USER MANUAL

R40
EEG System

lifelines
neuro

Imagine EEG Anywhere

MADE IN BRITAIN

Version History

V1.0 (24th June 2014)
- Initial release

V1.1 (7th July 2014)
V1.2 (31st July 2014)
V1.3 (18th September 2014)
V1.4 (29th September 2014)
- Various amendments for IEC 60601-1 3rd edition
- Amended Appendix 5 compliance levels.

V1.5 (17th October 2014)
- Added statements and warnings concerning multiple socket outlets to section 2.4
- Added statement that assembly and modification require evaluation to IEC 60601-1 in section 2.

V1.6 (27th October 2014)
- Amended operating temperature for PC in section 2.2

V1.7 (24th November 2014)
- Added caution in section 1.2 'Do not touch simultaneously...'
- Updated picture on front page and minor corrections (5/2/2105)

V1.8 (19th November 2015)
- Added "CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician" on page 8.
- Added "FDA cleared for use in USA" to EEG electrode warning on page 8.
- Amended "Indications for Use" statement on page 8 and deleted "Intended Use".
- Added "Compliance is provided by the recommended PC equipment" to Electromagnetic Immunity tables in Appendix 5.
- Changed EN references to IEC.
- Amended sampling rate and bandwidth specifications.
- Electromagnetic immunity compliance level amended on pages 39 & 40.

V1.9 (27th February 2018)
- Added disinfection information in section 2.6.
- Added device lifetime in section 2.7.
- Change of N.B. to 0086 (BSI).

V1.10 (19 July 2019)
- Updated with new cart design and Lenovo PC
- Software section updated
- EMC warnings and information updated

V1.11 (14 Oct 2019)
- Notified Body change and EC Rep information added.
- Updated with new Cover page and images.

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

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

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

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

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: 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.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the R40 EEG System, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

CAUTION: When in close proximity to the R40 EEG System, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.

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; 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
(When not in Transport Position)

Sitting prohibited

Pushbutton

Nonin Xpod Pulse Oximeter

Manufacturer

European Representative

DC power

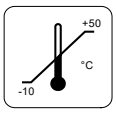
Protective earth (ground)

Equipotentiality

Electrocap

Internal battery hazard –
refer to section 1.7.

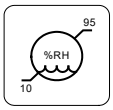
Storage and transport symbols



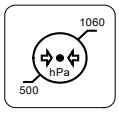
Temperature limits

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 power supply and an optional USB Photic Stimulator and arm. The system is mounted on a special wheeled cart, which houses all components and allows convenient mobility.

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

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
EEG System (Full System)	part number 1396
Cart, adjustable height	part number 1296
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 isolated power supply for PC
Degree of protection against harmful ingress of water	Ordinary (no protection)
Mode of operation	Continuous
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

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.

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

WARNING: The PC must only be connected to the medical-grade laptop power supply supplied or authorised by Lifelines. Do not use the standard, non-medical grade, power supply.
Only use the PC supplied or authorised by Lifelines.

The Setup and Recording Software
The R-40/Trackit setup software runs under Microsoft Windows 2000 (with SP2), Windows XP, Windows Vista, Windows 7, Windows 8.1 or Windows 10 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:

- Setup the input signals. See Section 4.3
- Setup and download the recording template. This includes which electrodes are used and the recording montage. See section 4.4.
- Perform a calibration check of the Amplifier. See section 4.8.
- Perform an Impedance check on the Amplifier. See Section 4.9.
- Perform an EEG recording. See Section 4.5.
- View on-going EEG traces. See Section 4.7.
- Review an EEG Recording. See Section 4.12

1.7 Replaceable parts

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

Internal battery replacement – service personnel only
The 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.

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 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.
4 Check for signs of damage that may have occurred during transit or storage. If any damage is found, do not use the instrument; contact your distributor.

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: All-in-one 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: All-in-one 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

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

- Maximum power: 105 W

- **R-40 Amplifier and Photic (USB)**
  - 5VDC (USB Port)
  - Maximum power: 2.5 W

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. Always use the power lead and connector supplied with the R-40 system, or a lead and connector of equivalent standard.
3. Do not use adaptor plugs or extension leads unapproved by Lifelines.
4. Only appropriately trained and qualified personnel should adjust, maintain or repair this equipment.
5. 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.

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 isolated, medical grade power supply, 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 IEC60601-1-2. 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: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the R40, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

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.), Mikro-Kill disinfectant wipes (Medline Industries, Inc.), Sani-Cloth HB Germicidal Wipes (PD International, Inc).

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

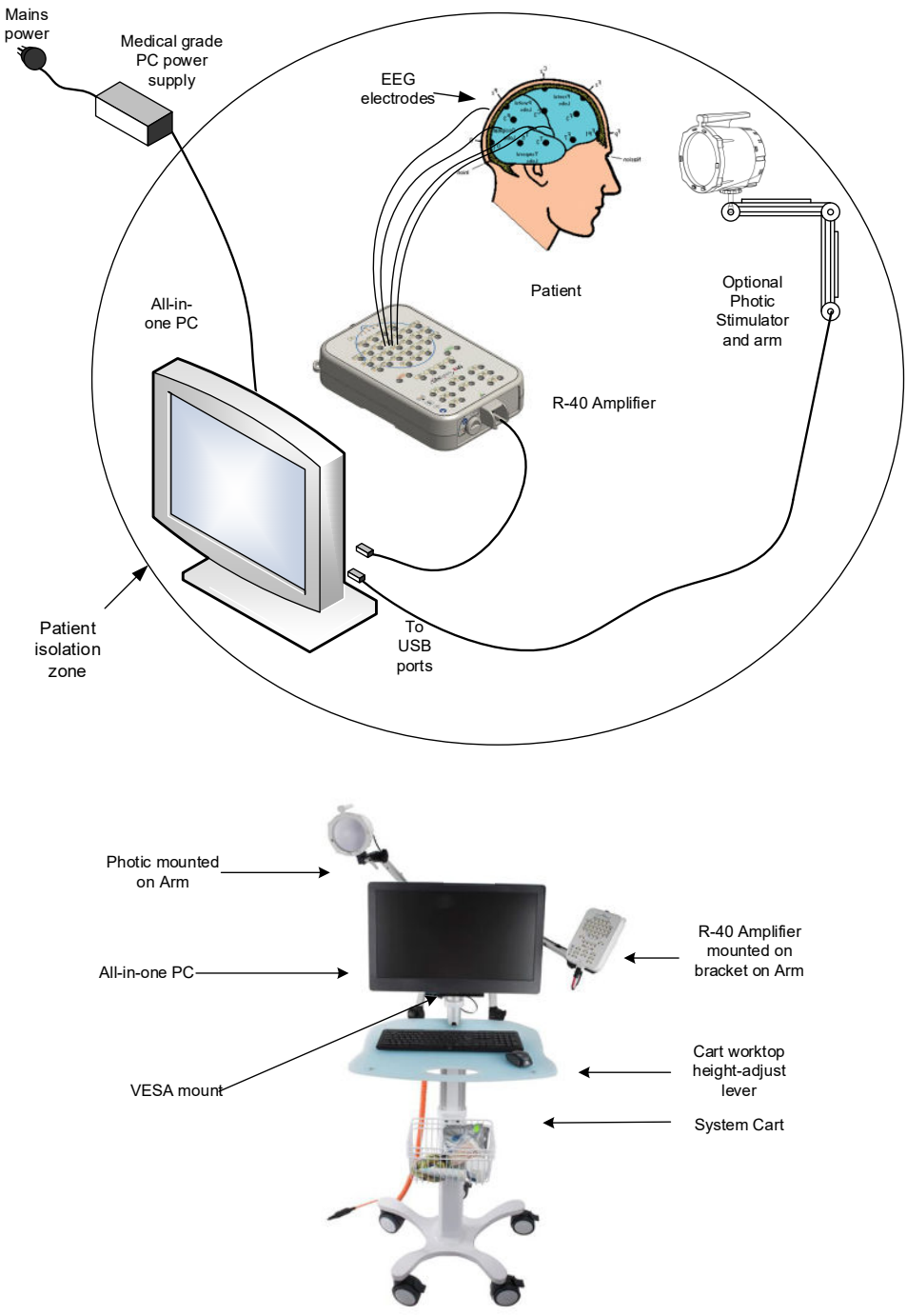


Figure 1 Connecting the R-40 System

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 medical power supply connected to the PC. The current recommended PC is the Lenovo ThinkCentre Tiny All-In-One system.

The PC

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

WARNING: The PC must only be connected to the medical-grade laptop power supply supplied or authorised by Lifelines. Do not use a standard laptop power supply.
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, a medi-rail, VESA display mount and an accessory tray.

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

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

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 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.

When the R40 EEG system is in operation, do not push the cart. Place the cart in the transportation position before moving it.

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.
- Fully retract arms.
- Release brakes.
- Push the cart using the handle on the worktop.

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 additional connections, as shown below.

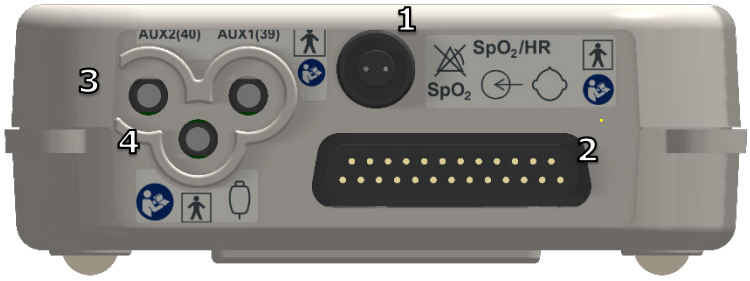


Figure 3 Connecting the R-40 Amplifier (front face)

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.
- Switch on the PC 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 ‘Stop Rec” button 

- Exit the Trackit program.
- Shut down Windows. This will automatically shut down the PC.
- Disconnect the mains supply.

4 Trackit Software - setup and recording software

4.1 Overview

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

The Trackit software is designed to work with both the R40 Amplifier and with the optional Photic Stimulator. The software is supported on Microsoft Windows XP, Windows Vista and Windows 7, Windows 8.1 and Windows 10. The USB drivers will be found on the CD. After connecting the Amplifier to the PC for the first time, at the Windows prompt, browse to the folder *CD Drive*:\USB Drivers. From there Windows will find the correct drivers for the version of Windows being used.

The software has the following functions:

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

The Trackit software has four menu options: File, Home, Settings and Help. Each option provides a Microsoft® style “ribbon” toolbar (see Figure 4 - Figure 7). The default view is the ‘Home’ ribbon.

Figure 4: Trackit Software ‘File’ Toolbar

Key

1 Open EEG file
2 Open EEG videos
3 Refresh playback files
4 Close all review files
5 View Events File
6 Measurement Graticule
7 Prints Screen
8 Video Resume
9 Print Keyboard Event Template
10 Exit Software

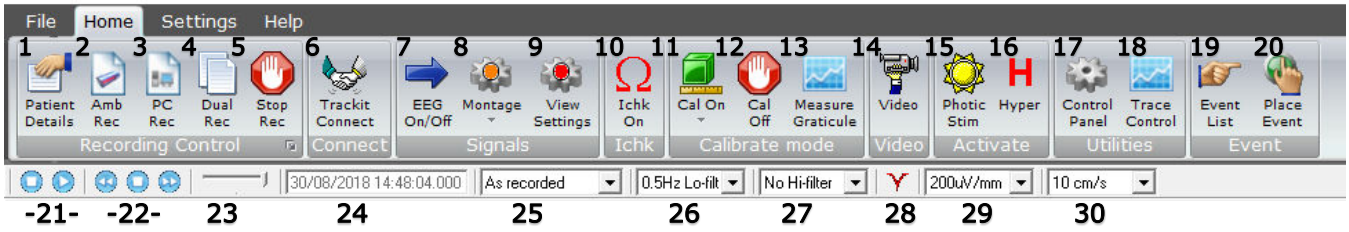
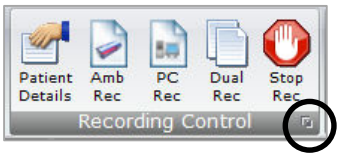


Figure 5: Trackit Software ‘Home’ Toolbar

Key

1 Patient Details	2 New Ambulatory Recording	3 New PC Recording
4 New Dual Recording	5 Stop Recording	6 Trackit Connect
7 EEG Signal Trace On/Off	8 Montage Editor / Montage Select	9 View Settings / Hookup
10 Impedance Check On	11 Calibration On/Amplitude	12 Calibration Off
13 Measurement Graticule	14 Videometry (optional)	15 Photic Stimulation
16 Hyperventilation	17 Trackit Control Panel*	18 Trace control
19 Get Trackit Events	20 Place Manual Event	21 Playback: Stop / Start
22 Paging: Back/Stop/Forward	23 Chart speed	24 Playback time
25 Montage selection	26 Lo-filter selection	27 Hi-filter selection
28 Notch Filter On/Off	29 Vertical sensitivity	30 Chart speed



***** The Trackit Control Panel can also be accessed by clicking on the "Expand" arrow of "Recording Control" group.

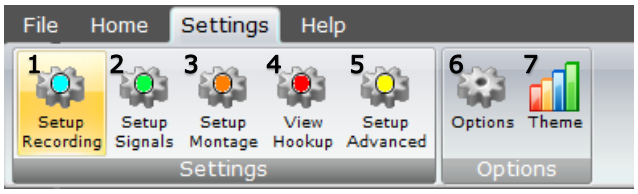


Figure 6: Trackit Software "Settings Toolbar

Key

1 Recording Setup	2 Signal Setup	3 Montage Setup
4 View Amplifier Hookup	5 Advanced Settings	6 Trackit Software Setup options (See Appendix 3)
7 Trackit software colour theme		

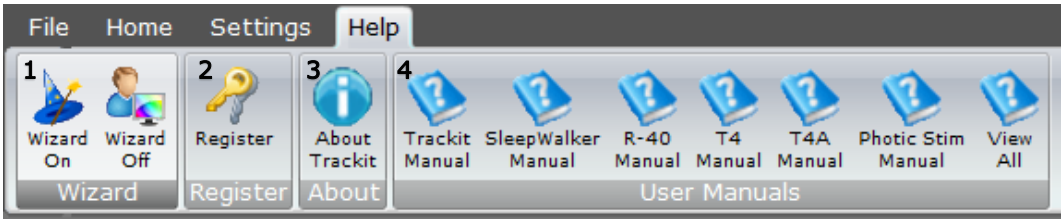


Figure 7: Trackit Software 'Help' Toolbar

Key

1: Wizard On/Off. The wizard guides the user through the recording setup when starting the Trackit software.
2: Software registration.
3: Trackit Software Version information
4: User manuals for various Trackit and Lifelines products.

4.2 Trackit Control Panel

The Trackit Control Panel shows the status of the connected Trackit amplifier and provides quick access to the common functions ("Connect", "Disconnect", "Send Setup" and "Setup Recording").
The Trackit Control Panel can be accessed by clicking on the "Control Panel" Icon in the Home Toolbar or clicking the "expand" arrow of the "Recording control" panel (See Figure 5).

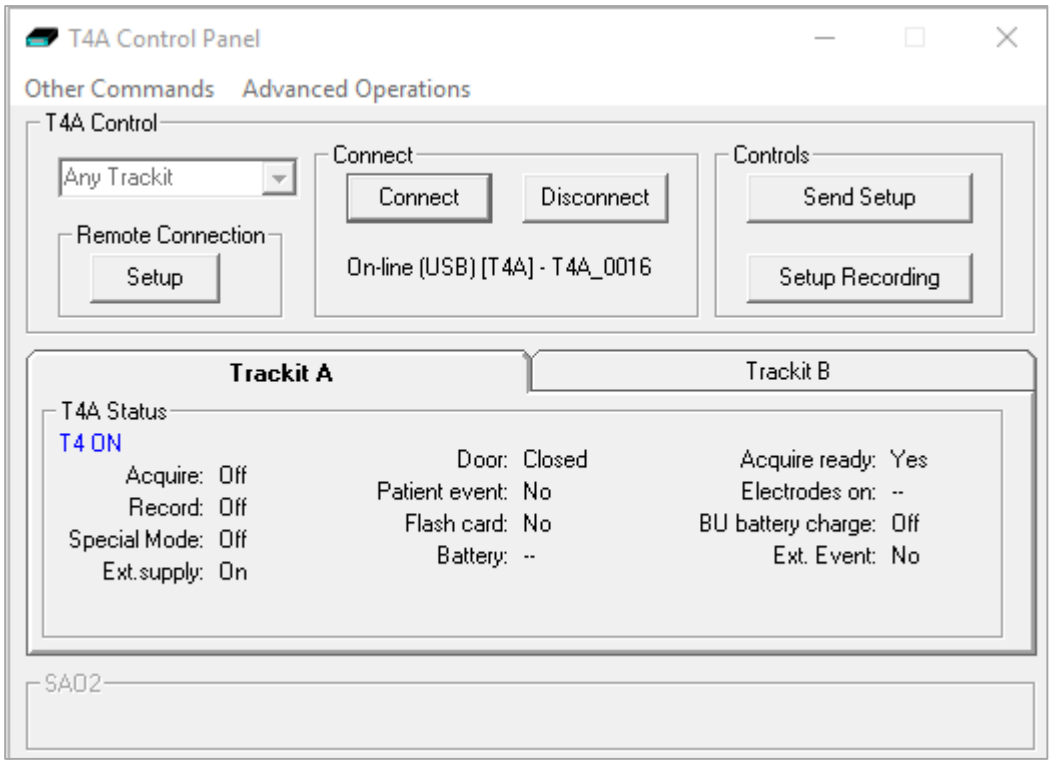


Figure 8: Trackit Control Panel

Connecting the Trackit

The Trackit application software will normally connect automatically to the R40 Amplifier as soon as it is plugged in to the computer via the USB cable.

To connect manually:

1. Open the Trackit Connect dialog box (Figure 9) by clicking on the Connect icon in the Home toolbar (Figure 5) or the Connect button in the Control Panel (Figure 8).

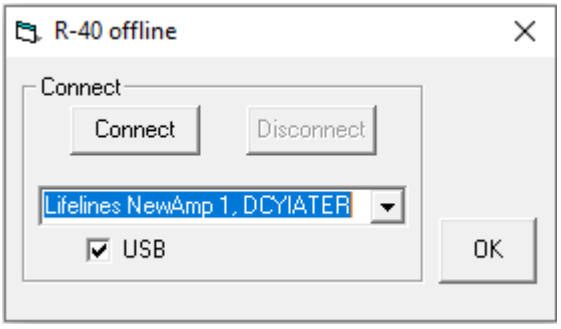


Figure 9: Connect Dialog Box

2. To connect via USB,
    a. Check that the R40 USB cable is connected properly.
    b. Select the “USB” checkbox. The name and serial number of the R40 will appear in the drop-down list. If multiple Trackit amplifiers are connected to the computer, this drop-down will list all the connected amplifier.
    c. Select the correct amplifier (check the amplifier’s serial number) and click on the Connect button.
3. Once connected, Click OK to close the Connect dialog box.

Once connected, the status will show "R40 ON". The Trackit software status bar (at the bottom of the screen) shows 'Online (USB) [R40] – R40_*xxxx*' (for USB connection) or 'Online (*COM Port name)* [R40]' (for Bluetooth connection) and displays the current setup parameters loaded into R40.

The parameters in the Status section shows whether a µSD card is present and the recording status of the device. These parameters are detailed below.

Check Amplifier status

The Control Panel can be used to check that the R40 is online and setup correctly. The "Trackit A" tab of the Control Panel gives you the following status information for the amplifier:

Acquire – on or off	Shows whether the amplifier is acquiring or not.
Record – on or off	Shows whether or not the amplifier is recording data to the SD card.
Special Mode – on or off	Shows whether a special recording mode (timed recording) has been configured
Door	Shows whether the battery compartment door is open or closed.
Patient event	Shows that the patient event marker has been activated (not applicable to R40).
Flash card	Shows whether a SD card is present.
Battery	Shows if the amplifier is running off batteries (not applicable to R40).
Acquire ready	Shows that a valid recording setup has been loaded into the amplifier.
BU Battery Charge	Shows whether the backup battery is being charged.
Ext Event	Shows that the remote patient event marker (via the External Event connector) has been activated.

Further status information is available on the 2nd tab ("Trackit B"). This includes the amplifier's time, Battery capacity, Recording time and SD card total and remaining capacity in (Megabytes (MB)) (see Figure 10).

Controls

The Trackit Control Panel includes two control buttons: "Send Setup" and "Setup Recording".
Clicking on the "Send Setup" button will send the last opened recording setup file to the Trackit. See Section 4.4 for details on setting up a Recording protocol.

The "Setup Recording" button will open the "Recording Control" panel. This allows the user to select the type of recording, and to start and stop a recording. See Section 4.5 for more details.

Menu Options

The Trackit Control panel has two menu options: "Other Commands" and "Advanced Operations". Refer to Section 4.13 Advanced Settings for more details on these options.

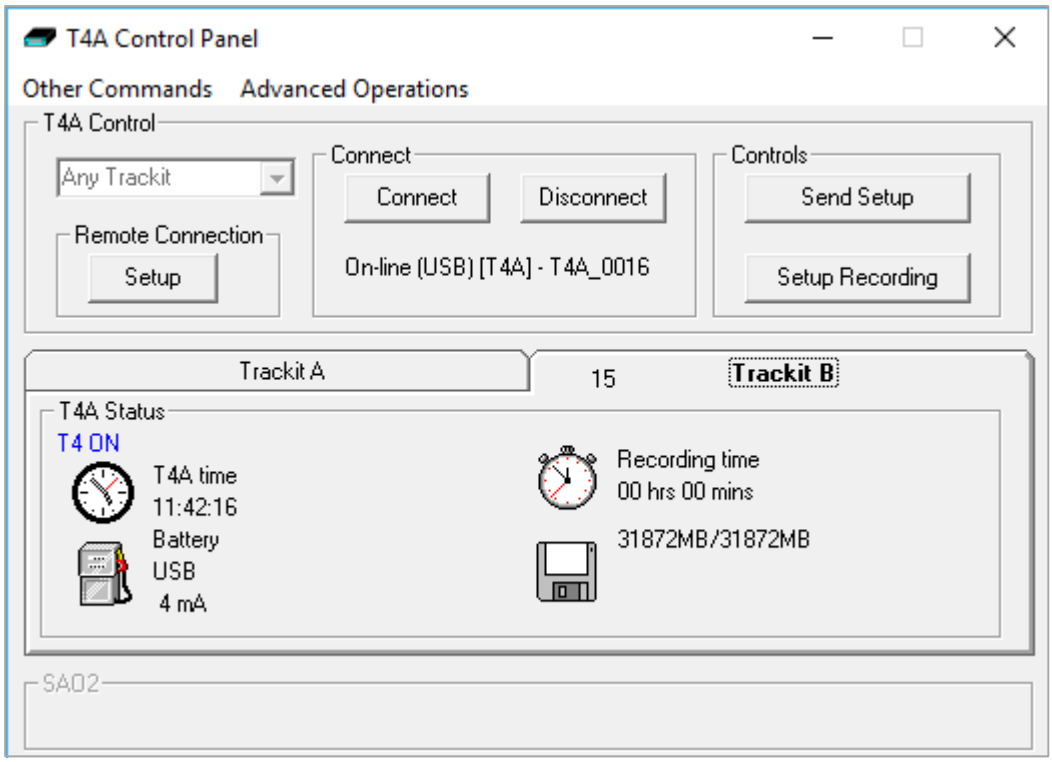


Figure 10: Trackit Control Panel "Status B"

4.3 Defining Input Signals

Defining signals is usually done once only or very occasionally. The R40 Amplifier arrives with a default set of signals that should suffice for most applications, hence it may only necessary to add signal types for poly-graphic recordings (airflow, respiration etc.). Refer to Appendix 6 for default setup.

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 a montage creation. The signal editor allows the creation of up to 256 distinct signals ranging from the standard 10/20 EEG signals such as FP1, O2, to Respiration, Pulse and other polygraphy inputs.

To define a signal:

1 Select on the “Setup Signals” icon in the Settings toolbar.

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

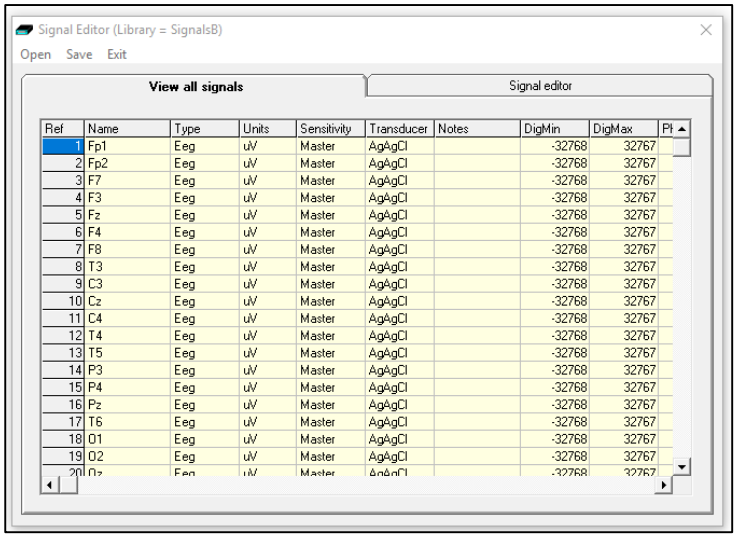


Figure 11: Signal List

3 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.

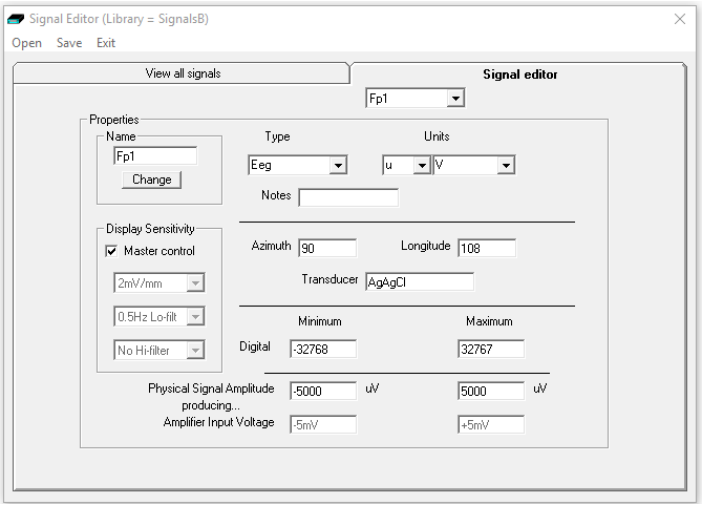


Figure 12: Signal Editing Tool

4 Type in the Signal name (e.g. Fp1). Note that for EEG signals this must be case-sensitive.
5 Select a signal type (in this case EEG).
6 Click on the Change button. The signal is now entered into the list under the View all signals tab.
7 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.

8 The Signals should be saved in a Signals "Library" (*.sl3 file).

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.

4.4 Setting up the Inputs and Recording channels

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. To open a saved setup or to create a new setup, proceed as follows:

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

2 If a pre-saved setup is available then this can be opened directly from the Open menu option (within the Setup Recording dialog box), and the rest of this section can be skipped. Setups are saved in a *.tsu file. If a new setup is being created, proceed as follows:

3 Under the "Amplifier Channels" tab, select the "R40/T4-68/T4-32" checkbox. This will update the channel list with the available channels on the Amplifier. The channel names will also be updated to show the 10-20 mapping on patient connection unit. Note, if the amplifier is online (connected), the checkbox will automatically be ticked and greyed out.

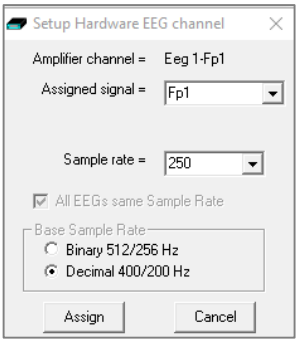


Figure 13: EEG setup

4 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. 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.

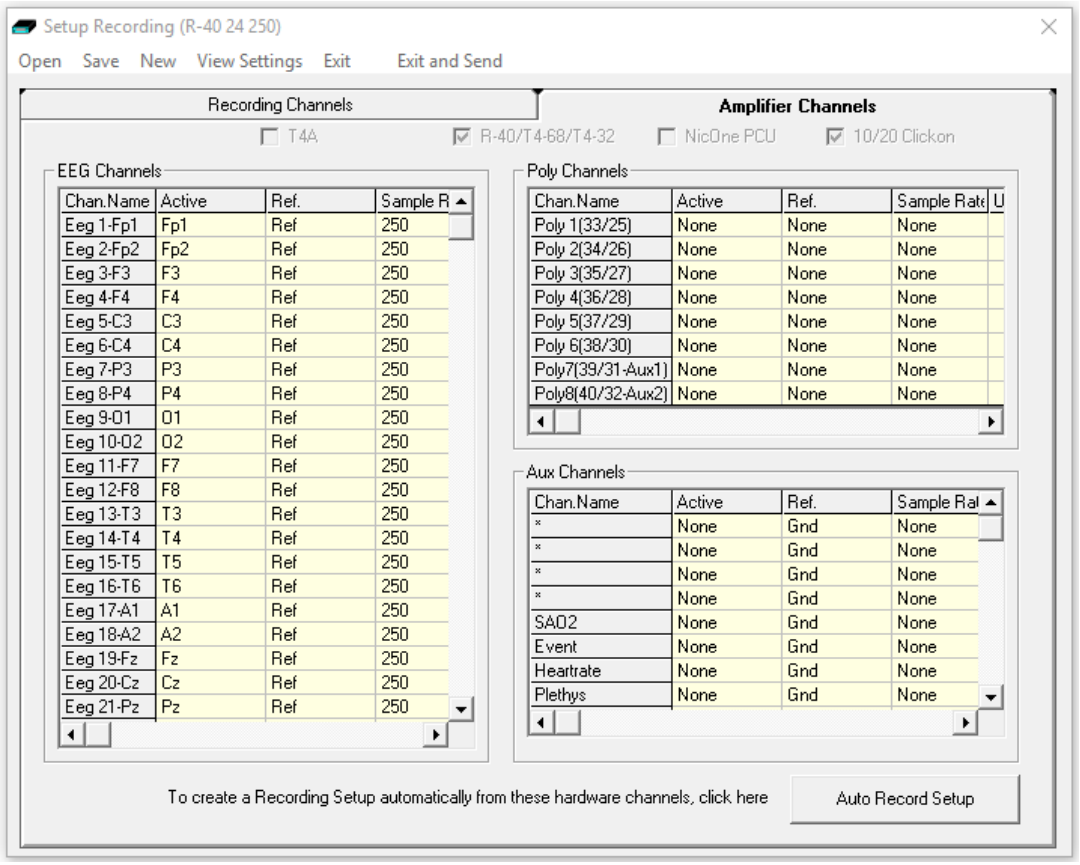


Figure 14: Setup Recording dialog

The Lifelines' EEG Amplifier range supports the following channels.

Amplifier	EEG	Poly	Aux (High level DC)	Event	Nonin SaO2	Heart Rate	Pulse Wave	Trigger input	Light Sensor	Sample Counter
R40	32	8	2	1	1	1	1	1	-	1
T4-32	24	8	1	1	1	1	1	1	1	1
T4-64	64	4	1	1	1	1	1	1	1	1
T4A	28	4	-	1	-	-	-	1	1	1

- Non EEG channels include:
  - Aux – High level DC input
  - Event – Remote patient event thumb switch
  - SaO2, Heart rate & Pulse wave (provided by Nonin module)
  - Trip I/P – Trigger input signal (requires special USB cable)
  - Light sensor I/P – Ambient light sensor on front panel of the amplifier
  - Sample – Special channel which records the EEG sample number.

Channels mark with an asterisk (*****) on the "Setup recording" window are not used on the selected amplifier. Configuring these channels will have no effect on the amplifier.

To use the recording channel order defined in Amplifier setup, click on "Auto Record Setup" button in the Setup Recording dialog box. You can then skip the next step (Define the recording channels).

Poly Channels: 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 a DC Poly input to reflect a required unit of scale for a given voltage input use the signal editor (see Section 4.3). Select the appropriate units, e.g. %, or mm Hg, and enter the Physical Signal Amplitude required to generate the Amplifier Input Voltage.

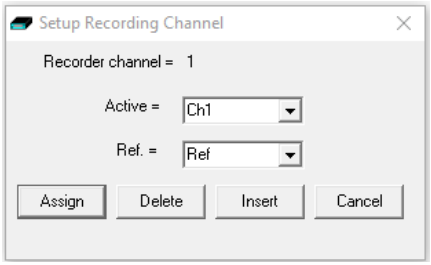


Figure 15: Channel setup

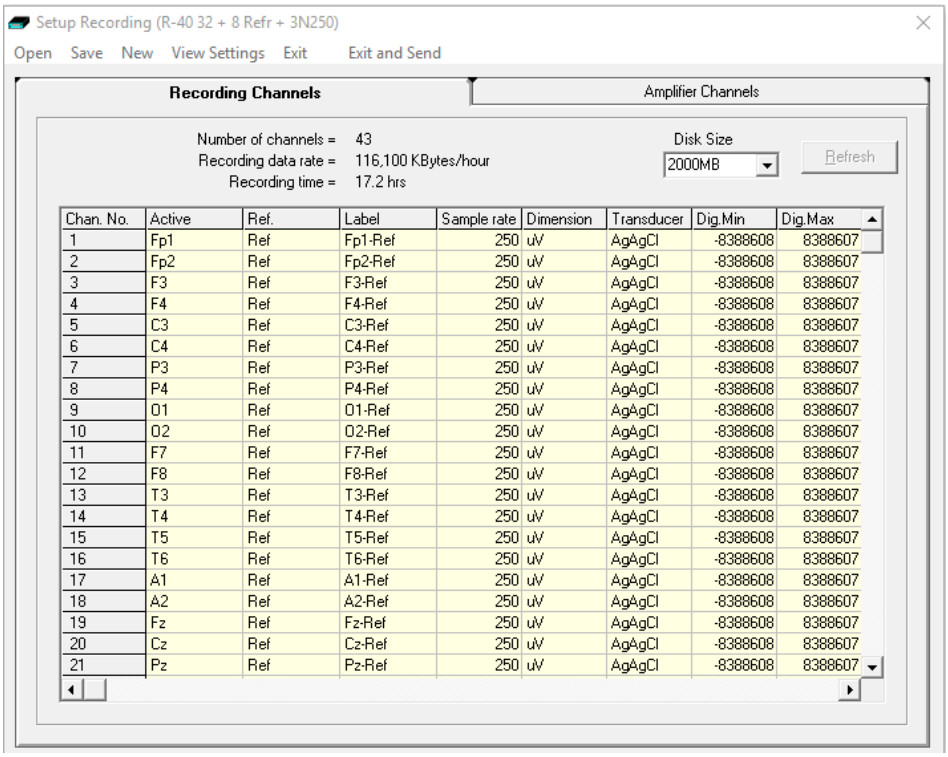
Define the recording channels

This step can usually be skipped, since the Auto Record Setup button will copy what the defined Inputs from the previous step 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.



Chan. No.	Active	Ref.	Label	Sample rate	Dimension	Transducer	Dig.Min	Dig.Max
1	Fp1	Ref	Fp1-Ref	250	uV	AgAgCl	-8388608	8388607
2	Fp2	Ref	Fp2-Ref	250	uV	AgAgCl	-8388608	8388607
3	F3	Ref	F3-Ref	250	uV	AgAgCl	-8388608	8388607
4	F4	Ref	F4-Ref	250	uV	AgAgCl	-8388608	8388607
5	C3	Ref	C3-Ref	250	uV	AgAgCl	-8388608	8388607
6	C4	Ref	C4-Ref	250	uV	AgAgCl	-8388608	8388607
7	P3	Ref	P3-Ref	250	uV	AgAgCl	-8388608	8388607
8	P4	Ref	P4-Ref	250	uV	AgAgCl	-8388608	8388607
9	O1	Ref	O1-Ref	250	uV	AgAgCl	-8388608	8388607
10	O2	Ref	O2-Ref	250	uV	AgAgCl	-8388608	8388607
11	F7	Ref	F7-Ref	250	uV	AgAgCl	-8388608	8388607
12	F8	Ref	F8-Ref	250	uV	AgAgCl	-8388608	8388607
13	T3	Ref	T3-Ref	250	uV	AgAgCl	-8388608	8388607
14	T4	Ref	T4-Ref	250	uV	AgAgCl	-8388608	8388607
15	T5	Ref	T5-Ref	250	uV	AgAgCl	-8388608	8388607
16	T6	Ref	T6-Ref	250	uV	AgAgCl	-8388608	8388607
17	A1	Ref	A1-Ref	250	uV	AgAgCl	-8388608	8388607
18	A2	Ref	A2-Ref	250	uV	AgAgCl	-8388608	8388607
19	Fz	Ref	Fz-Ref	250	uV	AgAgCl	-8388608	8388607
20	Cz	Ref	Cz-Ref	250	uV	AgAgCl	-8388608	8388607
21	Pz	Ref	Pz-Ref	250	uV	AgAgCl	-8388608	8388607

Figure 16: Recording Channel editing

When the Amplifier inputs and recording configuration have been completed, the setup can be saved (in a *.tsu file). If the EEG amplifier is connected and online, the new setup can be sent to the amplifier by selecting the “Exit and Send” menu option. If the amplifier is not connected, the Setup Recording dialog will close, but the setup would not have been sent to the amplifier.

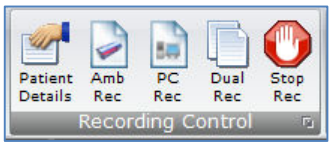
Note: If the Setup file (*.tsu) is to be copied to another PC, the corresponding Signal library (*.sl3 file) must be copied with the setup file. If the signal library is not copied with the setup, any new signals which are not in the default library will not be correctly displayed on the Montage editor.

4.5 Starting a Recording

Before a recording can be started, the required signals need to be defined (see Section 4.3) and the recording channels and montage needs to be set up (see Section 4.4). The preliminary steps are usually only required once. The recording setup can be saved and recalled for future use.

The following steps are the same for setting up an Ambulatory recording (stored on the SD card), PC recording (stored on the computer) or dual recording (PC and Ambulatory).

1. Click on “Patient Details” in the ‘Home’ Toolbar.



2. Enter the patient name and Recording ID into the “Patient Details” dialog box. This information is saved with the recording setup for download to the recorder in a future recording.

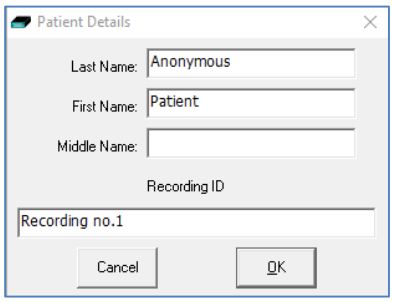


Figure 17: New Patient dialog

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

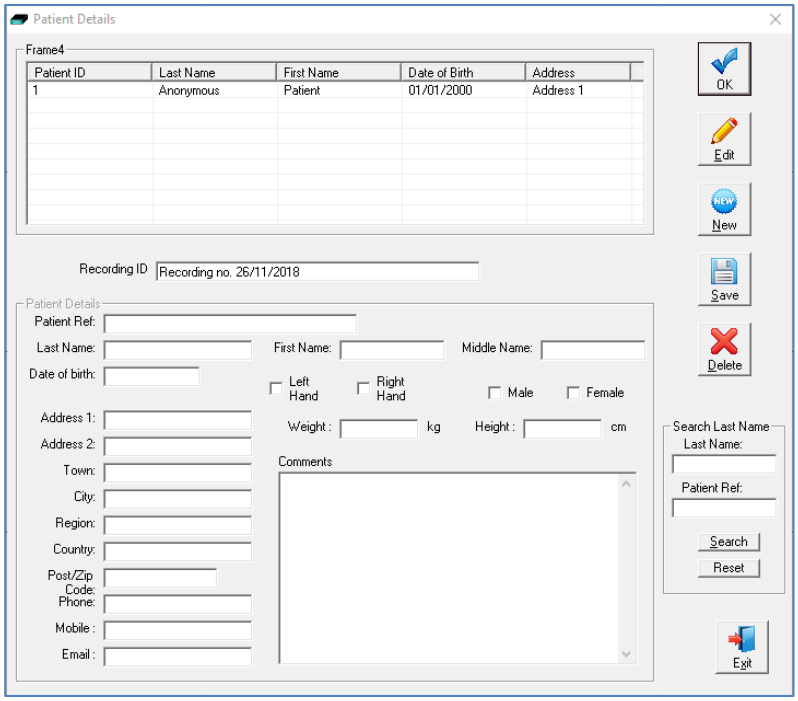


Figure 18: New Patient database

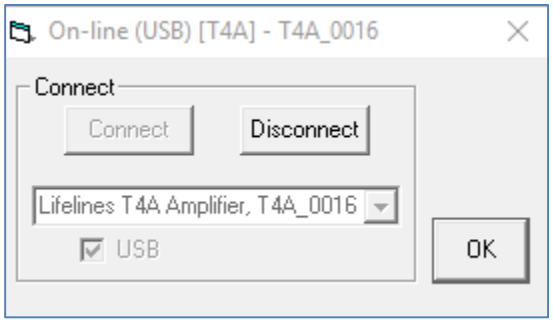
The database allows you to enter more extensive information about the patient and recording, and save it for future reference. See “PC Setup” in Appendix 3.

3. Once the patient details have been entered, click “OK”.

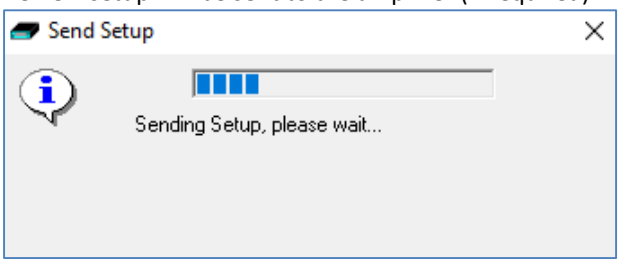
4. Select either the “Amb Rec”, “PC Rec” or “Dual Rec” button from the Home toolbar.
   Note: If the patient details have not been entered beforehand, the Patient Details window (Figure 17 or Figure 18) will appear first.

5. The ”Open Setup” dialogue box will appear; select the Recording setup file (as described in Section 4.4) and click “Open”. To bypass this step and use the setup loaded on the Trackit Amplifier, close this dialog box by clicking the ‘X’ in the top right hand corner.

6. The “Trackit Connect” dialog box will appear next. If the Trackit has not already been connected to the PC, connect via USB or Bluetooth (as described in Section 4.2) and click ‘OK’. If the Trackit is already connected, then just click ‘OK’



7. The new setup will be sent to the amplifier (if required). A warning will appear if this is not successful.



8. The next dialog box confirms if video is to be recorded? Select ‘Yes’ if doing a videometry recording.

9. The Recording Control panel (Figure 19) will appear.
    a. Select the Record mode (default mode is ‘Immediate’).
    b. Enter the desired file name for the recording file name.
    c. Confirm the SD card is ready by clicking “Check disk”
    d. Click Start to start the recording.
    e. The recording configuration will be sent to the amplifier. This may take a few seconds as the amplifier may need to prepare the SD card.
    f. The Recording Control panel will close if the recording started successfully.

    Refer to Section 4.6 for a description for recording options in the Recording Control panel.

10. After the recording has started, the following actions can be performed:
    a. View EEG Signal Traces (see Section 4.7)
    b. Perform a Calibration check (see Section 4.8)
    c. Perform an Impedance Check (see Section 4.9)

4.6 Recording Control Panel (Amplifier recording)

The Recording Control panel provides additional options when recording to the memory card on the amplifier. These options are not applicable when performing a PC recording. Click on the ‘Setup Recording’ button in the Trackit Control Panel to open the Recording Control dialog box (Figure 19). The Recording Control panel is also displayed by pressing the “Amb Rec” or “Dual Rec” button on the Home toolbar.

The patient’s name and the default file name for the recording are displayed. The default file name can be changed to a custom filename (up to 8 characters in length).

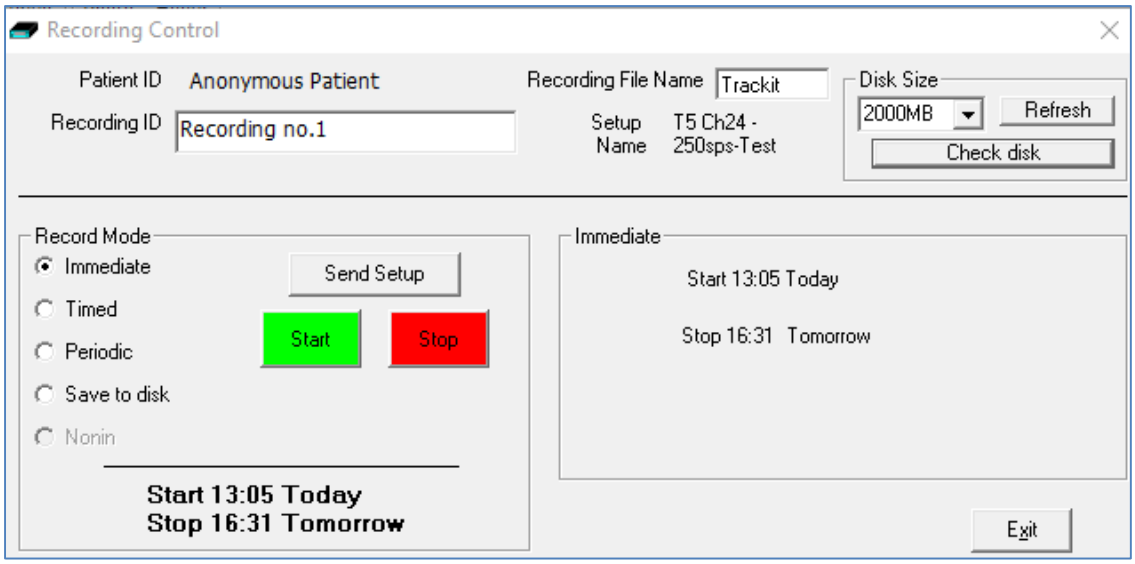


Figure 19: Recording Control panel

Default file names

To make the recording file name the same as the patient name:

1 Choose 'Options' from the Settings toolbar.
2 Put a checkmark by "Default to Patient Name" option.
3 Click on Exit.

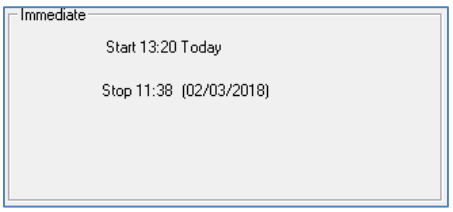
Recording modes

There are multiple ways to start a recording:

- Immediate
- Timed
- Periodic
- Save to Disk
- Nonin

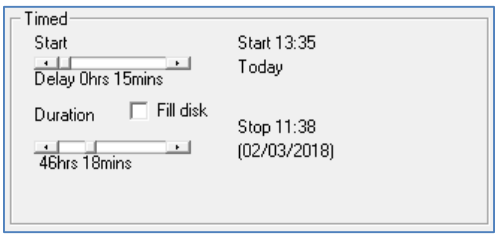
Immediate: the recording starts as soon as the Start button is pressed (Figure 19). Recording finishes when the Trackit is turned off, when the disk is full or when the recording is stopped.

1 Under Record Mode, choose Immediate.
2 Click the Send Setup button, then the Start button

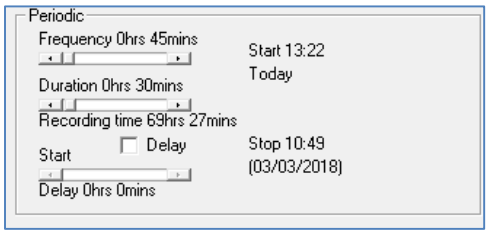


Timed: The Trackit amplifier records for a specified period of time.

1 Under Record Mode, choose Timed.
2 In the Recording Control dialog box, set a start time to start the recording, using the Start slider.
3 Either put a checkmark by 'Fill Disk', or use the Duration slider to set the recording duration.
4 Click the Send Setup button, then the Start button.

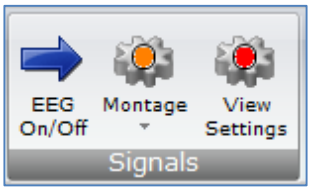


Periodic: The Trackit Amplifier records for specified periods of time at a defined interval (e.g. for periods of 30 minutes, with a 45-minute interval):



1 Under Record Mode, choose Periodic.
2 Use the frequency and duration sliders to define the length of the recording period, and the interval between periods.
3 For a delayed start (e.g. in an MSLT study), put a checkmark by the Delay box, and use the Start slider to set a start time for the recording.
4 Click the Send Setup button, then the Start button.

4.7 View EEG Signal Traces



To view the EEG signal traces at any time, whether recording or not, click on the "EEG On/Off" icon in the Home toolbar.

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

- If the amplifier 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 amplifier has not been sent a setup from the PC, the system asks for the recording setup held in the amplifier before displaying the traces.

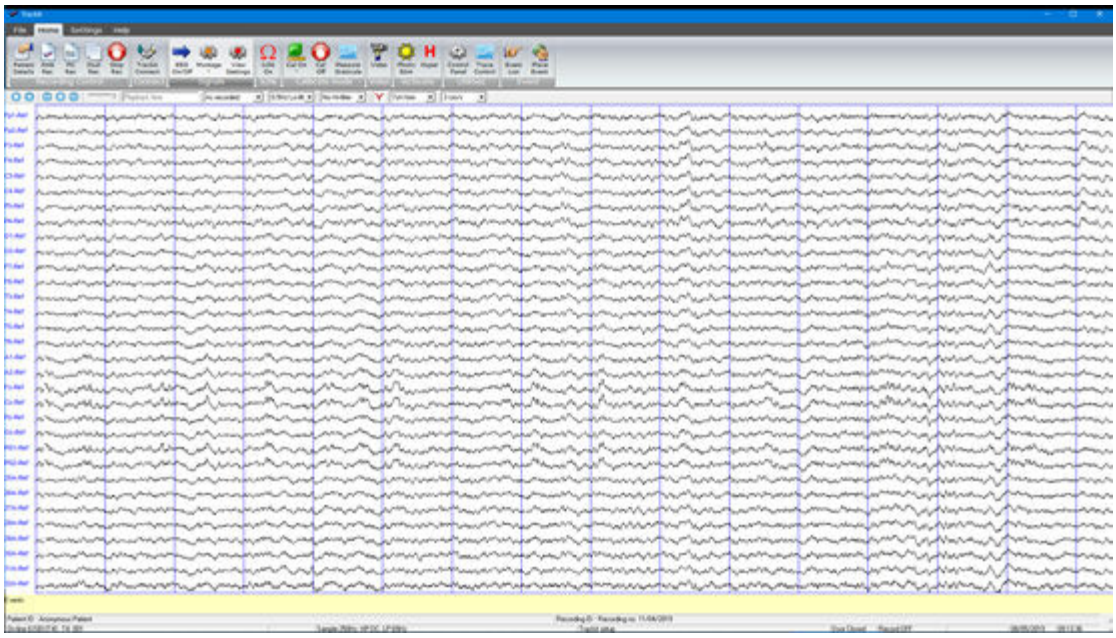
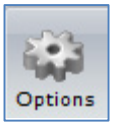


Figure 20: EEG Signal trace display

Notch filter: to set a notch filter, open the Trackit 'Options' window from the Settings toolbar. 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.

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 (see
Figure 5).

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.

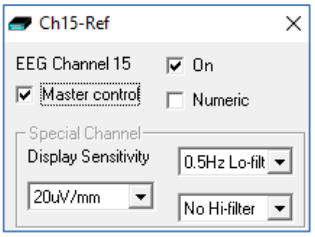
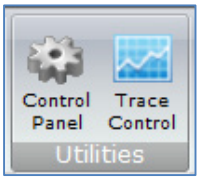


Figure 21: Adjust display parameters

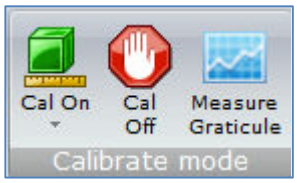
Number of displayed traces
The "Trace Control" icon provides the ability to adjust the number of displayed traces to 1, 4, 8, 12, 16, 24, 32 or all traces.

The 'Superimpose On/Off' option (under the Trace Control menu) will super-impose all the traces on top of each other. This is useful when checking DC offset and noise measurements.



When the number of displayed traces is less than the total number of recording channels, the "Trace Page Down" and "Trace Page Up" functions will cycle through all the available traces.

4.8 Calibration Check



To perform a Calibration check, whether recording or not, click on the Cal On icon on the 'Home' toolbar. Calibration check is turned off by pressing the 'Cal Off' icon.

Calibration check will start the acquisition and ongoing traces if not already active. The waveforms will show a square wave of amplitude 8mV pk-pk and frequency 1 Hz. The amplitude can be set to 8mV, 2mV, 500µV and 125µV by clicking on the down arrow on the 'Cal On' icon.

4.9 Impedance Check

An Impedance check can be performed on the EEG inputs, whether recording is active or not. To perform an Impedance Check click on the 'Ichk On' icon on the Home toolbar. This will start the Impedance Check on the amplifier and the Impedance Check panel will be displayed (Figure 22).

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 an orange background. Values below (pass) are displayed on a green background. Impedance Check is not performed on channels configured in bipolar mode and a value will not be displayed for these channels. The threshold can be set to 2kΩ, 5kΩ, 10kΩ, 20kΩ or 50kΩ on the Impedance Check panel.

The "View signals" option will start the ongoing traces display.

Clicking on 'Exit' will stop the Impedance check on the amplifier. Clicking on "Exit with Continuous Imp Check On" will close the Impedance check panel but leave the amplifier in Impedance check mode. The ongoing trace display will resume and the channel names of the channels which exceed the set limit will flash orange (see Figure 23).

Continuous Impedance Check can be cancelled by starting or stopping Ongoing EEG traces (EEG On/Off).

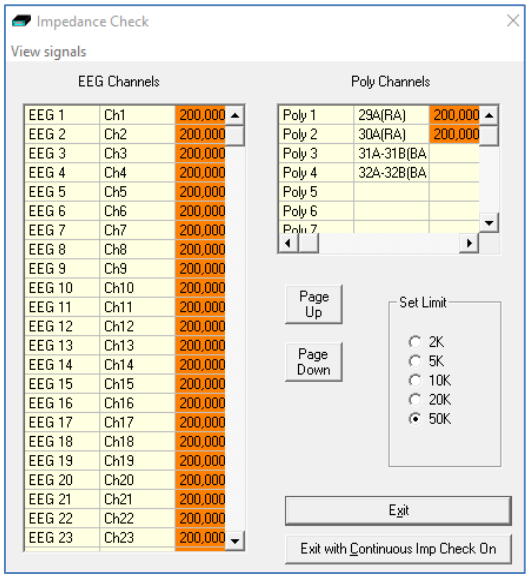


Figure 22: Impedance check

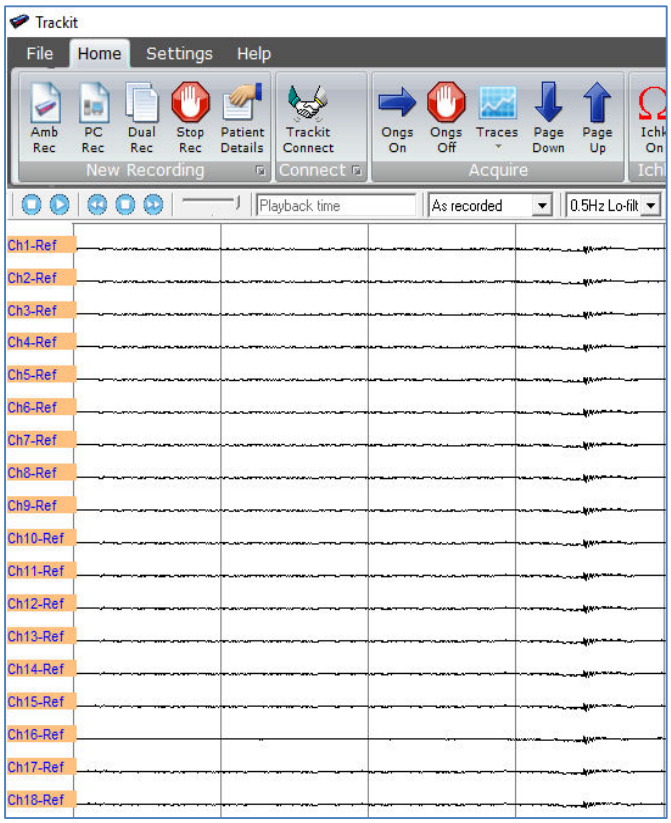
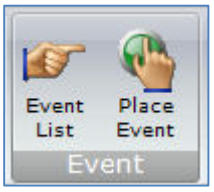


Figure 23: Continuous Impedance Check

4.10 Events

To view all recorded events in the recording online, click on the “Events List” icon in the Home toolbar.



Events are displayed in the Event viewer (Figure 24) with a description and time.

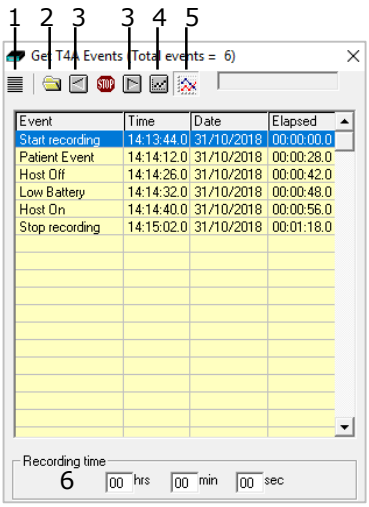


Figure 24: Event Viewer

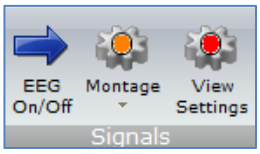
Key:
1 Opens the list of event types

Icons 2-6 are not used.

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.

4.11 Montage Editor



The Montage Editor is accessed by clicking on the “Montage” on the Home toolbar, which displays the Montage Editor as shown in Figure 25, below.

The Montage Editor allows the setting-up of 16 user montages and the As-recorded montage. The Montage Editor shows the location of the signals on the brain. Refer to Section 4.3 for details on defining the signal location.

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, selected on the brain image, or typed in directly.
2. Ref. channel name. This is either chosen from the drop-down list representing the current Signal Library signals (including Ref and Gnd), selected on the brain image, 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.  (Up). Selects the previous channel on the list
6.  (Append). This adds a channel to the end of the Montage list.
7.  (Remove). This removes the currently selected channel.
8.  (Insert). This insert a channel above the currently selected channel.
9.  (Down). Selects the next channel on the list
10. 

(Update). Copies the current settings into the currently selected channel.
11. Montage name.

To change an Active or Ref channel on the brain image;

1. Select the designed channel on the list (or add/ insert a new channel).
2. Click on the current Active or Ref signal on the brain (Active signal is coloured Red, Ref signal is coloured green),
3. Click on an unused signal. The selected signal shall change to the appropriate colour. If the desired signal is in use (coloured red or green), this signal must be un-assigned first.
4. Click Apply

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).

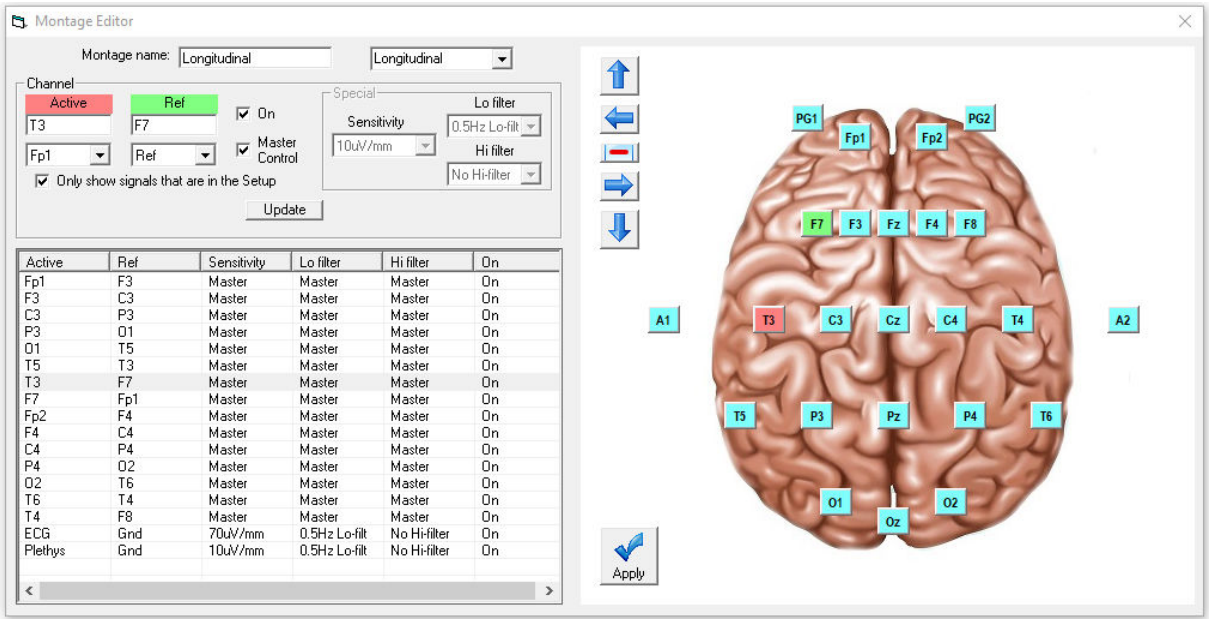
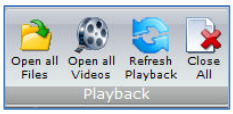


Figure 25: Montage Editor

4.12 Reading an EEG recording



Click the 'Open all files' button on the File Toolbar in the Trackit software to playback a recording and browse to the folder and file required. This will open the EDF/BDF 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/BDF file, 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 BDF-compatible viewer can be used to read the 24-bit BDF files recorded by the amplifier.

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

Lifelines currently recommends:

- Lifelines iEEG
- StratusEEG
- Lifelines Trackit Plus Software
- Persyst Insight EEG

4.13 Advanced Settings

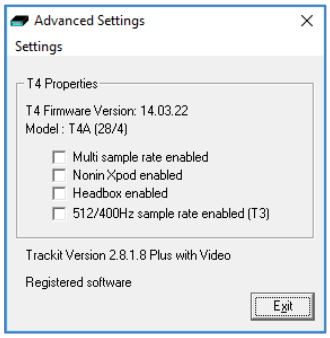
There are two menus under the Trackit Control Panel:

- Other Commands
- Advanced Operations

Other Commands

By default, these options are greyed out as they are not available to the typical user.
Other Commands duplicates some of the controls on the home toolbar and recording control. There are also miscellaneous controls for:
Set Trackit Time/Date: if the amplifier is not recording, this manually sets the amplifier's time and date to that of the PC. Note: this function is normally done automatically when recording is started.
Get Trackit Set-up: this manually retrieves the setup from the amplifier's memory and overwrites the currently loaded setup on the PC. Note: this function is normally done automatically whenever the software detects a mismatch between the amplifier's setup and the PC setup.
Quiet On: Not supported on the R40.
Quiet Off: Not supported on the R40.

Advanced Operations



Advanced Operations contains entries, some password-protected, that change the way the amplifier records its data. These settings include:

- Compensation for DC offsets
- Adjusting the idle and record time
- Enabling Auto start mode
- etc.

To see the available options under Advanced Operations:
1 Open on the Trackit Control Panel.
2 Click on Advanced Operations.
3 Click on Settings.

Set Trackit Defaults

[> Advanced Operations > Settings > Set Trackit Defaults]

Caution: please read the manual carefully before changing or updating the Trackit Defaults. If you want to enable auto-start from flash card or append features, make sure all the checkboxes in Trackit Defaults are checked.

Defaults Tab 1

This menu item activates a control dialog that adjusts how the amplifier behaves during a recording. Most options are not applicable to the R40. See Figure 26.

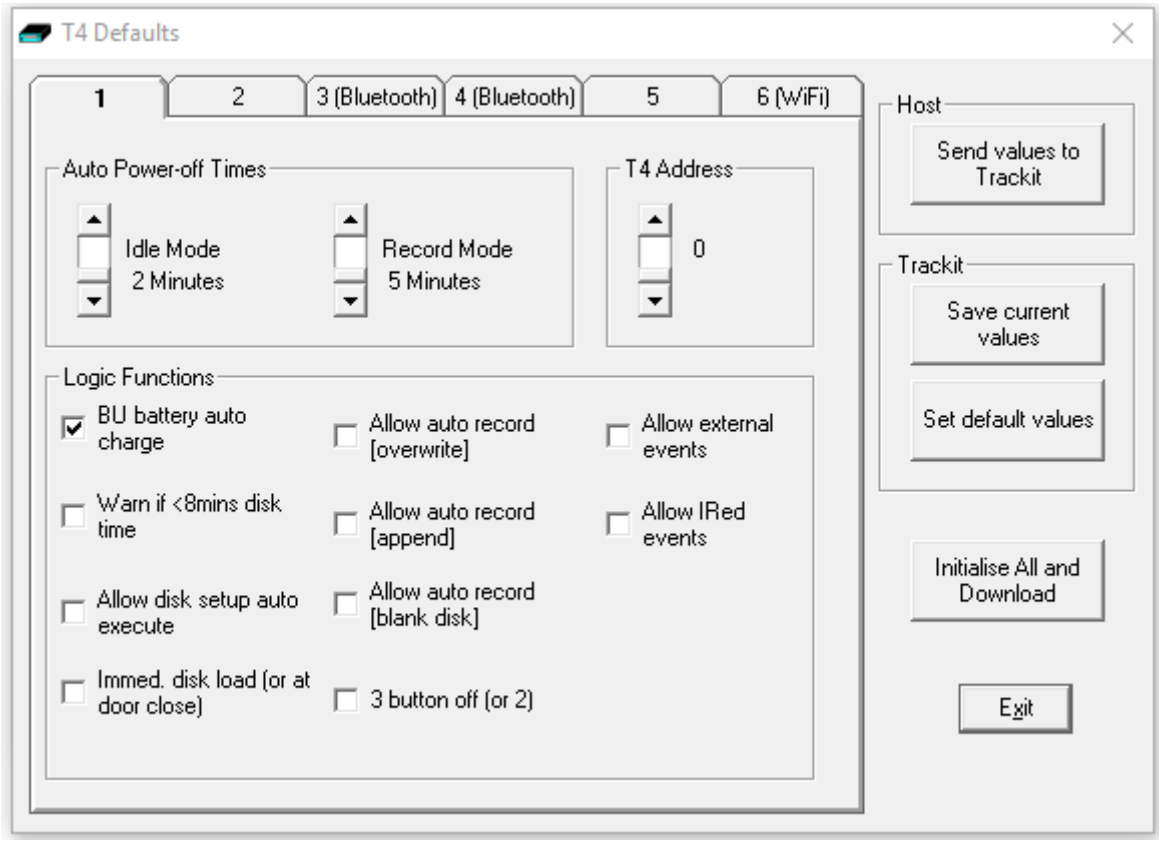


Figure 26: Defaults Tab 1

To save new defaults to Amplifier, press 'Send these values to Trackit', followed by 'Save current values'.

The following functions are supported:
Idle Mode: Amplifier turns itself off after a defined period when connected to a PC.

Record Mode: Not applicable on the R40

Trackit Address: sets the serial address of the amplifier. Not used on the R40.

BU battery auto charge: enables fast-charging of the backup battery when the amplifier is connected to USB or USB power bank.

Warn if <8 mins card time: Not supported on the R40.

Allow card setup auto execute: Not supported on the R40.

Allow auto record (overwrite): Not supported on the R40.

Allow auto record (append): Not supported on the R40.

Allow auto record (blank card): Not supported on the R40.

Allow external events: Not supported on the R40.

Allow IRed events: Not supported on the R40.

Immed. card load (or at door close): Not supported on the R40.

3 button Off (or 2): Not supported on the R40.

Defaults Tab 2
Additional setup parameters are accessed via tab 2 of Defaults panel, as shown in Figure 27 below.

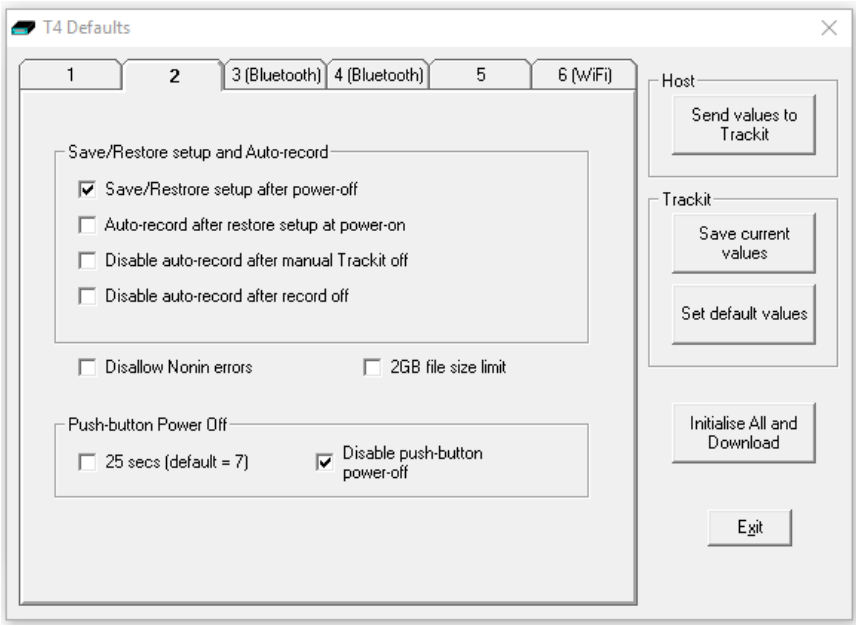


Figure 27: Defaults | Tab 2

Save/Restore setup and Auto-record

The amplifier is able to save its entire Setup before powering-off. When next powered-on, this Setup can be restored.

- **Save/Restore setup after power-off.** When checked, this enables the Amplifier to save the entire Setup including Patient Name and Recording ID after power-off and recall it at power-on. Note that the Patient Name and Recording ID are only retained for 15 minutes after power-off (refer below).
- **Auto-record after restore setup at power-on. (Not supported on R40)** When checked, this enables the Trackit Mk3 to continue recording if it was recording the last time is was powered-off, using the recalled Setup and Patient Name and Recording ID, but only if it has been powered-off for 15 minutes or less. If the Trackit Mk3 has been powered-off for longer than 15 minutes, then the Patient Name and Recording ID are overwritten with defaults (the current Setup remains). Note that the parameter above must also be checked to use this feature.
- **Disable auto-record after manual Trackit off. (Not supported on R40)** When checked, this causes a potential Auto-record situation to be cancelled whenever the amplifier is powered-off either from its own front-panel pushbutton or from the Host.
- **Disable auto-record after record off. (Not supported on R40)** When checked, this causes a potential Auto-record situation to be cancelled whenever the Hosts instructs the amplifier to stop recording.

Disallow Nonin Errors
Not supported on the R40.

2GB File size limit
When checked, the maximum recording file size to the SD card will be 2GB. When unchecked the maximum recording file size will be 4GB.

Push-Button Power Off
Not supported on the R40.

Get Card Info

[> Advanced Operations > Settings > Get Card Info]

Selecting Get Card Info opens a dialog showing the current status of the flash card, including the file name and any error codes ('Disk OK' is displayed to indicate a properly functioning card). Should any problem occur with the flash card, copy and paste this dialog and send it to your Lifelines distributor.

Note: The R40 does not support card formatting. The SD card should be formatted on a PC using the recommended SD card formatting software.

Factory Settings

[> Advanced Operations > Settings > Factory Settings]
Factory settings are protected by a password (via Options in the Settings toolbar). Only trained support staff should have access to factory settings.

Factory settings also allow you to compensate for any DC offsets that may be present on any of the recording inputs and save the values in the amplifier's non-volatile memory.

Configuration

[> Advanced Operations > Settings > Configuration]
Configuration gives access to the amplifier's factory configuration. The code displayed can be copied and emailed to Lifelines for an activation code to be sent back.

Backup battery charge ON / OFF

[> Advanced Operations > Settings > Backup battery charge ON]
[> Advanced Operations > Settings > Backup battery charge OFF]
These commands will turn the backup battery charger on and off.

Trackit OFF

(Not supported on R40)
[> Advanced Operations > Settings > Trackit OFF]
Turns the amplifier off. Note: Communication to the host PC will be lost.

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 isolated 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 an-aesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Medical Grade Power Supply Specifications

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

Lenovo ThinkCentre All-in-One PC Specifications

Safety and Regulatory Standards	IEC/EN60950-1
EMC	EN55032/CISPR 32 and FCC Part 15 Class B
	EN55024/CISPR 24
	EN61000-3-2 and EN61000-3-3
	EN 62311
Input voltage	20VDC
Power	90 W
Size	385 x 539 x 251 mm
Weight	6.8 kg

Lifelines Photic Stimulator

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

Appendix 2: Photic Stimulator and Hyperventilation

Photic Stimulation

An optional Lifelines Photic Stimulator is available which can be used with the 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”.

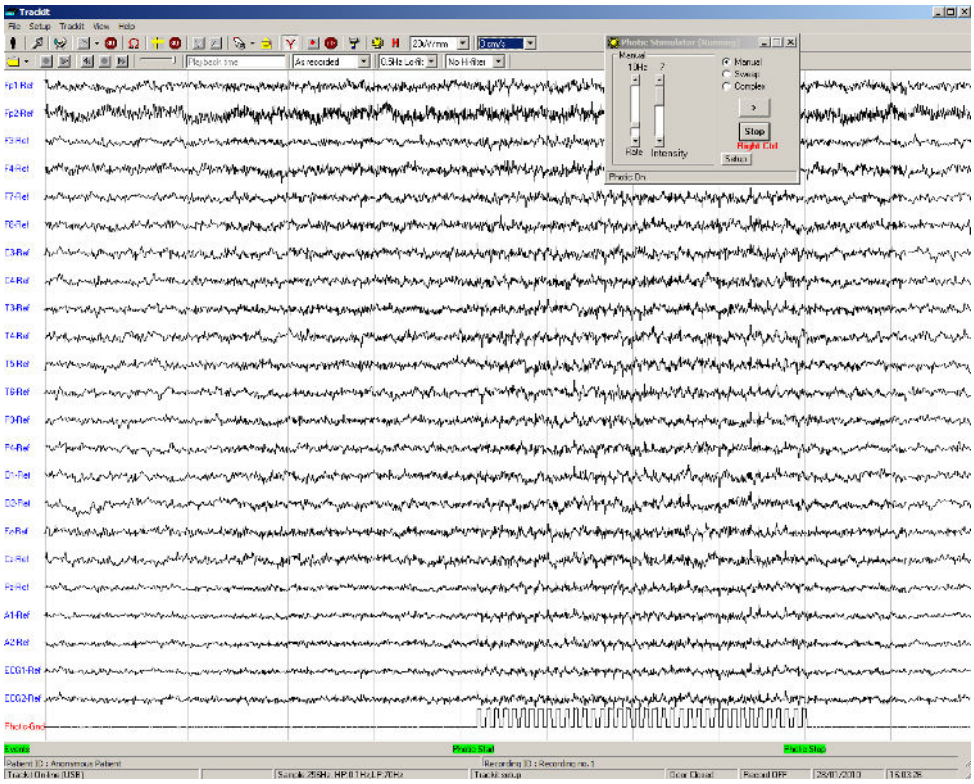


Figure 28 Photic Stimulation

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

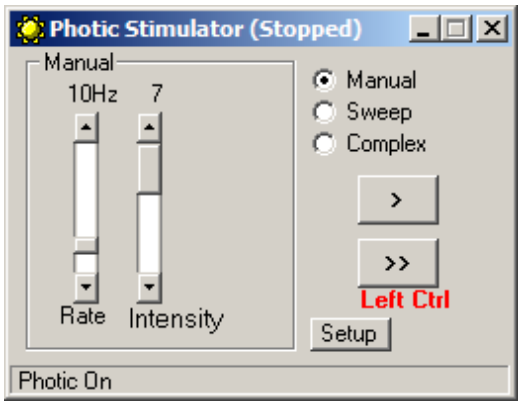


Figure 29 Photic Stimulation control window

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.

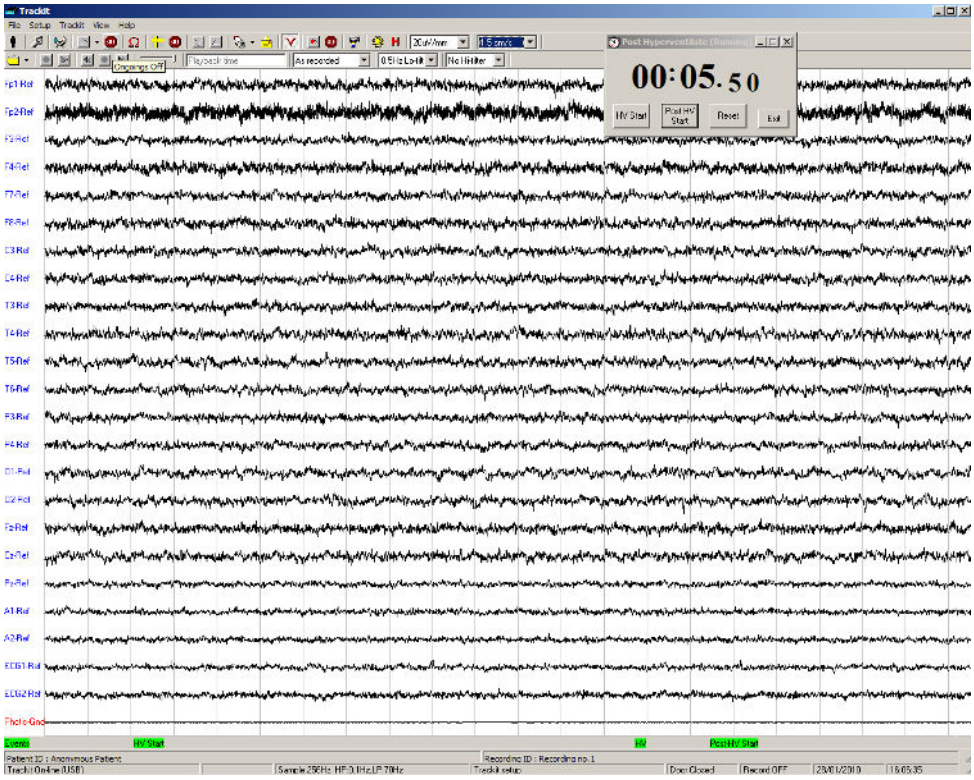


Figure 30 Hyperventilation

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

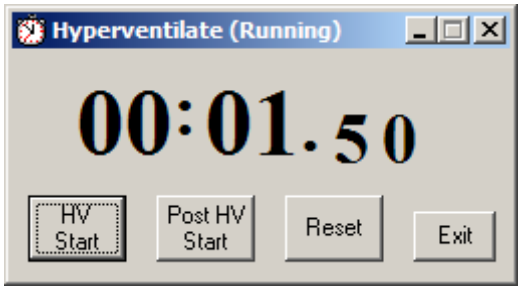


Figure 31 Hyperventilation control window

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.CheckMode	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 movement				Auto
	35	Trackit connect				Auto
	36	Trackit disconnect				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 re-stored 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.

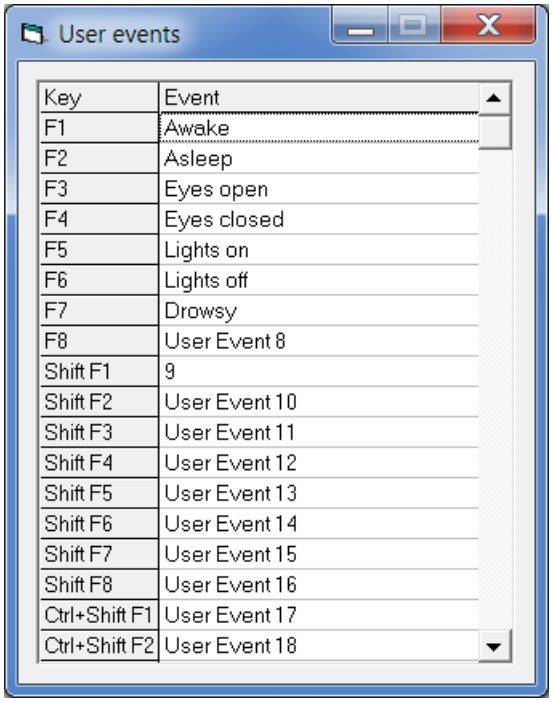


Figure 32 User Events

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.

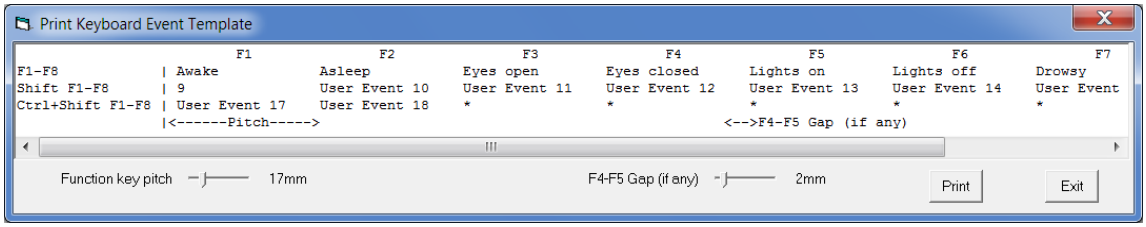


Figure 33 Events Template setup

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.

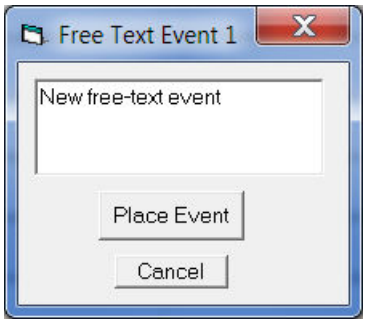
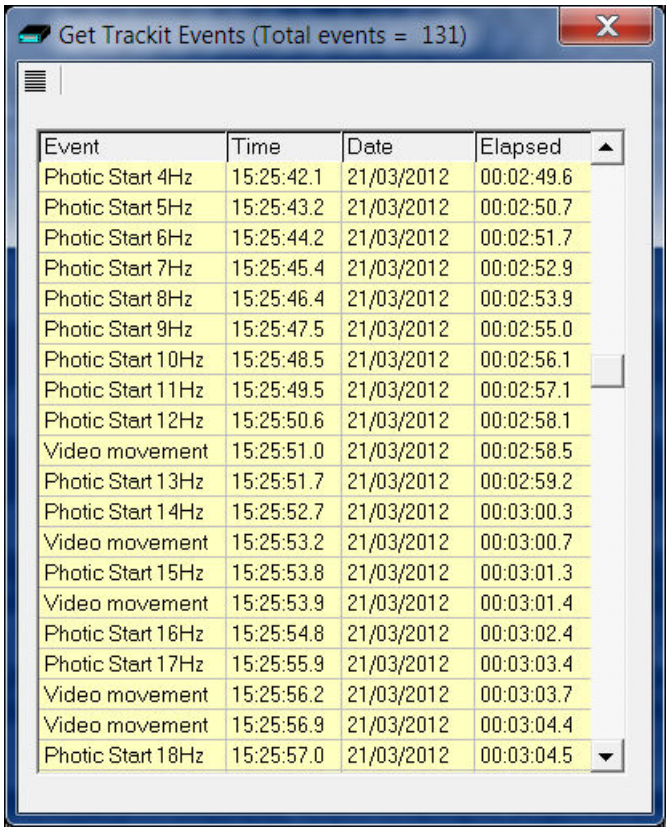


Figure 34 Free-text Event

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 chrono-logical 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 35 Event List

Appendix 4: PC Setup

Options | Tab 1

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

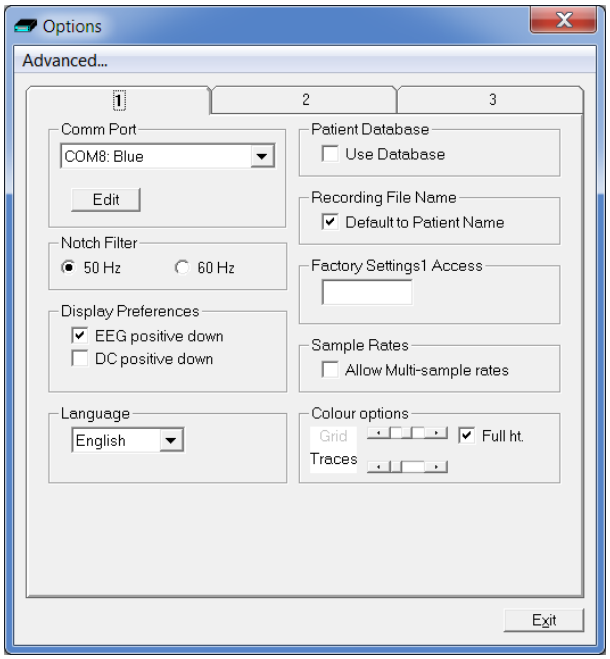


Figure 36 Options Tab 1

Options | Tab 2

The second tab in Options is shown below.

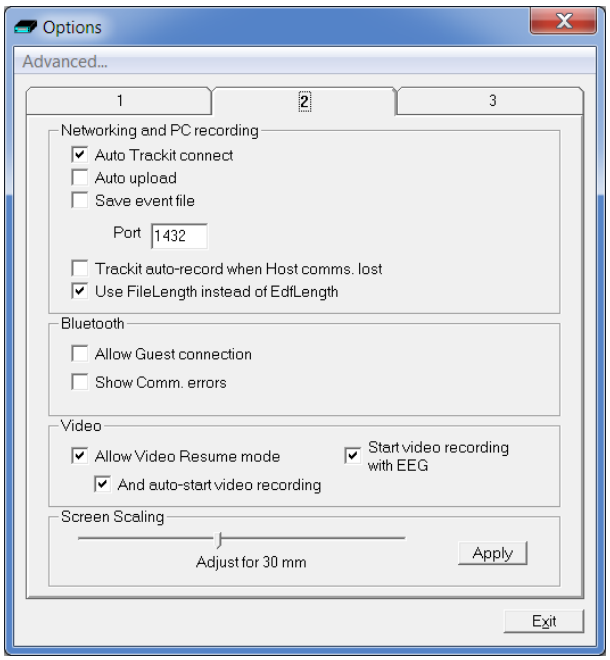


Figure 37 Options Tab 2

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 'Length' parameter embedded in the BDF 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

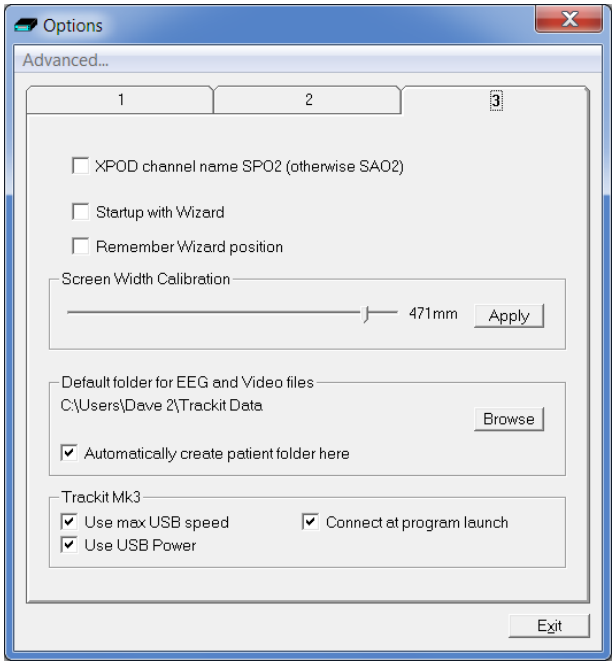


Figure 38 Options Tab 3

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 IEC 60601-1-2 and 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	Description
USB Interface Cable	USB	2.8 m	USB shielded cable
Input electrodes	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Input electrodes (E-cap)	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Nonin XPOD	Shielded	2 m	Nonin
Aux. Connector cable	Shielded	1 m	Shielded cable
Patient Event Switch	CM-5	2 m	Zygo – Two-core cable

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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

WARNING: When in close proximity to the equipment, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.

Guidance and Manufacturer's Declaration

Electromagnetic Emissions
IEC 60601-1-2 / 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 IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity
IEC 60601-1-2 / EN 60601-1-2

The 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	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	+/- 8 kV:Contact +/- 15 kV:Air	+/- 8 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% While in use, the patient should be stationery and not touch the R40 amplifier.
Electrical fast Transients/burst IEC 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Voltage dips,short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment. If the user of the 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 IEC 61000-4-8	3 A/m, 30A/m	3 A/m See Note e.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment

Immunity Test	IEC 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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V in ISM bands	3 Vrms	d = [3.5/V] √P = 1.2 √P Note: using unshielded input leads [c]
Radiated RF Electromagnetic Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m See Note f.	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.

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

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

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

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

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter 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.			