Trackit T4
EEG Amplifiers

32 channel version: **T4 32**
68 channel version: **T4 68**

lifelines
neuro

Imagine EEG Anywhere

MADE IN
BRITAIN

Version History

V 1 (23 June 2016)

- Initial release

V 1.1 (09 Aug 2016)

- Amended part numbers in section 1.4.

V 1.2 (28 Sep 2016)

- Various amendments for IEC 60601-1.

V 1.3 (13 Dec 2016)

- Amendments to Nonin and Aux Input specifications in section 1.6.
- Changed 'Contraindication' to 'Warning' in section 1.2. There are no contraindications for this device.

V 1.4 (08 February 2017)

- Added to section 1.2 "CONTRAINDICATIONS: There are no known contraindications to the use of this equipment".
- Added to section 1.2 and 2.3 "WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth".
- Removed drawing numbers in section 1.4.
- Amended section 2.4: Internal Li-Ion backup battery operation.
- Added to Section 4.1: "Note: If a Setup that uses greater than 32 channels plus the Nonin is attempted...".
- Added to section 3.3 details of battery replacement frequency.

V 1.5 (10 March 2017)

- Amended instructions concerning oximeter and Aux. input sensors.

V 1.6 (13 March 2017)

- Further amendments to instructions concerning oximeter and Aux. input sensors.

V 1.7 (22 March 2017)

- Added to Aux DC Input instructions – "for hospital and clinic use. Not for home use" in section 1.6 and 3.3.

V1.8 (18 August 2017)

- Photic operation added in Appendix 2.
- Wireless operation added in Appendix 5.

V1.9 (08 November 2017)

- Added disinfection information in section 2.8.
- Change of N.B. to 0086 (BSI).

V1.10 (5th September 2018)

- Added T4-PCU 32+3.
- Added further disinfection information in section 2.8.

V1.11 (7th October 2019)

- Updated EMC declaration and warnings.
- Changed Notified body and added EC Rep.
- Document style and images update.
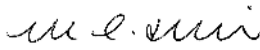- Software section updated

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All warranties for third-party products used within the T4 system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

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Responsibility of manufacturer

The manufacturer and distributor consider themselves responsible for the equipment's safety, reliability and performance only if:
- any peripheral equipment to be used with the T4 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.

Contents

Illustrations

1 Overview and Technical Description

1.1 General description

Indications for use

The T4 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 T4 EEG Amplifier is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications and due to its small size, can be used in ambulatory applications. In this situation, the EEG electrodes are fitted to the patient by a trained clinician prior to the patient being sent home. No subsequent intervention is required by the patient. Upon completion of the recording, the data which is stored on a memory card is reviewed by a clinician using review and analysis software on a PC.

It is a compact USB amplifier which provides 32 channels (or 68 channels with internal expansion option) with built-in calibration and electrode impedance measurement. Also provided is a Nonin pulse oximeter interface, a Patient Event input and an Aux DC input. Optional wireless communication is available (Bluetooth and WLAN WiFi).

There are two variants of the Trackit T4 EEG Amplifier:

- **Trackit T4-32** providing 24 referential + 8 poly channels.
- **Trackit T4-68** providing 64 referential + 4 poly channels (using internal expansion board).

Plug-on Patient Connection Units (PCUs) provide 32 channel touchproof inputs (model **T4-PCU 24+8**) or 68 channels (model **T4-PCU 64+4**).

Also available is model **T4-PCU 32+3** Patient Connection Unit which provides a dedicated Electrocap D-type connector plus an additional 10 channels of EEG and 3 poly bipolar channels.

The Amplifier is intended to be connected to a USB port on a PC which is powered from a medically approved power supply. In addition it can be battery powered in ambulatory applications.

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 T4 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 in intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. This equipment is not be used for the determination of brain death.

WARNING: 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: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit T4, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

CAUTION: When in close proximity to the Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

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

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

CAUTION: 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

Pushbutton

WLAN WiFi

Manufacturer

Nonin Xpod Pulse Oximeter

Memory card read/write

Internal battery hazard
- refer to section 1.7

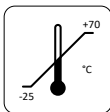On/Off and patient event switch

European Representative

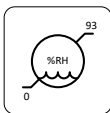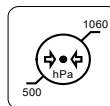**Storage and transport symbols**

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 T4 EEG Amplifier is a multi-channel electroencephalograph designed for use in routine EEG and lab monitoring applications.

It is a compact USB amplifier which provides 32 channels (or 68 channels with internal expansion option) with built-in calibration and electrode impedance measurement. A Nonin XPOD interface is provided, a Patient Event input and an Aux DC input. Optional wireless communication is available (Bluetooth and WLAN WiFi).

The Amplifier is intended to be connected to a specific PC and a medical grade power supply. Refer section 3.1 for details.

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

The T4 EEG Amplifier comprises the following components:

T4-32 Amplifier	part number 1505
T4-68 Amplifier	part number 1501
T4-PCU 24+8	part number 1552
T4-PCU 64+4	part number 1553
T4-PCU 32+3	part number 1556
USB Power Bank battery	part number 1560
Battery cable	part number 1561
T4 bag and straps	part number 1562
Patient event switch	part number 1353
Xpod Pulse Oximeter Nonin	part number 1327
Trackit tool	part number 1115
Amplifier USB cable	part number 1277
Lenovo ThinkPad laptop computer	part number 1389
Medical grade power supply	part number 1390
Mains cable, UK	part number 1066
Trackit software CD, standard	part number 1009

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

1.5   Specifications and safety

Refer to Appendix 1 for specifications.

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

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

*Note: Compliance is provided by the PC.

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.	Internally powered. Type BF applied parts.
		If a PC is supplied, it 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 T4 Amplifier

The T4 USB amplifier provides 32 channels (or 68 channels with internal expansion option) with built-in calibration and electrode impedance measurement. A Nonin XPOD interface is provided, a Patient Event input, an Aux DC input and an Electrocap connector. The Amplifier has built in type-BF patient isolation and has a USB interface to the PC. Optional wireless communication is available (Bluetooth and WLAN WiFi).

The Patient Connection Unit (PCU) connects the standard 1.5mm touchproof EEG recording electrodes attached to the patient to the T4 unit. It is available either as a T4-PCU 24+8 (32 channel) unit or a T4 PCU 64+4 (68 channel). The PCU is plugged into the front of the unit and retained with two screws operated by the supplied special tool.

Applied parts, type BF

EEG Electrodes

The amplifier connects to standard 1.5mm touchproof EEG recording electrodes arranged in a standard 10-20 pattern (T4 PCU 24+8) or the grid layout (T4 PCU 64+4), attached to the patient's head.

WARNING: Lifelines does not supply EEG electrodes. The Amplifier accepts standard 1.5 mm touchproof electrodes using DIN 42802-style connectors. To ensure patient safety, the electrodes used must be approved to the Medical Device Directive 93/42/EEC in Europe or to the relevant local standards outside Europe.

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

Oximeter Sensor

The amplifier is approved for use with a Nonin 8000AA sensor which attaches to the patient's finger.

Patient Event pushbutton

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

Aux DC Input

The amplifier is approved for use with a SleepSense body position sensor, type 1575, for hospital and clinic use. Not for home use.

CAUTION: Only use approved sensors as specified by Lifelines.

USB Cable

The Amplifier plugs directly into a USB port on the PC.

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

USB Power Bank battery pack for ambulatory applications

The Amplifier plugs directly into the USB port on the Power Bank.

WARNING: The Amplifier must only be used with the USB Power Bank supplied or authorised by Lifelines.

Micro-SD Memory Card
The micro-SD card is used to store the EEG data recorded by T4. Storage cards of varying capacity are available in the micro-SD format.

Bags and Straps for ambulatory applications
The Bag houses the Amplifier and battery.

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 2000 (with SP2), Windows XP, Windows Vista, Windows 7, 8 or 10 on the host PC and is used to setup and review the T4 Amplifier and to record on to the PC.

Functions of the software:
- Download the recording template. This includes which electrodes are used and the recording montage. See section 4.4 & 4.11
- Perform a calibration check of the Amplifier. See section 4.8.
- Perform an Impedance check on the electrode inputs. 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 T4 amplifier contains a replaceable lithium ion rechargeable coin cell, type LIR2450.

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

1. Remove PCU and the four screws from underside of instrument, two from the front and two from the rear mouldings. Remove bottom of case.
2. Un-clip the wrap-around screen to expose the battery beneath.
3. Grasp battery between thumb and forefinger and pull it from the socket.
4. Push replacement battery into the socket ensuring +ve is uppermost.
5. Re-clip the wrap-around screen and reassemble the case.

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

2 Installation and Maintenance

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

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

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

The manufacturer should be contacted (details on page 3) for assistance, if needed, in setting up, using or maintaining the equipment; or to report unexpected operation or events.

The assembly of the system and any modifications during its service life require evaluation to the requirements of IEC 60601-1.

2.1 Checks for completeness and integrity

1   Remove the equipment from the packaging case(s).
2   Use the parts list to check that all ordered items have been received.
3   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

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

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
Standard USB port.

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.

2.4   Battery Operation Time

USB Powerbank Li-Polymer battery pack
When fully charged the battery pack will typically power the unit for 36 hours depending on the number of channels, sample rate and wireless usage.
The typical service life is 2 years.

Internal Li-Ion backup battery
The internal backup battery will enable the unit to continue operating for a short period of time (15 mins approx.) to allow the main battery pack to be replaced. It is recharged automatically, whenever the main battery pack is connected, with acquire off. The state of charge is displayed, as described in section 3.4, whenever the unit is internally powered from the backup battery. To charge manually, operate the pushbutton several times to activate the backlight and if the reading drops below approximately 70%, charge the battery for about 10 minutes by connecting the main battery pack or connecting to a USB port.
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 and its battery 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 connection between the PC and the T4 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 sensor cables.

When the equipment is operated with or without its Bluetooth or WiFi on, other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment. The T4 may have internal radios fitted. These are approved industry-standard Bluetooth and Wi-Fi types which present minimal risk of reciprocal interference with other equipment.

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 T4 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 T4 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 arte-facts.

The T4 may have internal radios fitted. These are approved industry-standard Bluetooth and Wi-Fi types which present minimal risk of reciprocal interference with other equipment.

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

Caution: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit T4, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

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

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

2.8   Maintenance and cleaning

The T4 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, except for replacement of the external battery.

Cleaning
Prior to each re-use of the system, all the outer surfaces of the T4 Amplifier, bag and power pack 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.), Micro-Kill Disinfectant Wipes, Sani-Cloth HB Germicidal Wipes (Medline).

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

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

2.9   Disposal of equipment
The expected service life of the equipment, parts and accessories is three years, except for the USB Powerbank battery pack which is two 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.
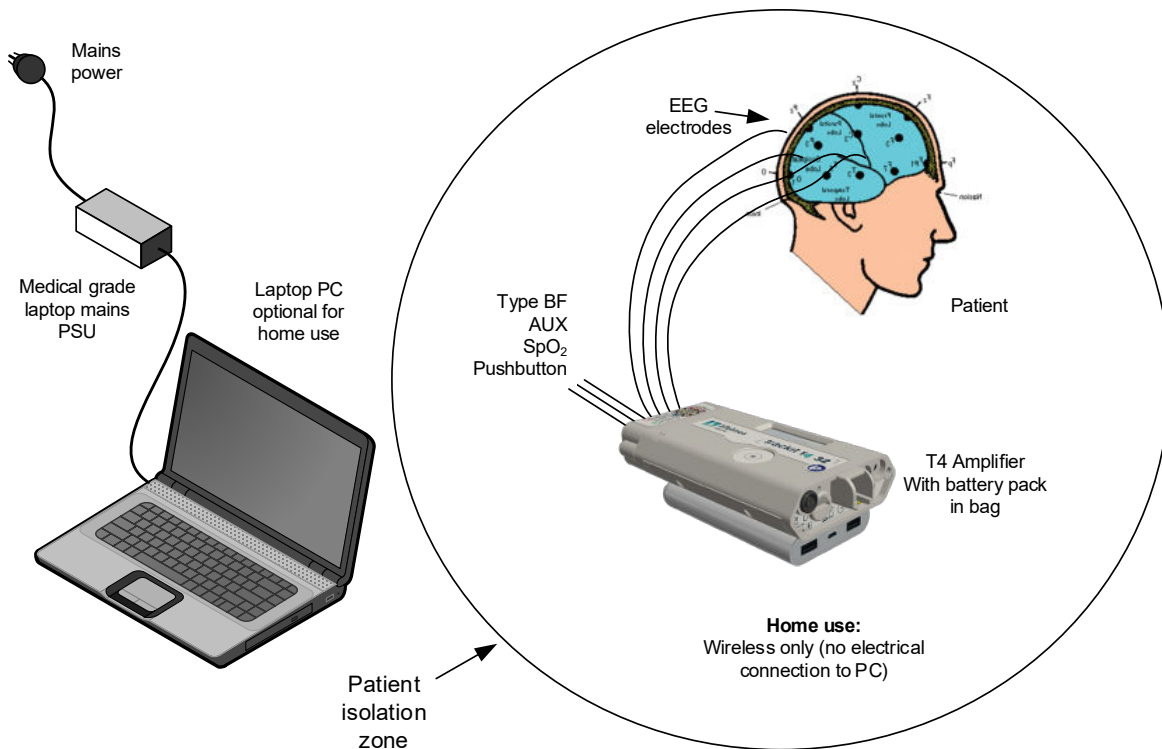**Caution**: Do not dispose of batteries by incineration.

3 Connections and usage

3.1 Overview
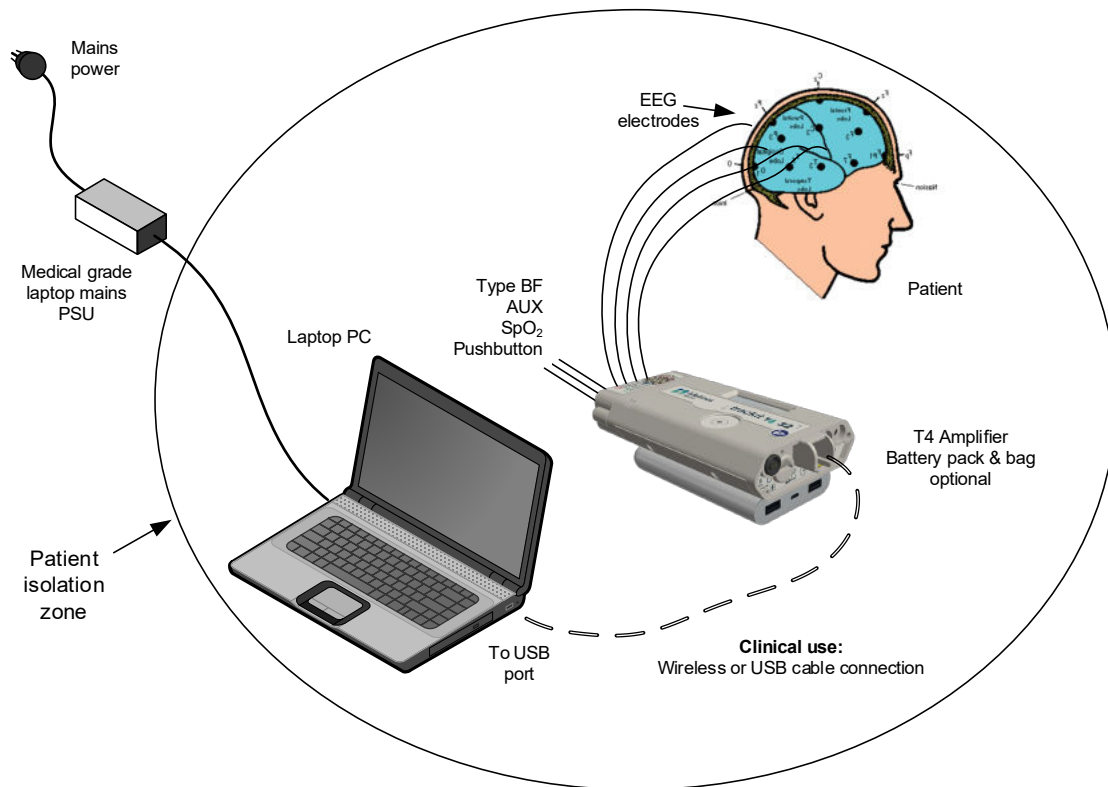
Figure 1 Connecting the T4 Amplifier – Clinical Use

Where the entire T4 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.

Figure 2 Connecting the T4 Amplifier - Home Use

The laptop PC is optional for home use where it may be used for video recordings. There is no connection between the PC and the T4 Amplifier unit, as all communication is accomplished wirelessly.

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   Connecting the T4 System

Clinical Use

The T4 Amplifier is optionally housed inside its bag with battery or used standalone. It is plugged into the PC USB port using the cable supplied, part number 1277 as shown below, or a wireless connection can be used instead. The USB Cable is plugged into the rear housing of the T4 Amplifier using the RJ45 plug and into any USB port on the laptop PC.

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

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.

Home Use

The T4 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 connection between the PC and the T4 Amplifier unit, as all communication is accomplished wirelessly.

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 and battery replacement. Refer to the Patient Instruction Sheet for details.

Estimating the precise recording time of the battery is difficult as it depends on the number of channels, whether Bluetooth or Wi-Fi are enabled, oximeter use, etc. For recordings over 24 hours in length it is recommended that the patient is given instructions to replace the battery every 24 hours.

Connecting the T4 Amplifier

The top face of the T4 houses the display and the patient event pushbutton. For display details refer to section 3.3 below. Pressing the pushbutton records a patient event and illuminates the back-light of the display. Above the pushbutton is a circular aperture which houses a light level sensor.

Figure 3 Connecting the T4 Amplifier (front face)

The front face of the Amplifier's PCU is laid out in a standard 10-20 format (T4 PCU 24+8) or a grid layout (T4 PCU 64+4). It accommodates standard touchproof electrode leads fitted with DIN 42802 connectors.

The **T4-PCU 32+3** has a standard 25-way D-type Electrocap socket providing 21 EEG channels. It uses the standard mapping Fp1 – Pz mapped to EEG channels 1 – 21, plus Ref and Gnd. An additional 10 independent EEG channels are provided by individual touchproof connectors, mapped to EEG channels 22 – 31. This takes account of users who may not want the Electrocap or maybe want to use some extra channels as well. These are labelled EEG 1 (22), EEG 2 (23) etc. Also provided are 3 bipolar channels.

The connections and channel mapping are as follows:

Electrocap connector					
Electrode	EEG channel No.	D25 pin No.	Electrode	EEG channel No.	D25 pin No.
Fp1	1	1	Fp2	2	14
F3	3	2	F4	4	15
C3	5	3	C4	6	16
P3	7	4	P4	8	17
O1	9	5	O2	10	18
F7	11	6	F8	12	19
T3	13	7	T4	14	20
T5	15	8	T6	16	21
NEUT	N	9	Cz	20	22
Fz	19	10	Pz	21	23
A1	17	11	A2	18	24
REF	R	13			

| Touchproof connectors	
Electrode	Channel No.
1_{22}	22
2_{23}	23
3_{24}	24
4_{25}	25
5_{26}	26
6_{27}	27
7_{28}	28
8_{29}	29
9_{30}	30
10_{31}	31
REF	-
GND	-
Bipolar channels	

Poly 1	Poly 1
Poly 2	Poly 2
Poly 3	Poly 3

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: Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

The top edge of the Amplifier provides for several other connections, as shown below.
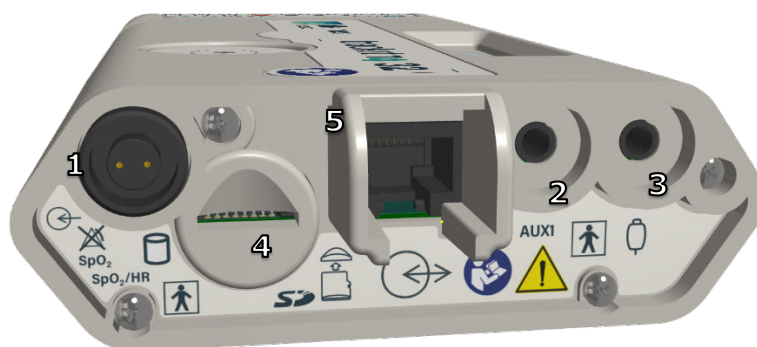
Figure 4 Connecting the T4 Amplifier (back face)

1. Nonin Xpod: the circular connector allows for the connection of a Nonin Xpod pulse oximeter for measuring SpO$_2$. This is plugged into the circular connector and the appropriate sensor plugged into the Xpod device. Note that Lifelines does not supply sensors and these will need to be sourced separately.

    Note: the Nonin Xpod should not be used if more than 32 channels are on.

    Refer to the manufacturer's instructions supplied with the sensor when fitting it to the patient.

    The appropriate recording setup will need to be used as described in section 4.1.

2. Aux1: a 3.5mm mono jack connector allows for the connection of the Sleepsense body position sensor, type 1575, for hospital and clinic use. Not for home use.

3. Patient Event: this 3.5mm jack connector allows for the connection of a standard Patient Event Thumb Switch.

    CAUTION: All these connections are type BF isolated. The conductive part of connectors and transducers should not contact other conductive parts including earth. Always ensure that the transducer fitted is suitable for a connection of this type.

4. Micro-SD memory card slot.

5. Host connection RJ45 socket.

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

3.4   Starting the system

To start the system proceed as follows:

- Plug the PC into the mains supply.
- Switch on the PC and wait for Windows to load.
- Ensure T4 Amplifier is connected via the USB lead.
- Launch Trackit application and continue as detailed in section 4.
- These procedures also apply following a mains interruption.

Indicators

The following indicators are shown on the display on the top face of the T4:

⊕	→	0	8	:	1	7		L/R	⊘	→	1	2	:	0	7
▯	→			7	2	%	B	Ψ	W	⊡	→	1	0	1	3	M

Where the symbols indicate the fields to the right to have the following meanings:

⊕   Current time, hh:mm

⊘   Elapsed recording time, hh:mm ('‐‐:‐‐' if not recording)

▯   Battery capacity, % or 'USB' if external power applied

⊡   Micro-SD card storage capacity in Mbytes, xxxxM (remaining capacity if recording)

B   If the internal Bluetooth option is fitted, this indicates that it is on. Pressing the pushbutton 4 times within 4 seconds toggles the setting to off, indicated with a b. If the Bluetooth option is not fitted, nothing is displayed.

W   If the internal WiFi option is fitted, this indicates that it is on. Pressing the pushbutton 5 times within 4 seconds toggles the setting to off, indicated with a w. If the WiFi option is not fitted, nothing is displayed.

Ψ   Whenever a wireless connection is made the Ψ symbol is displayed.

L/R   Recording in progress

     R   Recording in progress

     L   Recording and Low memory card capacity remaining (< 8 minutes) during recording (accompanied by auditory beep every 30 seconds)

     *   When the battery is low, there is an auditory beep at 1Hz rate. There is no additional information displayed.

3.5   Shutdown of the system

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

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

After the recording is finished, the Micro-SD memory card is removed for reading in a PC.

3.6   Battery replacement and charging

For ambulatory, body-worn applications the T4 is powered from a USB Power Bank. The T4 plugs directly into the USB port on the Power Bank. Ensure that this uses the 1A socket on the Power Bank. After connection, press the green 'ON' pushbutton on the side of the battery.

1
Open zip at bottom of bag to access battery
Unplug cable from battery
Withdraw discharged battery from bag
Do not connect cable to any other equipment

2
Insert charged battery into bag
Plug cable into battery
Turn battery on using button on side
Close zip

WARNING: The Amplifier must only be used with the USB Power Bank supplied or authorised by Lifelines.

- Do not short circuit this device. To avoid short circuit, keep the device away from any metal objects (e.g., hair clips and keys).
- This device may get hot during use, and this is normal. Hold carefully.
- This unit is not user repairable.
- Do not heat this device or throw it into a fire.
- Do not drop or place the unit under a heavy object.
- Keep this device away from high temperature, wet, or dusty environments.
- During charging keep the device out in the open to allow excess heat to dissipate.
- Charge M5 for 4 hours / M10 for 8 hours before initial use.
- Keep the USB output port and micro-USB input port clean and free of obstruction.
- For additional instructions, consult the documentation supplied with the battery.

To replace the battery in the Bag, unzip the bottom of the Bag to gain access to the battery connection. Unplug the USB connection to the battery and replace with a fully charged unit.

When not connected to the T4 unit, the battery is charged by using the micro-USB socket and connecting to a standard USB port, using the supplied cable.

Battery Charging

Connect the micro-USB charging cable supplied to the Battery and use a USB connection for charging. The battery capacity display will illuminate to show how much of the battery is charged. Once all the LEDs are lit, the battery is fully charged and is ready for use.

For additional instructions, consult the documentation supplied with the battery.

Do not charge the battery when used in the Home Environment.

WARNING: Do not charge the battery whilst it is connected to the T4 unit.

WARNING: Do not charge the battery when the equipment is in use.

4 The setup and recording software

4.1 Overview

The Trackit software is available on the included CD/USB disk or on the Lifelines FTP site. A readme file describes installation. The Trackit Software version 2.8.0.0 (or later) supports the T4 EEG Amplifier. Check with your distributor or Lifelines if a newer version of software is available.

The Trackit software is designed to work with both the T4 Amplifier and with the optional Photic Stimulator. The software is supported on Microsoft Windows XP, Windows Vista and Windows 7, Windows 8.1 and Windows 10. The USB drivers will be found on the CD. After connecting the Amplifier to the PC for the first time, at the Windows prompt, browse to the folder *CD Drive*:\USB Drivers. From there Windows will find the correct drivers for the version of Windows being used.

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

The Trackit software has four menu options: File, Home, Settings and Help. Each option provides a Microsoft® style "ribbon" toolbar (see Figure 5 - Figure 8). The default view is the 'Home' ribbon.

Figure 5: Trackit Software 'File' Toolbar

Key

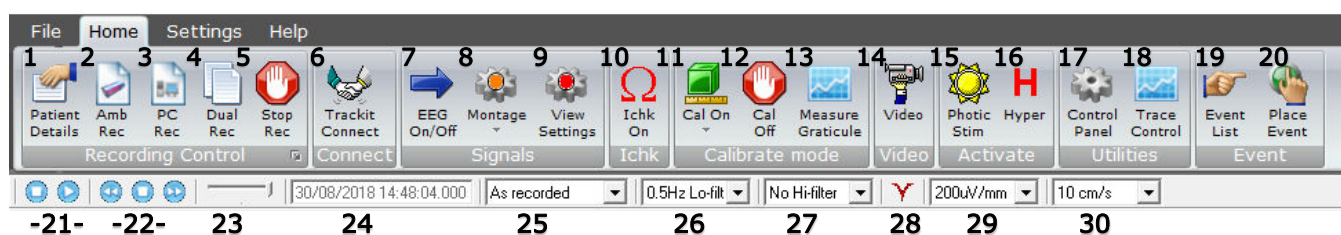|		
1 Open EEG file	2 Open EEG videos	3 Refresh playback files
4 Close all review files	5 View Events File	6 Measurement Graticule
7 Prints Screen	8 Video Resume	9 Print Keyboard Event Template
10 Exit Software		

Figure 6: Trackit Software 'Home' Toolbar

Key

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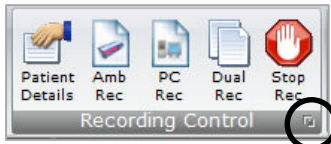
* The Trackit Control Panel can also be accessed by clicking on the "Expand" arrow of "Recording Control" group.
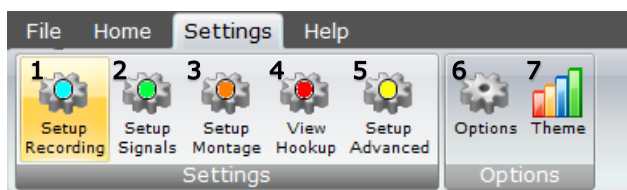
Figure 7: Trackit Software "Settings Toolbar

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		
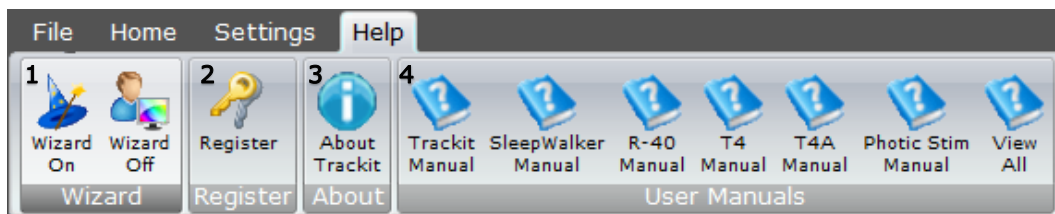
Figure 8: Trackit Software 'Help' Toolbar

Key

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

4.2 Trackit Control Panel

The Trackit Control Panel shows the status of the connected Trackit amplifier and provides quick access to the common functions ("Connect", "Disconnect", "Send Setup" and "Setup Recording").

The Trackit Control Panel can be accessed by clicking on the "Control Panel" Icon in the Home Toolbar or clicking the "expand" arrow of the "Recording control" panel (See Figure 6).
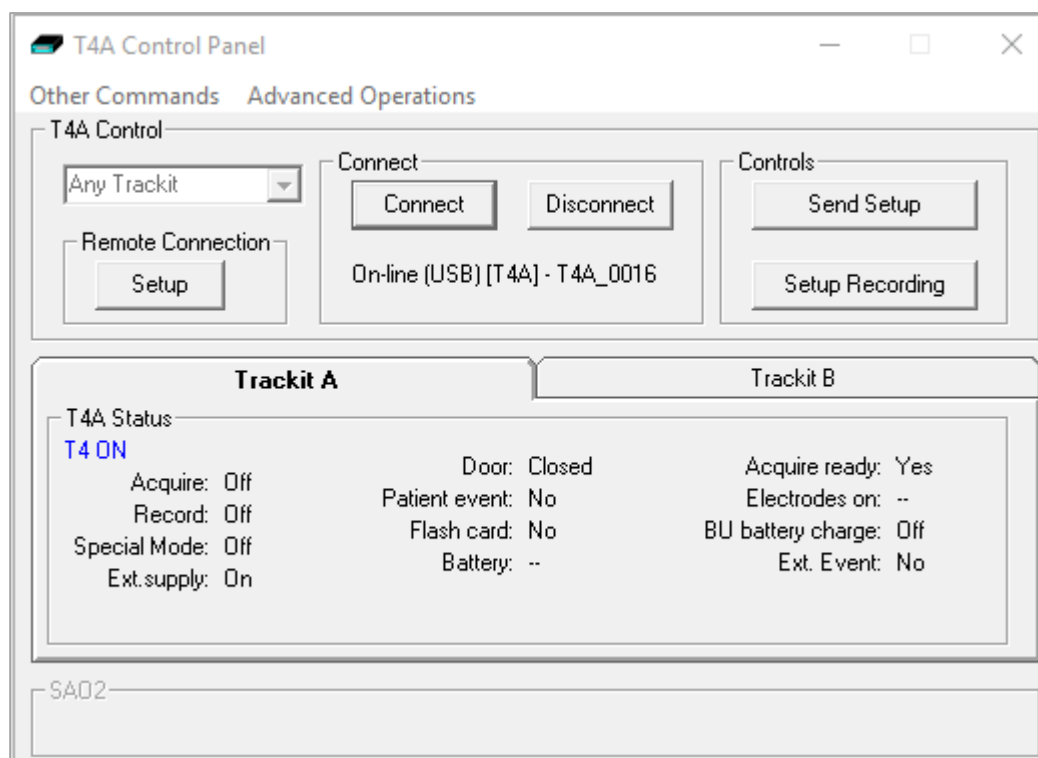
Figure 9: Trackit Control Panel

Connecting the Trackit

The Trackit application software will normally connect automatically to the T4 Amplifier as soon as it is plugged in to the computer via the USB cable.

To connect manually:

1. Open the Trackit Connect dialog box (Figure 10) by clicking on the Connect icon in the Home toolbar (Figure 6) or the Connect button in the Control Panel (Figure 9).
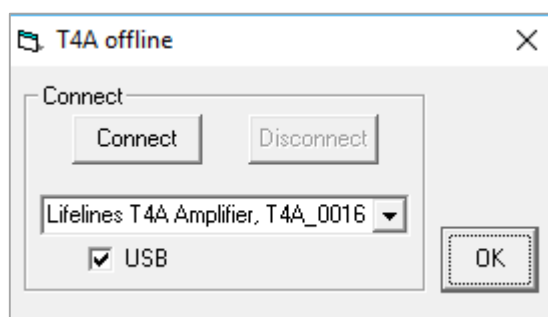

Figure 10: Connect Dialog Box

2. To connect via USB,

   a. Check that the amplifier USB cable is connected properly.

   b. Select the "USB" checkbox. The name and serial number of the T4 will appear in the drop-down list. If multiple Trackit amplifiers are connected to the computer, this drop-down will list all the connected amplifier.

   c. Select the correct amp (check the amplifier's serial number) and click on the Connect button.

3. To connect via Bluetooth:

   a. Switch on the Trackit T4. Ensure that the T4 has been paired to the computer first (see Appendix 5).

      b.   Un-tick the "*USB*" checkbox and select the correct COM port from the drop down list (see Appendix 5).

      c.   Click on the Connect button

  4.   Once connected, Click OK to close the Connect dialog box.

Once connected, the status will show "T4 ON". The Trackit software status bar (at the bottom of the screen) shows 'Online (USB) [T4] – T4_*xxxx*' (for USB connection) or 'Online (*COM Port name)* [T4]' (for Bluetooth connection) and displays the current setup parameters loaded into T4.

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

Check Amplifier status

The Control Panel can be used to check that the T4 is online and setup correctly. The "Trackit A" tab of the Control Panel gives you the following status information for the amplifier:

Acquire – on or off	Shows whether the amplifier is acquiring or not.
Record – on or off	Shows whether or not the amplifier is recording data to the SD card.
Special Mode – on or off	Shows whether a special recording mode (timed recording) has been configured
Door	Shows whether the battery compartment door is open or closed (not applicable to the T4).
Patient event	Shows that the patient event marker 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 amplifier.
BU Battery Charge	Shows whether the backup battery is being charged.
Ext Event	Shows that the remote patient event marker (via the External Event connector) has been activated.

Further status information is available on the 2nd tab ("Trackit B"). This includes the amplifier's time, Battery capacity, Recording time and SD card total and remaining capacity in (Megabytes (MB)) (see Figure 11).

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.
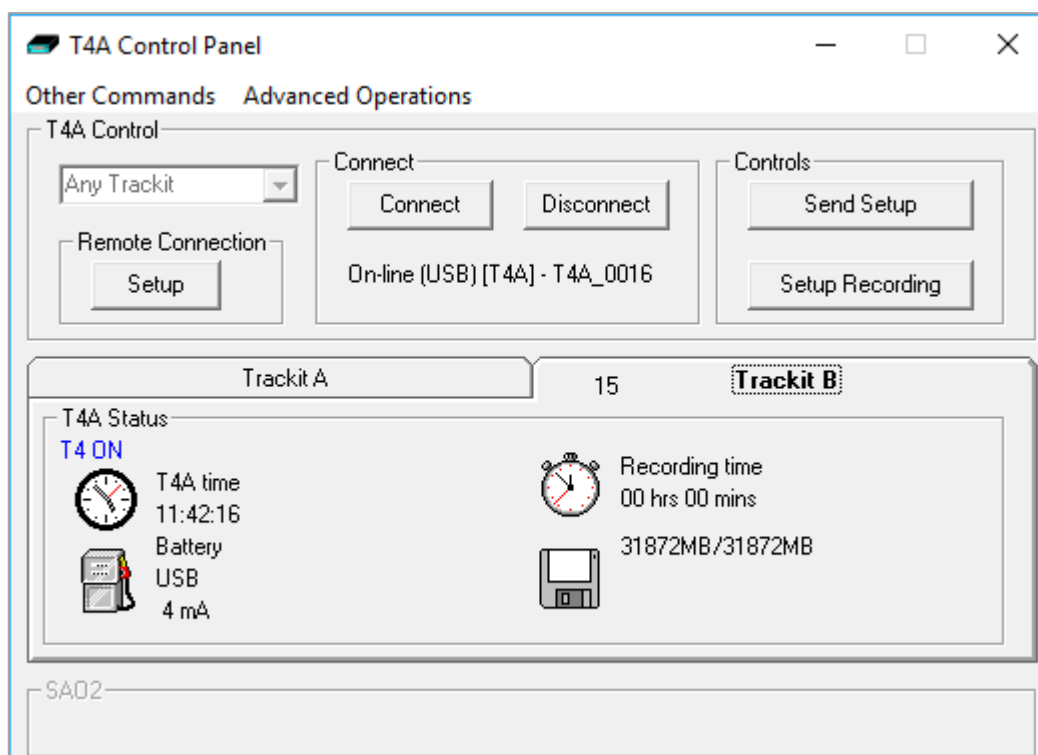
Figure 11: Trackit Control Panel "Status B"

4.3 Defining Input Signals

Defining signals is usually done once only or very occasionally. The T4 Amplifier arrives with a default set of signals that should suffice for most applications, hence it may only necessary to add signal types for polygraphic recordings (airflow, respiration etc.).

If for any reason the signals have not been created, it is necessary to define all the signals (labels) that are to be used for a montage creation. The signal editor allows the creation of up to 256 distinct signals ranging from the standard 10/20 EEG signals such as FP1, O2, to Respiration, Pulse and other polygraphy inputs.
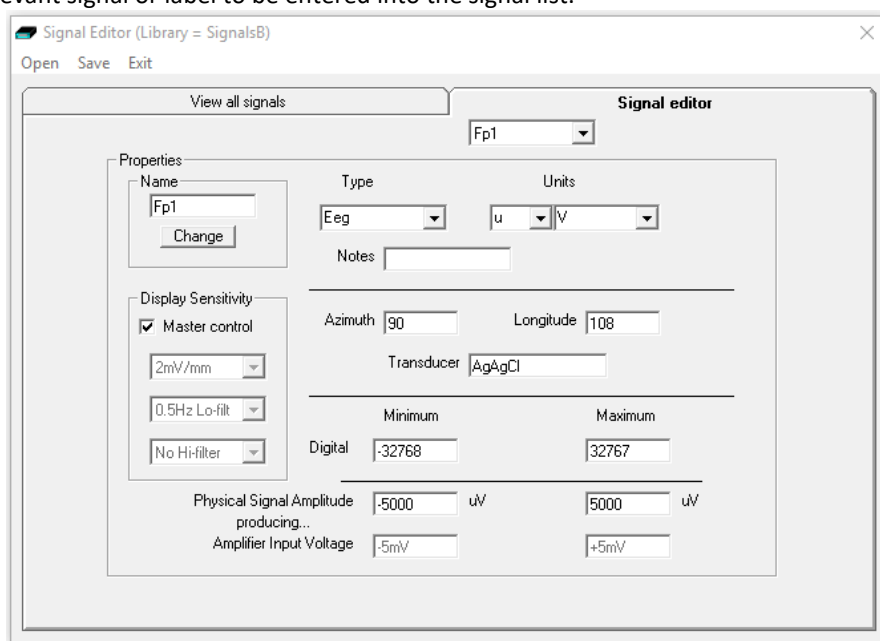
To define a signal:
1   Select on the "Setup Signals" icon in the Settings toolbar.

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

Figure 12: 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 13: Signal Editing Tool

4   Type in the Signal name (e.g. Fp1). Note that for EEG signals this must be case-sensitive.
5   Select a signal type (in this case EEG).
6   Click on the Change button. The signal is now entered into the list under the View all signals tab.
7   If the signal is not an EEG signal, it may be necessary to insert a display sensitivity value by unchecking the Master control check box.
8   The Signals should be saved in a Signals "Library" (*.sl3 file).

Signals that have been defined with their own independent sensitivities appear in red in the trace display. Further editing and changes to these sensitivity values in the trace display will be saved back into the signal library.

4.4   Setting up the Amplifier Inputs and Recording channels

Defining inputs, recording channels and montage is usually only done once per setup type. This entire setup can then be saved and recalled for future use. To open a saved setup or to create a new setup, proceed as follows:

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

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

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

Figure 14: EEG setup

4   Under the Amplifier Channels tab select the signals (labels) to be attached to the physical inputs. For example, EEG input 1 may require the label Fp1 and so on according to the standard 10/20 nomenclature.

29
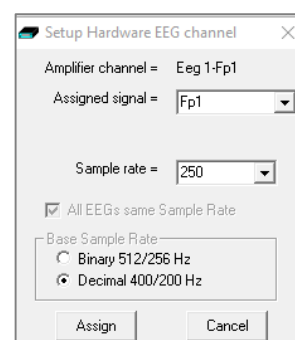
Double click the channel name and select the relevant signal label from the Setup Hardware EEG channel dialog. The order of the signal labels in the pull down list is the same as the order of the signals in the signal list defined using the signal-editing tool.
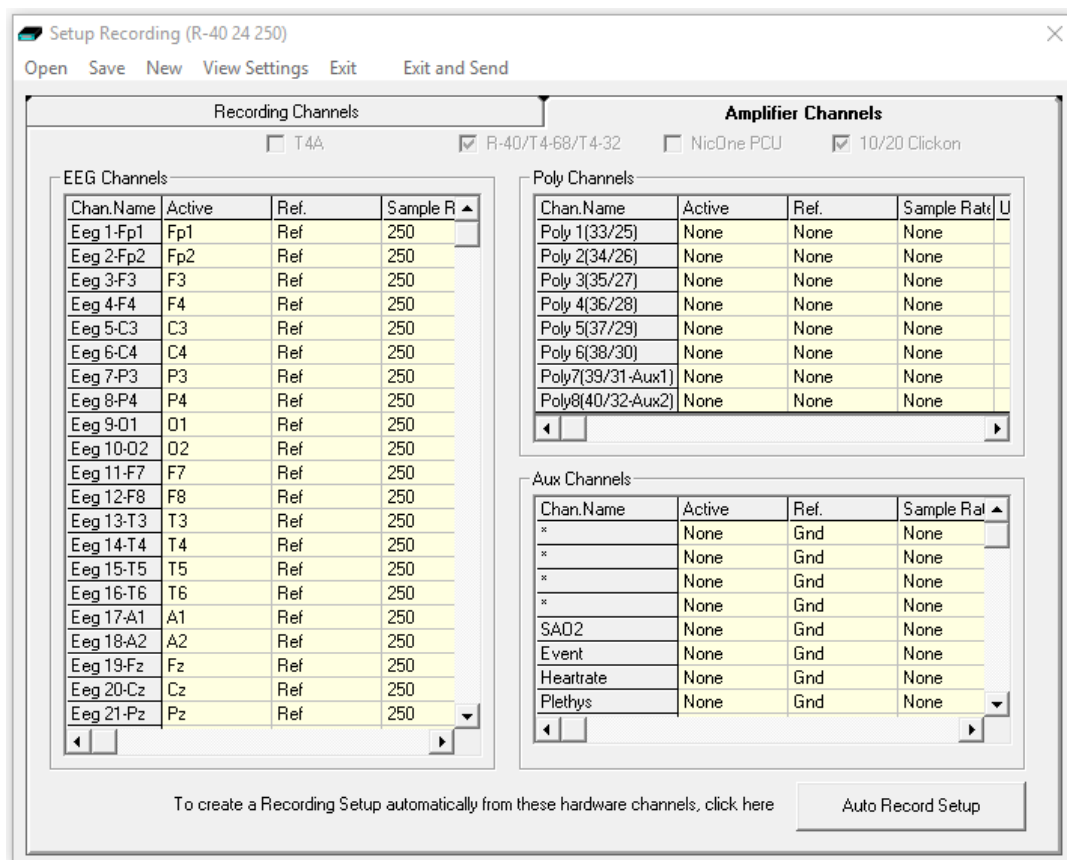

Figure 15: Setup Recording dialog

The Lifelines' EEG Amplifier range supports the following channels.

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

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

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

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

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

To calibrate a DC Poly input to reflect a required unit of scale for a given voltage input use the signal editor (see Section 0). Select the appropriate units, e.g. %, or mm Hg, and enter the Physical Signal Amplitude required to generate the Amplifier Input Voltage.

Figure 16: Channel setup

Define the recording channels

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

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

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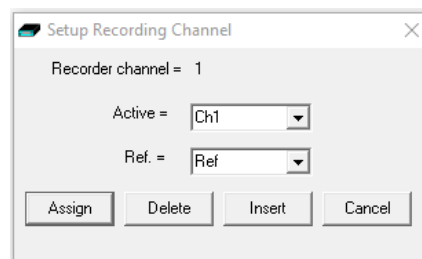
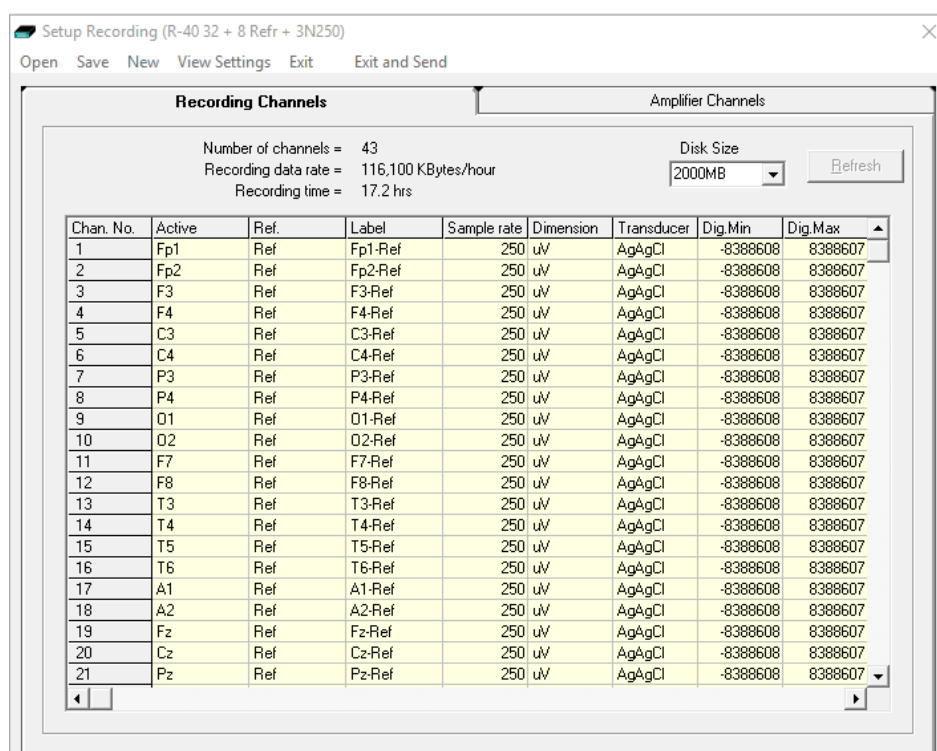An example of a recording montage is shown below.


Figure 17: Recording Channel editing

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

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

4.5 Starting a Recording

Before a recording can be started, the required signals need to be defined (see Section 0) and the recording channels and montage needs to be set up (see Section 4.4). The preliminary steps are usually only required once. The recording setup can be saved and recalled for future use.

The following steps are the same for setting up an Ambulatory recording stored on the SD card), PC recording (stored on the computer) or dual recording (PC and Ambulatory).
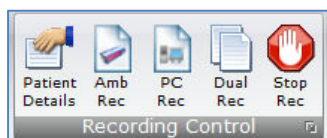
1. Click on "Patient Details" in the 'Home' Toolbar.

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

Figure 18: New Patient dialog

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

Figure 19: New Patient database

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

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

4. Select either the "Amb Rec", "PC Rec" or "Dual Rec" button from the Home toolbar.
   Note: If the patient details have not been entered beforehand, the Patient Details window (Figure 19 or Figure 20) will appear first.

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

6. The "Trackit Connect" dialog box will appear next. If the Trackit has not already been connected to the PC, connect via USB or Bluetooth (as described in Section 4.2) and click 'OK'. If the Trackit is already connected, then just click 'OK'
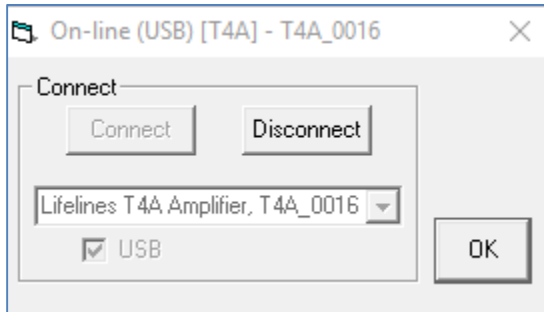
7. The new setup will be sent to the amplifier (if required). A warning will appear if this is not successful.
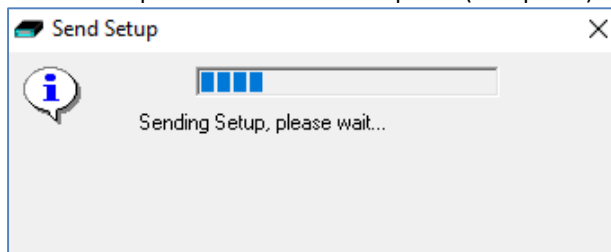
8. The next dialog box confirms if video is to be recorded? Select 'Yes' if doing a videometry recording.

9. The Recording Control panel (Figure 20) will appear.
   a. Select the Record mode (default mode is 'Immediate').
   b. Enter the desired file name for the recording file name.
   c. Confirm the SD card is ready by clicking "Check disk"
   d. Click Start to start the recording.
   e. The recording configuration will be sent to the amplifier. This may take a few seconds as the amplifier may need to prepare the SD card.
   f. The Recording Control panel will close if the recording started successfully.

   Refer to Section 4.6 **Error! Reference source not found.** for a description for recording options in the Recording Control panel.

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

4.6 Recording Control Panel (Amplifier recording)

The Recording Control panel provides additional options when recording to the memory card on the amplifier. These options are not applicable when performing a PC recording. Click on the 'Setup Recording' button in the Trackit Control Panel to open the Recording Control dialog box (Figure 20). 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).
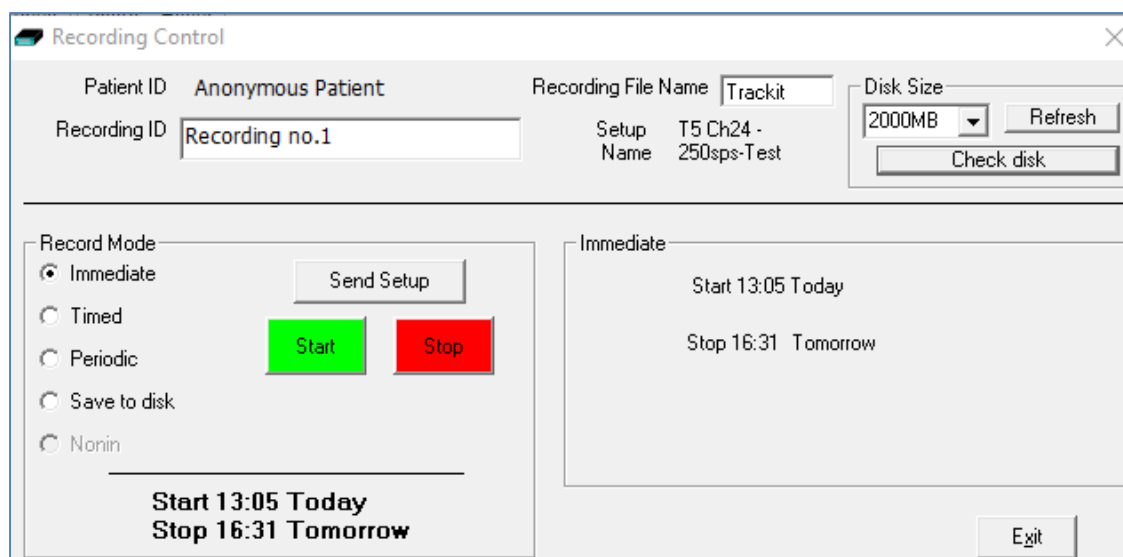
Figure 20: Recording Control panel

Default file names

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

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

Recording modes

There are multiple ways to start a recording:

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

Immediate: the recording starts as soon as the Start button is pressed (Figure 20). Recording finishes when the Trackit is turned off, when the disk is full or when the recording is stopped.

1 Under Record Mode, choose Immediate.
2 Click the Send Setup button, then the Start button
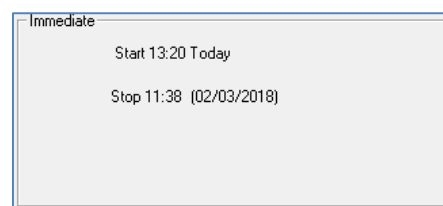
Timed: The Trackit amplifier records for a specified period of time.

1 Under Record Mode, choose Timed.
2 In the Recording Control dialog box, set a start time to start the recording, using the Start slider.
3 Either put a checkmark by 'Fill Disk', or use the Duration slider to set the recording duration.
4 Click the Send Setup button, then the Start button.
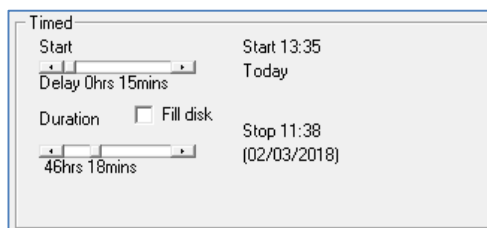
Periodic: The Trackit Amplifier records for specified periods of time at a defined interval (e.g. for periods of 30 minutes, with a 45-minute interval):

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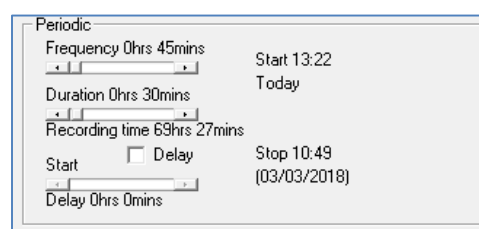
3   For a delayed start (e.g. in an MSLT study), put a checkmark by
    the Delay box, and use the Start slider to set a start time for the
    recording.
4   Click the Send Setup button, then the Start button.

4.7 View EEG Signal Traces

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

When you do this, one of the following things occur:
- If the amplifier is connected to the PC, and has been sent a valid recording
  setup, the traces appear wiping from left to right across the display.
- If the amplifier has not been sent a setup from the PC, the system asks for
  the recording setup held in the amplifier before displaying the traces.
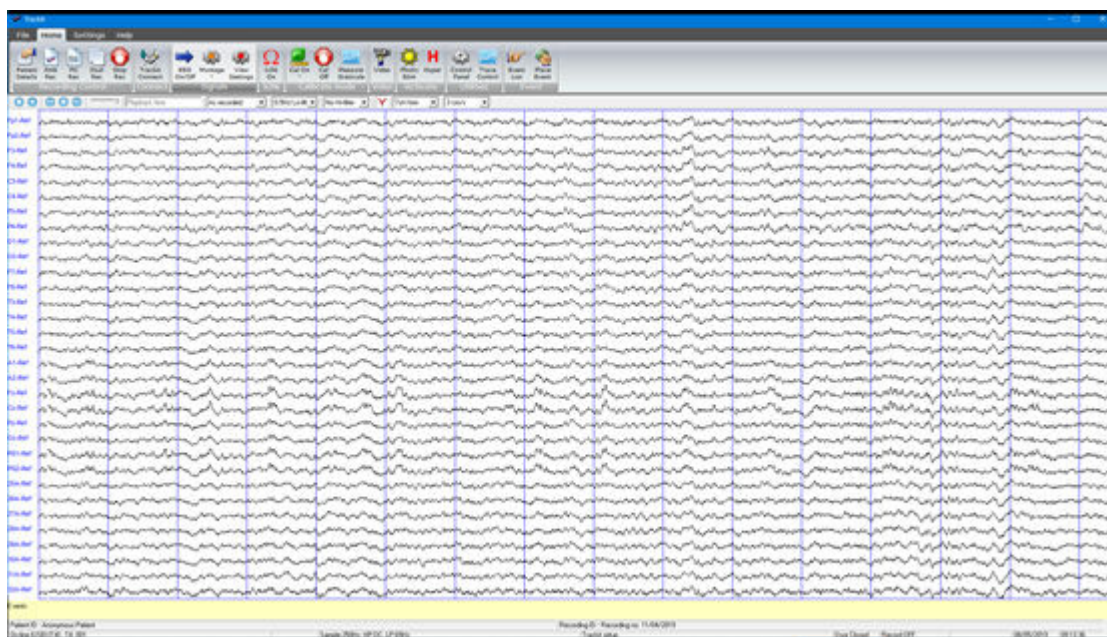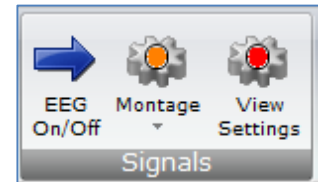
Figure 21: EEG Signal trace display

Notch filter: to set a notch filter, open the Trackit 'Options' window from the Settings toolbar.
Notch filters are either 50Hz or 60Hz depending on where the system is to be used (USA 60Hz; Europe 50Hz).
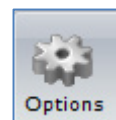
To activate the notch filter, click on the Notch Filter icon in the Trackit toolbar.

Sensitivity, Chart speed, Notch Filter and Hi/Lo filters: as is often the case when viewing a live trace
display, the sensitivity, chart speed and filters need be adjusted for optimal viewing. Use the drop down lists on
the toolbar (see
Figure 6).

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

When a channel is under individual channel control the label is depicted in red.
When display of that channel is turned off, the label is greyed out.
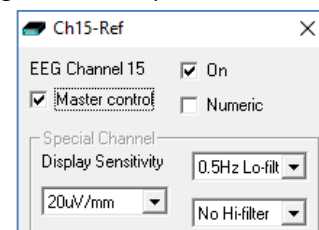
Figure 22: Adjust display parameters

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

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

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

4.8 Calibration Check

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

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

4.9 Impedance Check

An Impedance check can be performed on the EEG inputs, whether recording is active or not. To perform an Impedance Check click on the 'Ichk On' icon on the Home toolbar. This will start the Impedance Check on the amplifier and the Impedance Check panel will be displayed (Figure 23).

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

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

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

Clicking on 'Exit' will stop the Impedance check on the amplifier. Clicking on "Exit with Continuous Imp Check On" will close the Impedance check panel but leave the amplifier in Impedance check mode. The ongoing trace display will resume and the channel names of the channels which exceed the set limit will flash orange (see Figure 24).

Continuous Impedance Check can be cancelled by starting or stopping Ongoing EEG traces (EEG On/Off).
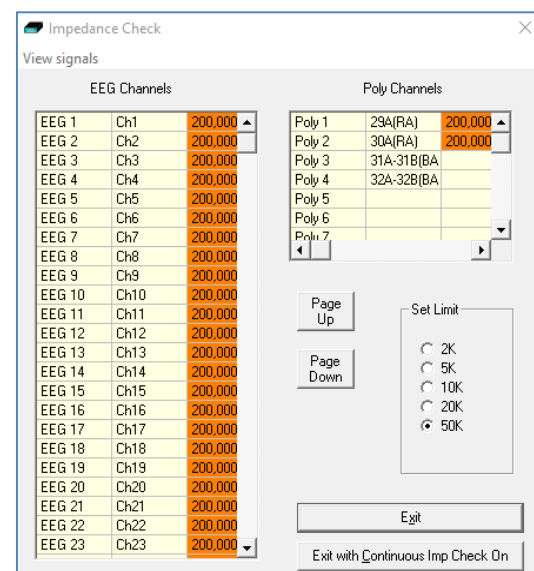
Figure 23: Impedance check
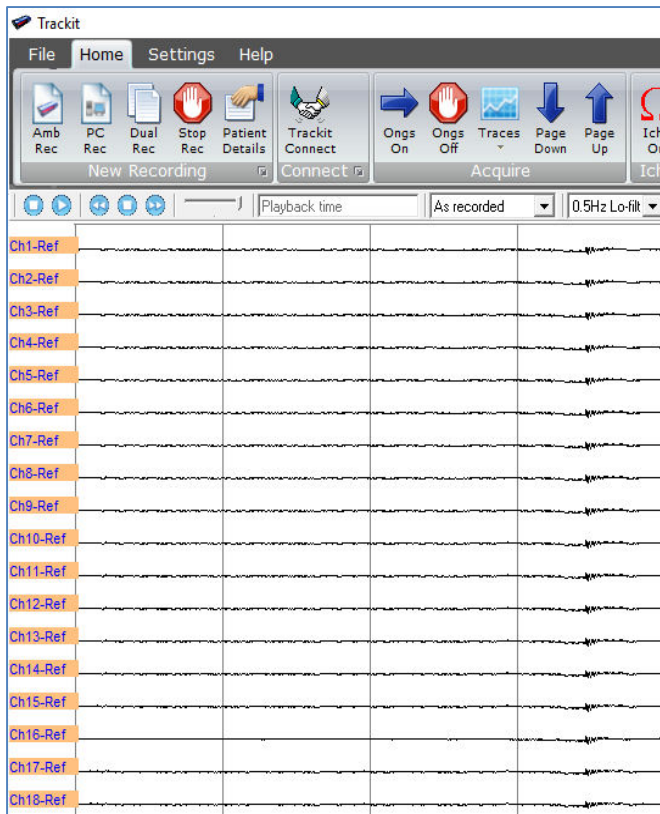
Figure 24: Continuous Impedance Check

4.10 Events

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

Events are displayed in the Event viewer (Figure 25) with a description and time.
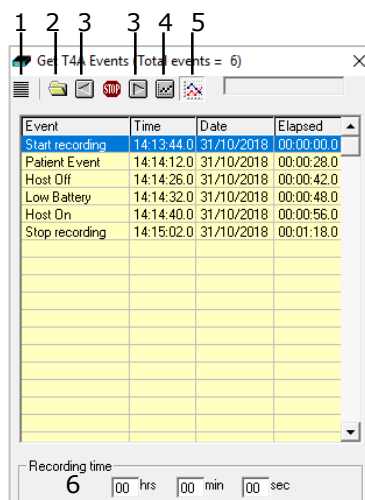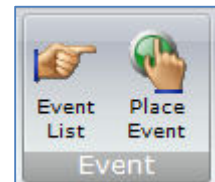
Key:
1   Opens the list of event types

Icons 2-6 are not used.

Figure 25: 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.

4.11 Montage Editor

The Montage Editor is accessed by clicking on the "Montage" on the Home toolbar, which displays the Montage Editor as shown in Figure 26, below.

The Montage Editor allows the setting-up of 16 user montages and the As-recorded montage. The Montage Editor shows the location of the signals on the brain. Refer to Section 0 for details on defining the signal location.
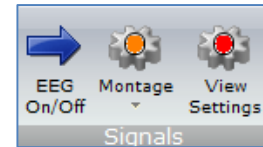
Note that the As-recorded montage can only have its channel on/off and channel master/special control edited (and if special, the channel sensitivity and filters). All the other 16 user montages are fully definable and can have the following parameters set for each channel:

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

Additional controls are provided to allow:

5. (Up). Selects the previous channel on the list

6. (Append). This adds a channel to the end of the Montage list.

7. (Remove). This removes the currently selected channel.

8. (Insert). This insert a channel above the currently selected channel.

9. (Down). Selects the next channel on the list

10. (Update). Copies the current settings into the currently selected channel.

11. Montage name.

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

If anything is changed, an option is presented to save all changes to disk or not. If not saved, changes are only temporary.
Note that some of the montage parameters can be changed outside the Montage Editor, by clicking on a channel label to bring up the Channel Information window. These changes are only temporary (although you can save them later by subsequently going into the Montage Editor).
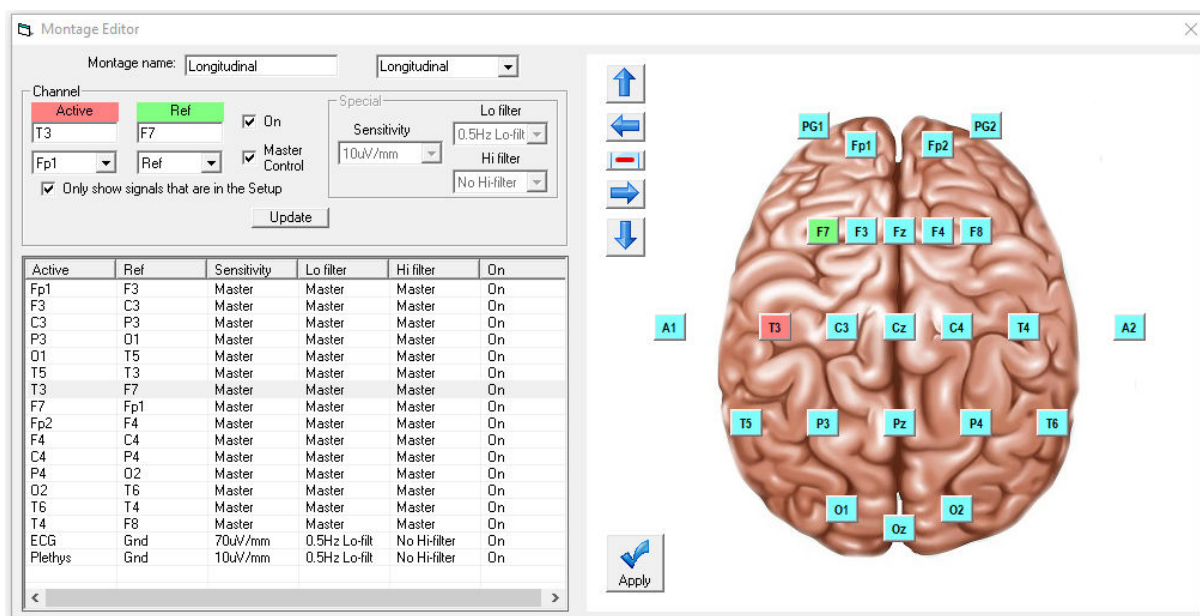
Figure 26: Montage Editor

4.12   Reading an EEG recording

Click the 'Open all files' button on the File Toolbar in the Trackit software to playback a recording and browse to the folder and file required. This will open the EDF/BDF file and any associated files.

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

As an alternative to the Trackit software which offers basic playback features, any BDF-compatible viewer can be used to read the 24-bit BDF files recorded by the amplifier.

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

Lifelines currently recommends:
- Lifelines iEEG
- Nihon Kohden 1100 and 1200 EEG
- Neurotronics Polysmith Sleep software
- Nicolet One EEG
- Natus Coherance 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 amplifier is not recording, this manually sets the amplifier's time and date to that of the PC. Note: this function is normally done automatically when recording is started.

Get Trackit Set-up: this manually retrieves the setup from the amplifier's memory and overwrites the currently loaded setup on the PC. Note: this function is normally done automatically whenever the software detects a mismatch between the amplifier's setup and the PC setup.

Quiet On: Not supported on the T4.

Quiet Off: Not supported on the T4.

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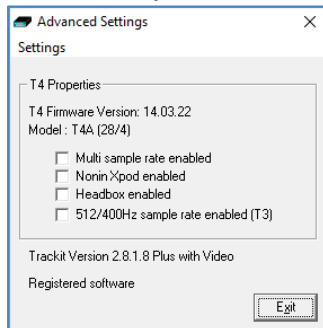
Advanced Operations contains entries, some password-protected, that change the way the amplifier records its data. These settings include:

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

To see the available options under Advanced Operations:

1   Open on the Trackit Control Panel.

2   Click on Advanced Operations.

3   Click on Settings.

Set Trackit Defaults

[> Advanced Operations > Settings > Set Trackit Defaults]

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

Defaults Tab 1

This menu item activates a control dialog that adjusts how the amplifier behaves during a recording. Most options are not applicable to the T4. See Figure 27.
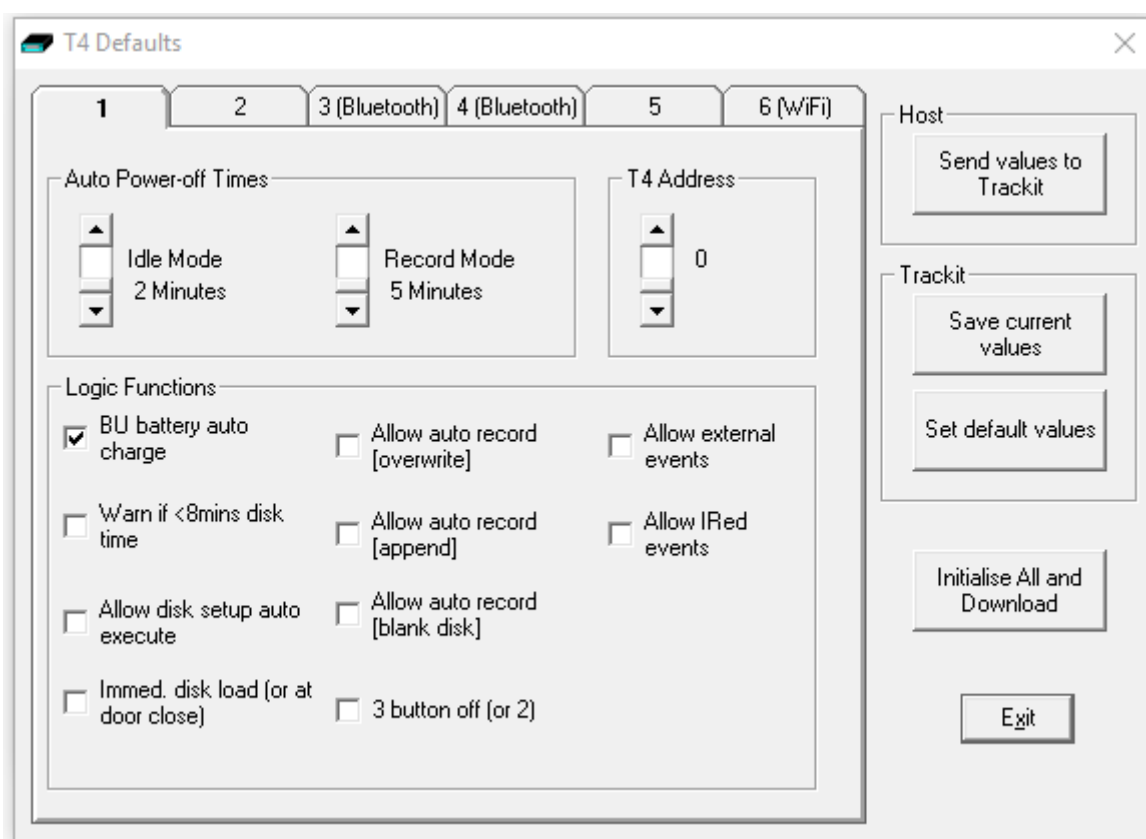
Figure 27: Defaults Tab 1

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

The following functions are supported:

Idle Mode: Amplifier turns itself off after a defined period when connected to a PC.

Record Mode: Not applicable on the T4

Trackit Address: sets the serial address of the amplifier. Not used on the T4.

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

Warn if <8 mins card time: the Trackit T4 starts beeping when the card has room for only another 8 minutes of recording.

Allow card setup auto execute: Not supported on the T4.

Allow auto record (overwrite): Not supported on the T4.

Allow auto record (append): Not supported on the T4.

Allow auto record (blank card): Not supported on the T4.

Allow external events: Not supported on the T4.

Allow IRed events: Not supported on the T4.

Immed. card load (or at door close): Not supported on the T4.

3 button Off (or 2): Not supported on the T4.

Defaults Tab 2
Additional setup parameters are accessed via tab 2 of Defaults panel, as shown in Figure 28 below.
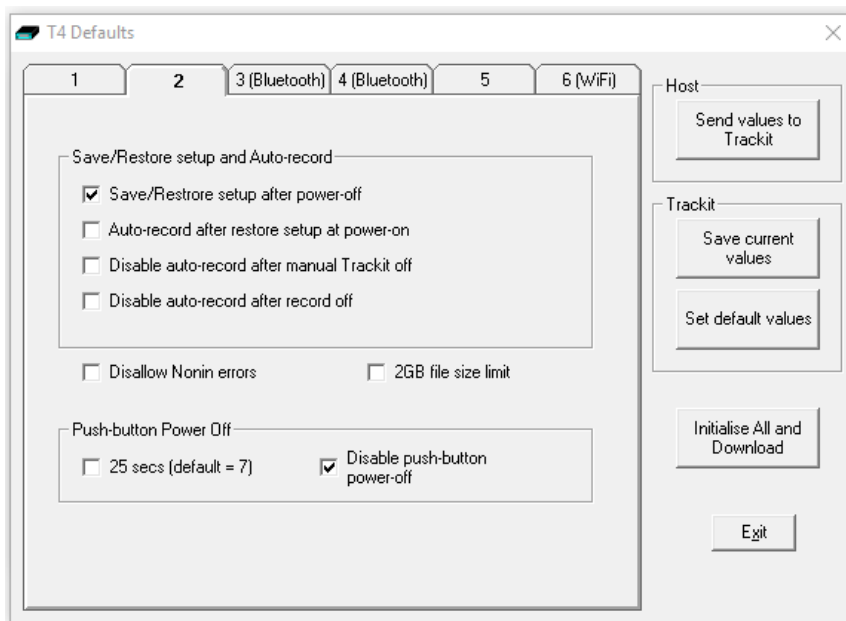
Figure 28: Defaults | Tab 2

Save/Restore setup and Auto-record

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

- **Save/Restore setup after power-off.** When checked, this enables the Amplifier to save the entire Setup including Patient Name and Recording ID after power-off and recall it at power-on. Note that the Patient Name and Recording ID are only retained for 15 minutes after power-off (refer below).
- **Auto-record after restore setup at power-on.** Not supported on T4
- **Disable auto-record after manual Trackit off.** When checked, this causes a potential Auto-record situation to be cancelled whenever the amplifier is powered-off either from its own front-panel pushbutton or from the Host.
- **Disable auto-record after record off.** When checked, this causes a potential Auto-record situation to be cancelled whenever the Hosts instructs the amplifier to stop recording.

Disallow Nonin Errors
Suppresses errors from the Nonin SPO2 sensor.

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

Push-Button Power Off
Sets the required time to hold the event button to power off the T4.

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 T4 does not support card formatting. The SD card should be formatted ion a PC using the recommended SD card formatting software.

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

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

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

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

Trackit OFF
[> Advanced Operations > Settings > Trackit OFF]
Turns the amplifier off. Note: Communication to the host PC will be lost.

Appendix 1: Specifications

Note: Lifelines reserves the right to change product specifications at any time without notice. This is in-line with the company's policy of continual product development.

T4 Amplifier Specifications

EEG inputs

Number of EEG channels	32 referential (monopolar) inputs, expandable to 64 with expansion option
ADC Resolution	24 bits
Sampling	250 – 16000 Hz
Input impedance	>20 Mohms
Common mode rejection ratio	>100dB @ 50 and 60 Hz
Equivalent input noise	<1.5µVpp, <0.2µV rms
Gain	12 ±0.5%
Max Input V_{diff}	750mVpp (including DC)
Quantisation	0.17uV/bit @ Gain = 12 and Bits = 22
Bandwidth (-3dB)	DC to 4193Hz
Max common mode input voltage	0.4Vpp
Input bias current	< ±0.3 nA
Front-end Calibration	8mVpp ±5% at 0.98Hz
Impedance Check current	24nA ±20% at 7.8Hz

Polygraphy inputs

Number of polygraphy inputs	8 poly (bipolar) inputs
ADC Resolution	24 bits
Sampling	250 - 16000 Hz
Input impedance	>20 Mohms
Common mode rejection ratio	>100dB @ 50 and 60 Hz
Equivalent input noise	<1.5µVpp, <0.2µV rms
Gain	12 ±0.5% (AC), 4 ±0.5% (DC)
Max Input V_{diff}	750mVpp AC setting (including DC), 2.25Vpp DC setting
Bandwidth (-3dB)	DC to 4193Hz
Quantisation	0.17uV/bit @ Gain = 12 and Bits = 22
Max common mode input voltage	0.4Vpp
Input bias current	< ±0.3 nA
Front-end Calibration	8mVpp ±5% at 0.98Hz
Impedance Check current	24nA ±20% at 7.8Hz

Aux. high-level DC Inputs

Number of Aux channels	1
ADC Resolution	24 bits
Sampling	250 - 16000 Hz
Input impedance	100 Kohms
Gain	4 ±0.5%
Max Input V_{diff}	2.25Vpp
Bandwidth (-3dB)	DC to 4193Hz

Connections, ports and controls

Patient Connection Unit	Plug-on unit with touchproof 1.5mm sockets. Variants: 24 referential channels + 8 bipolar (model T4-PCU 24+8) 64 referential channels + 4 bipolar (model T4-PCU 64+4)
Aux DC Inputs	1 Jack socket 3.5mm
Patient Event Input	1 Jack socket 3.5mm
Front-panel push-button	On/Off and Patient Event
Host PC Connector	1 RJ45 socket providing USB port (isolated from patient) or power input from external battery

Nonin Xpod (SaO2)	1 Binder 710 series 3-pin socket
LED indicators	LED for disk access
Micro-SD card port	1 Micro-SD socket
Internal Battery	1 type LIR2450 Lithium-ion rechargeable Coin cell
Internal beeper	
LCD display	Displays time/date, recording time, battery life and disk space

Bluetooth Wireless

Type	Bluetooth 4.0
Output power	11dBm max.
Output frequency	2.402 - 2.480 GHz, ISM band
Data rate	1.3 Mbps max.
Protocols	Standard Bluetooth - SPP, GATT, DUN, PAN
Modulation	GFSK, DQPSK. Frequency Hopping Spread-Spectrum (FHSS)
Error correction	Forward Error Correction (FEC), Automatic repeat request (ARQ).
Security	Authorization and authentication of devices, proprietary Interface Protocol
Type Approvals	Europe (ETSI R&TTE); US (FCC/CFR 47 part 15 unlicensed modular transmitter approval); Canada (IC RSS); Japan (MIC - formerly TELEC)
R&TTE Directive 1999/5/EC	Effective use of frequency spectrum: EN 300 328 EMC: EN 301 489-1, EN 301 489-17, EN 61000-6-2 Health and safety: EN 62479, EN 60950-1, IEC 60950-1
Medical Electrical Equipment	IEC 60601-1-2
Bluetooth Qualification	V4.0

Wireless LAN

Type	2.4 GHz IEEE Std. 802.11 b/g Wireless LAN Module
Output power	12dBm max.
Output frequency	2.412 to 2.462 GHz, ISM band
Data rate	230kbps max.
Protocols	TCP, UDP, DHCP, DNS, ICMP, ARP, HTTP Client, and FTP Client
Modulation	802.11b Compatibility: DSSS (CCK-11, CCK-5.5, DQPSK-2, DBPSK-1) - 802.11g: OFDM
Error correction	Forward Error Correction (FEC)
Security	WEP-128, WPA-PSK (TKIP), WPA2-PSK (AES)
FCC	Part 15.247 FCC T9J-RN171
IC	RSS-210 low-power communication device
CE	ID# 0681
REG	U9M21103-4249-C
Radio	EN 300328 V1.7.1 (10/2006)
EMC	EN 301489-1 V1.8.1 (04/2008) EN 301489-17 V2.1.1 (05/2009)
Safety	EN 60950-1:2006+A11:2010, EN 50371 2002-03

Physical characteristics

| Weight | 270g |
| Size | 17cm x 9cm 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	International standard for medical electrical equipment, general requirements and particular requirements for EEG systems.
ANSI/AAMI ES 60601-1	AAMI Deviations from IEC 60601-1 (USA).
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	International standard for medical electrical equipment, EMC requirements, calling:
*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

T4 Amplifier

Degree of protection against electrical shock (when connected to host system)	Type BF
Type of protection against electrical shock (when connected to host system)	Optically isolated USB amplifier Mains isolation transformer for PC
Degree of protection against harmful ingress of water	Ordinary (no protection)
Mode of operation	Continuous
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Appendix 2: Photic Stimulation

An optional Lifelines Photic Stimulator is available which can be used with the T4 to asses patient photosensitivity in EEG studies. For a detailed description of operation, connection and specifications please refer to the separate documentation "Lifelines Photic User Manual".
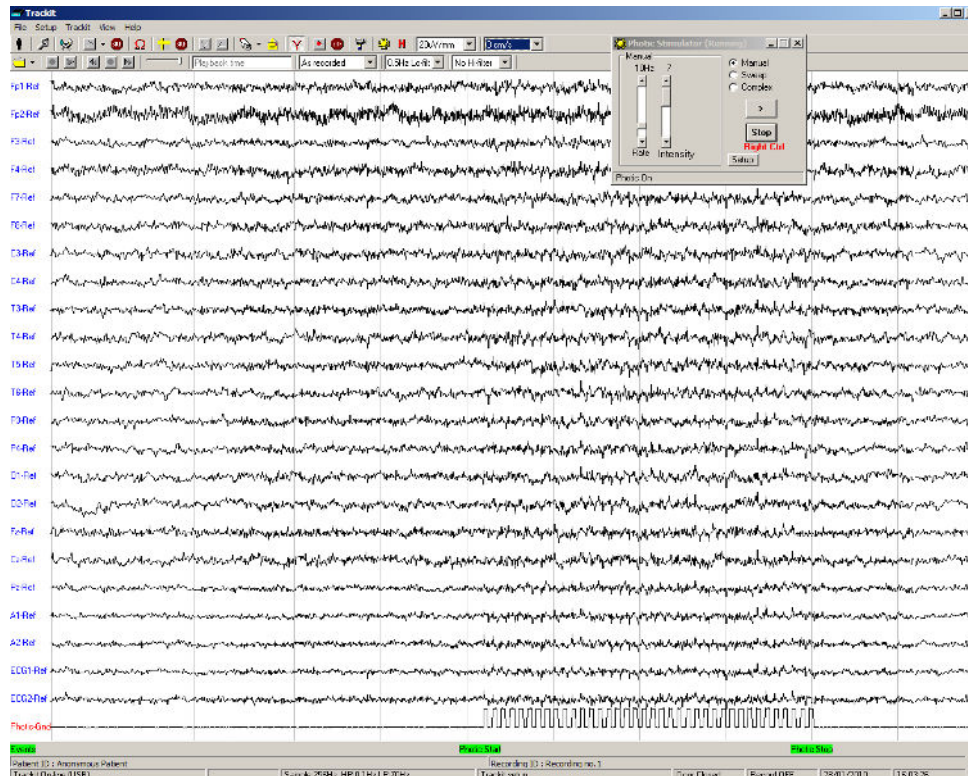
Figure 29 Photic Stimulation

Click on the Photic Stimulation icon in the top toolbar to bring up the Photic Stimulation control panel, shown below.
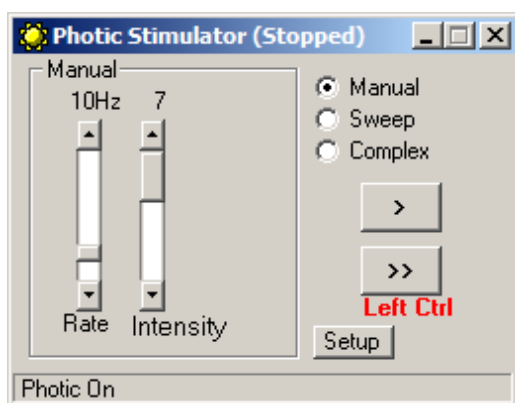
Figure 30 Photic Stimulation control window

This window allows single, manual, sweep and complex sequences of Photic stimulation to be produced. Photic start/stop events are recorded as shown above. By using the Trigger output from the Photic Stimulator and connecting to an Aux input on the T4, the actual Photic flash 'ticks' are produced in the recording.

Note: to setup a suitable Photic trigger signal definition open the Signal library as described in section 0, and define a signal with a name "Photic", set it to type DC, units mV and Physical Signal Amplitude of +- 1000mV/V. Set the sensitivity to non-master and 10mV/mm.

Figure 31 Photic trigger signal definition

Appendix 3: Additional Events Information
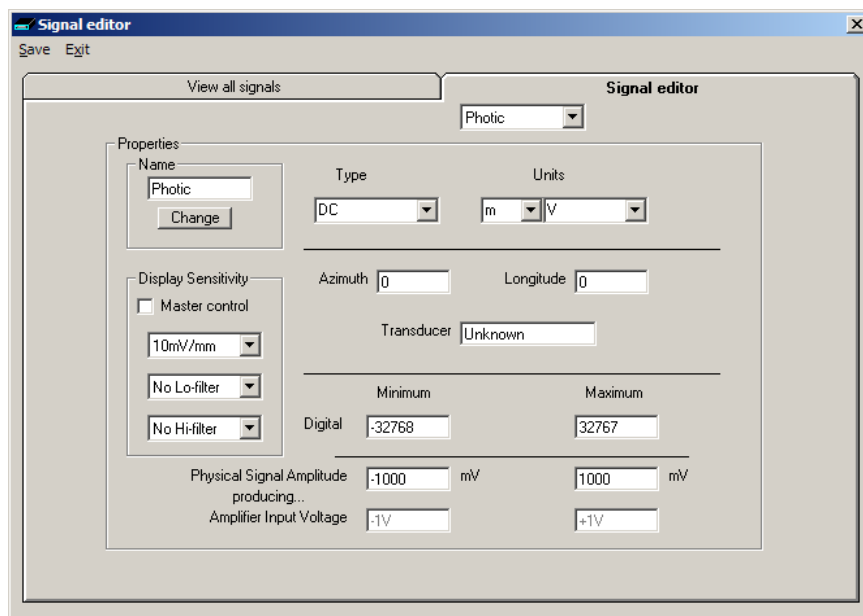
For the T4 EEG system, events types are as shown below.
- 56 Automatic events (hardware events, photic start/stop, video start/stop etc.)
- 40 user-configurable events
- Free-text events entered during acquisition

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

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

Clicking on the Events icon on the main program window allows these configurable events to be edited as shown below. If the system is recording, selecting an event marks it in the recording. If not recording, selecting an event allows it to be edited.
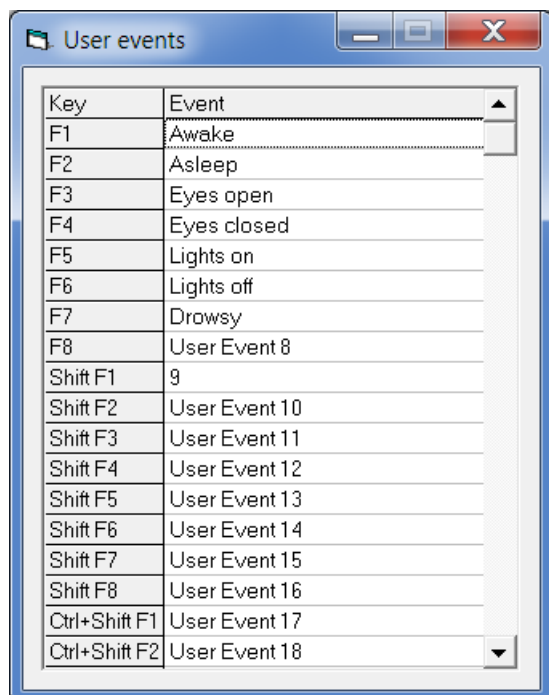
Figure 32 User Events

The Events icon also brings up an option to print an events template for overlaying on the keyboard. Facilities are provided to scale the printout to fit different size keyboards.
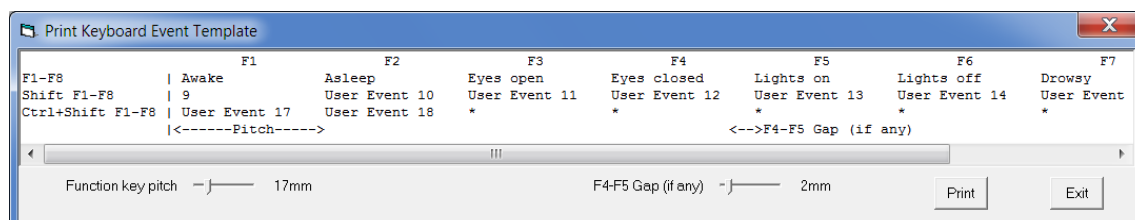
Figure 33 Events Template setup
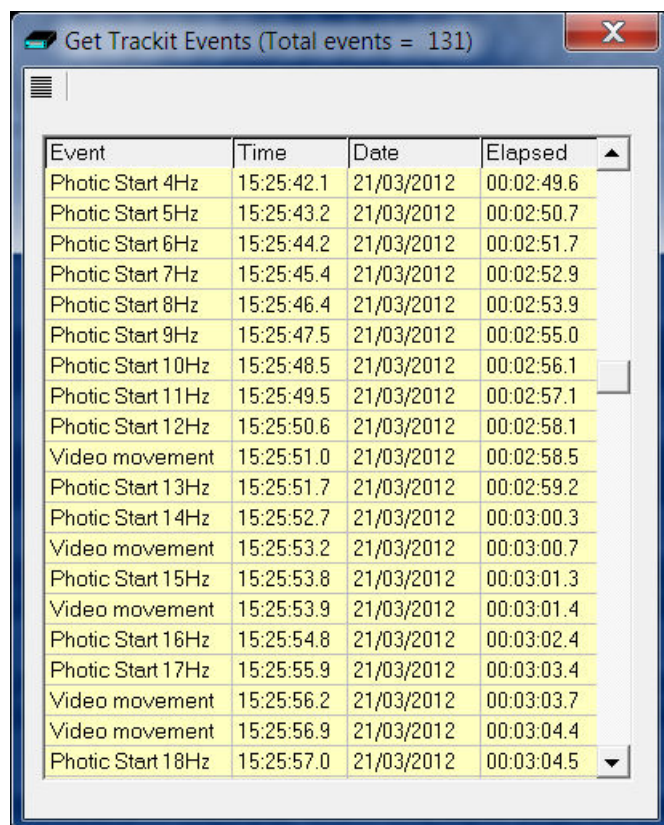
Free Text Events
During a recording, pressing the F12 keyboard key allow a free-text event to be created. The event is recorded at the time F12 is pressed and a window is displayed allowing the entry of descriptive text which can be entered at the user's leisure. During this time all the other types of events can be activated.
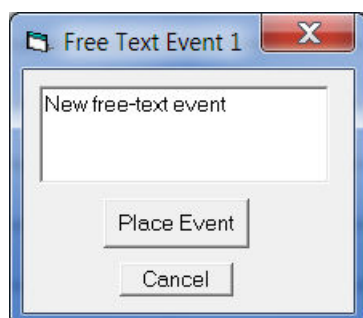
Figure 34 Free-text Event

During playback, all the events are displayed for the file by clicking on the Events icon. Double-clicking on an event in the list jumps to that point in the recording. All the events are also displayed in their correct position in relation to the EEG along the bottom of the main window.

The events may be sorted alphabetically by clicking on the 'Event' heading in the list. This is convenient for grouping all event types together, e.g. Photic. Clicking on the 'Time' heading sorts the events back into chrono-logical time.

Figure 35 Event List

Appendix 4: PC Setup

Options | Tab 1

The Options panel Tab 1 contains general settings which are self-explanatory as shown below.
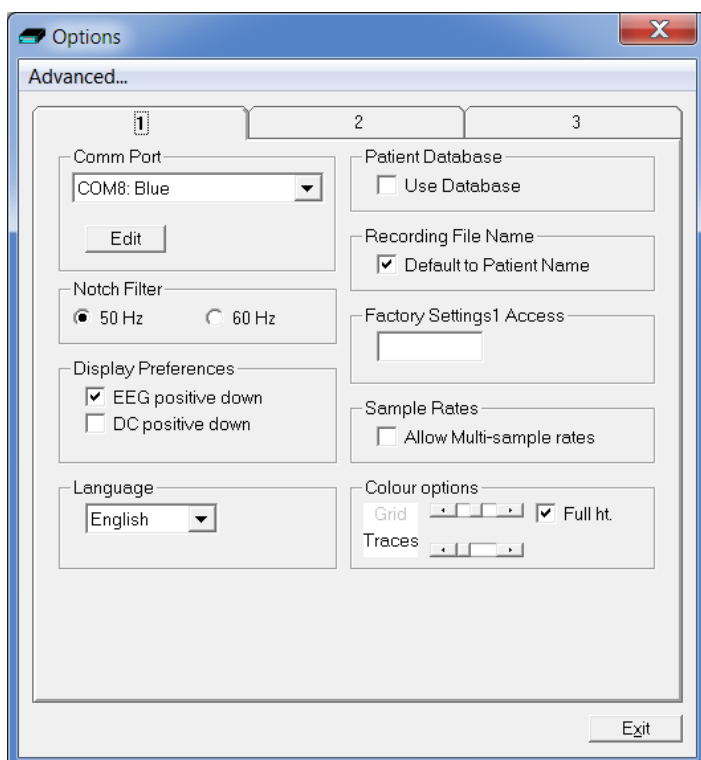
Figure 36 Options Tab 1

Options | Tab 2

The second tab in Options is shown below.
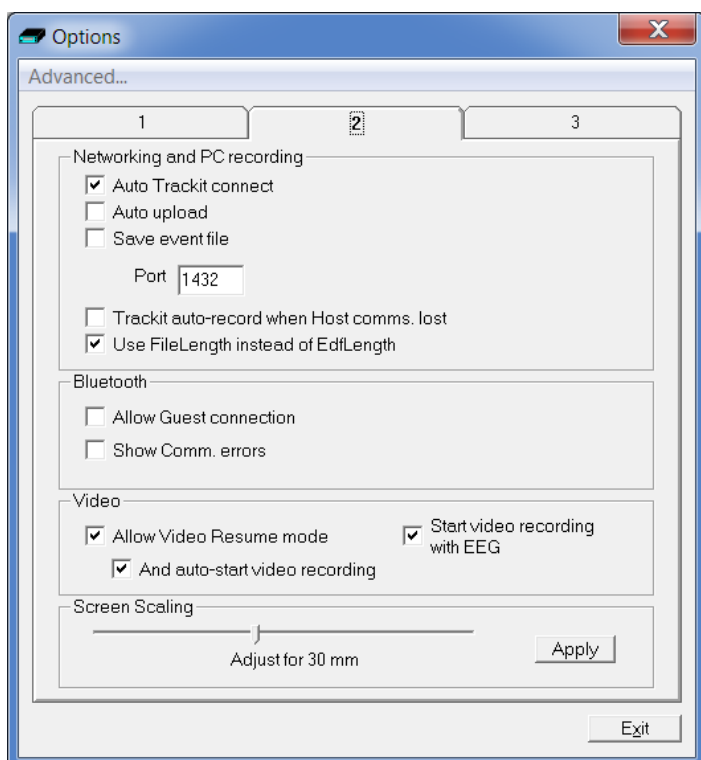
Figure 37 Options Tab 2

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Most of these options are not applicable to the T4, except for:

- **Use File Length instead of EDF Length.** This a playback feature and if ticked, the file length is used instead of the edf length parameter embedded in the edf header. Due to the fact that the T4's memory card can be removed at any time, there can be a partial 1s data block at the end of the file and so the actual size may not be an exact multiple of 1s.

Screen Size

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

Options | Tab 3
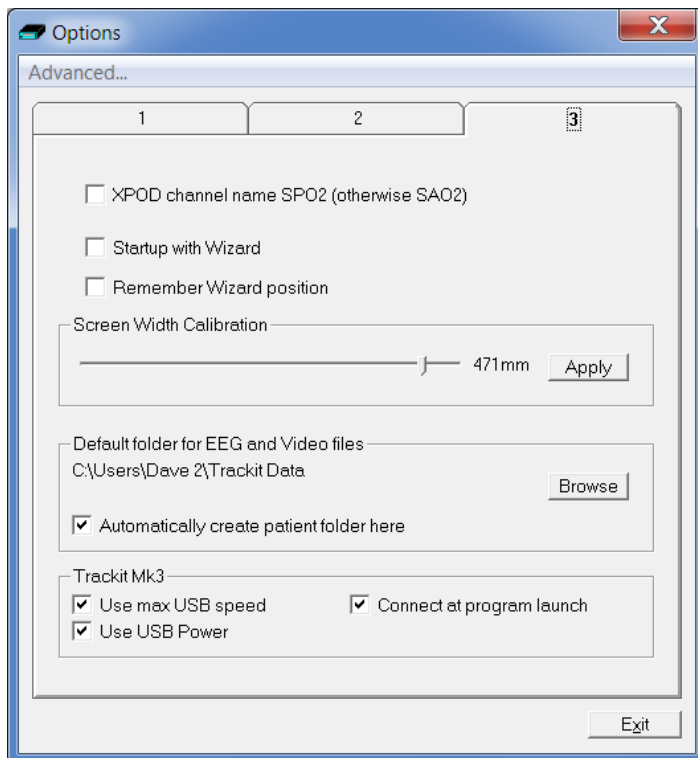
Figure 38 Options Tab 3

Most of these options are not applicable to the T4, except for:

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

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

- **Default folder for EEG and Video files.** This allows the program to always record EEG and/or video files to the same default folder. Use Browse to find and/or create the default folder for recordings.

  - **Automatically create patient folder here.** If checked, the program will automatically create a patient folder in the default recording folder set above without any user intervention. If not set, the user choses where to save the recording using the standard save file dialogue window.

- **Connect at program launch.** If checked, the program will automatically connect to the T4 at launch.

Appendix 5: Wireless

Introduction

T4 has optional built-in Bluetooth and WiFi capabilities.

Using the internal Bluetooth module in the T4, wireless connections can be established with it from a Bluetooth-enabled PC. Using the internal WiFi module in the T4 wireless connections can be established with it via a Wireless Access Point (WAP). This allows the T4 to be monitored remotely over a secure wireless link up to a range of about 100m or greater (dependent on hardware and environmental factors).

System overview

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

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

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

Connection and use

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

During the Bluetooth pairing process, the correct password must be entered to establish the connection. As shown below, a secure password authorization and authentication process takes place during the pairing procedure.
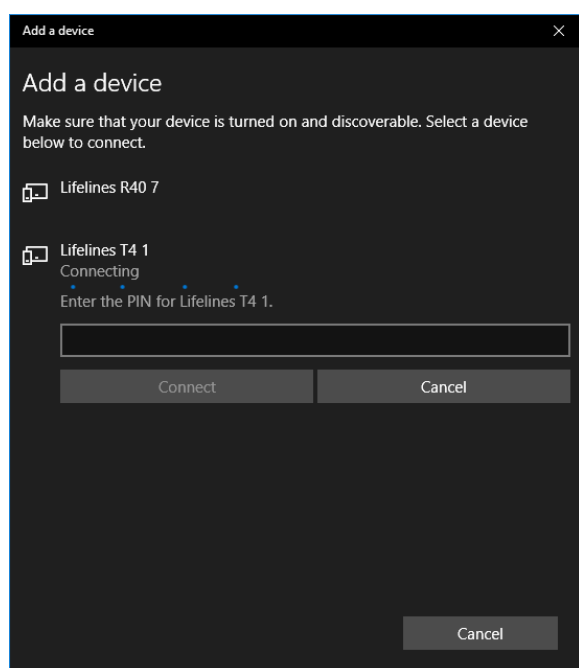
Once established, the T4 acts as the server and provides the SPP service to the PC acting as a client.

During the setup of the WiFi module, the WAP SSID is entered together with its password, as shown below.
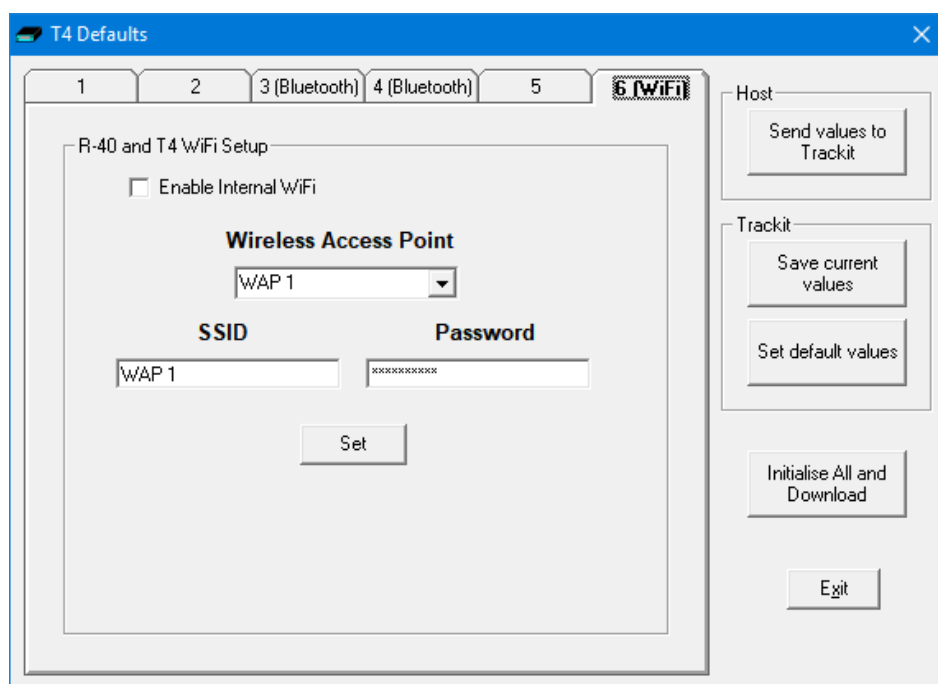
If an attempt is made to connect to an unsecure network without a password, this is prevented and an error displayed as shown below. For maximum security it is recommended that only WPA2 access is allowed.

When the Trackit application has established the Bluetooth connection, a connection quality monitor labelled "Comms.Q" is displayed in the status bar at the bottom left of the main screen, as shown below.
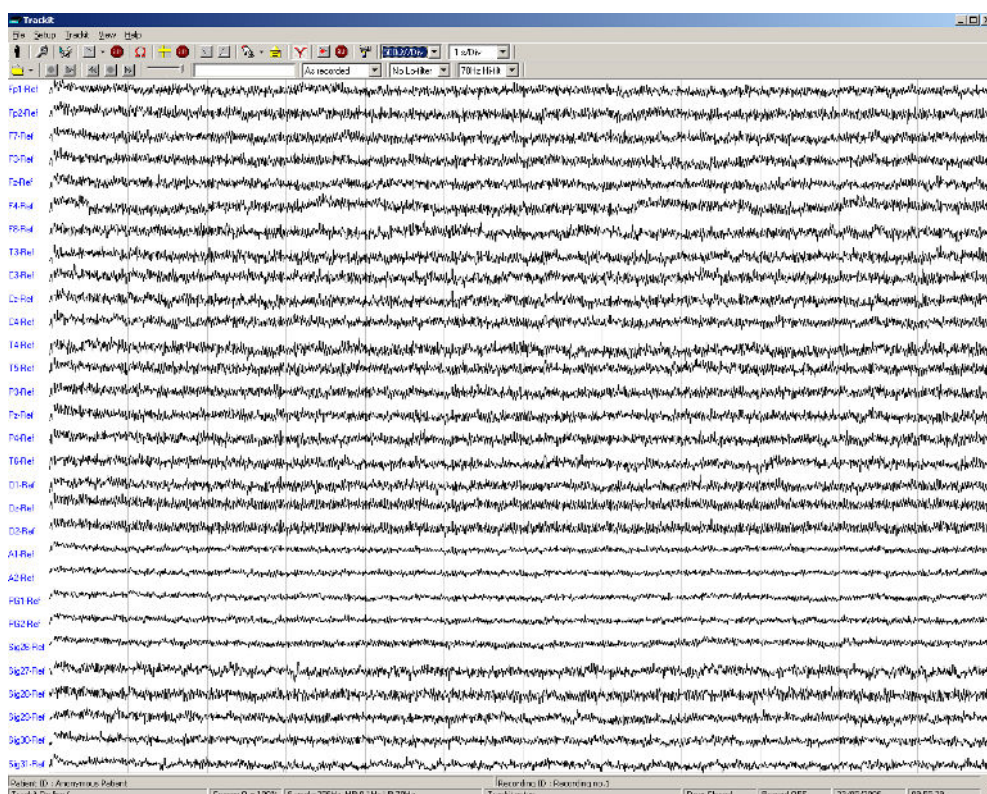
This number given as a percentage is an approximate indication of the amount of data received as a ratio to that expected, calculated every second. It is most likely to drop below 100% when either device is at the limit of the transmission range or when either antenna is adversely obscured or under the influence of interference. It will be noticed that the wireless transmission will use its available bandwidth to try to "catch-up" after a drop in signal quality and the indication can read more than 100% momentarily. A reading, therefore, of less than 100% does not necessarily mean a permanent bad connection since data flow can increase shortly afterwards. A sustained low value over several seconds will cause the Trackit application to close the connection. If the Autoconnect feature has been enabled in Options, the application will automatically attempt to reconnect to the T4 every 10 seconds.

Wireless Communication (general information)

A wireless link can be subject to interference and disruption to communication.
Bluetooth is a wireless technology designed for short-range wireless connections between devices in a wireless personal area network (WPAN). Bluetooth is compliant with the IEEE 802.15 standard and operates in the 2.4 GHz band. Wi-Fi is a wireless technology designed to connect devices and an infrastructure in a wireless local area network (WLAN). Wi-Fi is compliant with various IEEE 802.11 standards such as 802.11a, 802.11b, 802.11g, and 802.11n. 802.11b and 802.11g operate in the 2.4 GHz band, 802.11a operates in the 5 GHz band, and 802.11n can operate in both bands
Both Wi-Fi and Bluetooth are based on spread spectrum signal structuring. With this radio transmission technique, a narrowband signal is expanded across a given portion of the radio frequency spectrum to result in a broader or wideband signal. Such a wideband signal provides a very strong immunity to interference compared to a narrowband signal.

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

Both Bluetooth and WiFi technologies, however, use sophisticated error detection and error correction techniques to deliver correct data. Additionally, if a transmission cannot be decoded due to interference, the transmission is resent. This interference will, of course, increase as the number of coexistent devices in proximity to

each other increases. Due to the robust error detection mechanisms, however, as the interference level increases, data continues to be delivered correctly, but the data rate decreases as the number of dropped packets increases.

In terms of security, both system use authentication with encryption and pin codes/pass words. In addition, the T4 itself uses a proprietary Interface Protocol thus preventing a non-authorised user from taking control of the device.

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

Quality of Service and Associated Risks

1. The risk of corrupt data due to interference is very small due to error detection, error correction and resend data packet mechanisms. In addition to this error detection and correction, the application provides time-stamped data packages, which enables the detection of corrupt, delayed or missing data.

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

3. The risk of unauthorised users is very small due to the authentication requirements of the wireless link and the fact that the T4 Interface Protocol is proprietary.

4. The medical system uses mature, industry-standard hardware and protocols: Bluetooth and WiFi. This ensures that the system utilises all the benefits associated with these mature standards, concerning the authentication, data integrity and interference performance as discussed in this document.

5. The radio modules are tested according to their own EMC emissions and immunity standards: EN 300 328, EN 301 489-1, EN 301 489-17 and IEC 60601-1-2 (Bluetooth).

6. The radio modules are pre-certified and Type Approved.

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

Pre-compliant Wireless Modules

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

Specifications (taken from Appendix 1).
Bluetooth Module
Specifications:
- Type: Bluetooth 4.0.
- Output power: 11dBm max.
- Output frequency: 2.402 - 2.480 GHz, ISM band.
- Data rate: 1.3 Mbps max.

- Protocols: Standard Bluetooth - SPP, GATT, DUN, PAN.
- Modulation: GFSK, DQPSK. Frequency Hopping Spread-Spectrum (FHSS).
- Error Correction: Forward Error Correction (FEC), Automatic repeat request (ARQ).
- Security: authorization and authentication of devices, proprietary Interface Protocol.

Conformance:
- Type Approval: Europe (R&TTE), US (FCC/CFR 47 part 15), Canada (IC RSS).
- R&TTE Directive 1999/5/EC
- Effective use of frequency spectrum: EN 300 328
- EMC: EN 301 489-1, EN 301 489-17,EN 61000-6-2
- Health and safety: EN 62479, EN 60950-1, IEC 60950-1
- Medical Electrical Equipment IEC 60601-1-2
- Bluetooth Qualification v4.0.

WiFi Module

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

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

Interference

The T4 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: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit T4, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

Caution: when in close proximity to the amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.

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 6: Troubleshooting Guide

COM port problems with Bluetooth communication to Trackit T4

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

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

Problems starting the recording

The setup has not been sent correctly
Under Trackit 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 T4 setup. Try to adjust the transmission delay for serial communication in the Trackit software as described above.

An incorrect setup has been sent
If an incompatible setup has been sent to the Trackit T4 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 Formatter tool supplied on the Lifelines CD.

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

Trackit T4: always stop a recording, or if hot swapping wait for the write LED to go out, before removing the card.

Card reader: make sure the device is stopped, in Card Services, before removing the Card. This is especially important in Win2000 systems using a USB card reader, where the activity LED stays on for several seconds after deleting an old file. If the card is removed when this LED is on, the card will be corrupted and a reformat will be necessary. 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 SD card present', in the Status section of the Trackit Control Panel, will evidence this.

Appendix 7: Manufacturer's Declaration

EMC Compatibility

This section contains specific information regarding the device's compliance with IEC60601-1-2 and EN 60601-1-2.

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

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

Accessory name	Type	Length	Manufacturer / Description
USB Interface Cable	USB	2.8 m	USB shielded cable
Input electrodes	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Nonin XPOD	Shielded	2 m	Nonin
Aux. Connector cable	Shielded	1 m	Shielded cable
Patient Event Switch	CM-5	2 m	Zygo – two-core shielded cable

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

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit T4, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

CAUTION: When in close proximity to the T4 Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.

Guidance and Manufacturer's Declaration

Electromagnetic Emissions
IEC60601-1-2 / EN 60601-1-2

The T4 is intended for use in the electromagnetic environment specified below. The customer or user of the T4 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The T4 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 T4 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
IEC60601-1-2 / EN 60601-1-2

The T4 is intended for use in the electromagnetic environment specified below. The customer or user of the T4 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	+/- 8 kV:Contact +/- 15 kV:Air	+/- 8 kV:Contact +/- 15 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% In home environments and portable or transport situations, the T4 should be housed in the T4 bag to protect it from high ESD disturbances.
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 T4 requires continued operation during power mains interruptions, it is recommended that the T4 be powered from an uninterruptible power supply or a battery

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m, 30 A/m	3 A/m See Note e.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment
			Portable and mobile RF communications equipment should be used no closer to any part of the T4, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = [3.5/V] \sqrt{P}$ $= 1.2 \sqrt{P}$ Note: using unshielded input leads [c]
Radiated RF Electromagnetic Fields EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz 10V/m (Home Environment)	3 V/m See Note f.	$d = [3.5/E] \sqrt{P}$: 80 MHz to 800 MHz $= 1.17 \sqrt{P}$ $d = [7/E] \sqrt{P}$: 800 MHz to 2.5 GHz $= 2.33 \sqrt{P}$ Note: using unshielded input leads [d] Where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the T4 is used exceeds the applicable RF compliance level above, the T4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the T4.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

[c] The immunity levels for conducted RF are for unscreened input electrode leads 1 m in length and worse-case coupling, including any resonances across the frequency band. The interference is less when the coupling plane of the interference source is not in the same plane as the electrode leads.

[d] The immunity levels for radiated RF are for unscreened input electrode leads 1 m in length and worse-case coupling, including any resonances across the frequency band. The interference is less when the polarisation plane of the interference source is not in the same plane as the electrode leads.

[e] The Trackit T4 does not contain magnetic components and is not susceptible to power frequency magnetic field interference.

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

Recommended separation distance between portable and mobile RF communications equipment and the T4 EEG System
IEC60601-1-2 / EN 60601-1-2

The T4 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the T4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the T4 as recommended below, according to the maximum output power of the communications equipment.

If any electromagnetic interference is encountered, the patient and equipment should move to an area without interference. In any case, the electromagnetic interference does not pose any risks to the patient, as the Trackit T4 is a non-invasive recording device that does not modify or interact with the patient.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
W	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	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.