



lifelines trackit

t4^A EEG Amplifier

User Manual



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Version History

V 1.0 (2 May 2018)

- First release

V 1.1 (31 May 2018)

- Added power requirements for battery charger
- Added warning relating to the battery charger mains isolation
- Updated battery compartment image.



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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 Trackit t4A system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

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Trademarks

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Responsibility of manufacturer

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

- any peripheral equipment to be used with the Trackit t4A 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 Overview and Technical Description

1.1 General description

Indications for use

The Trackit t4A EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

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

General description

The Trackit t4A EEG amplifier is a 32-channel electroencephalograph recorder and is intended for use in ambulatory EEG and lab monitoring applications. The Trackit t4A Amplifier is intended to be used in a Professional healthcare Environment and a Home (healthcare) environment.

The Trackit t4A amplifier is powered by one or two lithium-polymer battery packs and is fitted with an internal lithium-ion backup battery. The amplifier features a local event pushbutton and has connection for an optional remote (cabled) event pushbutton. The input channels of the t4A amplifier have built-in calibration and electrode impedance measurement. Communication to a PC is through a wireless (Bluetooth) interface and a cabled (USB) interface. Recorded data is stored on a removable SD memory card. A pouch is provided to carry and protect the amplifier in ambulatory use.

The Trackit t4A amplifier is intended to be configured and set up by a trained clinician. In an ambulatory situation, the EEG electrodes are fitted to the patient by the clinician prior to the patient being sent home. The patient is intended to have minimal interaction with the Trackit t4A amplifier, with the only interacting being pressing the event pushbutton(s).

Upon completion of the recording, the data, which is stored on the SD card, is reviewed by a clinician using review and analysis software on a PC.

The amplifier is intended to be battery powered in ambulatory applications and communicates wirelessly with a host computer through Bluetooth. Alternatively it can be connected to a USB port on a PC which is powered from a medically approved power supply.

Two fully charged battery packs provide sufficient power to power the Amplifier for a minimum of 72 hours. The battery packs are intended to be replaced when the amplifier is not recording and not fitted to the patient. The t4A amplifier does not recharge the battery packs. The battery packs must be removed from the amplifier and recharged using a desktop charger.

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

WARNING: Do not use the Trackit t4A EEG Amplifier in an MRI environment, in an oxygen rich environment 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 is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. This equipment is not be used for the determination of brain death.

WARNING: Only use the PC and the medical-grade power supply as supplied or authorised by Lifelines.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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: Do not plug the USB connector into any device other than the PC supplied or authorised by Lifelines. Do not connect any other equipment to the PC.

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

WARNING: Strangulation hazard due to long cables. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION: Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.

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

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

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

WARNING: Replace the Lithium polymer battery packs with Lifelines supplied battery packs only. Use of another battery may present a risk of fire or explosion.

WARNING. If the Trackit t4A amplifier is not to be used for some time, the battery packs should be removed.

CAUTION: Do not touch the battery contacts (in the Trackit t4A battery housing) and the patient simultaneously.

CAUTION: The lithium-polymer battery packs used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate.

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

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

1.3 Explanation of symbols



Type BF applied part



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



Remote event pushbutton



Memory card read/write



Manufacturer



On/Off and patient event switch



Internal battery hazard
- refer to section 1.7

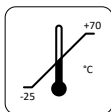


Battery door access
- refer to section 3.3



Battery pack identifier

Storage and transport symbols



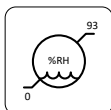
Temperature limits



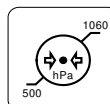
Fragile



Keep dry



Relative humidity limits



Atmospheric pressure limits

IP22

International protection code

Protected against ingress of solid object 12.5 mm diameter.

Protected against access to hazardous parts with finger.

Protected against ingress of water dripping (15° tilted).

1.4 The Amplifier and its parts

The Trackit t4A EEG Amplifier is a 32-channel electroencephalograph recorder intended to acquire EEG signals in an ambulatory environment. It is powered by either one or two lithium-polymer battery packs and is fitted with an internal, non-replaceable, lithium-ion backup battery. The amplifier features a local event pushbutton and has connection for an optional remote (cabled) event pushbutton.

In ambulatory applications the amplifier communicates with a host computer, wirelessly, through Bluetooth. Alternatively it can be connected to a USB port on a PC which is powered from a medically approved power supply. Refer to 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 Trackit t4A EEG Amplifier comprises the following components:

| | |
|--|-------------------|
| Trackit t4A Amplifier | part number: 1600 |
| Trackit t4A Amplifier USB cable | part number: 1601 |
| Trackit t4A bag and straps | part number: 1602 |
| Trackit t4A Lithium-polymer battery pack (x2) | part number: 1603 |
| Single bay battery charger with power supply | part number: 1604 |
| Trackit software CD, standard | part number: 1009 |
| Trackit T4A User Manual (<i>this document</i>) | part number: 1606 |
| Trackit T4A Quick Start Guide | part number: 1607 |
| Trackit T4A Patient Instruction Sheet | part number: 1608 |

The t4A EEG Amplifier can be used with the following accessories:

| | |
|---------------------------------|-------------------|
| Patient event switch | part number: 1353 |
| Lenovo ThinkPad laptop computer | part number: 1389 |
| Medical grade power supply | part number: 1390 |
| Mains cable, UK | part number: 1066 |

Part numbers may be preceded by 'L14' on labelling or packaging.

1.5 Specifications and safety

Refer to Appendix 1 for specifications.

The Trackit t4A amplifier has been certified and complies with the following standards:

| | |
|---------------------------|---|
| IEC 60601-1 and | Standard for medical electrical equipment, general requirements |
| IEC 60601-2-26 | and particular requirements for EEG systems. |
| IEC 60601-1-11 | Collateral standard for medical electrical equipment used in the home healthcare environment. |
| IEC 60601-1-6 | Collateral standard for usability. |
| ANSI/AAMI ES 60601-1 | AAMI Deviations from IEC 60601-1 (USA). |
| CAN/CSA 22.2 No 601.1 M90 | Canadian standard for medical electrical equipment, general requirements. |
| IEC 60601-1-2 | Standard for medical electrical equipment, EMC requirements, calling: |
| *CISPR11 | Conducted Emissions, Group 1, Class B |
| CISPR11 | Radiated Emissions, Group 1, Class B |
| IEC61000-4-2 | Electrostatic Discharges |
| IEC61000-4-3 | Immunity - Radiated RF Field |
| *IEC61000-4-4 | Immunity - Transients Bursts |
| *IEC61000-4-5 | Immunity – Surges |
| IEC61000-4-6 | Immunity – Conducted |
| IEC61000-4-8 | Immunity – Power frequency fields |
| *IEC61000-4-11 | Immunity – Voltage dips, interruptions |
| *IEC61000-3-2 | Harmonic Emissions |
| *IEC61000-3-3 | Voltage Fluctuations/flicker |

*Note: Compliance is provided by the PC.

Classification of system

| Classification | Clinical use | Home use |
|---|--|--|
| Degree of protection against electrical shock | Internally powered; or it can be connected to a PC which is powered by a medical grade Class I power supply. Type BF applied parts. | Trackit t4A Amplifier: Internally powered. Type BF applied parts. If a PC is supplied, the PC has no electrical connection to the Amplifier & has no applied parts. |
| Degree of protection against harmful ingress of water | Ordinary (no protection) or IP22 (Amplifier in bag) | IP22 (Amplifier in bag) |
| Mode of operation | Continuous operation | Continuous operation |
| Suitability for use in an oxygen rich environment | Not suitable | Not suitable |

1.6 Description of the components

The Trackit t4A Amplifier

The Trackit t4A amplifier provides 32 channels (28 referential, 4 bipolar) with built-in calibration and electrode impedance measurement. The amplifier has built in type-BF patient isolation and has a USB interface to the PC. Bluetooth wireless communication is included for ambulatory applications. EEG data is recorded to a removable SD card. The amplifier has a built-in accelerometer and light sensor.

Applied parts, type BF

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.

Patient Event pushbutton

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

Lithium Polymer Battery Packs

The Trackit t4A amplifier has provision to fit two Lithium-Polymer battery packs, which provide the main power source for the amplifier. The battery packs are housed in the battery compartment of the Trackit t4A amplifier and connected in parallel, so the Trackit t4A can operate with only one battery pack fitted. The Trackit t4A does not have the capability to recharge the battery packs and the battery packs must be removed from the Trackit t4A to be recharged in a desktop charger. Details for charging the batteries are provided in Section 3.9.

SD Memory Card

The SD card is used to store the EEG data recorded by Trackit t4A. Storage cards of varying capacity are available in the SD format. The Trackit t4A supports SD cards with a capacity up to 64GB.

Bags and straps for ambulatory applications

The t4A bag houses the Amplifier when used in ambulatory application. The bag protects the amplifier from water and dust (IP22 protection).

USB Cable for connection to PC

For non-ambulatory applications the Amplifier can be plugged 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 Laptop PC

Where EEG studies are conducted within the patient environment the leakage current must be controlled. The laptop PC mains power supply must be a special medical-grade type with appropriate safety standards, supplied or authorised by Lifelines.

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

The Setup and Recording Software

The Trackit setup software runs under Microsoft Windows XP, Windows Vista, Windows 7, 8 or 10 on the host PC and is used to setup and review the t4A Amplifier and to record on to the PC.

The Trackit t4A amplifier is connected to the PC via the USB cable or wirelessly with Bluetooth. The recording setup is downloaded to the device and checks can be made to verify that all the electrodes have been attached correctly. The Amplifier is then disconnected from the PC and the recording is started.

Functions of the software:

- Download the recording template. This includes which electrodes are used and the recording montage. See section 4.11.
- 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.

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 Trackit t4A amplifier contains a 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. Refer to the Trackit t4A Service Instructions.

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 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:

| | |
|----------------------|---------------------------|
| Temperature | +5°C to +40°C |
| Relative humidity | 15% to 93% non-condensing |
| Atmospheric pressure | 700 hPa to 1060 hPa |

Storage and transport:

| | |
|----------------------|-----------------------------------|
| Temperature | -25°C to +70°C |
| Relative humidity | Up to 93% non-condensing at +70°C |
| Atmospheric pressure | 500 hPa to 1060 hPa |

2.3 Power supply connections

Power requirements

3.7V Lithium-Polymer battery pack or Standard USB port (5V)

Power consumption

Maximum power from USB port: 2.5W.

Medical grade AC mains power supply module for Laptop PC

Where EEG studies are conducted within the patient environment the leakage current must be controlled. The mains power supply must be a special medical-grade type with appropriate safety standards, as supplied or authorised by Lifelines.

Mains power input: 100–240 Vac, 47–63 Hz, 1.4 A @ 115 Vac, 0.7 A @ 230 Vac.

Output: 20 Vdc, 5.25 A.

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

Only use the laptop supplied or authorised by Lifelines.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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

Supplied battery charger (P/N 1604)

AC/ DC power adapter

Mains Power input: 100-240VAC, 50/60Hz, 0.35A max.

Output: 5VDC, 1A Max. Micro-USB connector

Battery charging cradle

Power input: 5VDC, 1A nom.

Output: 4.2VDC, 1A max.

2.4 Battery Operation

Li-Polymer battery pack

The Trackit t4A amplifier is powered from one or two battery packs. When fully charged, two battery packs will typically power the unit for 72 hours depending on the number of channels, sample rate and wireless usage (36 hours if only one battery pack is used).

The typical service life of the battery packs is 500 charge-discharge cycles.

A desktop charger is required to recharge the battery packs. The Trackit t4A amplifier does not recharge the battery packs.

The clinician is intended to replace battery pack(s). This should be done before a recording is started. The patient should not replace the battery packs.

Li-Polymer battery pack Instructions for Use

- The battery packs are charged using the specified desktop charger. Refer to the instructions supplied with the charger.
- Operating time will be shorter than usual at low temperatures. The battery can be used between 0 C and 45 C, but will give best performance between 10 C and 30 C.
- If the battery pack start to give less operating times than usual, they have reached the end of their life and must be replaced. Dispose of used battery packs promptly and keep away from children.
- Since the battery packs will naturally discharge itself over a period of time, it is best to charge the battery packs a day or two before planning to use it.

Internal Li-Ion backup battery

The internal backup battery will enable the unit to continue operating for a short period of time (30 mins approx.) to allow the main battery pack to be replaced. It is recharged automatically, while the amplifier is switched on and either connected over USB or fitted with a battery pack. The state of charge is displayed, as described in section 3.5, whenever the unit is powered from the backup battery.

The typical service life is 500 charge-discharge cycles.

2.5 Use in the home environment

Where the equipment is intended to be used in the home, the unit should be operated in its bag where it is protected against ingress of solid objects and water to a degree of IP22.

The laptop PC is optional in the home environment and may be used for video recordings. There is no cable connection between the PC and the t4A Amplifier unit, as all communication is accomplished wirelessly.

Keep the equipment away from sources of heat.

Do not use mobile phones.

Do not allow pets or children to interfere with the equipment or sensor cables.

When the equipment is operated with or without its Bluetooth connected, other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment.

The Trackit t4A has an internal Bluetooth radio fitted. This is an approved industry-standard type which present minimal risk of reciprocal interference with other equipment.

2.6 Use with other equipment

Defibrillators and HF surgical equipment

The equipment is not defibrillator proof and should not be used in situations where a defibrillator is likely to be used.

The equipment should not be used with, or in the presence of, high frequency surgical equipment.

Other patient-connected equipment

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

Leakage current

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

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

2.7 Interference

The Trackit t4A will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of EN60601-1-2. However, the Trackit t4A 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 Trackit t4A has an internal Bluetooth radio fitted. This is an approved industry-standard type which present minimal risk of reciprocal interference with other equipment.

However, when the equipment is operated with or without Bluetooth connected, other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment

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.

2.8 Maintenance and cleaning

The t4A Amplifier and its accessories require no routine testing, calibration or maintenance procedures apart from occasional cleaning and checking for wear and damage to all parts including the accessories.

No servicing or maintenance of the equipment should take place while in use with a patient.

Cleaning and disinfection

Prior to each re-use of the system, all the outer surfaces of the t4A Amplifier and its bag may be cleaned, as required, with a cloth moistened with a mild detergent solution.

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.).

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

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

2.9 Disposal of equipment

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

Dispose of used battery packs promptly and keep away from children.

Caution: Do not dispose of battery packs into fire or by incineration.

3 Connections and usage

3.1 Overview

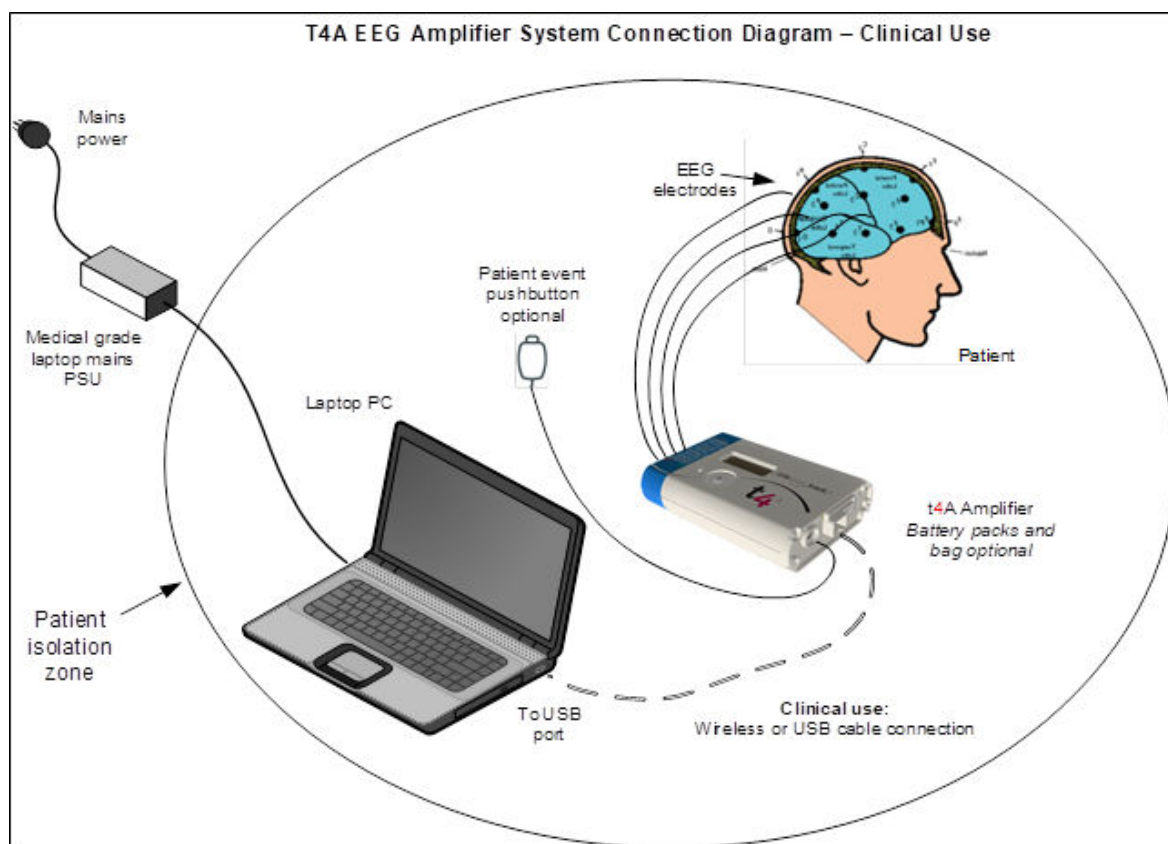


Figure 1: Connecting the Trackit t4A Amplifier – Clinical Use

Clinical Use

During Clinical use, the Trackit t4A Amplifier can be connected to a PC either using the USB cable or through a wireless Bluetooth connection (See Figure 1). Housing the amplifier in the t4A bag is optional and may be used to protect and secure the amplifier.

Note: In transportable, i.e. body-worn situations within the clinic, the Amplifier must be housed inside its bag after being disconnected from the PC, for protection against spillage of liquids.

Where the entire Trackit t4A system including the PC is used within the patient environment, the mains leakage currents and safety and regulatory requirements are met by the use of the special medical-grade laptop power supply.

Home Use

During home use, the Trackit t4A Amplifier is battery powered and is housed inside its bag where it is protected against ingress of solid objects and water to a degree of IP22. The laptop PC is optional and may be used for video recordings. There is no cable connection between the PC and the t4A Amplifier, as all communication is accomplished wirelessly (See Figure 2).

Note that for Home Use applications, the patient should be given a Patient Instruction Sheet, which details essential usage and safety instructions concerning the equipment. Refer to the Patient Instruction Sheet for details.

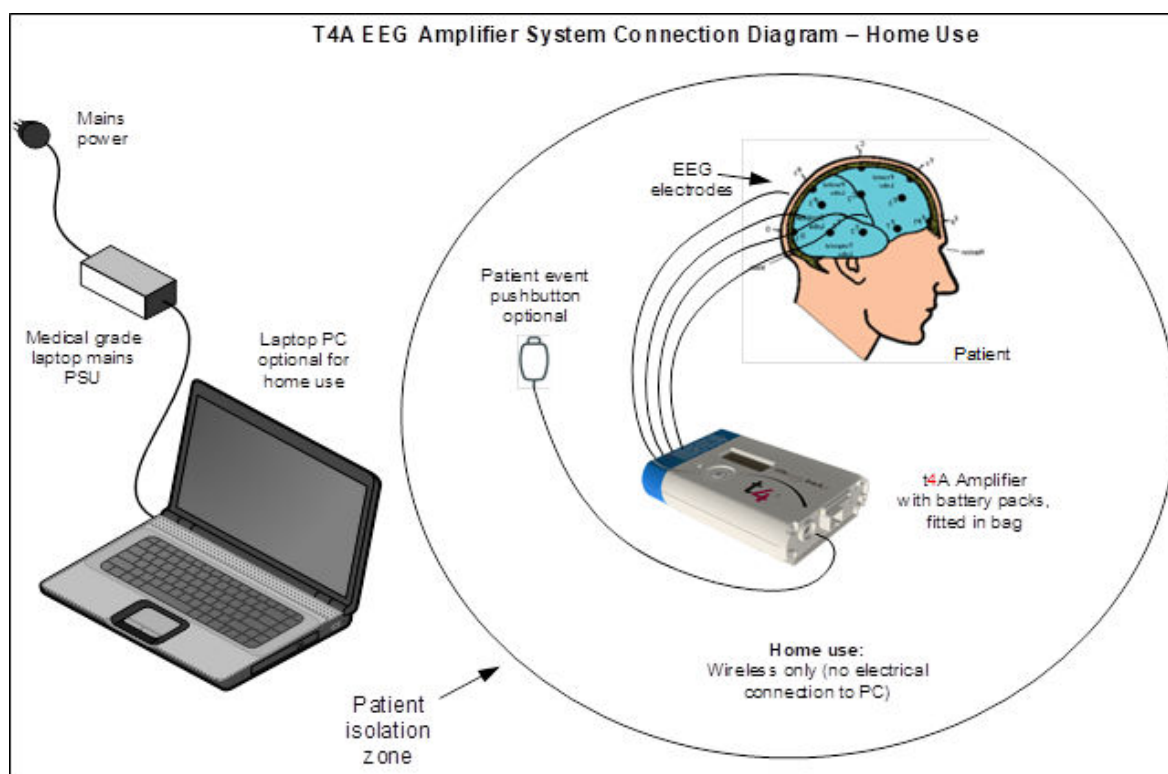


Figure 2: Connecting the Trackit t4A Amplifier - Home Use

3.2 Laptop installation and operation

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

1. Connect the power cord to the medical-grade power supply.
2. Connect the power supply output to the power input connector on the laptop.
3. Connect the power cord to mains power outlet.
4. Note that the mains power cord serves as a power disconnect device. It should be installed near the equipment and be easily accessible.
5. For laptop installation and operation refer to the manufacturer's instructions supplied with it.

3.3 Fitting the battery packs

WARNING: Only fit battery packs supplied or authorised by Lifelines, with the correct part number (PN 1603). Use of other battery packs may present a risk of fire or explosion.

WARNING: If the Trackit t4A amplifier is not to be used for some time, the battery packs should be removed.

For ambulatory, body-worn applications the Trackit t4A is powered from the battery pack(s). The fully charged battery pack(s) should be fitted into the t4A Amplifier before setting up an ambulatory recording. If the amplifier is to be used in a Clinical environment with the USB cable, the use of the battery packs is optional as the amplifier will be powered from the USB port.

1. Open the battery door by pressing the door-release button with a pointed object (for example, a pen). The battery door will spring open. See Figure 3.
2. If there are batteries in the unit, remove these first.
3. Insert the battery pack(s) (battery contacts facing down) into the amplifier. If only fitting one battery pack, fit the battery in battery location 1.
4. Gently push the battery door closed. The door will click shut and lock automatically.



CAUTION: Do not touch the battery contacts (in the Trackit t4A battery compartment) and the patient simultaneously.

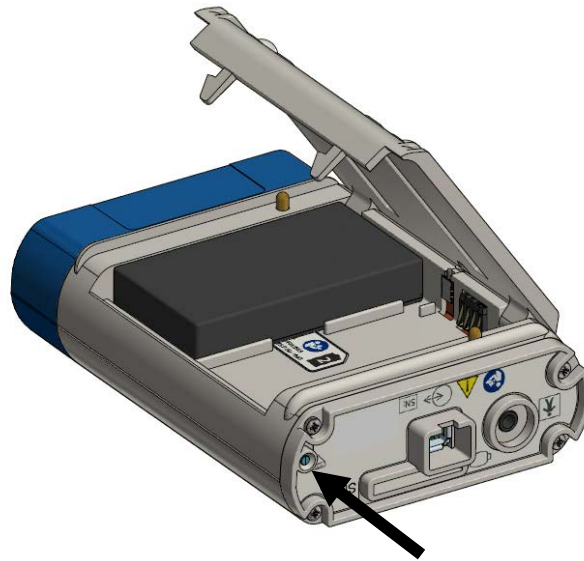


Figure 3: Battery replacement

While the battery door is open, and the amplifier is powered on, the display will show the remaining capacity of the fitted battery packs. If a battery pack is not fitted, the display will show two dashes, as shown below. This view will be cleared when the battery door is closed or the user presses the event button.

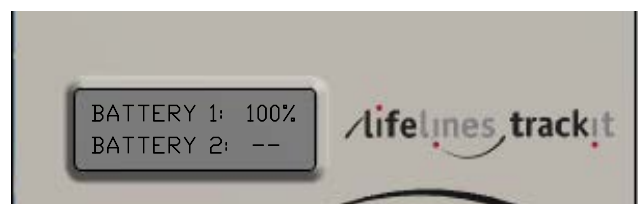


Figure 4: Battery capacity display

3.4 Connecting the Trackit t4A Amplifier


The top face of the Trackit t4A houses the display, the patient event pushbutton  and the ambient light sensor. For display details refer to section 3.5 below. Pressing the pushbutton records a patient event and illuminates the back-light of the display. Adjacent the pushbutton is a circular aperture which houses a sensor to measure the ambient light level.



Figure 5: Connecting the Trackit t4A Amplifier (front face)

The front face of the Amplifier is laid out in a standard 10-20 format, as shown in Figure 5. It 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.

WARNING: Cables must be routed carefully to avoid risk to the patient of entanglement and strangulation.

The side panel of the Amplifier provides for several connections, as shown below.



Figure 6: Connections and indicators on the t4A Amplifier, connector end

1. Patient Event remote switch: this 3.5mm jack connector allows for the connection of an optional Patient Event Thumb Switch.

CAUTION: Only the Patient Event Thumb Switch provided by Lifelines should be plugged into this connector.

2. SD memory card slot.
3. Host connection Data socket.
4. Battery door access button.
5. SD Card activity indicator.

USB Cable Connection

If the amplifier is to be connected using a cable, the supplied USB cable (PN 1602) is plugged into the data socket (item 3, Figure 6) on the connector end of the t4A Amplifier and into any USB port on the laptop PC. When used with a cable, the amplifier can operate with or without the battery packs.

WARNING: Do not plug the cable into any other equipment other than the laptop PC provided with the system.

CAUTION: Do not touch any conductive part of the USB cable or connector and the patient simultaneously.

When fully connected, the connector on the cable will latch into the socket on the amplifier.

To release the cable:

1. While holding the connector, push the lock ejector on the connector towards the amplifier.
2. Holding the lock ejector in place, pull the connector out of the socket.

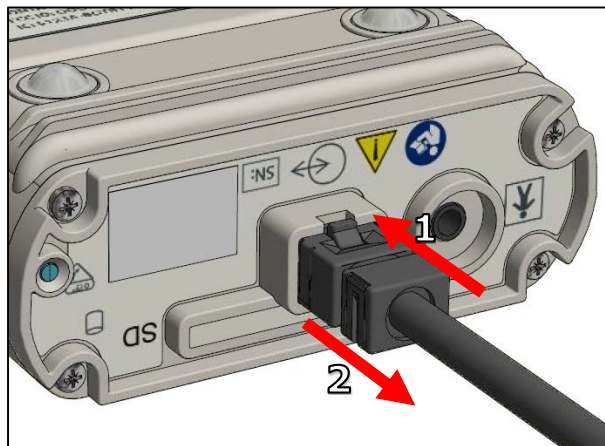


Figure 7: Releasing the data cable

Bluetooth Connection

To connect the t4A Amplifier to a PC via Bluetooth, the amplifier must first be paired with the PC. Refer to Appendix 4 for instructions to pair the amplifier to the PC.

When the t4A amplifier is to be used wirelessly, the amplifier must be powered by at least one battery pack.

3.5 Switching the Amplifier on and off

Switching on

To switch on, press and hold the Patient event button for 2 seconds. When the amplifier switches on, the display's backlight will turn on and an audible beep will sound. The amplifier will perform a self-test and after a few seconds display the status screen (Figure 8).

Note: The amplifier will switch on automatically as soon as it's connected to a PC with the USB cable.

Switching off

The amplifier will automatically switch off (after a period of inactivity) when not recording and disconnected from the PC. The inactivity timeout is configurable in software.










Indicators**Display**

The t4A amplifier's Status screen is shown below:



Figure 8: Trackit t4A display

The following indicators are shown on the display of the t4A:

| Symbol | Description |
|---|--|
|  | Clock: Represents the time of day in HH:MM format. When the t4A is connected to the PC, the clock is synchronised to the PC's clock. |
|  | Stopwatch Indicator: Represents the elapsed recording time in HH:MM format (--:-- if not recording). |
|  | SD Card Icon: Represents the remaining SD Card disk space, in megabytes (MB). If there is no SD card in the amplifier, "--- M" is displayed. If the disk capacity reaches zero during a recording, "FULL" is displayed. If the write protect switch on the SD card is in the LOCK position, "LOCKED" will be displayed. |
|  | Battery Icon: Represents the Main Battery pack(s) capacity or status. If one battery pack is fitted, the displayed value is the remaining capacity on the single battery. The value is display as a percentage of the capacity. If two battery packs are fitted, the displayed value is the remaining capacity of the battery packs combined. The value is display as a percentage of the combined capacity. If the T4A is powered from a USB Data Source (i.e. a computer) the word "USB" is displayed. If the T4A is powered from a USB charging Source (i.e. a USB Power Pack) the word "EXT" is displayed. |
|  | Backup Battery icon: Represents the capacity of the backup battery. This icon replaces the battery icon and is displayed when the t4A is operating from the backup battery. The value is display as a percentage of the capacity. |
|  | Bluetooth disconnected: This icon is displayed when the Bluetooth is on, but not connected to a host. |
|  | Bluetooth connected: This icon is displayed when the Bluetooth is on and connected to a host. |
|  | Displayed when the amplifier is recording to the SD card. |
|  | Displayed when recording and the remaining SD card space is low (< 8 minutes). (accompanied by auditory beep every 30 seconds) |

Display Backlight

The display features a white LED backlight. The backlight is turned on and remains on for 3 seconds during the following events:

- at power-up,

- when the local event button is pressed and
- during Bluetooth pairing.

SD card Indicator

The t4A amplifier is provided with an amber LED indicator on the connector panel (Figure 6, #5). This indicator will flash whenever there is any reading or writing activity on the SD card.

Buzzer

The t4A amplifier uses an audible buzzer to indicate user action feedback. A short beep will sound for the following events:

- Power on and power off
- local event button is pressed
- remote event button is pressed
- SD card is inserted or removed
- Record started / Record stopped.
- Battery door open / close
- Bluetooth pairing process

3.6 SD Card

SD Card Preparation

The t4A Amplifier supports SD and SDHC cards up to 64GB. Refer to Appendix 5 to determine the capacity required for the recording. The SD card needs to meet the following requirements:

- Formatted to FAT32 (Lifelines recommends that the SD card is formatted using the SD Formatting software supplied on the Lifelines CD).
- There should be no read-only files on the card.
- There should be no folders / directories on the card.

If these requirements are not met, the t4A Amplifier may not be able to read the card and will not be able to start the recording.

CAUTION: The t4A Amplifier will delete all the files on the SD card before starting a recording.

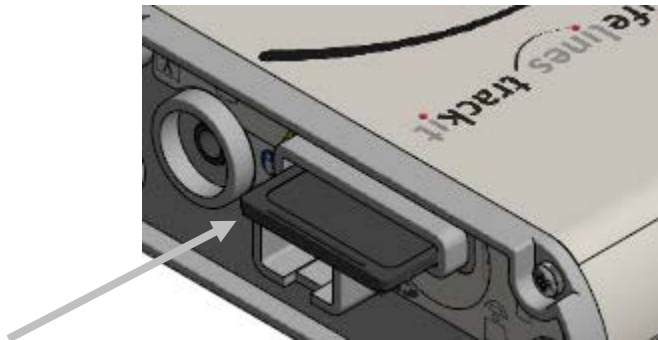


Figure 9: SD Card location

Insertion and Removal

The t4A Amplifier uses a “push-push” style of SD card holder (push to insert, push to remove).

1. To insert the card, slide the card into SD card slot (Figure 6, #2) with the SD card label facing up. The card will stop against a spring.
 2. Using the supplied card insertion tool, gently push the card further into the slot until it clicks into place.
 3. When full inserted and locked in place, the SD card will be recessed in the card slot.
-
1. To remove the card, gently push the SD card with the card insertion tool.
 2. Release the pressure on the card and the card will eject out the card slot.

The SD card can be inserted and removed while the t4A Amplifier is switched on.

When the SD card is inserted (and successfully read) or removed, an audible beep will sound. Upon card insertion, the t4A will read the card and the card capacity will be indicated on the display, accompanied by an audible beep. Upon removal, the display will show “ --- M”.

Note: If the t4A fails to read the card upon insertion, then remove and reinsert the card.

3.7 The t4A Bag

The t4A bag provides protection to the t4A amplifier when used in the home environment. The bag features a large zipped opening for fitting the amplifier into the bag. This opening has a fold-over flap to protect the zip from water ingress. A smaller zipped opening is provided to access the data and remote event connections. A large clear window provides a view of the LCD display and the event pushbutton.

CAUTION: The t4A must be housed in the bag when used in the home environment.

Note: In transportable, i.e. body-worn situations within the clinic, the Amplifier must be housed inside its bag after being disconnected from the PC, for protection against spillage of liquids.

Fitting the amplifier into the bag

1. When the t4A Amplifier has been set up (battery pack(s) and SD card fitted and electrodes connected), place the amplifier into the bag.



2. Close the zips around the electrode cables



3. Fold the flap over the EEG leads and zips.

The flap provides additional water ingress protection. To prevent the EEG leads from pulling up the flap, the EEG leads should be strapped / tapped to the shoulder strap buckle to prevent the leads from pulling.



4. Close the zip at the base of the bag (connector end).

Fitting the bag to the patient

The bag can be worn by patient over the shoulder or on a belt.

Note: The bag should always be worn upright (the connector end facing the ground).

CAUTION: Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.



WARNING: Strangulation hazard due to long cables. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

3.8 Remote Patient Event Thumb Switch (optional)

If using the patient event thumb switch, plug the switch into the 3.5mm socket (Figure 6, # 1),


marked with the  symbol. During recording, when the thumb switch is pressed a marker will be placed in the EEG recording. The Remote patient event switch must be configured when setting up the recording (See Section 4.4).



Figure 10: Patient Event Thumb Switch

3.9 Battery Pack Charging

The battery pack(s) can be recharged using the supplied single-bay desktop charger (part number 1604). The charger is capable of charging one battery at a time. Refer to the instruction sheet included with the charger.

- Remove the battery pack(s) from the t4A Amplifier and place in battery charger cradle.
- Connect the micro-USB plug of the power adapter into the charger cradle.
- Plug the charger's power adapter into a mains power outlet.
- **WARNING:** The charger's power adapter serves as the mains-supply disconnect device. When connected to a mains power outlet, it should be positioned so that it's easily accessible. The power adapter can be isolated from the mains supply by unplugging it.
- When the battery pack is fully charged, remove from the charger and fit the second battery pack (if required).
- When charging is complete, unplug the mains power adapter.

An LED on the charger shows the battery pack's state of charge, as shown in the table below:

| Charging Phase | Description | LED Indicator | | |
|------------------------------|--|---------------|--------|---------|
| | | Green | Orange | Red |
| No Charge | No battery connected, power on | | | ON |
| Pre-charge | 0V < battery voltage < 3.06V ($\pm 1\%$) pre-charge / pre-qualification / wake-up charge: I = 15mA for a max. period of 40 minutes. | | | FLASHES |
| Fast charge & Top-off charge | 3.06V($\pm 1\%$) < battery voltage < 4.20V ($\pm 1\%$) | | ON | |
| Battery Full / Standby | Battery cell full (4.2V $\pm 1\%$) | ON | | |
| Failure | Refer to charger's user manual | | | FLASHES |
| Other | Power off or charger broken | OFF | OFF | OFF |

- Do not short circuit the contacts on the battery pack. To avoid short circuit, keep the device away from any metal objects (e.g., hair clips and keys).
- The battery pack may get hot during charging, which is normal. Handle with care.
- This battery pack is not user repairable. Do not disassemble.
- Do not crush the battery packs.
- Do not heat the battery pack or throw it into a fire.

4 The setup and recording software

4.1 Overview

The setup software is available on CD. A readme file describes installation. Check with your distributor or Lifelines if a newer version of software is available.

The Trackit software is designed to work with both the Trackit t4A Amplifier and with the optional Photoc Stimulator.

The software is supported on Microsoft Windows XP, Windows Vista and Windows 7, Windows 8 and Windows 10.

The USB drivers will be found on the CD. After connecting the Amplifier to the PC for the first time, at the Windows prompt, browse to the folder *CD Drive:\USB Drivers*. From there Windows will find the correct drivers for the version of Windows being used.

The software has the following functions:

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

The Trackit software has four menu options: File, Home, Settings and Help. Each option provides a Microsoft® style “ribbon” toolbar (see Figure 11 - Figure 14). The default view is the ‘Home’ ribbon.

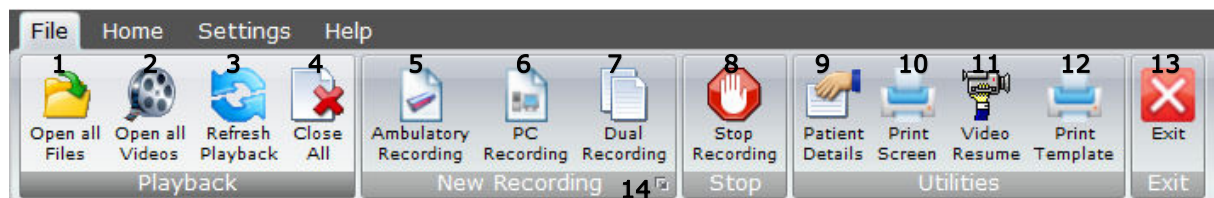


Figure 11: Trackit Software ‘File’ Toolbar

Key

- | | | |
|--------------------------|----------------------------|----------------------------------|
| 1 Open EEG file | 2 Open EEG videos | 3 Refresh playback files |
| 4 Close all review files | 5 New Ambulatory Recording | 6 New PC Recording |
| 7 New Dual Recording | 8 Stop Recording | 9 Patient Details |
| 10 Prints Screen | 11 Video Resume | 12 Print Keyboard Event Template |
| 13 Exit Software | 14 Trackit Control Panel* | |

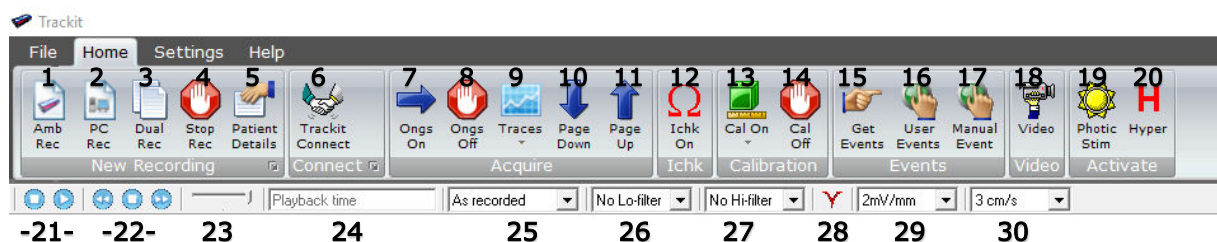


Figure 12: Trackit Software ‘Home’ Toolbar

Key

| | | |
|------------------------------|-------------------------|------------------------------------|
| 1 New Ambulatory Recording | 2 New PC Recording | 3 New Dual Recording |
| 4 Stop Recording | 5 Patient Details | 6 Connect & Trackit Control Panel* |
| 7 Ongoing On | 8 Ongoing Off | 9 Number of Traces & Superimpose |
| 10 Next Page | 11 Previous Page | 12 Impedance Check On |
| 13 Calibration On/Amplitude | 14 Calibration Off | 15 Get Trackit Events |
| 16 User Events | 17 Manual Event | 18 Videometry (optional) |
| 19 Photic Stimulation | 20 Hyperventilation | 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 be access by clicking on the “Expand” arrow of the “Connect” or “New Recording” group.

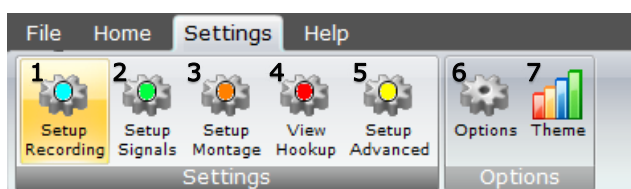


Figure 13: Trackit Software "Settings Toolbar

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 | | |

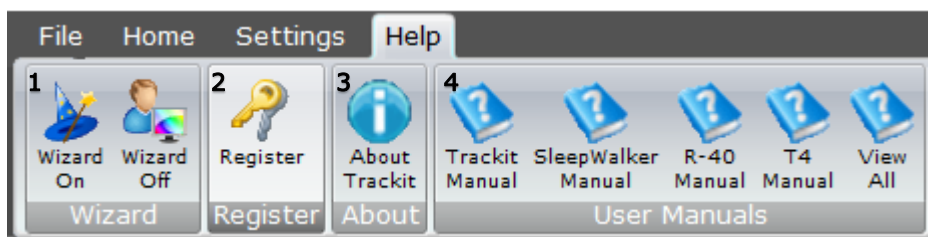


Figure 14: Trackit Software 'Help' Toolbar

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 access by clicking on the “Expand” arrow of the “Connect” button (See Figure 12).

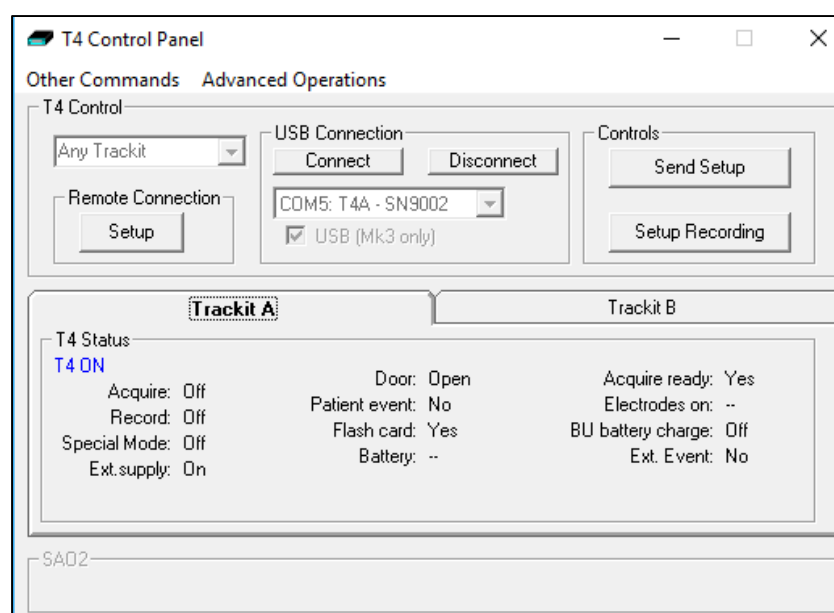


Figure 15: Trackit Control Panel

Connecting the Trackit

The Trackit application software will normally connect automatically to the t4A Amplifier as soon as it is plugged in.

To connect manually:

If connecting via USB, check that the t4A USB cable is connected properly. The software will normally connect automatically, however to do this manually, in the Control Panel (Figure 15) select the “USB (Mk3 only)” checkbox and click on the Connect button.

If connecting via Bluetooth; switch on the Trackit t4A. Ensure that the t4A has been paired to the computer first. Un-tick the “USB (Mk3 only)” checkbox, select the correct COM port from the drop down list and click on the Connect button. See Appendix 4 for additional Bluetooth information.

After a couple of seconds the status will show “T4 ON”. The Trackit software status bar (at the bottom of the screen) shows ‘Trackit Online (USB) [T4A]’ (for USB connection) or ‘Trackit Online [T4A]’ (for Bluetooth connection) and displays the recording parameters loaded into t4A.

The parameters in the Status section show whether the battery and SD card are present, whether the battery door is open or closed and the recording status of the device. These parameters are detailed below.

Check Trackit status

The Control Panel can be used to check that the Trackit t4A is online and setup correctly. The “Trackit A” tab of the Control Panel gives you the following status information for the t4A:

| | |
|--------------------------|--|
| Acquire – on or off | Shows whether the t4A is acquiring or not. |
| Record – on or off | Shows whether or not the t4A 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 (on the t4A’s front panel) has been activated. |
| Flash card | Shows whether a SD card is present. |
| Battery | Shows if the amp is running off batteries. |

| | |
|-------------------|---|
| Acquire ready | Shows that a valid recording setup has been loaded into the t4A. |
| 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 Trackit t4A time, Battery capacity, Recording time and SD card total and remaining capacity in (Megabytes (MB)) (see Figure 16).

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.

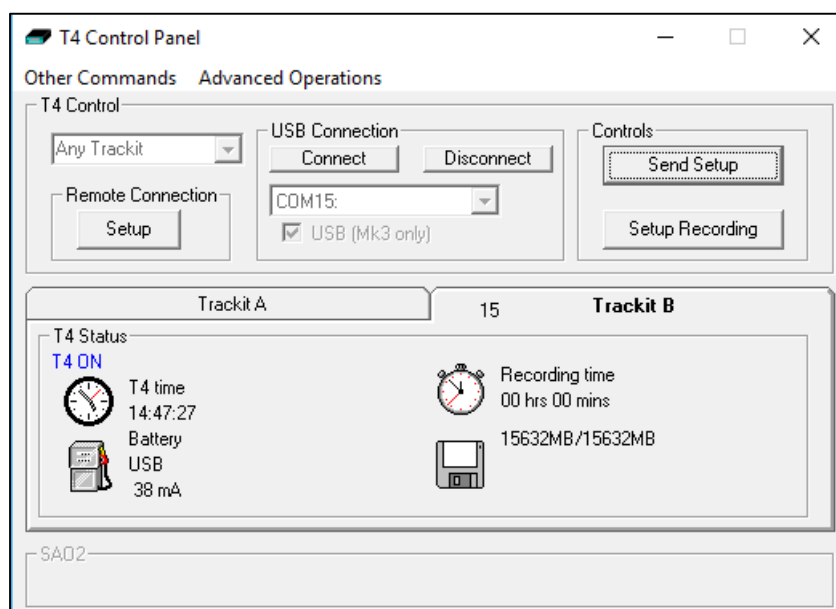


Figure 16: Trackit t4A "Status B"

4.3 Defining Input signals

Defining signals is usually done once only or very occasionally. The t4A Amplifier arrives with a default set of signals that should suffice for most applications, hence it may only necessary to add signal types for polygraphic recordings (airflow, respiration etc). 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 64 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.

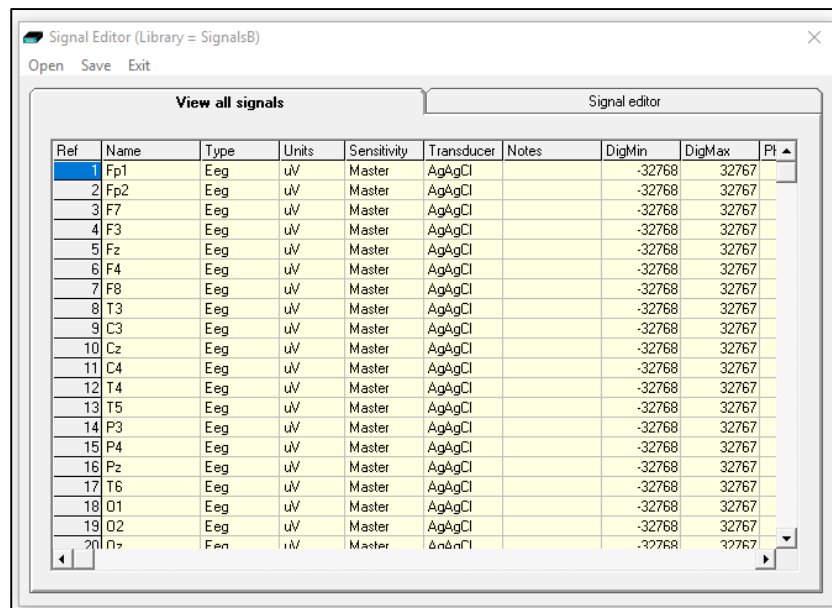


Figure 17: Signal List

- 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.

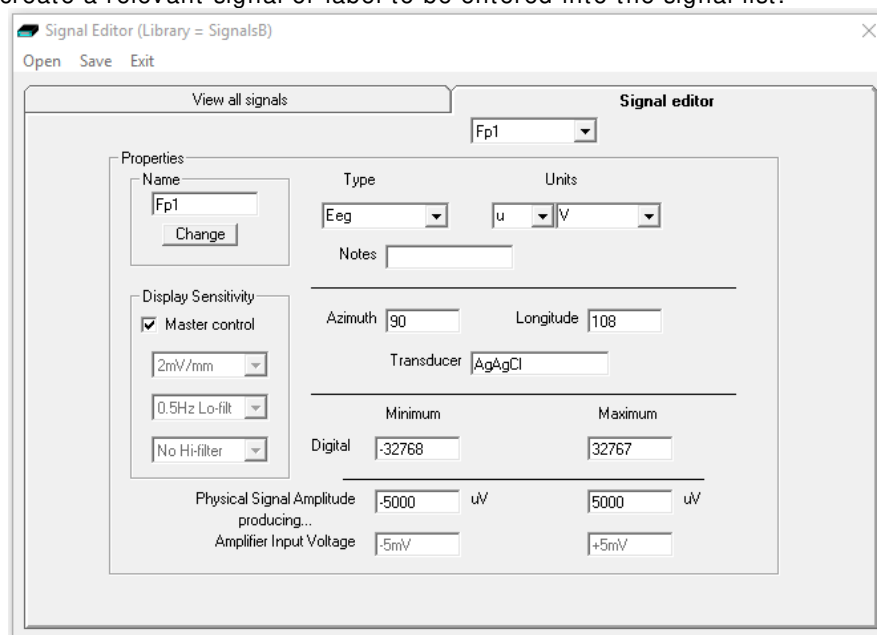


Figure 18: Signal Editing Tool

- 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.

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. Otherwise, if a new setup is being created, proceed as follows:

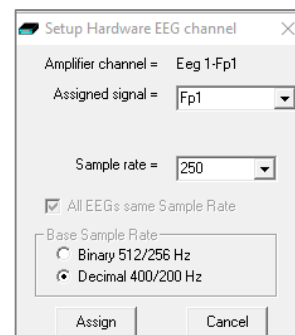


Figure 19: EEG setup

- 3 Under the “Amplifier Channels” tab, select the “T4A” checkbox. This will update the channel list with the available channels on the Trackit t4A. The channel names will also be updated to show the 10-20 mapping on patient connection unit. Note, if the t4A amplifier is online (connected), the checkbox will automatically be ticked and greyed out.

- 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.

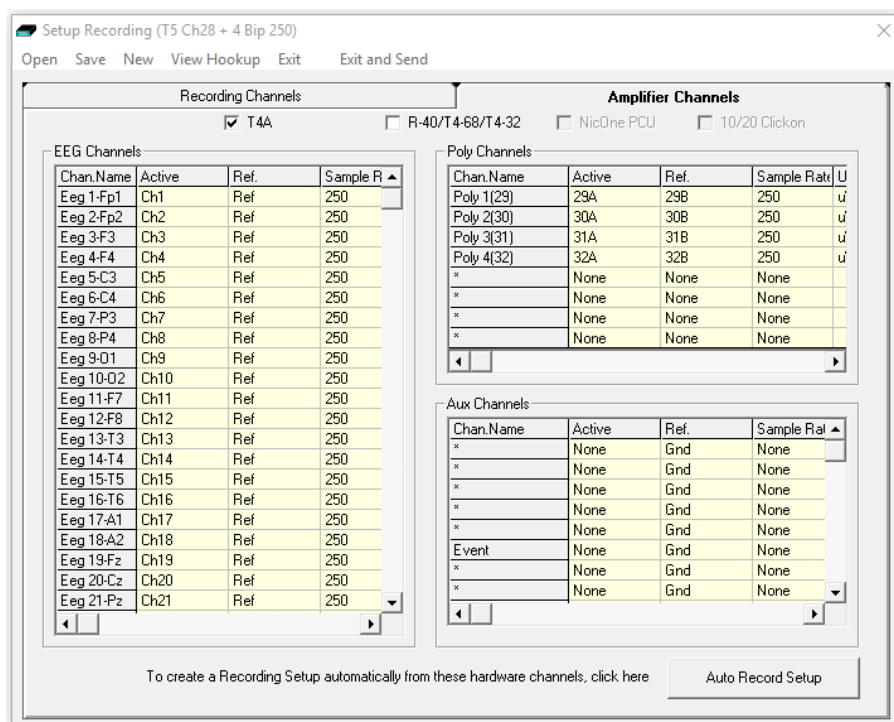


Figure 20: Setup Recording dialog

The Trackit t4A Amplifier supports the following channels.

- EEG Channels: EEG 1 – EEG 28
- Poly Channels: Poly 1 – Poly 4 (channels 29+/- to 32 +/-)
- Aux Channels:
 - Event – Remote patient event thumb switch
 - Trip I/P – Trigger input signal (requires special USB cable)
 - Light I/P – Ambient light sensor on front panel of the amplifier

Channels mark with an asterisk (*) are not used on the t4A. 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.

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.

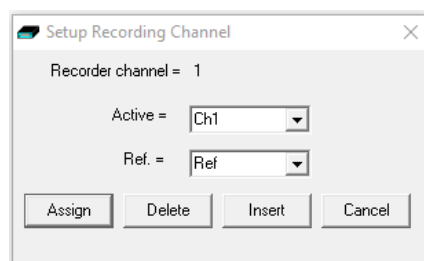


Figure 21: Channel setup

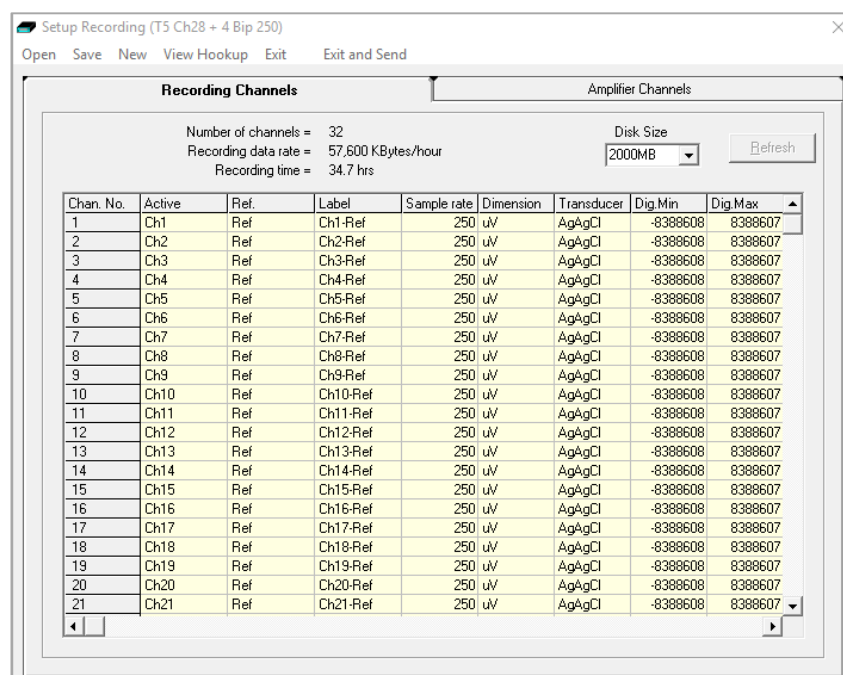


Figure 22: Recording Channel editing

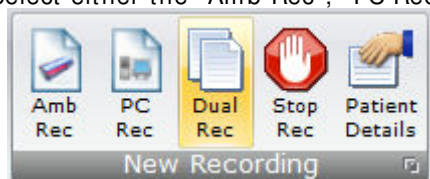
When the Amplifier inputs and recording configuration have been completed, the setup can be saved. If the t4A is connected and online, the new setup can be sent to the amplifier by selecting the “Exit and Send” menu option. If the amplifier is not connected, the Setup Recording dialog will close, but the setup would not have been sent to the amplifier.

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. Select either the “Amb Rec”, “PC Rec” or “Dual Rec” button from the Home or File 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.

Note: The patient details can be defined beforehand by clicking on the “Patient Details” icon in the Home or File toolbar.

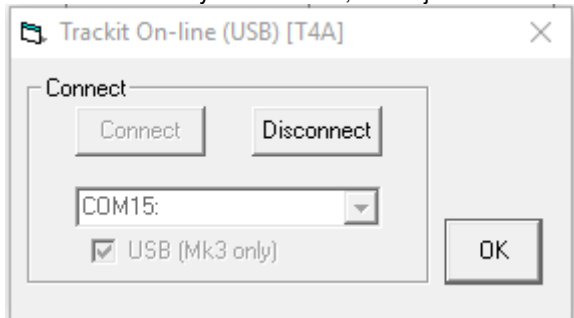
Figure 23: New Patient dialog

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

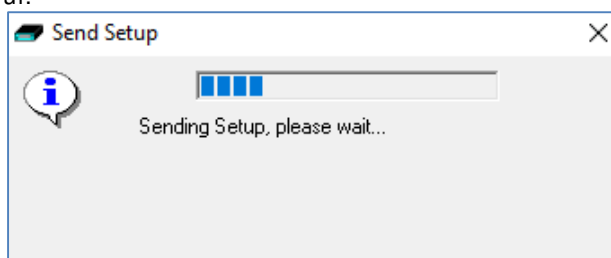
Figure 24: New Patient database

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

3. Once the patient details have been entered, click “OK”.
4. In the next dialog box, 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.
5. 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’



6. The new setup will be sent to the t4A (if required). A warning will appear if this is not successful.



7. The next dialog box confirms if video is to be recorded? Select ‘Yes’ if doing a videometry recording.
8. The Recording Control panel (Figure 25) 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 Trackit. This may take a few seconds as the Trackit t4A prepares 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.

9. After the recording has started, the following actions can be performed:
 - a. View Ongoing EEG 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

Click on the ‘Setup Recording button’ in the Trackit Control Panel to open the Recording Control dialog box (Figure 25). 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).

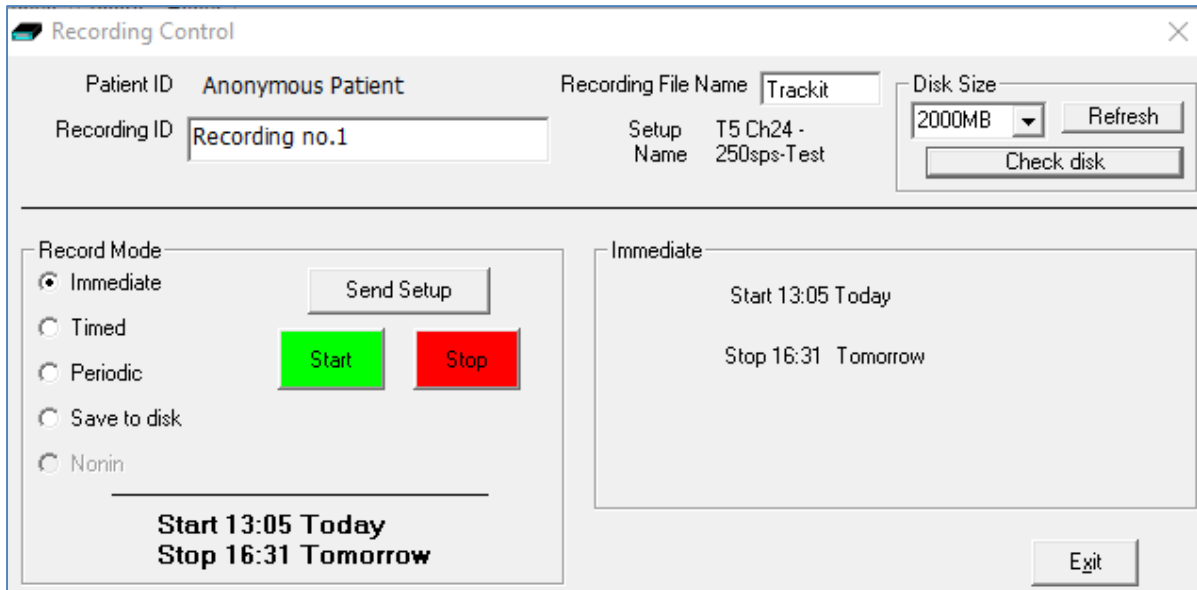


Figure 25: Recording Control panel

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.

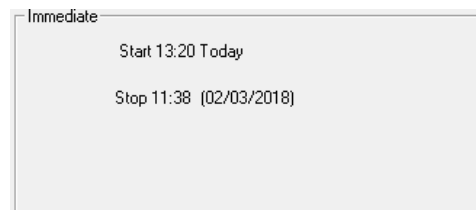
Recording modes

There are four ways to start a recording:

- Immediate
- Timed
- Periodic
- Save to Disk (Not supported on the t4A)
- Nonin (option greyed out. Not supported on the t4A)

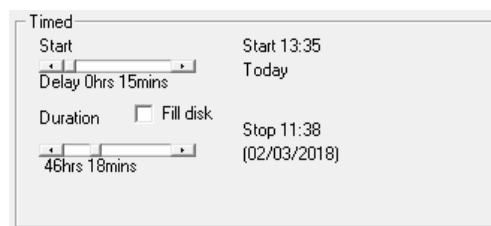
Immediate: the recording starts as soon as the Start button is pressed (Figure 25). Recording finishes when the Trackit is turned off, when the disk is full or when the recording is stopped.

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



Timed: Trackit t4A 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: Trackit t4A 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.

Periodic

Frequency 0hrs 45mins Start 13:22 Today

Duration 0hrs 30mins

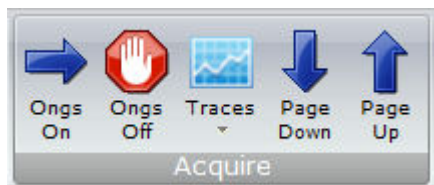
Recording time 69hrs 27mins

Start ☐ Delay Stop 10:49 (03/03/2018)

Delay 0hrs 0mins

4.7 View Ongoing Traces

To view the ongoing traces at any time, whether recording or not, click on the “Ongs On” icon in the Home toolbar.



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

- If the Trackit t4A 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 Trackit t4A has not been sent a setup from the PC, the system asks for the recording setup held in the t4A before displaying the traces.

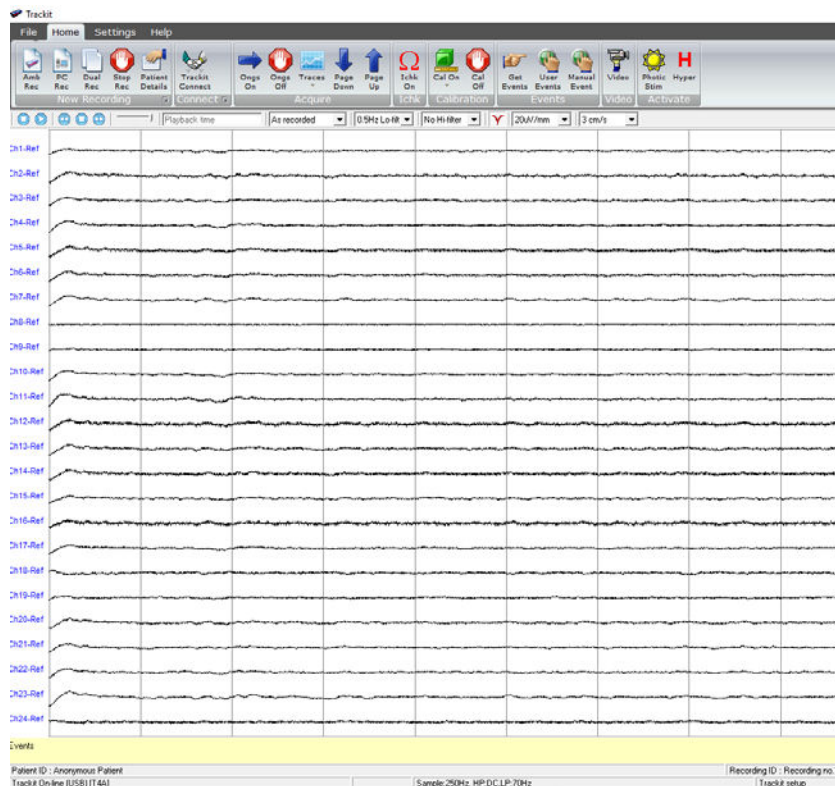
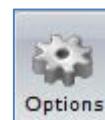


Figure 26: Ongoing trace display

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 12).

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

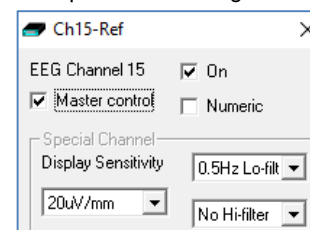


Figure 27: Adjust display parameters

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.

Number of displayed traces

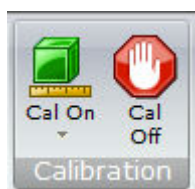
The number of displayed traces can be adjusted to display 1, 4, 8, 12, 16, 24, 32 or all traces. The available options are shown by clicking on the arrow on the "Traces" icon.

The 'Superimpose On/Off' option 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 Page Down and Page Up functions will cycle through all the available traces.

4.8 Calibration Check

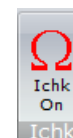
To perform a Calibration check, whether recording or not, click on the Cal On icon on the 'Home' toolbar. Calibration check is turned off by pressing the 'Cal Off' icon.



Calibration check will start the acquisition and ongoing traces if not already active. The waveforms will show a square wave of amplitude 8 mV 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 28).



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

The impedance check works via pass/fail threshold selection. Impedance values above the selected threshold (fail) are displayed on a 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 29).

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

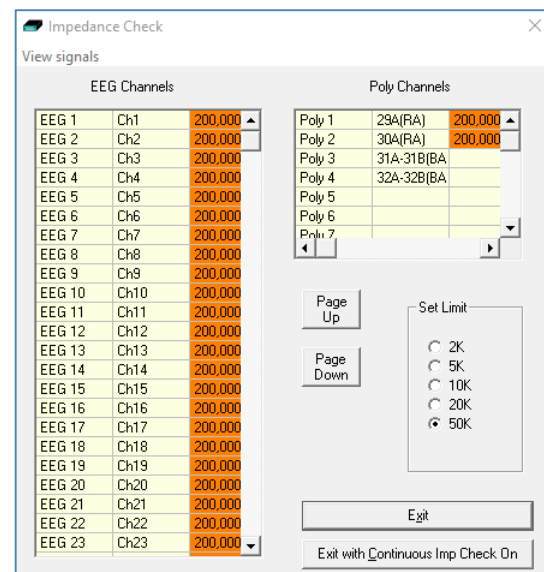


Figure 28: Impedance check

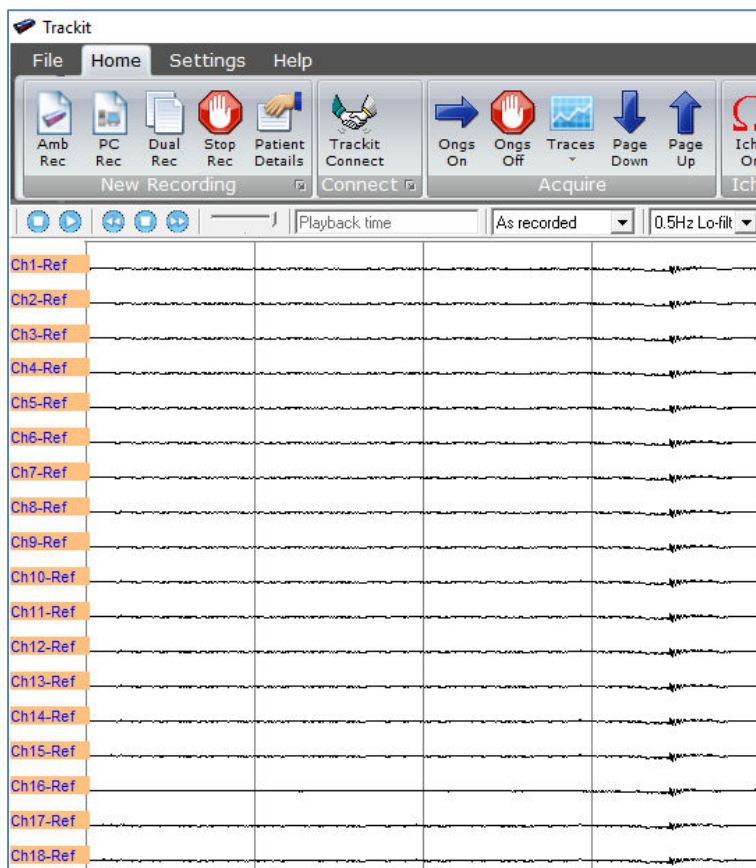


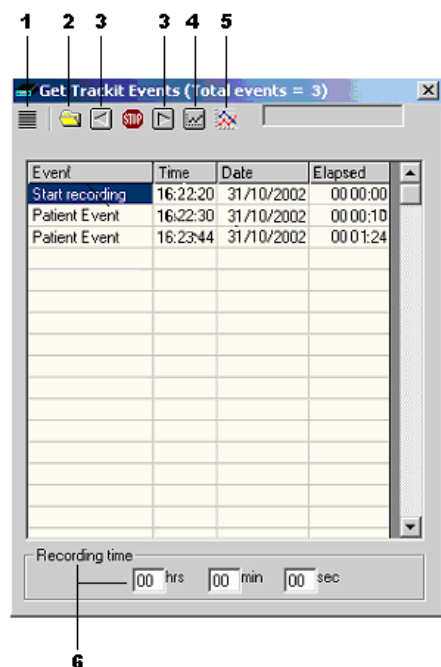
Figure 29: Continuous Impedance Check

4.10 Events

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



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



Key:

- 1 Opens the list of event types

Additional icons at Playback time:

- 2 Opens an event file for an older re-cording
- 3 Navigate forwards or backwards
- 4 Selects the best trace resolution
- 5 Selects the max. number of traces
- 6 Enter a 'Go to' time here

Figure 30: Online Event Viewer

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

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

4.11 Montage Editor

The Montage Editor is accessed by clicking on the "Setup Montage" on Settings toolbar, which displays the Montage Editor as shown below.

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

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

Additional controls are provided to allow:

5. Update. Copies the current settings into the currently selected channel.
6. Add. This adds a channel to the end of the Montage list.

7. Insert. This insert a channel above the currently selected channel.
8. Remove. This removes the currently selected channel.
9. Montage name.

If anything is changed, an option is presented to save all changes to disk or not. If not saved, changes are only temporary.

Note that some of the montage parameters can be changed outside the Montage Editor, by clicking on a channel label to bring up the Channel Information window. These changes are only temporary (although you can save them later by subsequently going into the Montage Editor).

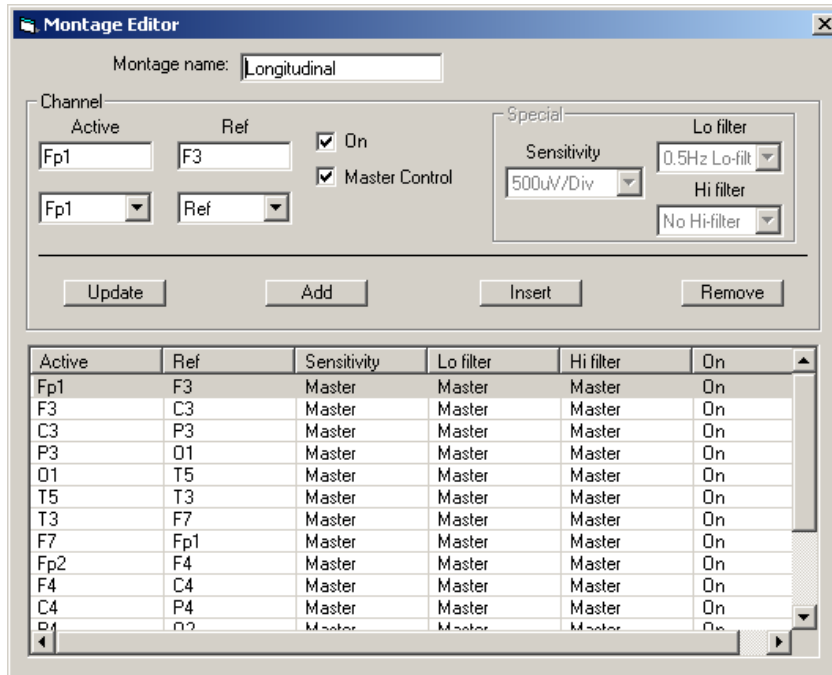


Figure 31: Montage Editor

4.12 Reading an EEG recording

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

If currently recording to the PC, it is possible to open this file for simultaneous playback. This will open the current EDF/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 EDF-compatible viewer can be used to read the 24-bit BDF files recorded by the Trackit t4A.

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
- Nihon Kohden 1100 and 1200 EEG
- Neurotronic Polysmith Sleep software
- Nicolet One EEG
- Natus Coherence EEG (formerly Deltamed/Itmed)
- 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:

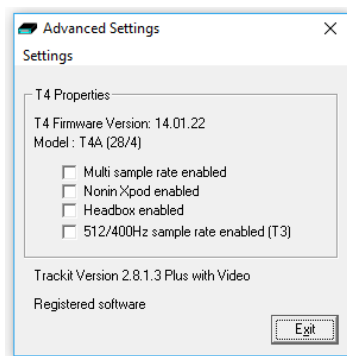
Set Trackit Time/ Date: if the Trackit Mk3 is not recording, this manually sets the Trackit's time and date to that of the PC. Note: this function is normally done automatically when recording is started.

Get Trackit Set-up: this manually retrieves the setup from the Trackit'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 Trackit's setup and the PC setup.

Quiet On: if a host PC is connected, this temporarily disables the warning beep if the battery door is opened while the Trackit t4A is turned on. It is automatically re-enabled after the PC is disconnected.

Quiet Off: if a host PC is connected, this re-enables the warning beep if the battery door is opened while the Trackit t4A is turned on.

Advanced Operations



Advanced Operations contains entries, some password-protected, that change the way a Trackit t4A 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.

T4A Defaults Tab 1

This menu item activates a control dialog that adjusts how the Trackit t4A behaves during a recording. See Figure 32.

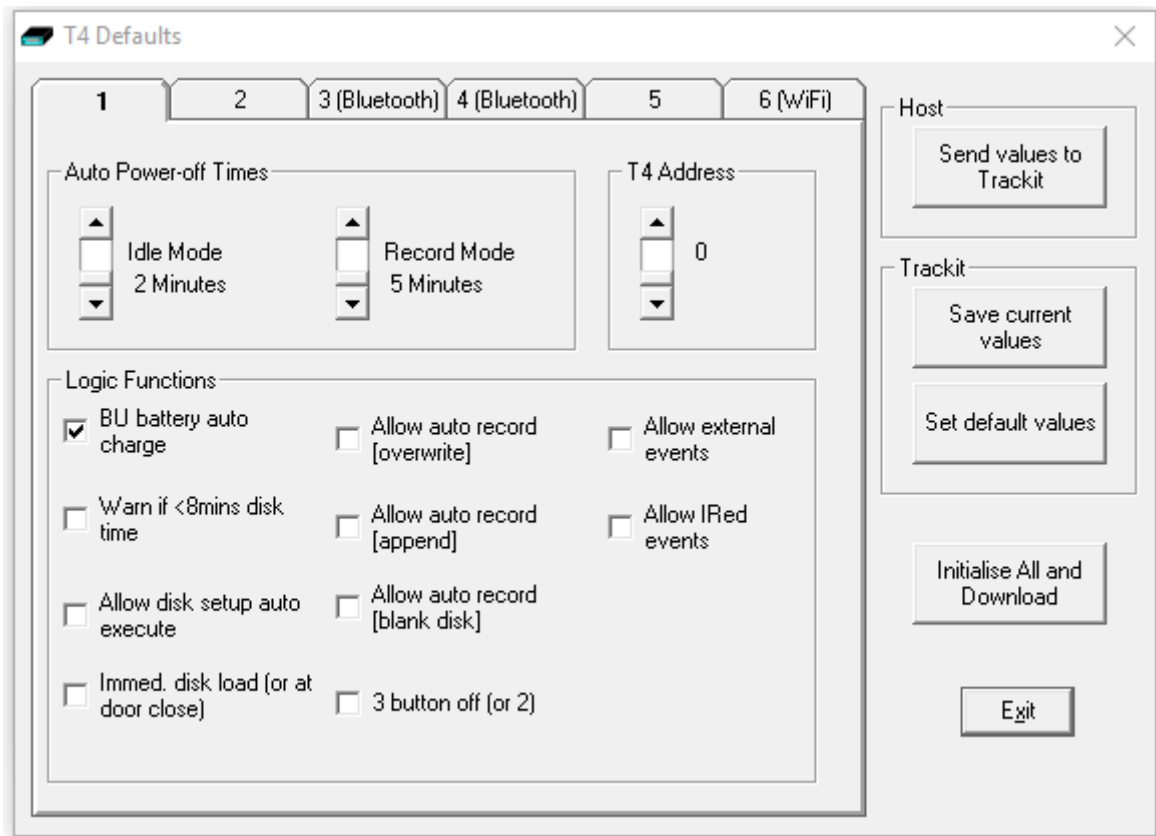


Figure 32: T4 Defaults Tab 1

To save new defaults to Trackit t4A, press 'Send these values to Trackit', followed by 'Save current values'.

The following functions are supported:

Idle Mode: Trackit t4A turns itself off after a defined period when not recording.

Record Mode: Trackit t4A turns itself off after a defined period after having recorded. Trackit t4A waits for a defined period for a SD card to be reinserted to append to an existing file which is < 24 hours old. Otherwise it starts a new recording on a blank card. 60 minutes is enough for a user to remove a card, read it and reinsert it to continue recording until the card is full.

Trackit Address: sets the serial address of the Trackit t4A. Use to identify the Trackit t4A if several Trackits are connected to one PC.

BU battery auto charge: enables fast-charging of the backup battery when the Trackit t4A is connected to USB or battery packs are fitted.

Warn if < 8 mins card time: the Trackit t4A starts beeping when the card has room for only another 8 minutes of recording.

Allow card setup auto execute: Not supported on the t4A.

Allow auto record (overwrite): Not supported on the t4A.

Allow auto record (append): Not supported on the t4A.

Allow auto record (blank card): Not supported on the t4A.

Allow external events: Not supported on the t4A.

Allow IRed events: Not supported on the t4A.

Immed. card load (or at door close): Not supported on the t4A.

3 button Off (or 2): Not supported on the t4A.

T4A Defaults Tab 2

Additional setup parameters are accessed via tab 2 of T4 Defaults panel, as shown in Figure 33 below.

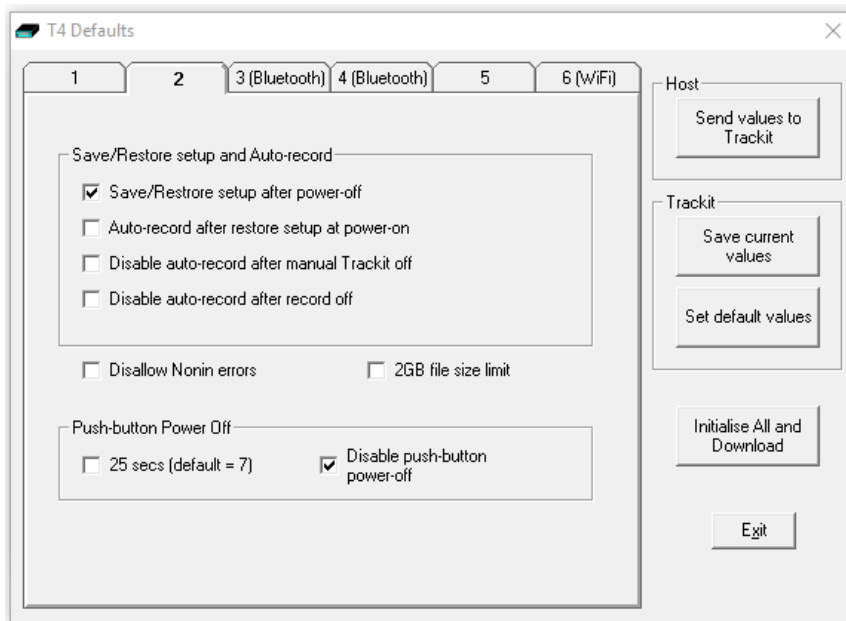


Figure 33: T4 Defaults | Tab 2

Save/ Restore setup and Auto-record

The Trackit Mk2 and Mk3 have much increased internal non-volatile memory. This memory allows it to save its entire Setup before powering-off. When next powered-on, it is able to restore its last saved Setup. This feature can significantly speed-up the download of a Setup to the Trackit because the Host software automatically determines if the Trackit is already Setup correctly.

Another benefit to this save/recall of Setup is that the Trackit can resume recording in exactly the same state it was in the last time it was powered-off. This is especially useful if, during a recording, the User takes a long time to replace the batteries. To control this feature, the following options are available:

- **Save/ Restore setup after power-off.** When checked, this enables the Trackit t4A 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.** When checked, this enables the Trackit Mk3 to continue recording if it was recording the last time it 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.** When checked, this causes a potential Auto-record situation to be cancelled whenever the Trackit t4A is powered-off either from its own front-panel pushbutton or from the Host.
- **Disable auto-record after record off.** When checked, this causes a potential Auto-record situation to be cancelled whenever the Hosts instructs the Trackit t4A to stop recording.

Note that in all these Auto-record situations, the same rules apply to data storage on the flash card as defined in the User Manual for the current Trackit Default Options | Tab 1. To summarise these rules:

- The Trackit Mk3 will not record over a data file on the card which is less than 24 hours old.
- The Trackit Mk3 will append new data, if enabled, if the data file on the flash card is less than 24 hours old and the Trackit Mk3's Setup and Patient Name and Recording ID are identical to that on the card.
- The Trackit Mk3 will overwrite data on the flash card, if enabled, if the data on the card is more than 24 hours old.
- The Trackit Mk3 will write new data to a blank flash card, if enabled.

Disallow Nonin Errors

Not supported on the t4A.

2GB File size limit

When checked, the maximum recording file size will be 2GB. When unchecked the maximum recording file size will be 4GB.

Push-Button Power Off

- **25 Secs (default = 7)** When checked, the event pushbutton should be held for 25 seconds to turn off the t4A amplifier
- **Disable push-button power off. (default = checked)** When checked, this disables the push-button power off function. The t4A will only turn off after an idle period.

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 t4A 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 Trackit t4A's non-volatile memory.

Configuration

[> Advanced Operations > Settings > Configuration]

Configuration gives access to the Trackit'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

[> Advanced Operations > Settings > Trackit OFF]

Turns the Trackit t4A off. Note: Communication to the host PC will be lost.

5 The ambulatory recording

5.1 Preparing the Ambulatory Recording

The procedure to set up an ambulatory recording is as follows:

1. Fit one or two **fully charged** battery packs into the t4A amplifier (see Section 3.3).
 - One battery packs will record for approximately 37 hours @ 250sps
 - Two battery packs will record for approximately 74 hours @ 250sps
2. Fit a prepared SD card into the t4A amplifier. The SD card capacity should be large to record the full recording duration (See Appendix 5). Check the display to ensure the card has been loaded correctly (see Section 3.6).
3. Connect the EEG electrodes to the patient.
4. Setup and initiate the recording (see Section 4).
5. Fit the amplifier in the bag (see Section 3.7).
6. Fit the bag to the patient (see Section 3.7).

5.2 Patient Instruction Sheet

The Patient Instruction Sheet provides important safety information for the patient. The patient should be provided with a copy of the Patient Instruction Sheet and informed of the safety precautions before being sent home.

The only interaction the patient has with the t4A amplifier is to press the event button if they need to log an event.

5.3 Event marking

Once a recording has commenced, the button on the front panel of Trackit t4A acts as an event marker. Events are stored in an event file (filename.tev), from which on review the events are inserted into the displayed data.

The recorded events can be viewed before replaying the recording using the Trackit EEG review program or the Eventit.exe program that comes with the Trackit installation.

The Trackit t4A can record 15 different event types. These can be seen by looking at the Trackit event types in the online event viewer. See Trackit Events, in Section 4.10.

5.4 Ending a recording

To stop a recording:

- 1 Connect the Trackit t4A to the host software.
- 2 Click on the Stop Recording button in the Trackit control panel.

Alternatively, to stop the Trackit t4A recording in the field:

Press the button on the front panel and hold it for approximately 5 seconds.

Note; This feature can be disable in software.

5.5 Identifying a recording

It is not possible to record more than one test on a single card. This test is uniquely identified by the user-definable file name, entered during the setup procedure.

Appendix 1: Trackit t4A Amplifier 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.

EEG inputs

| | |
|-------------------------------|--|
| Number of EEG channels | 28 referential (monopolar) inputs |
| ADC Resolution | 24 bits |
| Sampling | 250 – 2000 Hz (up to 32 channels (EEG & Bipolar)) 4000 Hz (up to 16 Channels (EEG & Bipolar)) 8000 Hz (up to 8 Channels (EEG & Bipolar)) |
| Input impedance | > 20 Mohms |
| Common mode rejection ratio | > 110dB @ 50 and 60 Hz |
| Equivalent input noise | < 4 μ Vpp |
| Gain | 8 \pm 0.5% |
| Max Input V _{diff} | 750mVpp (including DC) |
| Quantisation | 0.17 μ V/bit @ Gain = 8 and Bits = 22 |
| Bandwidth (-3dB) | DC to 4193Hz |
| Max common mode input voltage | 0.4Vpp |
| Input bias current | < 5nA |
| Front-end Calibration | 8mVpp \pm 5% at 0.98Hz |
| Impedance Check current | 24nA \pm 20% at 7.8Hz |

Polygraphy inputs

| | |
|-------------------------------|--|
| Number of polygraphy inputs | 4 poly (bipolar) inputs |
| ADC Resolution | 24 bits |
| Sampling | 250 - 8000 Hz (see sampling rate for EEG inputs) |
| Input impedance | > 20 Mohms |
| Common mode rejection ratio | > 110dB @ 50 and 60 Hz |
| Equivalent input noise | < 4 μ Vpp |
| Gain | 8 \pm 0.5% (AC), 2 \pm 0.5% (DC) |
| Max Input V _{diff} | 750mVpp AC setting (including DC), 3Vpp DC setting |
| Bandwidth (-3dB) | DC to 4193Hz |
| Quantisation | 0.17 μ V/bit @ Gain = 8 and Bits = 22 |
| Max common mode input voltage | 0.4Vpp |
| Input bias current | < 5nA |
| Front-end Calibration | 8mVpp \pm 5% at 0.98Hz |
| Impedance Check current | 24nA \pm 20% at 7.8Hz |

Connections, ports and controls

| | |
|-----------------------------|---|
| Patient Connections | 38 x Touchproof 1.5mm sockets to DIN 42802. |
| Patient Event Input | 1 Jack socket 3.5mm |
| Front-panel push-button | On/Off and Patient Event |
| Host PC Connector | 1 data socket providing USB port (isolated from patient) |
| LED indicators | LED for disk access |
| SD card port | 1 SD card socket |
| Battery connection | 2 x 4-way Modular connections in battery compartment |
| Internal Battery | 1 type LIR2450 Lithium-ion rechargeable Coin cell (non-replaceable) |
| Internal beeper | |
| LCD display, with backlight | Displays time/date, recording time, battery life and disk space |
| Ambient light sensor | Located on front panel |

Bluetooth Wireless

| | |
|--------------|---|
| Type | Bluetooth 4.2 Smart-ready (LE & BR/EDR) |
| Output power | 12dBm max. |

| | |
|-------------------------|---|
| Output frequency | 2.402 - 2.480 GHz, ISM band |
| Data rate | 1.0 Mbps max. |
| Protocols | Standard Bluetooth - SPP, GATT, PAN |
| Modulation | GFSK, DQPSK. Frequency Hopping Spread-Spectrum (FHSS) |
| Error correction | Forward Error Correction (FEC), Automatic repeat request (ARQ). |
| Security | Authorization and authentication of devices, Simple Secure Pairing (SSP), proprietary Interface Protocol |
| Type Approvals | Europe (RE-D); US (FCC/CFR 47 part 15) FCC ID: QOQBT121; Canada (IC RSS) IC ID 5123A-BGBT121; Japan (MIC - formerly TELEC) |
| RE-D (2014/53/EU) | Effective use of frequency spectrum: EN 300 328 EMC: EN 301 489-1, EN 301 489-17, EN 61000-6-2 Health and safety: EN 60950-1+A11:2009 + A1:2010+A12:2011+A2:2013, IEC 60950-1 |
| Bluetooth Qualification | V4.2 |

Physical characteristics

| | |
|--------|---|
| Weight | 250g (without battery packs), 345g (with 2 battery packs) |
| Size | 12.6cm x 8.5cm x 3cm |

Safety and EMC standards

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

| | |
|---|--|
| IEC 60601-1 and IEC 60601-2-26 IEC 60601-1-11 | European standard for medical electrical equipment, general requirements and particular requirements for EEG systems. Collateral standard for medical electrical equipment used in the home healthcare environment. |
| IEC 60601-1-6 | Collateral standard for usability. |
| ANSI/AAMI ES 60601-1 | AAMI Deviations from IEC 60601-1 (USA). |
| CAN/CSA 22.2 No 601.1 M90 | Canadian standard for medical electrical equipment, general requirements. |
| IEC 60601-1-2 | 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

| | |
|---|---------|
| Applied parts degree of protection against electrical shock | Type BF |
|---|---------|

Classification of system

| Classification | Clinical use | Home use |
|---|--|---|
| Degree of protection against electrical shock | Internally powered; or it can be connected to a PC which is powered by a medical grade Class I power supply. Type BF applied parts. | Trackit t4A Amplifier: Internally powered. Type BF applied parts. |
| | | If a PC is supplied, the PC has no electrical connection to the Amplifier & has no applied parts. |
| Degree of protection against harmful ingress of water | Ordinary (no protection) or IP22 (Amplifier in bag) | IP22 (Amplifier in bag) |
| Mode of operation | Continuous operation | Continuous operation |
| Suitability for use in an oxygen rich environment | Not suitable | Not suitable |

Battery pack specifications (per battery pack)

| | |
|-------------------------|--|
| Rated capacity | 2300mAh min., 2400mAh typical |
| Nominal voltage | 3.7V |
| Watt-Hour rating | 8.9Wh |
| Overdischarge detection | 2.40V \pm 0.035V |
| Overcurrent detection | 3.2A to 5.2A |
| Temperature range | Limited to 500mA by the t4A's internal overcurrent protection. |
| | Charge: 0 to +45°C |
| | Discharge: -10 to +60°C |
| | Storage: Less than 1 month at -20 to +60°C |
| | Less than 3 months at -20°C to +45°C |
| | Less than 1 year at -20°C to +30°C |
| Humidity | 65 \pm 20% RH |
| Certification | UN38.3, IEC 62133 ed 2, UL 2054 Listed |
| Dimensions | 1.14cm x 3.66cm x 6.45cm |
| Weight | 48g |

Appendix 2: Additional Events Information

For the t4A EEG Amplifier, events types are as shown below.

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

| Event List Key | Event No. | Contents | Type | Size | Total size | Mapping |
|----------------|-----------|--------------------|-------------------------|---------|------------|-------------------------------|
| 0 | 0 | No event | Fixed | 16 x 16 | 256 | Auto |
| | 1 | Stop recording | Fixed | | | Auto |
| | 2 | Start recording | Fixed | | | Auto |
| | 3 | Door Open | Fixed | | | Auto |
| | 4 | Door Closed | Fixed | | | Auto |
| | 5 | Host On | Fixed | | | Auto |
| | 6 | Host Off | Fixed | | | Auto |
| | 7 | Low Battery | Fixed | | | Auto |
| | 8 | OK Battery | Fixed | | | Auto |
| | 9 | Imp.Check-Mode | Fixed | | | Auto |
| | 10 | Calibrate Mode | Fixed | | | Auto |
| | 11 | Normal Mode | Fixed | | | Auto |
| | 12 | Electrodes on | Fixed | | | Auto |
| | 13 | Electrodes off | Fixed | | | Auto |
| | 14 | Patient Event | Fixed | | | Auto |
| | 15 | External Event | Fixed | | | Auto |
| 1 | 16 | Awake # | User-config | 16 x 16 | 256 | F1 |
| | 17 | Asleep # | User-config | | | F2 |
| | 18 | Eyes open # | User-config | | | F3 |
| | 19 | Eyes closed # | User-config | | | F4 |
| | 20 | Lights on # | User-config | | | F5 |
| | 21 | Lights off # | User-config | | | F6 |
| | 22 | Drowsy # | User-config | | | F7 |
| | 23 | # | User-config | | | F8 |
| | 24 | Photic start | Fixed | | | Auto |
| | 25 | Photic stop | Fixed | | | Auto |
| | 26 | HV start | Fixed | | | Auto |
| | 27 | HV >> | Fixed | | | Auto |
| | 28 | HV stop | Fixed | | | Auto |
| | 29 | Post HV start | Fixed | | | Auto |
| | 30 | Post HV >> | Fixed | | | Auto |
| | 31 | Post HV stop | Fixed | | | Auto |
| 2 | 32 | Video start | Fixed | 32 x 32 | 1024 | Auto |
| | 33 | Video stop | | | | Auto |
| | 34 | Video 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 restored by the program. For ease of entry during acquisition, 24 of these events are mapped to the keyboard F1- F8 keys, Shift F1 – F8 and Control + Shift F1 – F8 keys.

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

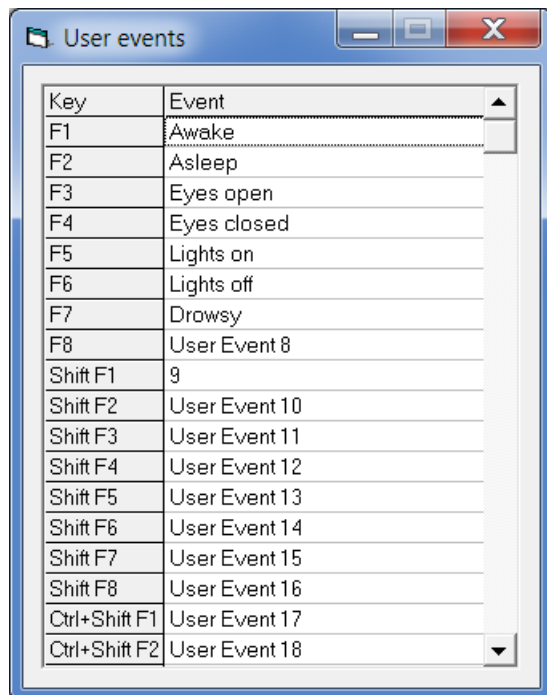


Figure 34: User Events

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.

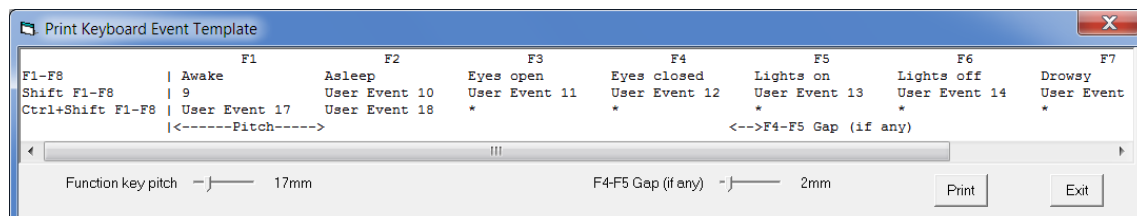


Figure 35: Events Template setup

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.

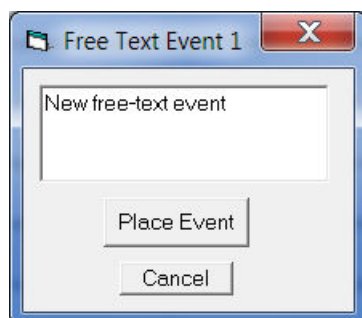
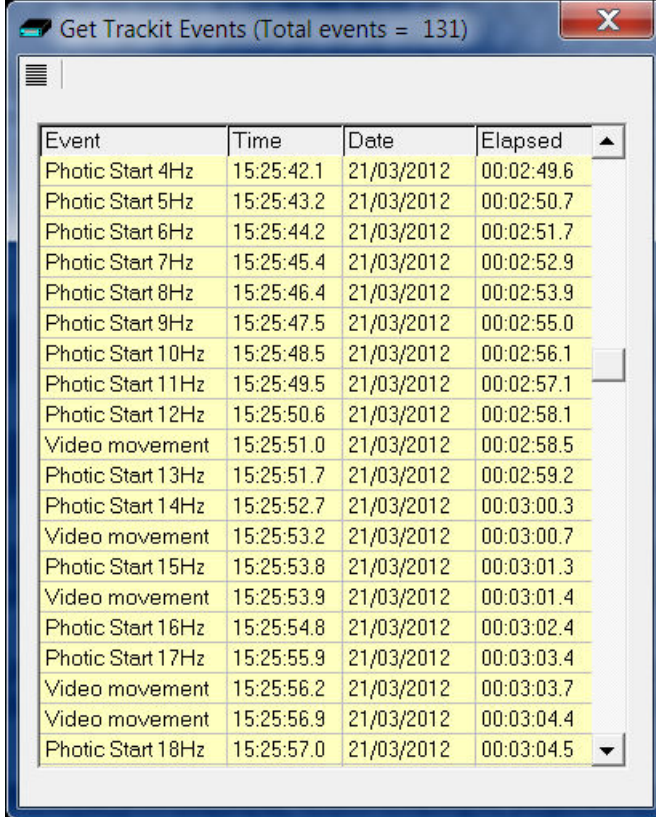


Figure 36: Free-text Event

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



Get Trackit Events (Total events = 131)

| 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 37: Event List

Appendix 3: PC Setup

The Options panel is accessed by pressing the “Options” icon on the Settings toolbar.

Options | Tab 1

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

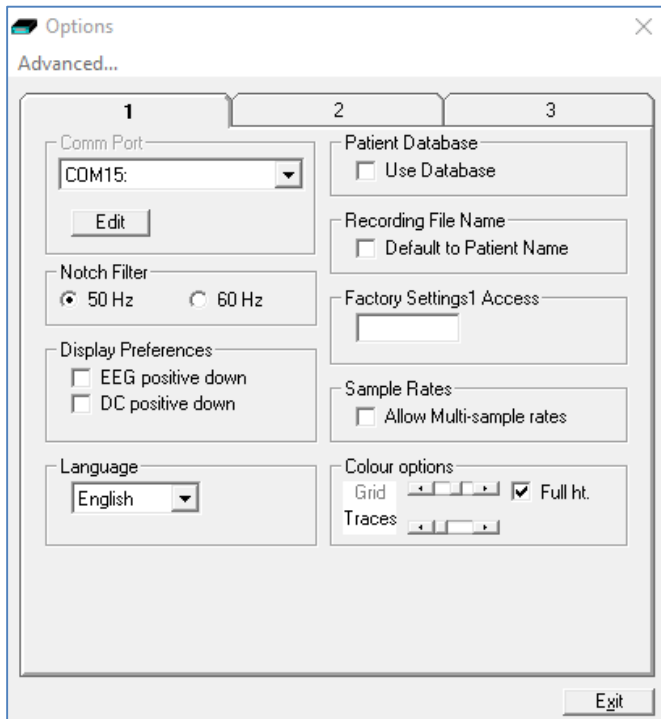


Figure 38: Options Tab 1

Options | Tab 2

The second tab in Options is shown below.

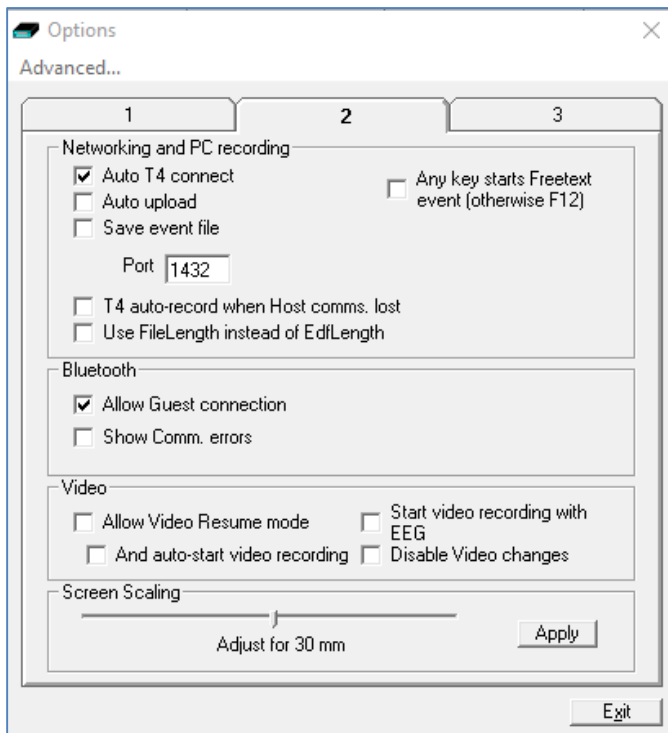


Figure 39: Options Tab 2

The following options are applicable to the t4A:

Networking and PC recording Options

- **Auto T4 connect.** If ticked this will cause the application to attempt to reconnect to the designated t4A after a disconnect. The disconnect can be due to loss of the Bluetooth link or an unplugged cable etc. Autoconnect starts after the first manual connection.
- **Auto upload.** If ticked this will cause the application to automatically upload the t4A's setup immediately after a connection is established. It is only enabled if Auto Trackit Connect is enabled.
- **Save Event File.** If ticked this will cause the application to automatically upload the t4A's event file immediately after a connection is established and save it in a temporary file called TempEve1.tev in the default application path. This file can be viewed or emailed out at a later time with or without the t4A connected. It is only enabled if Auto Trackit Connect and Auto upload are enabled.
- **T4 auto-record when Host comms. lost.** If ticked the t4A will automatically start recording when the Host communication is lost if it has been in Headbox mode (Host PC recording). This feature is most useful with a wireless Bluetooth connection, but it will work for any type of connection.
Note that the t4A will not automatically stop recording upon reconnection. This must be done manually from the Host if required.
- **Use File Length instead of EDF Length.** This is a playback feature and if ticked, the file length is used instead of the edf length parameter embedded in the edf header. Due to the fact that the t4A's SD card can be removed at any time, there can be a partial EDF record at the end of the file and so the actual file size may not be an exact multiple of EDF records.

Bluetooth

- **Allow Guest connection.** If ticked this will allow the application to become a Bluetooth GUEST. Before actual connection the application will listen on the connection to ascertain whether a MASTER is already in control of the designated Trackit. In these situations, the new application becomes a GUEST connection if allowed. Note that this option concerns the application only. There are other options that configure the t4A and the Bluetooth module as regards GUEST connections (see below).
- **Show Comm. errors.** This allows any Comm. errors to be displayed on the main screen status bar below the Patient ID. This applies to all connections, whether direct, USB or Bluetooth. It can be useful when assessing signal quality.

Video

- **Allow Video Resume mode.** This allows Video synchronised recordings to be resumed after the PC has been powered-off.
 - **And auto start video recording.** This allows the video to automatically start recording after a Video Resume has occurred.
- **Start video recording with EEG.**
- **Disable Video changes.**

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

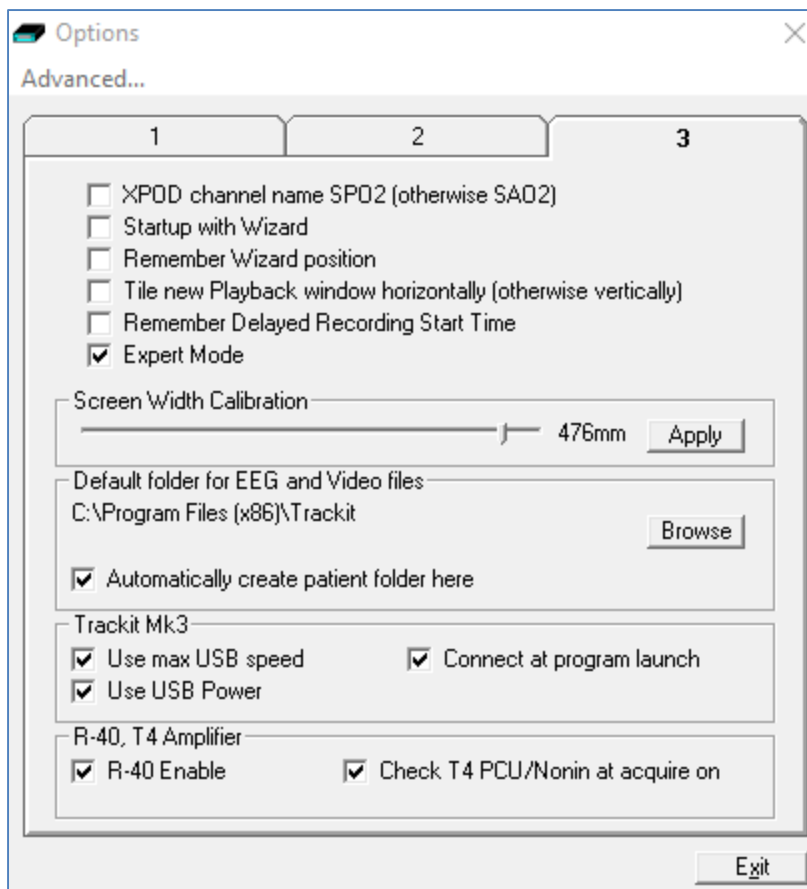


Figure 40: Options Tab 3

The following options are applicable to the t4A:

- **Startup with Wizard.** If checked, the Trackit program will next start with the Wizard.
- **Remember Wizard position.** If checked, the last Wizard window position will be remembered and recalled. Otherwise it will appear centrally.
- **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 chooses 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 t4A at launch.
- **R-40 Enable.** Enables advanced features applicable to the newer amplifiers (R40, T4, t4A). This option should remain ticked.

Appendix 4: Bluetooth

Introduction

The Trackit t4A Amplifier has built-in Bluetooth wireless capabilities, which allows the t4A to communicate, wirelessly, with a Bluetooth-enabled PC. This allows the t4A to be monitored remotely over a secure wireless link up to a range of about 100m or greater (dependent on hardware and environmental factors).

System overview

The Bluetooth module is Bluetooth Qualified v4.2. For full specifications, refer below.

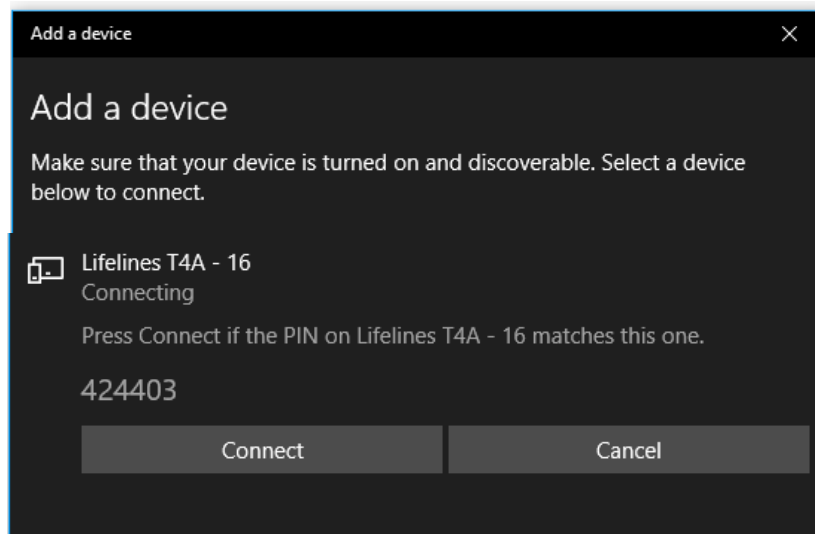
Bluetooth is a device-to-computer wireless connection and will connect to any suitably certified Bluetooth host, like a PC or laptop. The connection process uses authentication and password protection.

Connection and use

The Bluetooth connection on the t4A uses Simple Secure Pairing (SSP) authentication. When the t4A is paired with a computer, a random pin is generated and shared between the t4A and the PC. The pin code must be confirmed on both the PC and the amplifier in order to connect the two devices. This prevents other devices from interrupting the pairing process.

To pair to a t4A Amplifier:

- 1: In the Windows Bluetooth options, search for new devices. The t4A will be shown as Lifelines T4A – xx, where xx is the serial number.
- 2: Select the desired t4A amplifier and click the “Pair” button.
- 3: A pin code is displayed, as shown below.



- 4: At the same time, the T4A should display the same pin code on its display.



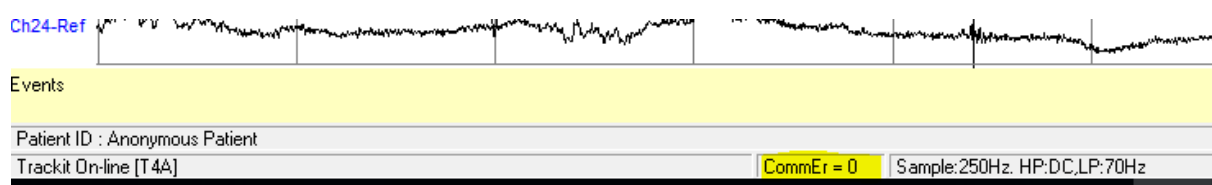
5: If the pin codes match, press the Event button on the t4A amplifier and the Connect button on the PC.

Note: There is a 10 second timeout on the t4A amplifier. If the Event button is not pressed within 10 seconds, the pairing will fail.

6: Once the pin codes have been confirmed on both the PC and the amplifier, the pairing process will be complete.

Once established, the t4A acts as the server and provides the SPP service to the PC acting as a client.

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



The displayed number is the number of invalid messages received. If the number of invalid received messages increases significantly, it will cause the Trackit application to close the connection. If the Autoconnect feature has been enabled in Options, the application will automatically attempt to reconnect to the t4A every 10 seconds.

1. The radio modules are tested according to their own EMC emissions and immunity standards: EN 300 328, EN 301 489-1 and EN 301 489-17
2. The radio module is pre-certified and Type Approved.

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

Pre-compliant Wireless Modules

The use of a pre-compliant, certified and Type-approved internal Bluetooth wireless module which complies with applicable national radio regulations ensures best performance, interoperability, co-existence and quality of service is achieved.

Interference

The t4A Amplifier will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of IEC60601-1-2. However, the amplifier records signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. Such interference may cause signal artefacts.

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.

Caution: when using the amplifier in close proximity to other devices using Bluetooth or WiFi communication, orientate or position these devices for least interference. If possible separate the devices or turn off their wireless communication.

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

Appendix 5: SD Card Information

BDF File Format

The Trackit t4A Amplifier records EEG data to the SD card in BDF format, which is the 24-bit variation of the native EDF (European Data Format). The Trackit software and other EEG applications can view EEG data in BDF format. The table below shows the comparison between the EDF header and the BDF header. Each data sample in a BDF file is stored in 3 bytes.

| Length in bytes | BDF Header: | EDF Header: | Description | T4A Default |
|-----------------|--|-------------------------|--|-------------------|
| 8 bytes | Byte 1: "255" (non ascii) (0xFF) | Byte 1: "0" (ASCII) | Identification code | (0xFF) |
| | Bytes 2-8 : "BIO-SEMI" (ASCII) | Bytes 2-8 : "(ASCII)" | | BIOSEMI |
| 80 bytes | User text input (ASCII) | | Local subject identification | Anonymous Patient |
| 80 bytes | User text input (ASCII) | | Local recording identification | Recording no. 1 |
| 8 bytes | dd.mm.yy (ASCII) | | Startdate of recording | 01.01.17 |
| 8 bytes | hh.mm.ss (ASCII) | | Start time of recording | 09.00.00 |
| 8 bytes | (ASCII) | | Number of bytes in header record | 8192 |
| 44 bytes | "24BIT" (ASCII) | "BIOSEMI" (ASCII) | Version of data format. | 24BIT |
| 8 bytes | (ASCII) | | Number of data records "-1" if unknown | 0 |
| 8 bytes | e.g.: "1" (ASCII) | | Duration of a data record, in seconds | 0.1 |
| 4 bytes | e.g.: "257" or "128" (ASCII) | | Number of channels (N) in data record | 32 |
| N x 16 bytes | e.g.: "Fp1", "Fpz", "Fp2", etc (ASCII) | | Labels of the channels | See table below |
| N x 80 bytes | e.g.: "active electrode", "respiration belt" (ASCII) | | Transducer type | AgAgCl |
| N x 8 bytes | e.g.: "uV", "Ohm" (ASCII) | | Physical dimension of channels | uV |
| N x 8 bytes | e.g.: "-262144" (ASCII) | e.g.: "-32768" (ASCII) | Physical minimum in units of physical dimension | -375000 |
| N x 8 bytes | e.g.: "262143" (ASCII) | e.g.: "32767" (ASCII) | Physical maximum in units of physical dimension | 375000 |
| N x 8 bytes | e.g.: "-8388608" (ASCII) | e.g.: "-32768" (ASCII) | Digital minimum | -8388608 |
| N x 8 bytes | e.g.: "8388607" (ASCII) | e.g.: "32767" (ASCII) | Digital maximum | 8366807 |
| N x 80 bytes | e.g.: "HP:DC; LP:410" | e.g.: "HP:0,16; LP:500" | Prefiltering | HP:0Hz LP:70Hz |
| N x 8 bytes | For example: "2048" (ASCII) | | Number of samples in each data record (Sample-rate if Duration of data record = "1") | 25 |
| N x 32 bytes | (ASCII) | | Reserved – Used by Trackit to identify the Hardware channels | |

SD Card Capacity Calculation

To determine the required SD card capacity, use the following table and calculation.

The table below shows the amount of data that will be stored to the card in a **24 hour recording**. The number in brackets is the minimum card size that should be used for the selected configuration.

For longer recordings (greater than 24 hours), multiply the data size by the expected duration of the recording (in number of days).

For example: A 3 day recording (72 hours) at 250sps and 24 channels will store 4680 MB of data and require an 8GB card.

| | 8 Channels | 16 Channels | 24 Channels | 32 Channels |
|-----------------|---------------------------|---------------------------|-------------------------|---------------------------|
| 250 sps | 520 MB (1 GB) | 1040 MB (2 GB) | 1560 MB (2 GB) | 2080 MB (4 GB) |
| 500 sps | 1040 MB (2 GB) | 2080 MB (4 GB) | 3120 MB (4 GB) | 4160 MB (8 GB) |
| 1000 sps | 2080 MB (4 GB) | 4160 MB (8 GB) | 6240 MB (8 GB) | 8320 MB (16 GB) |
| 2000 sps | 4160 MB (8 GB) | 8320 MB (16 GB) | 12480 (16 GB) | 16640 MB (32 GB) |
| 4000 sps | 8320 MB (16 GB) | 16640 MB (32 GB) | | |
| 8000 sps | 16640 MB (32 GB) | | | |

Appendix 6: Default Setup on Amplifier

| Channel | Signal Type | Channel Label | Physical Signal Range | | | |
|---------|----------------|---------------|-----------------------|---------|-------|--|
| | | | Min | Max | Units | |
| 1 | AC Referential | Fp1-Ref | -375,000 | 375,000 | μV | |
| 2 | AC Referential | Fp2-Ref | -375,000 | 375,000 | μV | |
| 3 | AC Referential | F3-Ref | -375,000 | 375,000 | μV | |
| 4 | AC Referential | F4-Ref | -375,000 | 375,000 | μV | |
| 5 | AC Referential | C3-Ref | -375,000 | 375,000 | μV | |
| 6 | AC Referential | C4-Ref | -375,000 | 375,000 | μV | |
| 7 | AC Referential | P3-Ref | -375,000 | 375,000 | μV | |
| 8 | AC Referential | P4-Ref | -375,000 | 375,000 | μV | |
| 9 | AC Referential | O1-Ref | -375,000 | 375,000 | μV | |
| 10 | AC Referential | O2-Ref | -375,000 | 375,000 | μV | |
| 11 | AC Referential | F7-Ref | -375,000 | 375,000 | μV | |
| 12 | AC Referential | F8-Ref | -375,000 | 375,000 | μV | |
| 13 | AC Referential | T3-Ref | -375,000 | 375,000 | μV | |
| 14 | AC Referential | T4-Ref | -375,000 | 375,000 | μV | |
| 15 | AC Referential | T4A-Ref | -375,000 | 375,000 | μV | |
| 16 | AC Referential | T6-Ref | -375,000 | 375,000 | μV | |
| 17 | AC Referential | A1-Ref | -375,000 | 375,000 | μV | |
| 18 | AC Referential | A2-Ref | -375,000 | 375,000 | μV | |
| 19 | AC Referential | Fz-Ref | -375,000 | 375,000 | μV | |
| 20 | AC Referential | Cz-Ref | -375,000 | 375,000 | μV | |
| 21 | AC Referential | Pz-Ref | -375,000 | 375,000 | μV | |
| 22 | AC Referential | Oz-Ref | -375,000 | 375,000 | μV | |
| 23 | AC Referential | PG1-Ref | -375,000 | 375,000 | μV | |
| 24 | AC Referential | PG2-Ref | -375,000 | 375,000 | μV | |
| 25 | AC Referential | 25-Ref | -375,000 | 375,000 | μV | |
| 26 | AC Referential | 26-Ref | -375,000 | 375,000 | μV | |
| 27 | AC Referential | 27-Ref | -375,000 | 375,000 | μV | |
| 28 | AC Referential | 28-Ref | -375,000 | 375,000 | μV | |
| 29 +/- | AC Bipolar | 29A-29B | -375,000 | 375,000 | μV | |
| 30 +/- | AC Bipolar | 30A-30B | -375,000 | 375,000 | μV | |
| 31 +/- | AC Bipolar | 31A-31B | -375,000 | 375,000 | μV | |
| 32 +/- | AC Bipolar | 32A-32B | -375,000 | 375,000 | μV | |

Appendix 7: Troubleshooting Guide

COM port problems with Bluetooth communication to Trackit t4A

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

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

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

Problems starting the recording

The setup has not been sent correctly

Under T4 Status, in the Control Panel, check that Acquire Ready shows Yes. If it is not ready, acquisition cannot begin. This could be caused by incomplete transmission of the Trackit t4A setup. Check that all channels in the Recording setup have the same sample rate. The t4A does not support multi-sample rate.

An incorrect setup has been sent

If an incompatible setup has been sent to the Trackit t4A the message; "unable to comply" will indicate that. If an incorrect setup has been sent, the Trackit Control Panel will show 'Acquire Ready: No'.

The card is not formatted correctly

If the card is not formatted with a correct 32-bit FAT, a recording cannot commence. Format the flash card using the SD Card Formatter PC utility. See 'Get Card Info', in 5.5 Advanced Settings.

The card is corrupted

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

Trackit t4A: always stop a recording, or if hot swapping wait for the write LED to go out, before removing the card.

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

The card is not inserted correctly

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

Appendix 8: Manufacturer's Declaration

EMC Compatibility

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

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

WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.

| Accessory name | Type | Length | Manufacturer |
|----------------------|---------------------|--------|--------------------------------|
| USB Interface Cable | USB | 2.8 m | USB shielded cable |
| Input electrodes | EEG disc electrodes | 1 m | Unshielded EEG disc electrodes |
| Patient Event Switch | CM-5 | 2 m | Zygo |

WARNING: The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

EN 60601-1-2

The t4A is intended for use in the electromagnetic environment specified below. The customer or user of the t4A should assure that it is used in such an environment.


| Emissions Test | Compliance | Electromagnetic Environment Guidance |
|--|------------|--|
| RF emissions CISPR11/EN55011 | Group 1 | The t4A 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 t4A is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. Note: Only the recommended or supplied PC must be used in the system to ensure compliance. |
| Harmonic emissions EN 61000-3-2 | Class A | |
| Voltage fluctuations/Flicker emissions EN 61000-3-3 | Complies | |

Electromagnetic Immunity

EN 60601-1-2

The t4A is intended for use in the electromagnetic environment specified below. The customer or user of the t4A should assure that it is used in such an environment.

| Immunity Test | EN 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic discharges (ESD) EN 61000-4-2 | +/- 6 kV: Contact +/- 8 kV: Air | +/- 6 kV: Contact +/- 8 kV: Air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast Transients/burst EN 61000-4-4 | Compliance is provided by the recommended PC equipment. | Compliance is provided by the recommended PC equipment. | Mains power should be that of a typical commercial and/or hospital environment |
| Surge EN 61000-4-5 | Compliance is provided by the recommended PC equipment. | Compliance is provided by the recommended PC equipment. | Mains power should be that of a typical commercial and/or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11 | Compliance is provided by the recommended PC equipment. | Compliance is provided by the recommended PC equipment. | Mains power should be that of a typical commercial and/or hospital environment. If the user of the t4A system requires continued operation during power mains interruptions, it is recommended that the t4A system be powered from an uninterruptible power supply or a battery |
| Power frequency (50/60 Hz) magnetic field EN 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment |

| Immunity Test | EN 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|--|-----------------------------|------------------|--|
| | | | <p>Portable and mobile RF communications equipment should be used no closer to any part of the t4A, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> |
| RF Common mode/ Conducted Susceptibility EN 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | $d = [3.5/V] \sqrt{P}$ $= 1.2 \sqrt{P}$ <p>Note: using unshielded input leads ^c</p> |
| Radiated RF Electromagnetic Fields EN 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = [3.5/E] \sqrt{P} : 80 \text{ MHz to } 800 \text{ MHz}$ $= 1.17 \sqrt{P}$ $d = [7/E] \sqrt{P} : 800 \text{ MHz to } 2.5 \text{ GHz}$ $= 2.33 \sqrt{P}$ <p>Note: using unshielded input leads ^d</p> |
| | | | <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>^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 t4A is used exceeds the applicable RF compliance level above, the t4A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the t4A.</p> | | | |
| <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |
| <p>^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.</p> | | | |
| <p>^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.</p> | | | |

Recommended separation distance between portable and mobile RF communications equipment and the t4A EEG System
EN 60601-1-2

The t4A is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t4A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the t4A as recommended below, according to the maximum output power of the communications equipment.

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

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

NOTE 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.