

R40 EEG System

User Manual



Part no. 1338 Issue 1.9

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 - 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.

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• Amended operating temperature for PC in section 2.2

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- 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.

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



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

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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.

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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.

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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.

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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



Input/output connection



Follow operating instructions

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.





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 'Pure-Light' 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 ANSI/AAMI ES 60601-1	European standard for medical electrical equipment, general re- quirements and particular requirements for EEG systems. AAMI Deviations from IEC 60601-1 (USA).
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general re- quirements.
IEC 60601-1-2	European standard for medical electrical equipment, EMC require- ments, 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	lmmunity – Power frequency fields
*IEC61000-4-11	Immunity – Voltage dips, interruptions
IEC61000-3-2	Harmonic Emissions
*IEC61000-3-3	Voltage Fluctuations/flicker
*Note: Compliance is provid	led by the PC

Classification of system

Degree of protection against electrical shockClass I. Type BF applied partsType of protection against electrical shockOptically isolated USB amplifier
Mains isolation transformer for PCDegree of protection against harmful ingress of waterOrdinary (no protection)Mode of operationContinuousDegree of safety of application in the presence of a flam-
mable anaesthetic mixture with air or with oxygen or ni-
trous oxideNot 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 DCInputs

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 I solation Transformer for Desktop PC

The mains power supply limits the mains leakage current of the system and is a special medicalgrade 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.
- Remove cable gland using suitable assembly tool¹ 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:

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- 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.



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.

🛋 New Patient	×
Last name :	Anonymous
First name :	patient
Middle name :	
_	Recording ID
17-05-20010-01	
Cancel	ОК

Figure 4 New Patient dialog

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

- Patient Details Last Name : Another	_		OK
First Name : 🗛	Middle Name : д	🔽 Male	Edit
Date of birth : 12/02/99	(Format = 01/01/00)		New Save
Patient Ref : 7747477891n			Delete
Address 1 :		_	
Address 2 :	Phone :		
Town:	Comments :		Previous
City :	PMH of transient ischemic Recently was witnessed to	attacks. have what appeared to be a	Next
Region :	GM type seizure		
Country :		_	
Post/Zip Code :			Exit
Recording ID		Search Last Name	

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.

	Vi	ew all signa	als	L	Signal editor					
Name	Туре	Units	Sensitivity	Transducer	DigMin	DigMax	PhyMin	PhyMax	A 🔺	
Air nose	AC	uV	Master	Unknown	-32768	32767	-5000	5000		
Snore	AC	uV	Master	Unknown	-32768	32767	-5000	5000		
Sa02	S02	%	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	υV	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	υV	Master	Unknown	-32768	32767	-5000	5000		
Ch16B	Eeg	υV	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.

	Y	(6: 1 P.	
view all signals			
Properties		IFpi 💽	
Name	Туре	Units	
JFp1	Eeg 💌	u V V	
	Azimuth 90	Longitude 108	-
Display Sensitivity	1		
Master control	Transduce	er AgAgCl	
500uV/Div	Minimum	Maximum	-
	Digital -32768	32767	
Physical Signal producin	Amplitude 5000	uV 5000 uV	
Amplifier Inp	ut Voltage 5mV	+5mV	

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 unchecking 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 <u>Open menu item</u>, 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.

💐 Setup Hardware	EEG channel 🛛 🔀
Amplifier channel =	EEG 5
Assigned signal =	
	Sample Bate
Base sample rate-	
C 256 Hz	200 Hz
Assign	Cancel

Figure 8 EEG setup

	Heco	rang channe	5			Amp	uner Chan	1013;
Channels-					Poly Channels			
Chan.Name	Active	Ref.	Sample Rat	1	Chan.Name	Active	Ref.	Sample Rate
EEG 1	Fp1	Ref	200		Poly 1	None	None	None
EEG 2	Fp2	Ref	200		Poly 2	None	None	None
EEG 3	F7	Ref	200		Poly 3	None	None	None
EEG 4	F3	Ref	200		Poly 4	None	None	None
EEG 5	F4	Ref	200		Poly 5	None	None	None
EEG 6	F8	Ref	200		Poly 6	None	None	None
EG 7	T3	Ref	200		Poly 7	None	None	None
EG 8	C3	Ref	200		Poly 8	None	None	None
EG 9	Cz	Ref	200					•
EG 10	C4	Ref	200					
EG 11	T4	Ref	200		L			
EG 12	T5	Ref	200	T	- Aux Channels			
EG 13	P3	Ref	200		From Granners			
EG 14	P4	Ref	200		Chan.Name	Active	Ref.	Sample R. A
EG 15	T6	Ref	200		Aux 1	None	Gnd	None
EG 16	01	Ref	200		Aux 2	None	Gnd	None
EG 17	02	Ref	200		Aux 3	None	Gnd	None
EG 18	ECG+	Ref	200		Aux 4	None	Gnd	None
EG 19	ECG_	Ref	200		SA02	None	Gnd	None
EG 20	None	None	None	V				
• –			j					

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.

An example of a recording montage is shown below.

🖷 Setup Recording	Channel 🔀
Recorder Channel =	1
Active =	Fp1
Ref. =	Ref
Assign	elete Insert Cancel

Figure 10 Channel setup

	Reco	ording Char	nels]	Amplifier Channels				
Number of Recording Channels = 23 Recording Time per Recording data rate = 33,120 KBytes/hour						er disk = 30.2 hrs Disk size			
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	01	Ref	01-Ref	200	uV	AgAgCl	-32768	32767	
19	02	Ref	02-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	-
	-								
لملك									Ľ.

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.





Кеу		
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

Acquire - on or off

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:

Shows whether the B-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 2^{nd} 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: Impedance 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.

🛋 Tra	
Ele S	
Fp1 Ref	a manufate in which and and and a second share a second sha
Fp2Rel	a more all the stand of the second of the
F3Ref	when any and a second a second and a second as
F4-Ref	in and an interesting the state the second and the second state second and and a second a second a second a second a second as a second a second as a second a
F7-Ref	have a second and the second and a second a se
F8-Rel	le internet and the second of the second and the second of the
C3Rel	a war production and a strand and a strand and the strand and a strand and the st
C4Rel	a well despite the manufalter and a second start of the spite and the second start despite and the second
13Ref	a manufacture and a second and a
14Rel	nature day war and a second and the second and the second second and the second and the second and
15.Rel	was construction of the production of the second and the second and the second second the second second and the
16Rel	have all and the second as a se
P3Rel	a all aparters and a second decomposition of the contraction o
P4-Rel	a real construction and the construction of the second of the
01-Ref	a management and the second and the
02Ref	a man and more thank and the second
FzRel	an and a second of the second and a second of the
CaRel	a norther was a second of the property of the
PaRel	a management and the product of the
A1-Ref	with an unlarge from the second interview in the construction of the second s
A2Rel	a water and the second and the secon
ECG1-R	for a second
ECG2R	and and an and and
Photic G	4
Events	
Patient Tasckit	9 (50%) John Reported 10 : Recording to . 1 December 2010 December 2010

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 checkbox 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.

🕳 Body Pos-G	×
Poly Channel 4 (DC)	🔽 On
Special Channel—	
Display Sensitivity	0.5Hz Lo-filt 💌
2007/1111	30Hz Hi-filt 💌



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

E	EG Channels			Poly Channe	ls
EEG1	Fp1	200.000	Polv 1	FT7(BA)	
EEG 2	Fp2	200.000	Polv 2	FT8(BA)	
EEG 3	F3	200,000	Poly 3	TP7(BA)	
EEG 4	F4	200,000	Poly 4	TP8(BA)	
EEG 5	C3	200,000	Poly 5	29(BA)	
EEG 6	C4	200,000	Poly 6	30(BA)	
EEG 7	P3	200,000	Poly 7	31(BA)	
EEG 8	P4	200,000	Poly 8	32(BA)	
EEG 9	01	200,000		<i>`</i>	
EEG10	02	200,000			
EEG11	F7	200,000	Page	- Sot	imit
EEG12	F8	200,000	Up	380	Larin
EEG13	T3	200,000		-	01/
EEG14	T4	200,000	Page	0	ZK
EEG15	T5	200,000	Down	0	5K
EEG16	T6	200,000		9	10K
EEG17	A1	200,000		9	20K
EEG18	A2	200,000		0	50K
EEG19	Fz	200,000			
EEG 20	Cz	200,000			
EEG 21	Pz	200,000			
EEG 22	Oz	200,000			1
EEG 23	PG1	200,000			Exit
EEG 24	PG2	200,000			

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.

vent	Time	Date 21, 11 0 Joseph	Elapsed	
Nant recording	16:22:20	31/10/2002	00.00:00	-
Patient Event	16:23:44	31/10/2002	00.00124	
GROWN E VOIN	10.23.44	01710/2002	0001.24	
				100

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).

montage	Editor					
м	lontage name: Long	oitudinal				
Channel	,					
Active Fp1	Ref F3	On Master (Control	ecial Sensitivity	Lo filter 0.5Hz Lo-filt 🔽]
Fp1	▼ Ref ▼			OuV/Div 🔽	Hi filter No Hi-filter 🔽]
Upda	ate	Add	Ins	ert	Remove]
Active	Ref	Sensitivity	Lo filter	Hi filter	On	
Active Fp1	Ref F3	Sensitivity Master	Lo filter Master	Hi filter Master	0n On	-
Active Fp1 F3	Ref F3 C3	Sensitivity Master Master	Lo filter Master Master	Hi filter Master Master	On On On	-
Active Fp1 F3 C3	Ref F3 C3 P3	Sensitivity Master Master Master	Lo filter Master Master Master	Hi filter Master Master Master	On On On On	
Active Fp1 F3 C3 P3	Ref F3 C3 P3 01	Sensitivity Master Master Master Master Master	Lo filter Master Master Master Master Master	Hi filter Master Master Master Master Master	On On On On On On	-
Active Fp1 F3 C3 P3 O1	Ref F3 C3 P3 01 T5	Sensitivity Master Master Master Master Master Master	Lo filter Master Master Master Master Master	Hi filter Master Master Master Master Master Master	On On On On On On On	•
Active Fp1 F3 C3 P3 01 T5	F3 F3 C3 P3 01 T5 T3	Sensitivity Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master	On On On On On On On On	•
Active Fp1 F3 C3 P3 01 T5 T3	Ref F3 C3 P3 01 T5 T3 F7	Sensitivity Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master Master	On On On On On On On On On	
Active Fp1 F3 C3 P3 01 T5 T3 F7	Ref F3 C3 P3 01 T5 T3 F7 Fp1	Sensitivity Master Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master Master Master	On On On On On On On On On On	
Active Fp1 F3 C3 P3 01 T5 T3 F7 F7 Fp2	F3 F3 C3 P3 01 T5 T3 F7 F7 Fp1 F4	Sensitivity Master Master Master Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master Master Master Master Master	On On On On On On On On On On On	
Active Fp1 F3 C3 P3 O1 T5 T3 F7 F7 Fp2 F4	Ref F3 C3 P3 01 T5 T3 F7 Fp1 F4 C4	Sensitivity Master Master Master Master Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master Master Master Master Master	0n 0n 0n 0n 0n 0n 0n 0n 0n 0n 0n 0n	
Active Fp1 F3 C3 P3 01 T5 T3 F7 F7 Fp2 F4 C4	F3 C3 C3 01 T5 T3 F7 Fp1 F4 C4 P4	Sensitivity Master Master Master Master Master Master Master Master Master Master Master Master	Lo filter Master Master Master Master Master Master Master Master Master Master Master Master	Hi filter Master Master Master Master Master Master Master Master Master Master Master Master	On On On On On On On On On On On On On	

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

<u>EEG inputs</u>

32 monopolar touchproof inputs		
24 bits		
250 – 16000 Hz		
>20 Mohms		
>100dB @ 50 and 60 Hz		
< 1.5µVpp		
<0.2uV rms		
12 ±0.5%		
750mVpp (including DC)		
0.17uV/bit @ Gain = 12 and Bits = 22		
DC to 4193 Hz max.		
0.4Vpp		
< ±0.3 nA 8mVpp ±5% at 0.98Hz 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 Front-end Calibration Impedance Check current	< ±0.3 nA 8mVpp ±5% at 0.98Hz 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

55 Touchproof 1.5mm
1 Standard 25-pin D socket
2 Jack socket 3.5mm (Channels 39 and 40)
1 Jack socket 3.5mm
1 push-button Impedance Check –
1 push-button Impedance Check +
1 RJ45 socket providing USB port (isolated from patient)
1 Binder 710 series 3-pin socket
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
1 Micro-SD socket
1 type LIR2450 Lithium-ion rechargeable Coin cell

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 ANSI/AAMI ES 60601-1	European standard for medical electrical equipment, general re- quirements and particular requirements for EEG systems. AAMI Deviations from IEC 60601-1 (USA).
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general re- quirements.
IEC 60601-1-2	European standard for medical electrical equipment, EMC require- ments, 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 con-Type BF nected to host system) Type of protection against electrical shock (when con-Optically isolated USB amplifier Mains isolation transformer for PC nected to host system) Degree of protection against harmful ingress Ordinary (no protection) of water Mode of operation Continuous Degree of safety of application in the presence of a Not suitable flammable anaesthetic mixture with air or with oxygen or nitrous oxide

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".

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Patient	10 : Anonymous Patient		Recording 1	: Recording no.1		
Trackit	On-line (USB)	Sample 256Hz, HP:0.1Hz,LF	70Hz Trackit setup		Noor Closed Record OFF	28/01/2010 16:03:26

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.

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Phote-G	nd				
Evente	HV Start			HV Post-HV Start	
Patient	ED : Anonymous Patient On-line (USB)	Sample 256Hz. HP:0.1Hz LP:70Hz	Recording ID : Recording no. 1 Trackit setup	Door Closed Record OF	F 28/01/2010 16:06:35

Figure 21 Hyperventilation

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

🐉 Hyperventilate (Runnin	1g) _ 🗆 🗙
00:01	50
HV Post HV Start Start F	Reset Exit

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	Event No.	Contents	Туре	Size	Total size	Mapping
0	0	No event	Fixed	16 x 16	256	Auto
0	1	Stop recording	Fixed	10 x 10	250	Auto
	2	Stop 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-	Fixed	-		Auto
	-	Mode				
	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-				Auto
		ment				
	35	Trackit connect				Auto
	36	Trackit discon-				Auto
		nect				
	37 - 63	Reserved				Auto
3	64 – 95	?	User-config	32 x 32	1024	Shift F1–8
						Ctrl+Shift F1-
	0.6 1.77				1005	8
4	96 – 159	?	User-config	64 x 64	4096	F12
			(free-text)			
	1	1			1	1

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.

R40 EEG System User Manual

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.

🖪. User ever	its 📃 🗆 🗙		
Key	Event 🔺		
F1	Awake		
F2	Asleep		
F3	Eyes open		
F4	Eyes closed		
F5	Lights on		
F6	Lights off		
F7	Drowsy		
F8	User Event 8		
Shift F1	9		
Shift F2	User Event 10		
Shift F3	User Event 11		
Shift F4	User Event 12		
Shift F5	User Event 13		
Shift F6	User Event 14		
Shift F7	User Event 15		
Shift F8	User Event 16		
Ctrl+Shift F1	User Event 17		
Ctrl+Shift F2	User Event 18 🔹 🗸		
,			

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.

🖪. Print Keyboard E	vent Template						X
	F1	F2	F3	F4	F5	F6	F7
F1-F8	Awake	Asleep	Eyes open	Eyes closed	Lights on	Lights off	Drowsy
Shift F1-F8	9	User Event 10	User Event 11	User Event 12	User Event 13	User Event 14	User Event
Ctrl+Shift F1-F8	User Event 17	User Event 18	*	*	*	*	*
	<pitch< td=""><td>-></td><td></td><td><</td><td>>F4-F5 Gap (if</td><td>any)</td><td></td></pitch<>	->		<	>F4-F5 Gap (if	any)	
•			III				•
Function key pi	itch — J——— 17mm	1		F4-F5 Gap (if any) - J-	2mm	Print	Exit

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. Doubleclicking 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.

Coptions	X
Advanced	
I Comm Port COM8: Blue Edit Notch Filter © 50 Hz Display Preferences ✓ EEG positive down DC positive down	2 3 Patient Database Use Database Recording File Name ✓ Default to Patient Name Factory Settings1 Access Sample Rates ✓ Allow Multi-sample rates
English	Colour options Grid Full ht. Traces
	<u> </u>

Figure 27 Options Tab 1

Options | Tab 2

The second tab in Options is shown below.

Coptions	X
Advanced	
Networking and PC recording	
Auto Trackit connect	
Save event file	
Port 1432	
Trackit auto-record when Host comms. lost	
✓ Use FileLength instead of EdfLength	
Bluetooth	
Allow Guest connection	
j Snow Comm. errors	
Video-	=
Allow Video Resume mode	
And auto-start video recording	
Screen Scaling	
Adjust for 30 mm Apply	
	E <u>x</u> it

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

R40 EEG System User Manual

- Options
Advanced
T XPOD channel name SPO2 (otherwise SAO2)
☐ Startup with Wizard
Remember Wizard position
Creen Width Calibration
J 471mmApply
Default folder for EEG and Video files
C:\Users\Dave 2\Trackit Data Browse
✓ Automatically create patient folder here
Trackit Mk3
 ✓ Use max USB speed ✓ Connect at program launch ✓ Use USB Power
<u> </u>

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	Туре	Length	Manufacturer
USB Interface Ca-	USB	2.8 m	USB shielded ca-
ble			ble
Input electrodes	EEG disc elec-	1 m	Unshielded EEG
	trodes		disc electrodes
Input electrodes	EEG disc elec-	1 m	Unshielded EEG
(E-cap)	trodes		disc electrodes
Nonin XPOD	Shielded	2 m	Nonin
Aux. Connector	Shielded	1 m	Shielded cable
cable			
Patient Event	CM-5	2 m	Zygo
Switch			

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	Group 1	The R-40 uses RF energy only for its internal function. Therefore, its RF
CISPR11/EN55011		emissions are very low and are not likely to cause any interference in
		nearby electronic equipment.
RF emissions	Class B	The R-40 is suitable for use in all establishments, including domestic
CISPR11/EN55011		establishments and those directly connected to the public low voltage
Harmonic emissions	Class A	power supply network that supplies buildings used for domestic pur-
EN 61000-3-2		poses.
Voltage fluctuations/Flicker	Complies	
emissions EN 61000-3-3		

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 ma- terial, the relative humidity should be at least 30%
Electrical fast Transi- ents/burst EN 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is pro- vided by the recom- mended PC equip- ment.	Mains power should be that of a typical com- mercial and/or hospital environment
Surge EN 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is pro- vided by the recom- mended PC equip- ment.	Mains power should be that of a typical com- mercial and/or hospital environment
Voltage dips,short in- terruptions and voltage variations on power supply input lines EN 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is pro- vided by the recom- mended PC equip- ment.	Mains power should be that of a typical com- mercial and/or hospital environment. If the user of the R-40 requires continued operation during power mains interruptions, it is recom- mended 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 environ- ment

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 rec- ommended 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 = $[3.5/V] \sqrt{P}$ = 1.2 \sqrt{P} Note: using unshielded input leads °
Radiated RF Electromag- netic Fields EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = $[3.5/E] \sqrt{P}$: 80 MHz to 800 MHz = 1.17 √P d = $[7/E] \sqrt{P}$: 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 sur- vey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equip- ment 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.

 $^{\rm b}$ 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 out- put power of trans- mitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz d = [1.17/V] √P	80 MHz to 800 MHz d = [1.17/E] √P	800 MHz to 2.5 GHz d = [2.33/E] √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.