done once only or very occasionally. The R-40 Amplifier arrives with a default set of signals that should suffice for most applications, hence it may only necessary to add signal types for polygraphic recordings (airflow, respiration etc).

If for any reason the signals have not been created, it is necessary to define all the signals (labels) that are to be used for montage creation in Step 3. The signal editor allows the creation of up to 64 distinct signals ranging from the standard 10/20 EEG signals such as FP1 O2, to Respiration, Pulse and other polygraphy inputs.

Step 3 explains how to calibrate an AUX input.

To define a signal:

1 Click the View all signals tab in the Signal editor dialog box.



Name	Type	Units	Sensitivity	Transducer	DigMin	DigMax	PhyMin	PhyMax
Air nose	AC	uV	Master	Unknown	-32768	32767	-5000	5000
Snore	AC	uV	Master	Unknown	-32768	32767	-5000	5000
Sa02	SO2	%	Special	Nonin	-32768	32767	-32768%/V	32768%/V
Sp02	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
pC02	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
CPAP	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
iPAP	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
ePAP	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
BiPAP	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
Move	AC	uV	Master	Unknown	-32768	32767	-5000	5000
Tremor	AC	uV	Master	Unknown	-32768	32767	-5000	5000
Light	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
Temp	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
Temp Amb	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
Pressure	DC	uV	Special	Unknown	-32768	32767	-5000uV/V	5000uV/V
Position	DC	uV	Special	Unknown	-32768	32767	-1uV/V	1uV/V
Ch15	Eeg	uV	Master	Unknown	-32768	32767	-5000	5000
Ch16B	Eeg	uV	Master	Unknown	-32768	32767	-5000	5000
Ch17b	Eeg	uV	Master	Unknown	-32768	32767	-5000	5000

Figure 6 Signal List

2 Double click on the signal you want to edit. This brings up the Signal editor tab), allowing you to create a relevant signal or label to be entered into the signal list.

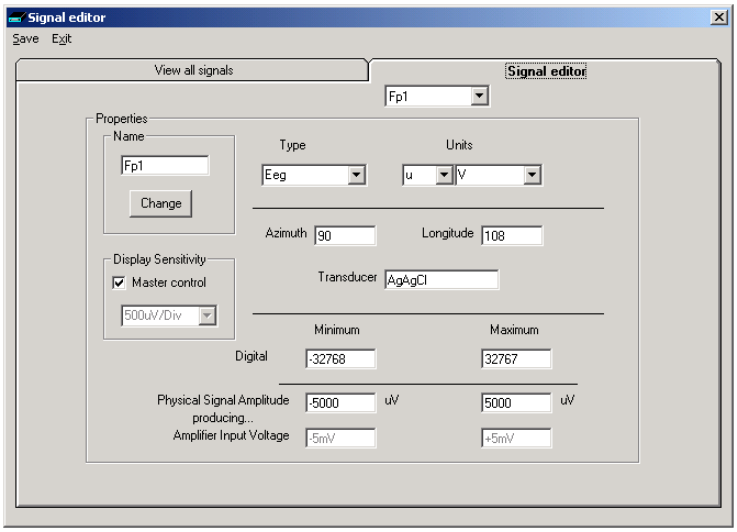


Figure 7 Signal Editing Tool

3 Type in the Signal name (e.g. Fp1). Note that for EEG signals this must be case-sensitive.
4 Select a signal type (in this case EEG).
5 Click on the Change button. The signal is now entered into the list under the View all signals tab.
6 If the signal is not an EEG signal, it may be necessary to insert a display sensitivity value by un-checking the Master control check box.
Signals that have been defined with their own independent sensitivities appear in red in the trace display. Further editing and changes to these sensitivity values in the trace display will be saved back into the signal library.

Step 3 Define the inputs

Note that if a pre-saved setup is available then this can be opened directly from the Open menu item, and this section skipped. Otherwise, if a new setup is being created, proceed as follows:

1 Select the Spanner icon on the toolbar. This opens the tabbed Setup Recording dialog.

Spanner icon
2 Under the Amplifier Channels tab select the signals (labels) to be attached to the physical inputs.
For example, EEG input 1 may require the label Fp1 and so on according to the standard 10/20 nomenclature.
Double click the channel name and select the relevant signal label from the Setup Hardware EEG channel dialog.

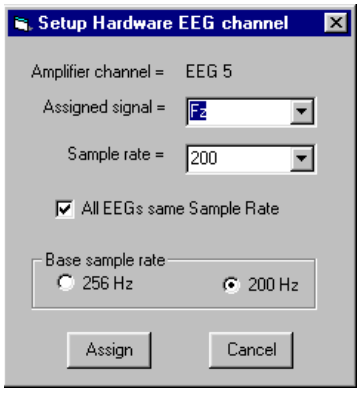


Figure 8 EEG setup

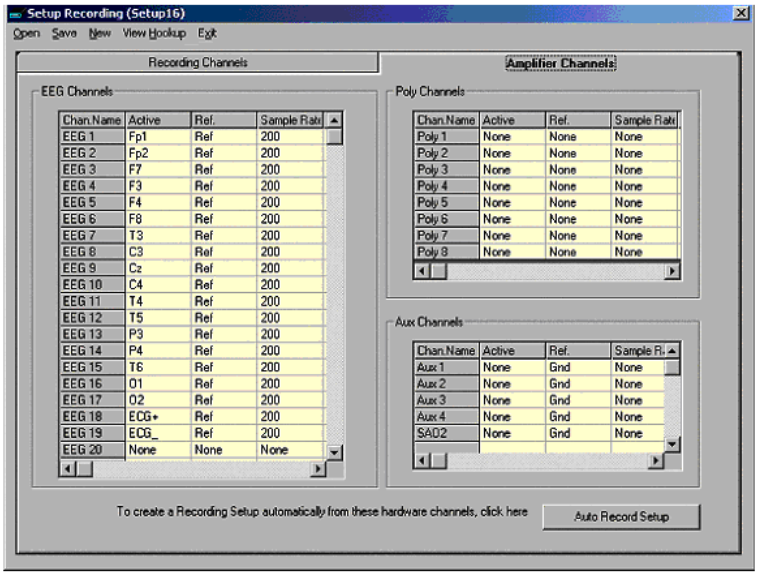


Figure 9 Setup Recording dialog

The order of the signal labels in the pull down list is the same as the order of the signals in the signal list defined using the signal-editing tool.

Amplifier setup: amplifier setup activates the recording inputs in preparation for a recording. For most applications you need perform amplifier setup only once – when the system is first installed – since the amplifier setup is saved with the recording montage for future recall and usage. See Step 4 below.

If you want to use the recording channel order defined in amplifier setup, click on Auto Record Setup in the Setup Recording dialog box. You can then skip Step 4 (Define the recording channels).

Poly and AUX inputs: these inputs can be set to either referential (EEG mode), bipolar AC or bipolar DC. They are ideal for polygraphic signals such as respiration, airflow, EKG, body position (DC mode) etc.

To calibrate an AUX input to reflect a required unit of scale for a given voltage input use the signal editor - see **Error! Reference source not found.**). Select the appropriate units, e.g. %, or mm Hg, and enter the Physical Signal Amplitude required to generate the Amplifier Input Voltage.

Step 4 Define the recording channels

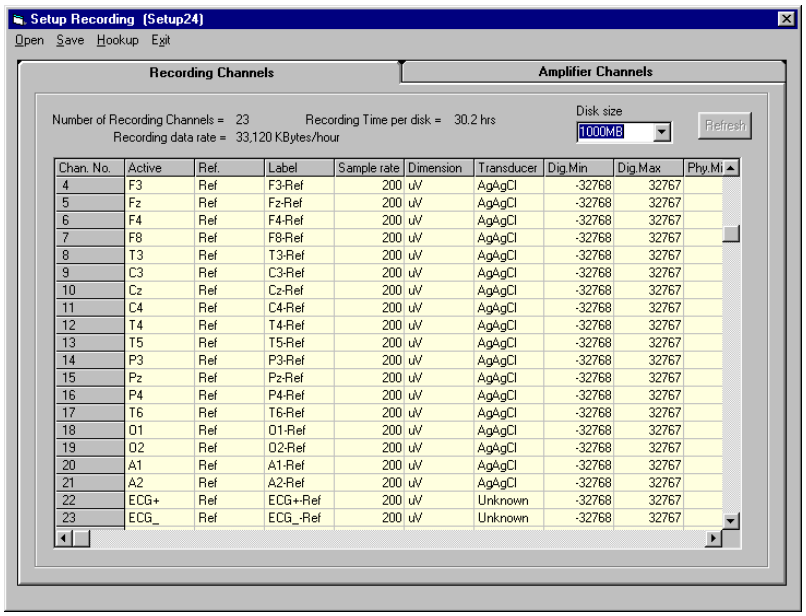
Step 4 can usually be skipped, since the Auto Record Setup button will copy what you have defined under the inputs in Step 3 into the list of recording channels.

However, you can define and save recording montages for specific recording needs, and recall them for future usage.

Creating a montage follows the same principle as the signal creation and input definition tool: click on the channel number to define the active and reference label of choice.

Figure 10 Channel setup

An example of a recording montage is shown below.



Chan. No.	Active	Ref.	Label	Sample rate	Dimension	Transducer	Dig.Min	Dig.Max	Phy.Mi
4	F3	Ref	F3-Ref	200	uV	AgAgCl	-32768	32767	
5	Fz	Ref	Fz-Ref	200	uV	AgAgCl	-32768	32767	
6	F4	Ref	F4-Ref	200	uV	AgAgCl	-32768	32767	
7	F8	Ref	F8-Ref	200	uV	AgAgCl	-32768	32767	
8	T3	Ref	T3-Ref	200	uV	AgAgCl	-32768	32767	
9	C3	Ref	C3-Ref	200	uV	AgAgCl	-32768	32767	
10	Cz	Ref	Cz-Ref	200	uV	AgAgCl	-32768	32767	
11	C4	Ref	C4-Ref	200	uV	AgAgCl	-32768	32767	
12	T4	Ref	T4-Ref	200	uV	AgAgCl	-32768	32767	
13	T5	Ref	T5-Ref	200	uV	AgAgCl	-32768	32767	
14	P3	Ref	P3-Ref	200	uV	AgAgCl	-32768	32767	
15	Pz	Ref	Pz-Ref	200	uV	AgAgCl	-32768	32767	
16	P4	Ref	P4-Ref	200	uV	AgAgCl	-32768	32767	
17	T6	Ref	T6-Ref	200	uV	AgAgCl	-32768	32767	
18	O1	Ref	O1-Ref	200	uV	AgAgCl	-32768	32767	
19	O2	Ref	O2-Ref	200	uV	AgAgCl	-32768	32767	
20	A1	Ref	A1-Ref	200	uV	AgAgCl	-32768	32767	
21	A2	Ref	A2-Ref	200	uV	AgAgCl	-32768	32767	
22	ECG+	Ref	ECG+-Ref	200	uV	Unknown	-32768	32767	
23	ECG_	Ref	ECG_-Ref	200	uV	Unknown	-32768	32767	

Figure 11 Recording Channel editing

4.2 Configuring the amplifier

When you have finished setting up the recording protocol, connect the R-40 to the host computer. Steps 5 to 9 describe configuration and set-up of an ambulatory EEG.

Step 5 Activate the recording control

The Trackit application software will normally connect automatically to the R-40 Amplifier as soon as it is plugged in. Otherwise, from the Trackit toolbar select the Trackit Control Panel ('hand-shake') icon which will allow for manual connection.

Figure 12 Trackit software toolbar

Key

1 New Patient	2 Setup Recording	3 Trackit Control Panel
4 Ongoings On	5 Ongoings Off	6 Impedance Check On
7 Calibration On	8 Calibration Off	9 Page Down
10 Page Up	11 Get Trackit Events	12 Email Events List
13 Notch Filter On/Off	14 PC Record On	15 PC Record Off
16 Videometry (optional)	17 Photic Stimulation	18 Hyperventilation
19 Vertical sensitivity	20 Chart speed	21 Open files for playback
22 Stop playback	23 Start playback	24 Page back
25 Stop paging	26 Page forward	27 Paging speed
28 Playback time	29 Montage selection	30 Lo-filter selection
31 Hi-filter selection		

Clicking on the 'handshake' icon brings up the Control Panel dialog box.

Step 6 Connect R-40

Check that the R-40 is connected properly. The software will normally connect automatically, however to do this manually, in the Control Panel select the USB option for the R-40 and click on Connect.

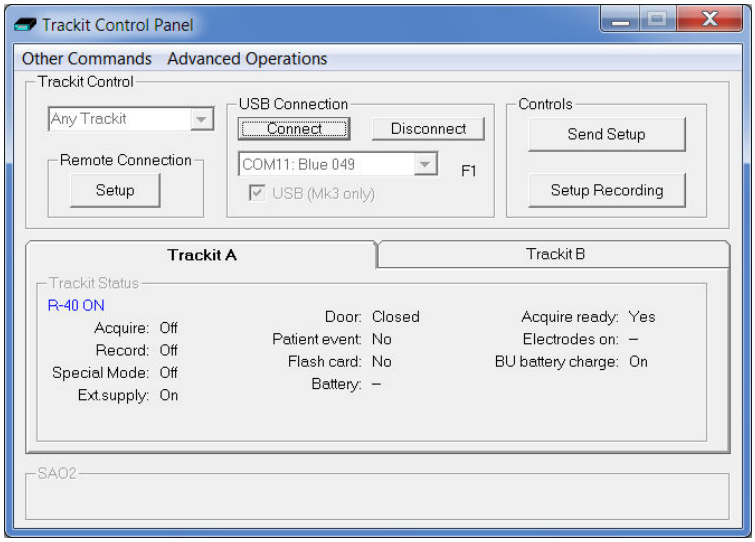


Figure 13 Trackit Control Panel

After a couple of seconds Status shows 'R-40 Online'.

Most of the parameters in the Status section do not apply to the R-40 and the panel is disabled. However the few that do apply are detailed in the next step.

Step 7 Check R-40 status

Use the Control Panel to check that the R-40 is correctly online. For the R-40, the Status part of the Control Panel gives you the following information:

Acquire – on or off	Shows whether the R-40 is acquiring or not.
Patient event	Shows that the external patient event marker is activated.
CF card	Shows whether a CF card is present.
Acquire ready	Shows that a valid recording setup has been loaded into the R-40.

Note that further status information is available on the 2nd tab. These parameters do not apply to the R-40.

Step 8 Start a recording

Click on the Send Setup button. Wait for the setup to upload to the Trackit recorder. This should take a few seconds.

Click on the Start Record icon  on the main screen in the toolbar to start recording. Ongoing traces will be displayed on the PC. These can be turned on or off by clicking on this icon: 

To perform an Impedance Check click on this icon:  . The channel LED will illuminate to indicate when the electrode impedance is greater than the set level. The set level can be set with the two push-buttons on the amplifier front panel.

To perform a Calibration check, click on this icon:  . The waveforms will show a square wave of amplitude 8 mV pk-pk and frequency 1 Hz.

Step 9 View the ongoing EEG traces

To view the ongoing traces at any time, whether recording or not, click on the following icon:

When you do this, one of the following things occur:

- If the R-40 is connected to the PC, and has been sent a valid recording setup, the traces appear wiping from left to right across the display.
- If the R-40 has not been sent a setup from the PC, the system asks for the recording setup held in the R-40 before displaying the traces.

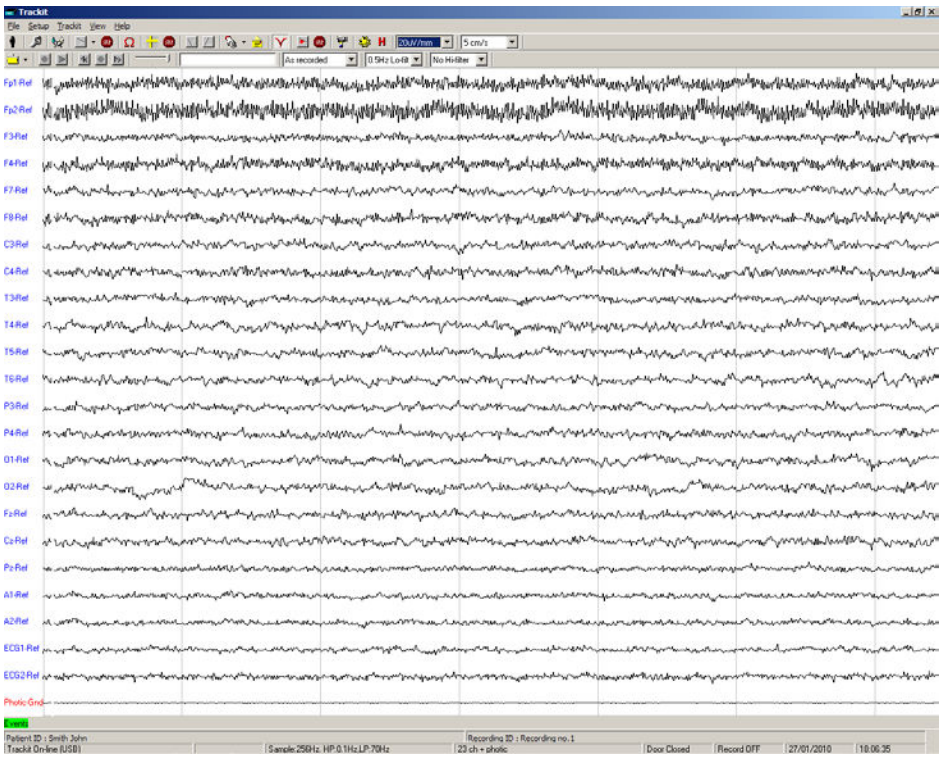


Figure 14 Ongoing trace display

Sensitivity, Chart speed, Notch Filter and Hi/ Lo filters: as is often the case when viewing a live trace display, the sensitivity, chart speed and filters need be adjusted for optimal viewing. Use the drop down lists on the toolbar.

To adjust the display parameters for an individual channel, click on the channel label. This displays a dialog box for that channel, with a check-box for master control, trace On or Off, and Numeric. Click on Numeric if you want the numeric value displayed under the label. This can be useful when for displaying units such as mmHg or degrees C.

When a channel is under individual channel control the label is depicted in red. When display of that channel is turned off, the label is greyed out.

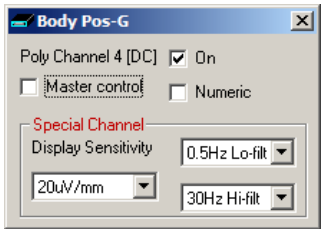


Figure 15 Adjust display parameters

Impedance check: to carry out an impedance check, click on the impedance check icon on the Trackit toolbar.

If recording has started , the impedance check is displayed on the trace display with an impedance check event.

The impedance check works via pass/fail threshold selection. Impedance values above the selected threshold (fail) are displayed on a red background. Values below (pass) are displayed on a green background

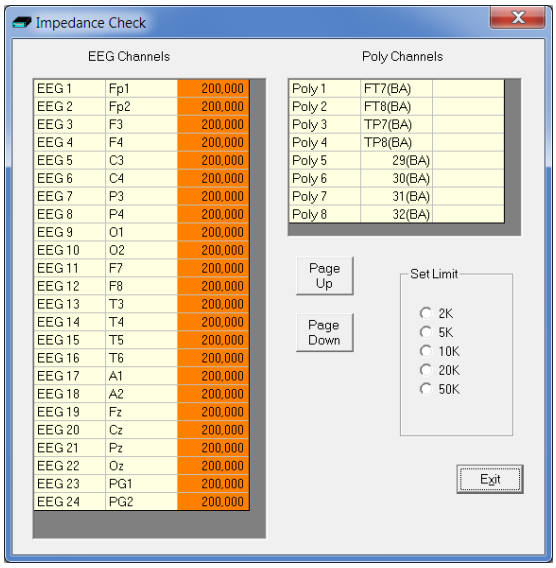


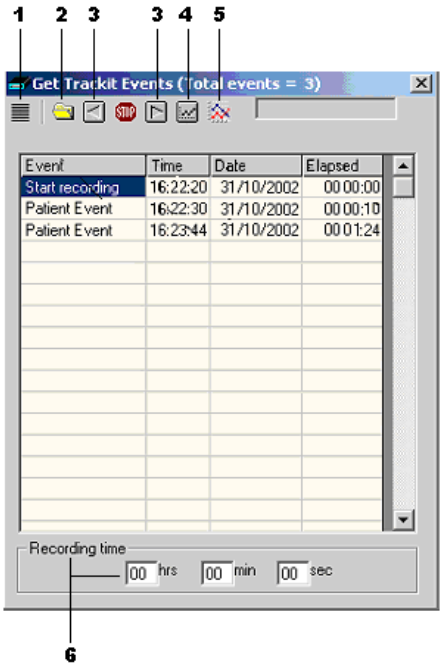
Figure 16 Impedance check

Notch filter: to set a notch filter, use Other Options from the View Menu. Notch filters are either 50Hz or 60Hz depending on where the system is to be used (USA 60Hz; Europe 50Hz).

To activate the notch filter, click on the Notch Filter icon in the Trackit toolbar.

Trackit events: to view all recorded events in the recording online, click on the Get Trackit Events icon in the Trackit toolbar.

Events are displayed in the online event viewer with a description and time.



Key:
1 Opens the list of event types

Additional icons at Playback time:
2 Opens an event file for an older recording
3 Navigate forwards or backwards
4 Selects the best trace resolution
5 Selects the max. number of traces
6 Enter a 'Go to' time here

Figure 17 Online Event Viewer

The event list allows the user not only to see when events took place, but to also view the data behind those events.

To display a page of EEG around an event of interest, double click on the event in the list. To navigate forwards or backwards, press the forward or backward arrow buttons. Or you can go to a particular time in the recording by entering the time (as hrs, min, sec) in the recording time fields.

4.3 Montage Editor

This is available via the Setup | Montage menu on the main screen, and displays the Montage Editor as shown below.

The Montage Editor allows the setting-up of 16 user montages and the As-recorded montage. Note that the As-recorded montage can only have its channel on/off and channel master/special control edited (and if special, the channel sensitivity and filters). All the other 16 user montages are fully definable and can have the following parameters set for each channel:

1. Active channel name. This is either chosen from the drop-down list representing the current Signal Library signals, or typed in directly.
2. Ref. channel name. This is either chosen from the drop-down list representing the current Signal Library signals, plus Ref and Gnd, or typed in directly.
3. Channel On or Off. If off, the channel label is greyed-out and no trace is displayed.
4. Master or Special Control. If Special, then the Sensitivity, Low Filter and High Filter can be set.

Additional controls are provided to allow:

5. Update. Copies the current settings into the currently selected channel.
6. Add. This adds a channel to the end of the Montage list.
7. Insert. This insert a channel above the currently selected channel.
8. Remove. This removes the currently selected channel.
9. Montage name.

If anything is changed, an option is presented to save all changes to disk or not. If not saved, changes are only temporary.
Note that some of the montage parameters can be changed outside the Montage Editor, by clicking on a channel label to bring up the Channel Information window. These changes are only temporary (although you can save them later by subsequently going into the Montage Editor).

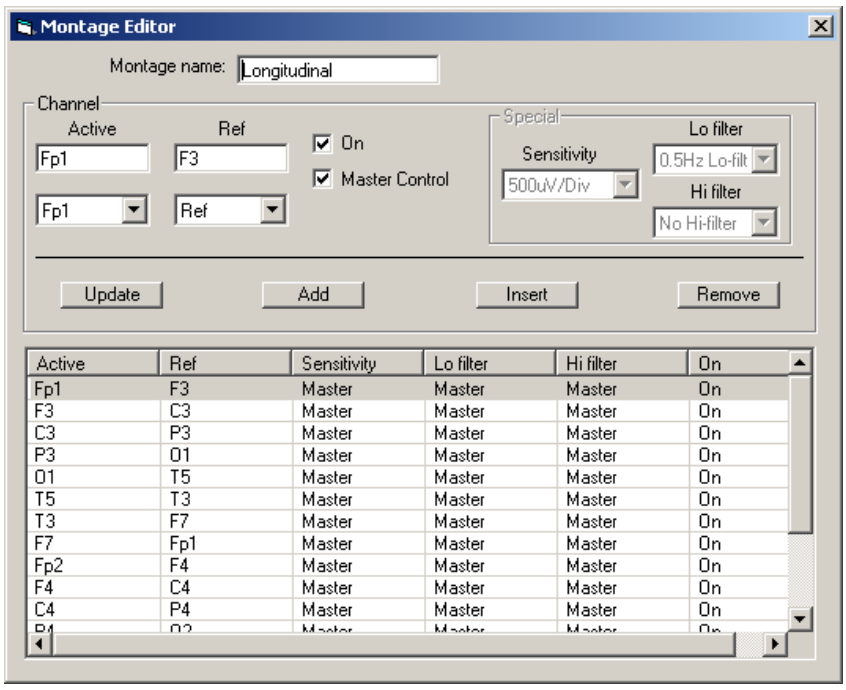


Figure 18 Montage Editor

4.4 Reading an EEG recording

Click the 'Open all playback files' button on the left hand side of the Trackit software toolbar to playback a recording and browse to the folder and file required. This will open the EDF file and any associated files.

If currently recording to the PC, it is possible to open this file for simultaneous playback. This will open the current EDF file and all video files and the current Events list. Playback occurs in the normal way. The 2nd playback window can be set to tile horizontally or vertically.

As an alternative to the Trackit software which offers basic playback features, any EDF-compatible viewer can be used to read the standard EDF files recorded by the Trackit.

All Trackit recordings have a user-definable 8-character file name with '.edf' extension. They are stored in EDF format, readable in all EDF-compatible EEG browsers. In an EDF-compatible browser, the patient's name and recording ID are displayed in the test properties.

Lifelines currently recommends:

- Lifelines iEEG
- Nihon Kohden 1100 and 1200 EEG
- Neurotronics Polysmith Sleep software
- Nicolet One EEG
- Natus Coherance EEG (formerly Deltamed/Itmed)
- Persyst Insight EEG

Appendix 1: Specifications

Note: 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.

R-40 Amplifier Specifications

EEG inputs

Number of EEG channels	32 monopolar touchproof inputs
ADC Resolution	24 bits
Sampling rate	250 – 16000 Hz
Input impedance	>20 Mohms
Common mode rejection ratio	>100dB @ 50 and 60 Hz
Equivalent input noise	<1.5μVpp
	<0.2uV rms
Gain	12 ±0.5%
Max Input V_{diff}	750mVpp (including DC)
Quantisation	0.17uV/bit @ Gain = 12 and Bits = 22
Bandwidth (-3dB)	DC to 4193 Hz max.
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
	<0.2uV rms
Gain	12 ±0.5% (AC)
	4 ±0.5% (DC)
Max Input V_{diff}	750mVpp AC setting (including DC)
	2.25Vpp DC setting
Bandwidth (-3dB)	DC to 4193 Hz max.
Quantisation	0.17uV/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 V_{diff}	2.25Vpp
Bandwidth (-3dB)	DC to 4193 Hz

Connections, ports and controls

Electrode Input connectors	55 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	40 LEDs for Impedance Check indication (1 per channel)
	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 IEC 60601-2-26	European 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	European standard for medical electrical equipment, EMC requirements, calling:
IEC55011	Conducted Emissions, Group 1, Class B
IEC55011	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

R-40 Amplifier

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 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

Reomed Mains Isolation Transformer Specifications

Two models of Reomed Mains Isolation are provided which are conveniently housed in the base of the Combo-EEG Cart and provide a medical-grade mains isolation transformer to power the Dell desktop PC and monitor. They are both 600VA rating but allow for different local mains supply:

Part Number 1288: Reomed model 600 230V/230V, Input 230V, Output 230V
Part Number 1289: Reomed model 600 115V/115V, Input 115V, Output 115V

Refer to the enclosed documentation for detailed information.

Input and Output Voltage	230V or 115V depending on model
Power Rating	600VA
Number of outlets	6
Dielectric Strength	> 4kV
Earth Leakage Current	< 500uA
Safety and Regulatory Approvals	IEC/EN60601-1
	IEC/EN60601-1-2
Size	270 x 170 x 95 mm
Weight	7 kg

Dell Optiplex PC Specifications

Safety and Regulatory Standards	IEC/EN60950-1
EMC	EN55022/CISPR 22 and FCC Part 15 Class B
	EN55024/CISPR 24
	EN61000-3-2 and EN61000-3-3
Input voltage	90 – 264 VAC
Frequency	47 – 63 Hz
Power	240 W
Size	312 x 93 x 290 mm
Weight	5.7 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 R-40 to assess patient photosensitivity in EEG studies. For a detailed description of operation, connection and specifications please refer to the separate documentation “Lifelines Photic User Manual”.

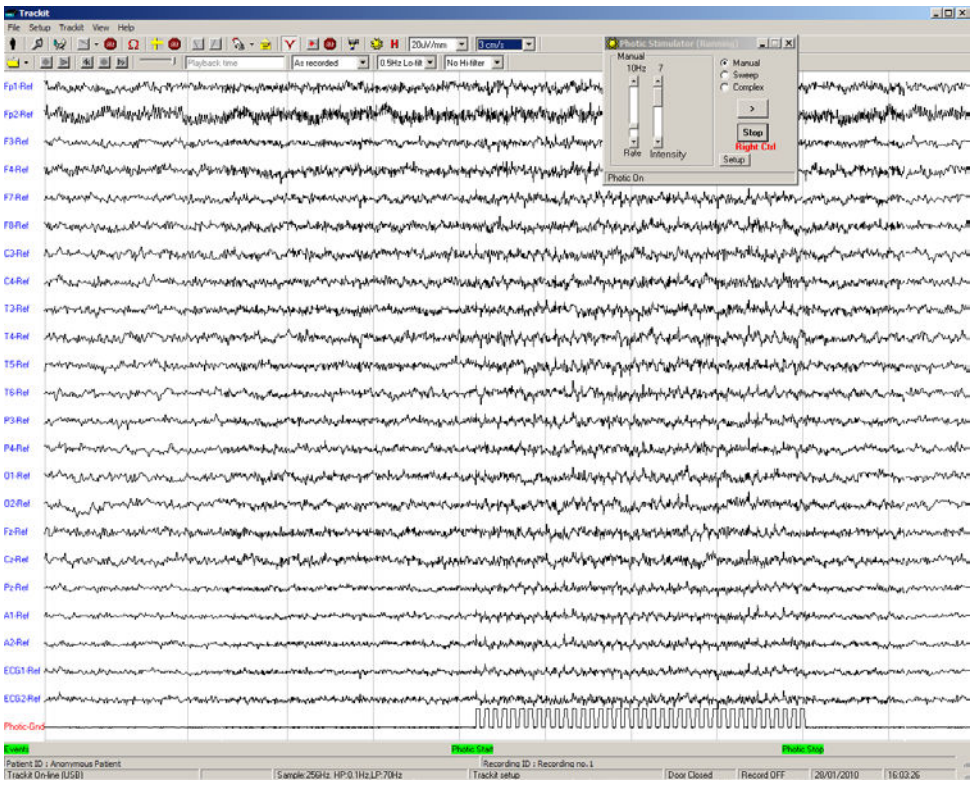


Figure 19 Photic Stimulation

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

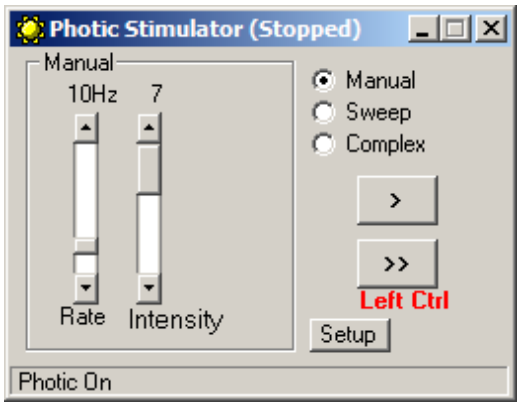


Figure 20 Photic Stimulation control window

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.

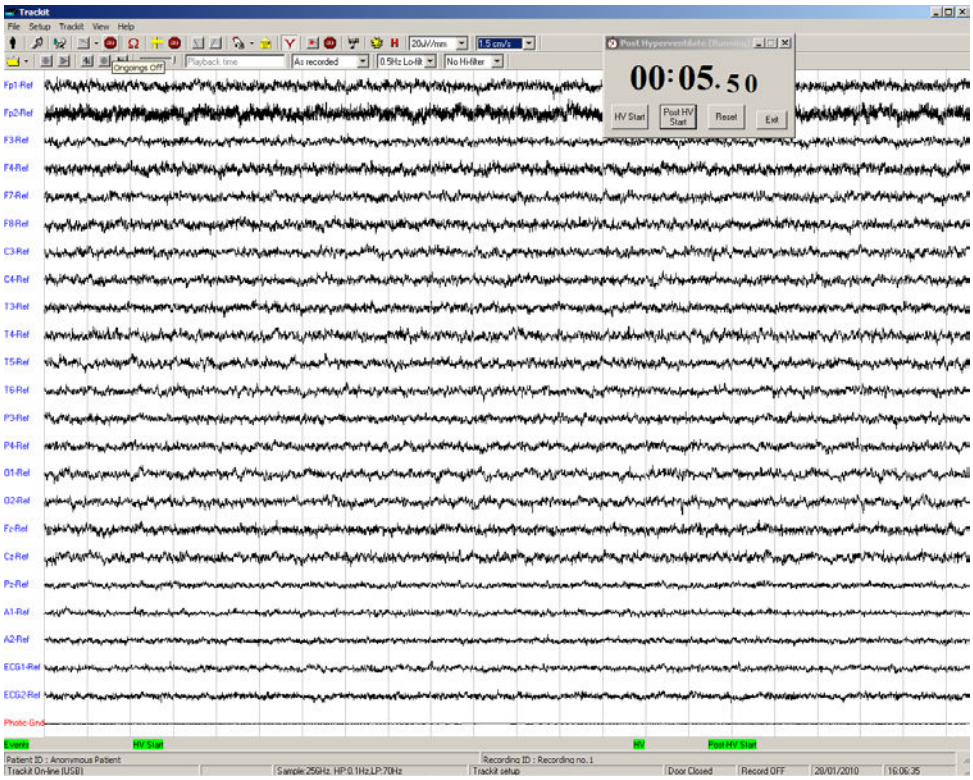


Figure 21 Hyperventilation

Click on the Hyperventilation icon on the top toolbar to bring up the control window as shown below.

Figure 22 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 that 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 R-40 EEG system, 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

Event List Key	Event No.	Contents	Type	Size	Total size	Mapping
0	0	No event	Fixed	16 x 16	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	16 x 16	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	32 x 32	1024	Auto
	33	Video stop				Auto
	34	Video move-ment				Auto
	35	Trackit connect				Auto
	36	Trackit discon-nect				Auto
	37 - 63	Reserved				Auto
3	64 – 95	?	User-config	32 x 32	1024	Shift F1–8 Ctrl+Shift F1-8
4	96 – 159	?	User-config (free-text)	64 x 64	4096	F12

The user-configurable events are edited and setup before acquisition. These are automatically saved and restored by the program. For ease of entry during acquisition, 24 of these events are mapped to the keyboard F1- F8 keys, Shift F1 – F8 and Control + Shift F1 – F8 keys.

Clicking on the Events icon on the main program window allows these configurable events to be edited as shown below. If the system is recording, selecting an event marks it in the recording. If not recording, selecting an event allows it to be edited.

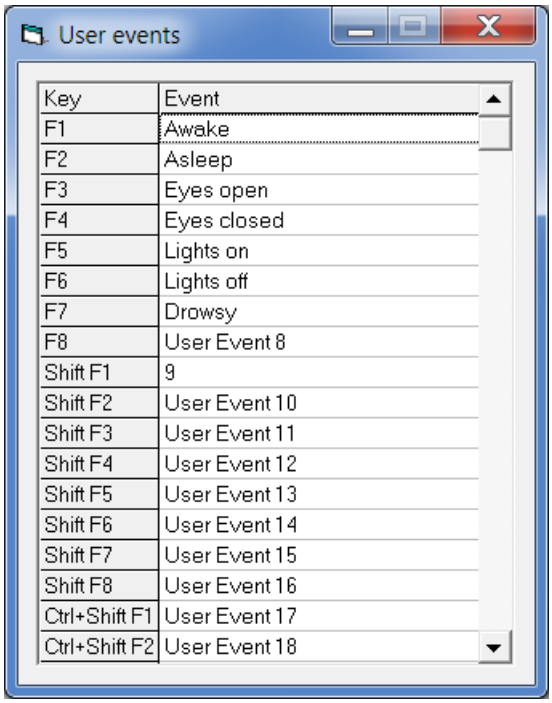


Figure 23 User Events

The Events icon also brings up an option to print an events template for overlaying on the keyboard. Facilities are provided to scale the printout to fit different size keyboards.

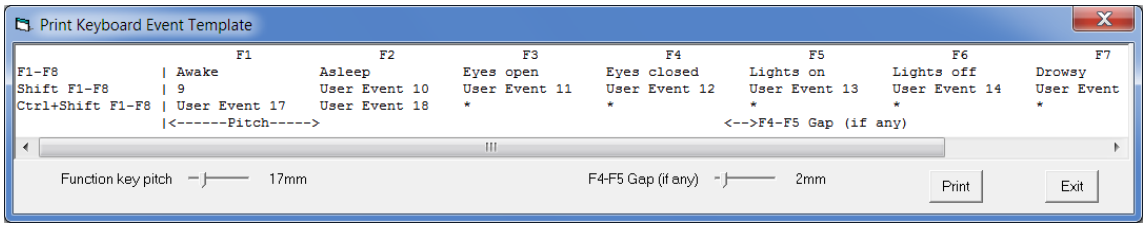


Figure 24 Events Template setup

Free Text Events

During a recording, pressing the F12 keyboard key allow a free-text event to be created. The event is recorded at the time F12 is pressed and a window is displayed allowing the entry of descriptive text which can be entered at the user's leisure. During this time all the other types of events can be activated.

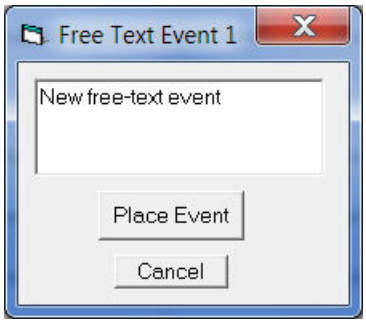
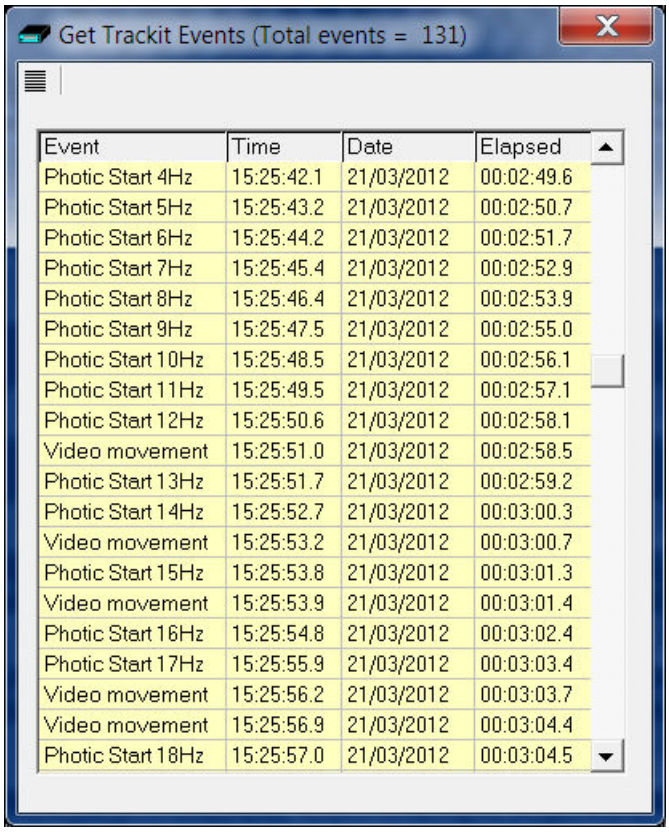


Figure 25 Free-text Event

During playback, all the events are displayed for the file by clicking on the Events icon. Double-clicking on an event in the list jumps to that point in the recording. All the events are also displayed in their correct position in relation to the EEG along the bottom of the main window.
The events may be sorted alphabetically by clicking on the 'Event' heading in the list. This is convenient for grouping all event types together, e.g. Photic. Clicking on the 'Time' heading sorts the events back into chronological time.



Event	Time	Date	Elapsed
Photic Start 4Hz	15:25:42.1	21/03/2012	00:02:49.6
Photic Start 5Hz	15:25:43.2	21/03/2012	00:02:50.7
Photic Start 6Hz	15:25:44.2	21/03/2012	00:02:51.7
Photic Start 7Hz	15:25:45.4	21/03/2012	00:02:52.9
Photic Start 8Hz	15:25:46.4	21/03/2012	00:02:53.9
Photic Start 9Hz	15:25:47.5	21/03/2012	00:02:55.0
Photic Start 10Hz	15:25:48.5	21/03/2012	00:02:56.1
Photic Start 11Hz	15:25:49.5	21/03/2012	00:02:57.1
Photic Start 12Hz	15:25:50.6	21/03/2012	00:02:58.1
Video movement	15:25:51.0	21/03/2012	00:02:58.5
Photic Start 13Hz	15:25:51.7	21/03/2012	00:02:59.2
Photic Start 14Hz	15:25:52.7	21/03/2012	00:03:00.3
Video movement	15:25:53.2	21/03/2012	00:03:00.7
Photic Start 15Hz	15:25:53.8	21/03/2012	00:03:01.3
Video movement	15:25:53.9	21/03/2012	00:03:01.4
Photic Start 16Hz	15:25:54.8	21/03/2012	00:03:02.4
Photic Start 17Hz	15:25:55.9	21/03/2012	00:03:03.4
Video movement	15:25:56.2	21/03/2012	00:03:03.7
Video movement	15:25:56.9	21/03/2012	00:03:04.4
Photic Start 18Hz	15:25:57.0	21/03/2012	00:03:04.5

Figure 26 Event List

Appendix 4: PC Setup

Options | Tab 1

The Options panel Tab 1 contains general settings which are self-explanatory as shown below.

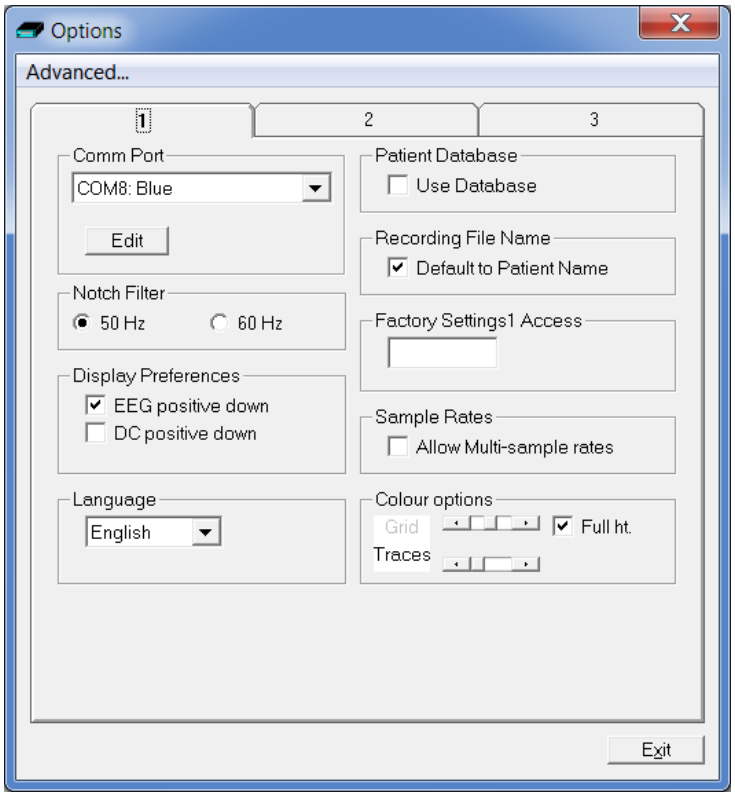


Figure 27 Options Tab 1

Options | Tab 2

The second tab in Options is shown below.

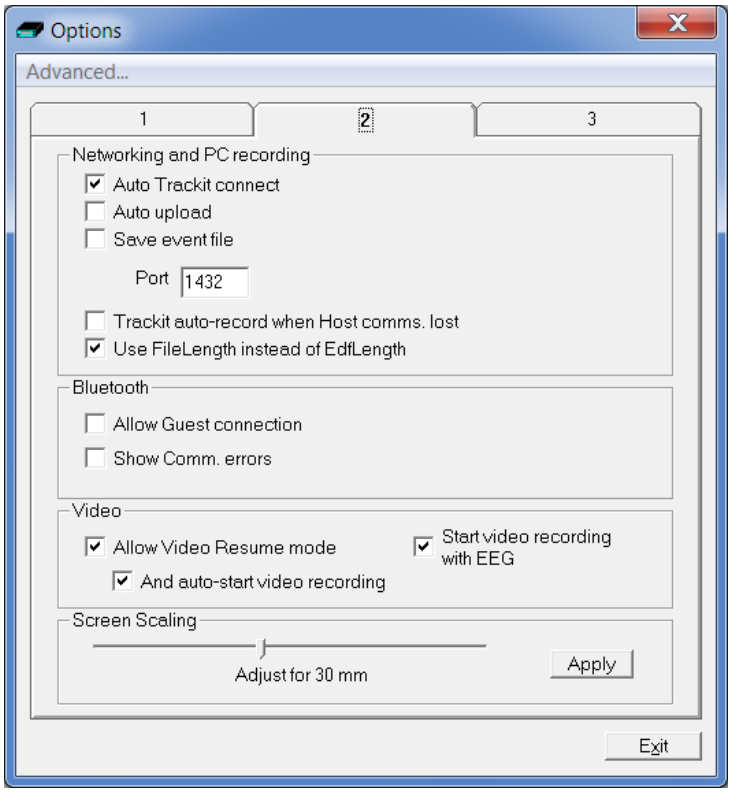


Figure 28 Options Tab 2

Most of these options are not applicable to the R-40, except for:

- **Use File Length instead of EDF Length.** This a playback feature and if ticked, the file length is used instead of the edf length parameter embedded in the edf header. Due to the fact that the R-40's memory card can be removed at any time, there can be a partial 1s data block at the end of the file and so the actual size may not be an exact multiple of 1s.

Screen Size

This Slider Bar allows the screen size to be set so that the Chart Speed for the traces exactly matches the cm/s selected. To use, adjust the slider so that it is 30 mm from the left-hand end.

Options | Tab 3

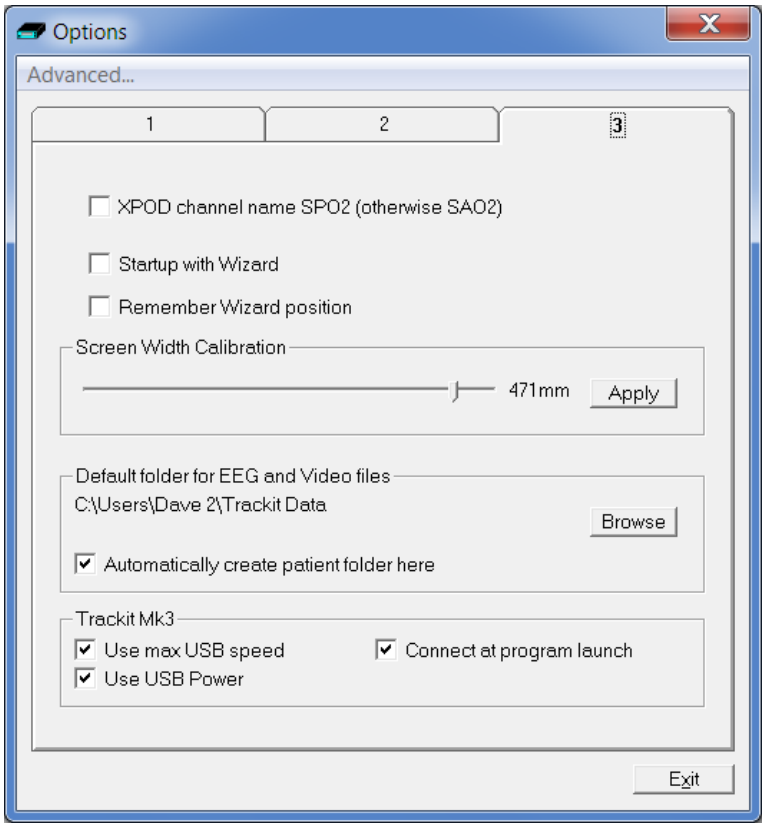


Figure 29 Options Tab 3

Most of these options are not applicable to the R-40, except for:

- **XPOD channel name SPO2 (otherwise SAO2).** This option allows the XPOD channel name to be either SPO2 or SAO2. This is because some playback software requires a specific label to enable recognition.

- **Screen Width Calibration.** This allows the program to be calibrated to the screen width.

- **Default folder for EEG and Video files.** This allows the program to always record EEG and/or video files to the same default folder. Use Browse to find and/or create the default folder for recordings.
    - **Automatically create patient folder here.** If checked, the program will automatically create a patient folder in the default recording folder set above without any user intervention. If not set, the user choses where to save the recording using the standard save file dialogue window.

- **Connect at program launch.** If checked, the program will automatically connect to the R-40 at launch.

Appendix 5: Manufacturer's Declaration

EMC Compatibility

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

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

WARNING: 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.

Accessory name	Type	Length	Manufacturer
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	Zygo

WARNING: 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.

Guidance and Manufacturer's Declaration

Electromagnetic Emissions
EN 60601-1-2

The R-40 is intended for use in the electromagnetic environment specified below. The customer or user of the R-40 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The R-40 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 R-40 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.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions EN 61000-3-3	Complies	

Electromagnetic Immunity
EN 60601-1-2

The R-40 is intended for use in the electromagnetic environment specified below. The customer or user of the R-40 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) EN 61000-4-2	+/- 6 kV:Contact +/- 8 kV:Air	+/- 6 kV:Contact +/- 8 kV:Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast Transients/burst EN 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 EN 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 EN 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 R-40 requires continued operation during power mains interruptions, it is recommended that the R-40 be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the R-40, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
RF Common mode/ Conducted Susceptibility EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = [3.5/V] √P = 1.2 √P Note: using unshielded input leads [c]
Radiated RF Electromagnetic Fields EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = [3.5/E] √P : 80 MHz to 800 MHz = 1.17 √P d = [7/E] √P : 800 MHz to 2.5 GHz = 2.33 √P Note: using unshielded input leads [d]
			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 R-40 is used exceeds the applicable RF compliance level above, the R-40 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the R-40.

[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.

Recommended separation distance between portable and mobile RF communications equipment and the R-40 EEG System
EN 60601-1-2

The R-40 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the R-40 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the R-40 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter m**		
W	150 kHz to 80 MHz $d = [1.17/V] \sqrt{P}$	80 MHz to 800 MHz $d = [1.17/E] \sqrt{P}$	800 MHz to 2.5 GHz $d = [2.33/E] \sqrt{P}$
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 1. At 80 MHz and 800 MHz, the separation distance for 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.			