lifelines neuro

trackit T4

MADE IN BRITAIN

USER MANUAL

Imagine EEG Anywhere®

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Customer Responsibility

The Trackit T4 amplifier is reliable only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and inserts. A defective system should not be used. Parts that may be broken or missing or those that are clearly worn or contaminated should be replaced immediately with new original replacement parts that have been manufactured by or are available from Lifelines Neuro.

The owner of this system has the sole responsibility for any malfunction resulting from improper use or maintenance, or repair done by anyone other than a qualified Lifelines Neuro representative and for any malfunctions caused by any parts that have been damaged or modified by anyone other than a qualified Lifelines Neuro representative.

The owner of this system has the sole responsibility for the connection of this product to other systems not satisfying the electrical safety requirements class I, type BF, standards IEC 60601-1, IEC 60601-2-26, IEC 60601-1-11, IEC 60601-1-2 for medical devices.

Disclaimers & Warranties

Except as stated below, Lifelines Ltd makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Lifelines shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this material.

Lifelines shall warrant its products against all defects in material and workmanship for one year from the date of delivery.

Misuse, accident, modification, unsuitable physical or operating environment, improper maintenance or damage caused by a product for which Lifelines is not responsible will void the warranty.

Lifelines do not warrant uninterrupted or error-free operation of its products.

Lifelines or its authorised agents will repair or replace any products that prove to be defective during the warranty period, provided that these products are used as prescribed in the operating instructions in the user's and service manuals.

No other party is authorised to make any warranty to assume liability for Lifelines products. Lifelines will not recognise any other warranty, either implied or in writing. In addition, services performed by someone other than Lifelines or its authorised agents or any technical modification or changes of products without Lifelines prior, written consent may be cause for voiding this warranty.

Defective products or parts must be returned to Lifelines or its authorised agents, along with an explanation of the failure. Shipping costs must be prepaid.

Lifelines Ltd. manufactures hardware and software to be used on or with standard PC-compatible computers and operating software. Lifelines, however, assumes no responsibility for the use or reliability of its software or hardware with equipment that is not furnished by third-party manufacturers accepted by Lifelines at the date of purchase.

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

Trademarks

Microsoft, Windows and Windows NT are registered trademarks of the Microsoft Corporation. All other trademarks and product names are the property of their relevant owners.

Responsibility of manufacturer

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

- any peripheral equipment to be used with the 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:

- 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.
- Virus scanning should be set to manual mode or automatic if desired but at a time when the system is not being used.
- 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.
- Adopt formal departmental or organisational procedures to ensure the integrity and safe operation of the medical equipment and supporting systems.

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1 Overview and Technical Description

1.1 General description

Indications for use

The 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.

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 non-overlapping 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 Warnings and Cautions

	Warning sign indicates a situation or procedures that may be dangerous for the patient and/or user.		**Caution** sign indicates a situation or procedures that may cause equipment damage or its improper usage.

	Do not use the T4 EEG Amplifier in an MRI environment, in an oxygen rich environment or during defibrillation.
	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.
	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.
	Only use the laptop and the medical-grade power supply as supplied or authorised by Lifelines. Do not use the standard laptop power supply
	The Amplifier must only be used with the USB Power Bank supplied or authorised by Lifelines.
	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	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.
	The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth.
	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.
	Do not touch simultaneously any accessible USB or other contacts on the PC and the patient.
	Strangulation hazard due to long cables. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
	Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.

	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.
	Do not open or modify the equipment without the authorization of the manufacturer.
	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.
	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.
	When in close proximity to the T4 Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
	Only use approved sensors as specified by Lifelines.
	The Amplifier must only be used with the USB cable provided with the unit.
	Do not allow any liquid to enter the case of the instrument or connector. Do not use acetone on any of the instruments.
	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

Symbol	Meaning
	Type BF applied part
	Input/output connection
	Special recycling required*
	Consult warnings in User Manual
	Remote event pushbutton
	On/Off and patient event switch
	Manufacturer
	Internal battery hazard - refer to section **1.7**

Symbol	Meaning
	Follow operating instructions
	Input connection
	Bluetooth
	WLAN WiFi
	Nonin Xpod Pulse Oximeter
	Memory card read/write
	European Representative

* 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.

Storage and transport symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	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 or laptop and a medical grade power supply. Refer to section 3.1 for details.

	The PC or laptop must only be powered using the medical-grade mains power supply, as supplied or authorised by Lifelines.

The T4 EEG Amplifier comprises the following components:

Component	Part Number
T4-32 Amplifier	1505
T4-68 Amplifier	1501
T4-PCU 24+8	1552
T4-PCU 64+4	1553
T4-PCU 32+3	1556
USB Power Bank battery 10Ah	1581
USB Power Bank battery 20Ah	1582
Battery cable	1561
T4 bag and straps	1562
Patient event switch	1353
Xpod Pulse Oximeter Nonin	1327
Trackit tool	1115
Amplifier USB cable	1277
Medical grade power supply	1390
Mains cable, UK	1066
Trackit software CD, standard	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:

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

**Note: Compliance is provided by the PC.*

Classification of system

Classification	Clinical use	Home use
Degree of protection against electrical shock	Internally powered; or it can be connected to a PC which is powered by a medical grade Class I power supply. Type BF applied parts.	Trackit T4 Amplifier: Internally powered. Type BF applied parts. If a PC is supplied, the PC has no electrical connection to the Amplifier and 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 and an Aux DC input. 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 touch¬proof EEG recording electrodes attached to the patient to the T4 unit. It is available either as a T4-PCU 24+8 (32 channel) unit, a T4-PCU32+3 (ECAP + 10 channels), 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, attached to the patient's head.

!	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.
!	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 mark 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.

⚠	Only use approved sensors as specified by Lifelines.

USB Cable for connection to PC

For non-ambulatory applications the Amplifier can be plugged directly into a USB port on the PC.

⚠	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.

⊘	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.

⊘	Only use the laptop and the medical-grade power supply as supplied or authorised by Lifelines. Do not use the standard laptop power supply

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.
- Perform a calibration check of the Amplifier.
- Perform an Impedance check on the electrode inputs.
- Perform an EEG recording.
- View on-going EEG traces.

Refer to the Trackit Plus software manual for more details.

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.

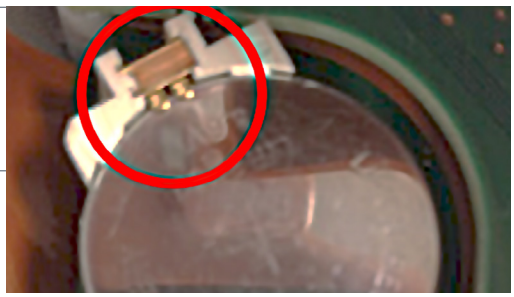
Internal battery replacement – service personnel only

The T4 amplifier contains a replaceable lithium ion rechargeable coin cell, type LIR2450.

	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 the PCU.
2. Remove the four screws from the underside of the T4 amplifier as well as the two screws from the front (PCU end) moulding and the two screws from the connector end moulding. Remove the bottom of the case.
3. Unclip the wraparound screen to expose the battery beneath.
4. Using a **NON-CONDUCTIVE** tool (for example, a spudger, plastic card or pen lid) place the tool under the coin cell battery and, without exerting any stress on the holder itself, gently prise out the battery at the negative terminal end. The battery should release from the battery holder.
5. Remove the battery from the battery holder.
6. Locate the replacement battery, positive side up, against the POSITIVE terminal of the battery holder.
7. Gently push the battery, at the negative terminal end, into the battery holder. The battery will click into place.

NOTE: The positive terminal of the battery holder has a metal tab. The battery must be located UNDER the tab. Take care not to bend the tabs when inserting the battery. The image (right) shows the metal tab.



8. Gently push the battery, at the negative terminal end, into the battery holder. The battery will click into place.
9. Re-clip the wraparound 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

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

⚠	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 ii) 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:		Storage and transport:	
Temperature	+5°C to +40°C (+41°F to +104°F)	Temperature	-25°C to +70°C (-13°F to +158°F)
Relative humidity	15% to 93% non-condensing	Relative humidity	Up to 93% non-condensing at +70°C (158°F)
Atmospheric pressure	700 hPa to 1060 hPa	Atmospheric pressure	500 hPa to 1060 hPa

2.3 Power supply connections

Trackit T4 Amplifier

Power requirements	Standard USB port (5V)
Power consumption	Maximum power from USB port: 2.5W.

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

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.

Medical grade AC mains power supply module for Laptop PC	
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.

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

2.4 Battery Operation Time

USB Powerbank

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 60 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 should be operated in its bag where it is protected against ingress of solid objects and water to a degree of IP22.

The laptop PC is optional in the home environment and may be used for video recordings. There is no cable connection between the PC and the 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 equipment or 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 WiFi 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 artefacts.

The T4 may have internal radios fitted. These are approved industry-standard Bluetooth and WiFi 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

⚠	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.
⚠	When in close proximity to the T4 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.

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 and disinfection

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.

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

2.9 Disposal of equipment

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

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

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

3 Connections and usage

3.1 Overview

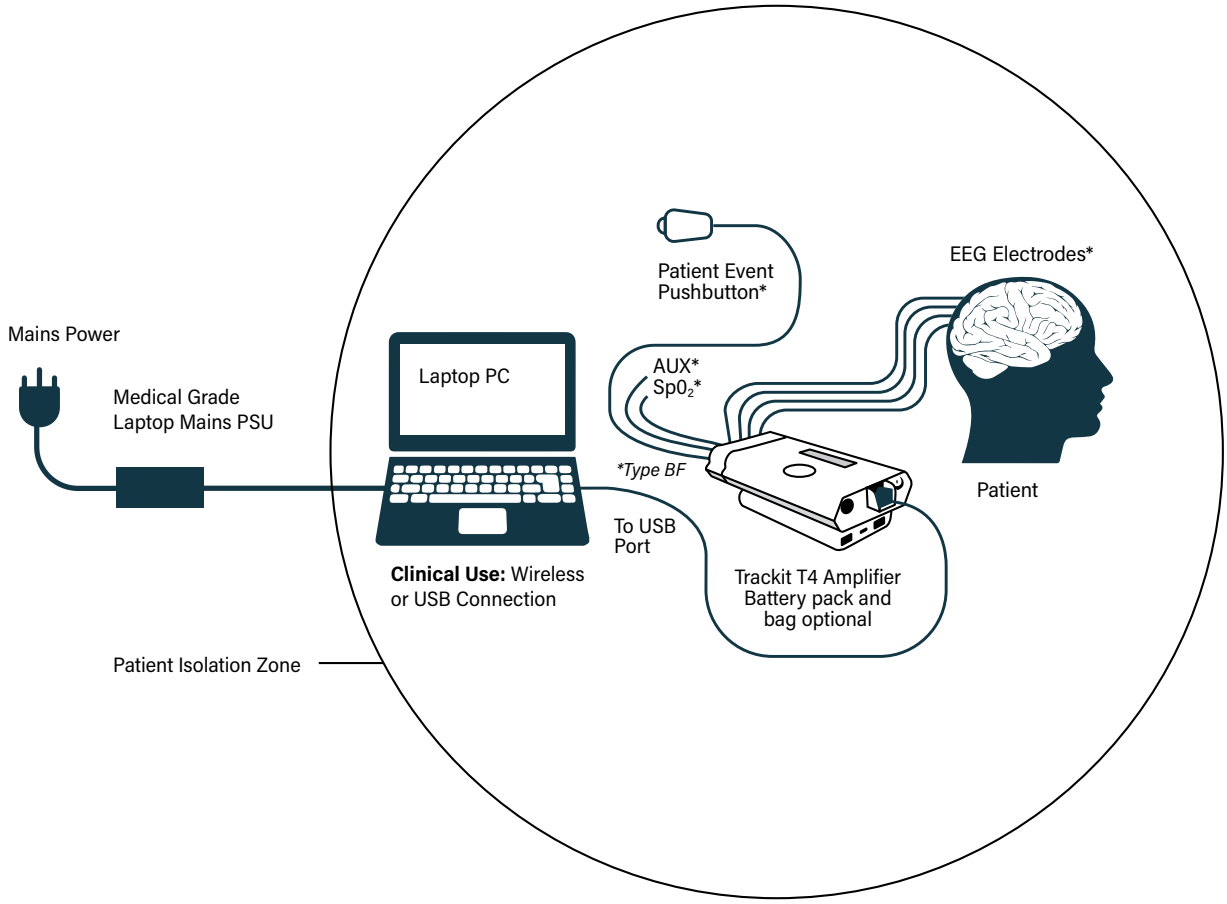


Figure 1: Connecting the T4 Amplifier – Clinical Use

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.

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.

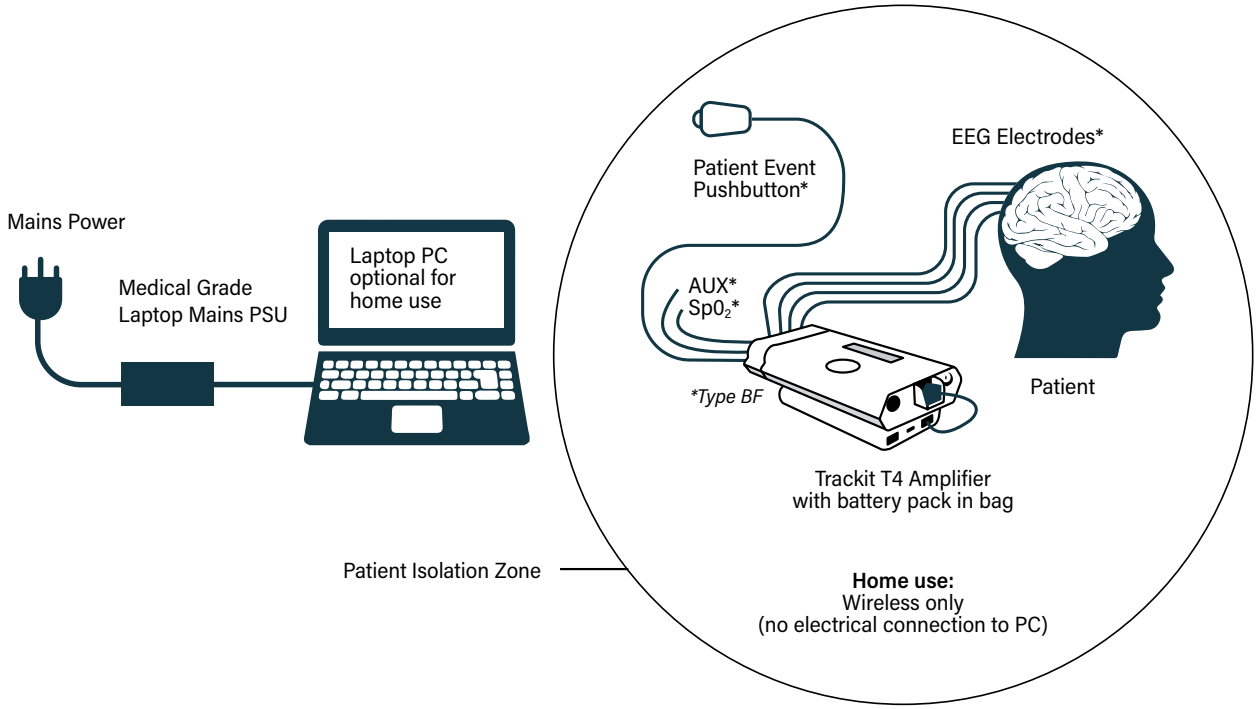


Figure 2: Connecting the T4 Amplifier - Home Use

3.2 Laptop installation and operation

⚠	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.

NOTE: The mains power cord serves as a power disconnect device. It should be installed near the equipment and be easily accessible.

4. For laptop installation and operation refer to the manufacturer's instructions supplied with it.

⚠	Do not touch simultaneously any accessible USB or other contacts on the PC and the patient. If the USB cable is used in the home, the laptop and power supply must be placed 1.5m away from the patient.

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, 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.

	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: 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 WiFi 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.

Electrode connections

!	The Amplifier accepts standard 1.5 mm touchproof electrodes using DIN 42802-style connec¬tors. 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.
!	Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation
!	The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth.

The front face of the Amplifier's PCU is laid out in a standard 10-20 format (**T4 PCU 24+8**), a grid layout (**T4 PCU 64+4**), or as an Electrocap (Ecap) connector **(T4 PCU 32+3)**. It accommodates standard touchproof electrode leads fitted with DIN 42802 connectors.

Figure 3: T4 amplifiers and PCUs

T4-PCU 32+3 Connections

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.

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

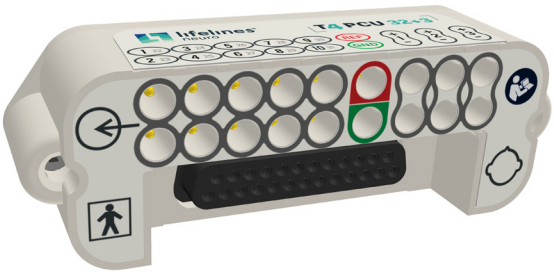


Figure 4: T4 PCU 32+3

The back edge of the Amplifier provides for several other connections, as shown below.

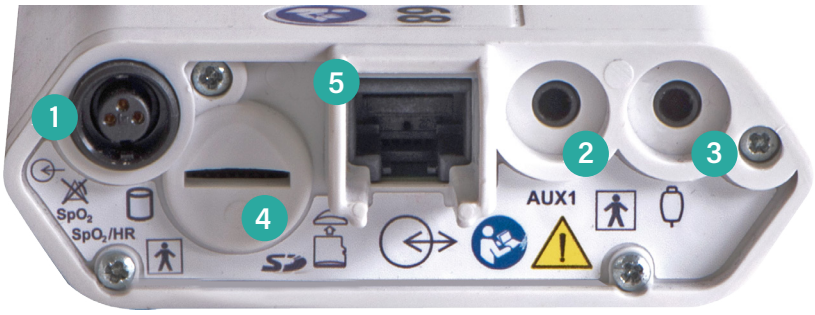


Figure 5 Connecting the T4 Amplifier (back face)

1. Nonin Xpod: the circular connector allows for the connection of a Nonin Xpod pulse oximeter for measuring SpO2. 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.

⚠	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.

⊘	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:

Figure 6: T4 Amplifier display indicators

The symbols have the following meaning:

Symbol	Description
	Clock: Represents the time of day in HH:MM format. When the T4 is connected to the PC, the clock is synchronised to the PC's clock.
	Stopwatch Indicator: Represents the elapsed recording time in HH:MM format (--:-- if not recording).
	Battery capacity: % or 'USB' if external power applied
	Micro-SD card: 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 pushbutton on the side of the battery to turn it on.

1

Figure 7: Battery replacement 1

a. Open zip at bottom of bag to access battery
b. Unplug cable from battery
c. Withdraw discharged battery from bag
d. Do not connect cable to any other equipment

2

Figure 8 Battery replacement 2

a. Insert charged battery into bag
b. Plug cable into battery
c. Turn battery on using button on side
d. Close zip

!	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 the 10Ah powerbank for approximately 5 hours and the 20Ah powerbank for approximately 9 hours before 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 USB Powerbank 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.

ⓘ	Do not charge the battery whilst it is connected to the T4 unit.
ⓘ	Do not charge the battery when the equipment is in use.

3.7 Micro-SD Card

SD Card Preparation

The T4 Amplifier supports micro SD and SDHC cards up to 32GB.

The SD card needs to meet the following requirements:

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

If these requirements are not met, the T4 Amplifier may not be able to read the card and will not be able to start the recording.

High Endurance (MLC) type SD cards are recommended for the T4 Amplifier.

NOTE: The T4 Amplifier will delete all the files on the SD card before starting a recording.

Insertion and Removal

The T4 Amplifier uses a “push-push” style of micro-SD card holder (push to insert, push to remove).

To install the card:

1. Slide the card into the SD card slot (Figure 5, #4) with the micro-SD card gold contacts facing down. The card will stop against a spring.
2. Using the T4/T4A tool (supplied), gently push the card further into the slot until it clicks into place.
3. When fully inserted and locked in place, the micro-SD card will be recessed in the card slot.

To remove the card:

1. Gently push the micro-SD card with the T4/T4A tool.
2. Release the pressure on the card and it will eject out of the card slot.

The micro-SD card can be inserted and removed while the T4 Amplifier is switched on.

When the micro-SD card is inserted (and successfully read) or removed, an audible beep will sound. Upon card insertion, the T4 will read the card and the card capacity will be indicated on the display, accompanied by an audible beep. Upon removal, the display will show "⊡→ 0M".

NOTE: If the T4 fails to read the card upon insertion, then remove and reinsert the card.

Recorded Files

During an Ambulatory or Dual recording, the T4 will record the EEG data and events in two files on the micro-SD card. The two files will have the same file name; The EEG data is stored in a *.BDF and the events are stored in a *.TEV file. The file name can be set in the software to use the Patient ID or a user-defined file name. The T4 only supports file names in 8.3 format (i.e. the file name shall be 8 characters or less)

The T4 uses a FAT32 file-system, which supports a maximum file size of 4GB. If the recording exceeds 4GB, the data will span over multiple files. The file name for the extended files shall be sequentially numbered, as follows: "FILENAME.BDF", "FILENA_1.BDF", "FILENA_2.BDF", etc (where FILENAME is the user-defined file name). Each BDF file will have a corresponding TEV event file, with the same file name and number.

When loading the recorded data into the review software, ensure that all the BDF and TEV files are loaded. Refer to the instructions for the specific review software.

4 Trackit Software - 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 2.8.1.7 (or later) supports the Trackit T4. Check with your distributor or Lifelines if a newer version of software is available.

The Trackit software is designed to work with both the Trackit T4 Amplifier and with the optional Photic Stimulator.

The software is supported on Microsoft Windows XP, Windows Vista and Windows 7, Windows 8 and Windows 10. The USB drivers will be found on the CD. After connecting the Amplifier to the PC for the first time, at the Windows prompt, browse to the folder CD Drive:\USB Drivers. From there Windows will find the correct drivers for the version of Windows being used.

The software has the following functions:

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

NOTE: See separate Trackit Plus software manual for setup and recording details.

Appendix 1: Trackit T4 Amplifier Specifications

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

EEG inputs	
Number of EEG channels	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 Vdiff	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 Vdiff	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 Vdiff	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) 31 referential channels (21 on Ecap connector) + 3 bipolar (model T4-PCU 32+3)
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 equip¬ment, general require-ments and particular requirements for EEG systems.
IEC 60601-1-11	Collateral standard for medical electrical equipment used in the home healthcare environment.
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 equip¬ment, 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

Classification of system		
Classification	**Clinical use**	**Home use**
Degree of protection against electrical shock	Internally powered; or it can be connected to a PC which is powered by a medical grade Class I power supply. Type BF applied parts.	Trackit T4 Amplifier: Internally powered. Type BF applied parts.
		If a PC is supplied, the PC has no electrical connection to the Amplifier and 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

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" and the Trackit Plus Software manual.

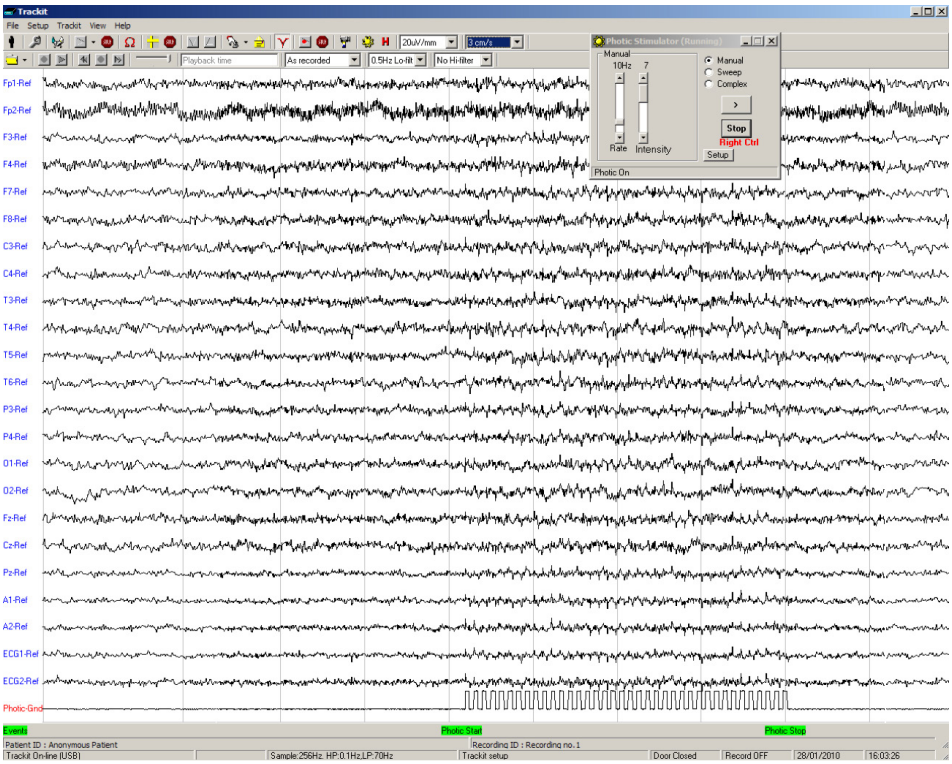
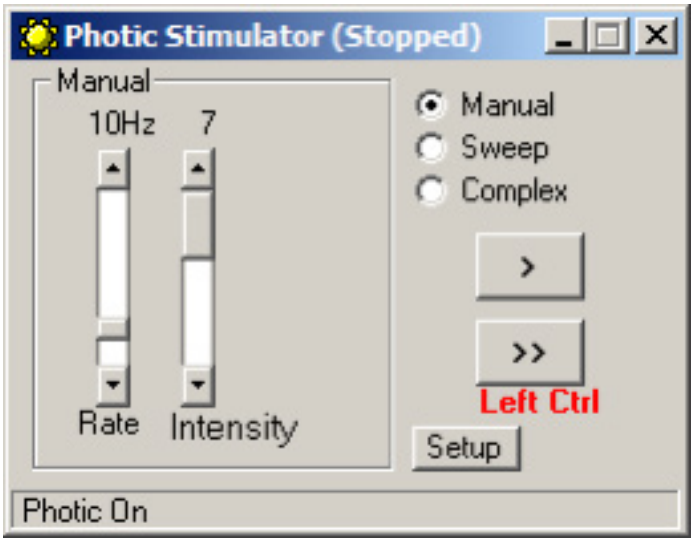


Figure 9 Photic Stimulation (using Trackit Plus software)



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

Figure 10 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.

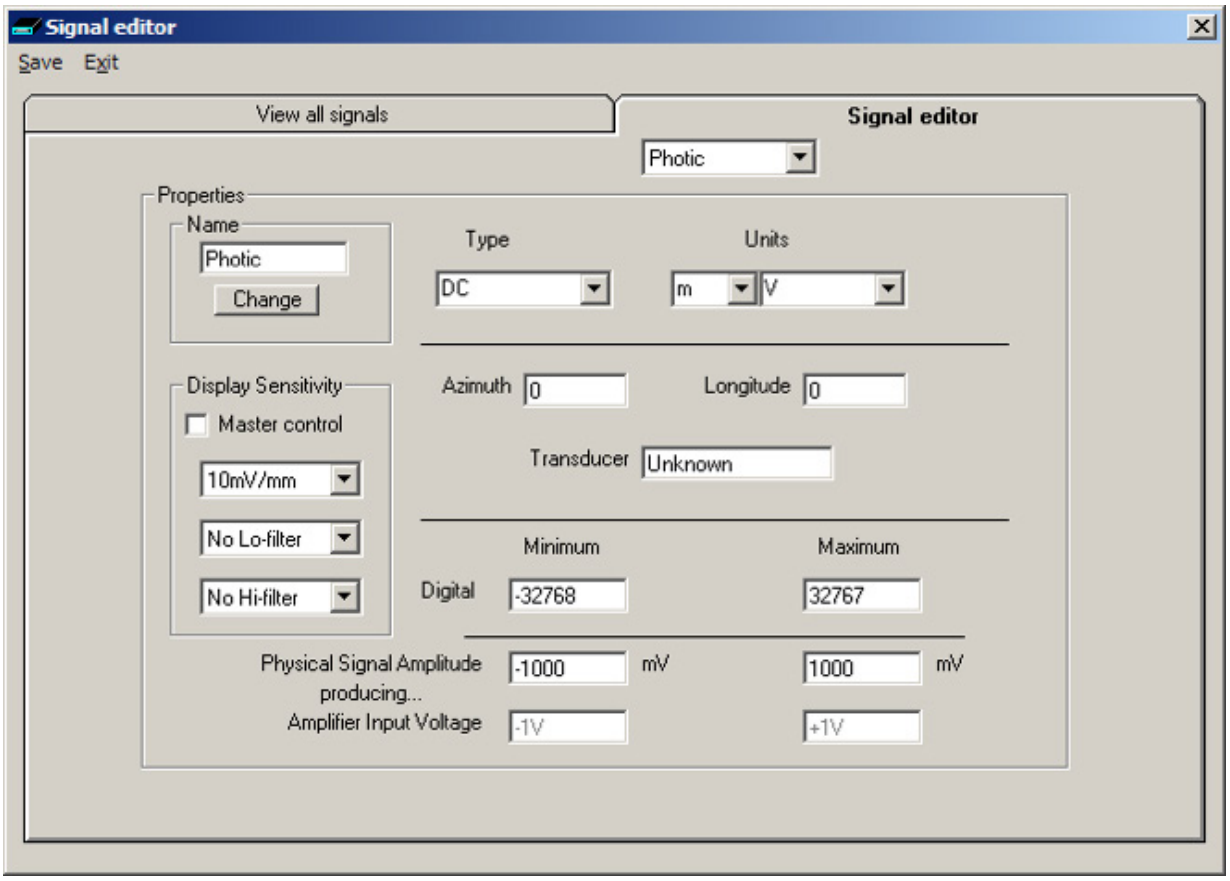


Figure 11: Photic trigger signal definition

Appendix 3: Additional Events Information

For the T4 EEG Amplifier, events types are as shown below.

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

Refer to the Trackit Plus software manual for more information

Event List Key	Event No	Contents	Type	Size	Total size	Mapping
0	0	No event	Fixed	16x16	256	Auto
	1	Stop recording	Fixed			Auto
	2	Start recording	Fixed			Auto
	3	Door Open	Fixed			Auto
	4	Door Closed	Fixed			Auto
	5	Host On	Fixed			Auto
	6	Host Off	Fixed			Auto
	7	Low Battery	Fixed			Auto
	8	OK Battery	Fixed			Auto
	9	Imp. Check Mode	Fixed			Auto
	10	Calibrate Mode	Fixed			Auto
	11	Normal Mode	Fixed			Auto
	12	Electrodes On	Fixed			Auto
	13	Electrodes Off	Fixed			Auto
	14	Patient Event	Fixed			Auto
	15	External Event	Fixed			Auto
1	16	Awake #	User-config	16x16	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	32x32	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	32x32	1024	Shift F1–8 Ctrl+Shift F1-8
4	96-159	?	User-config (free text)	64x64	4096	F12

Appendix 4: 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.

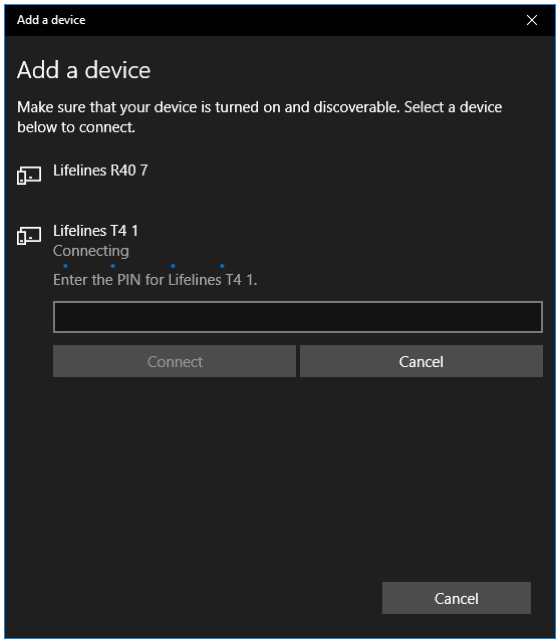


Figure 12: Bluetooth pairing

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.

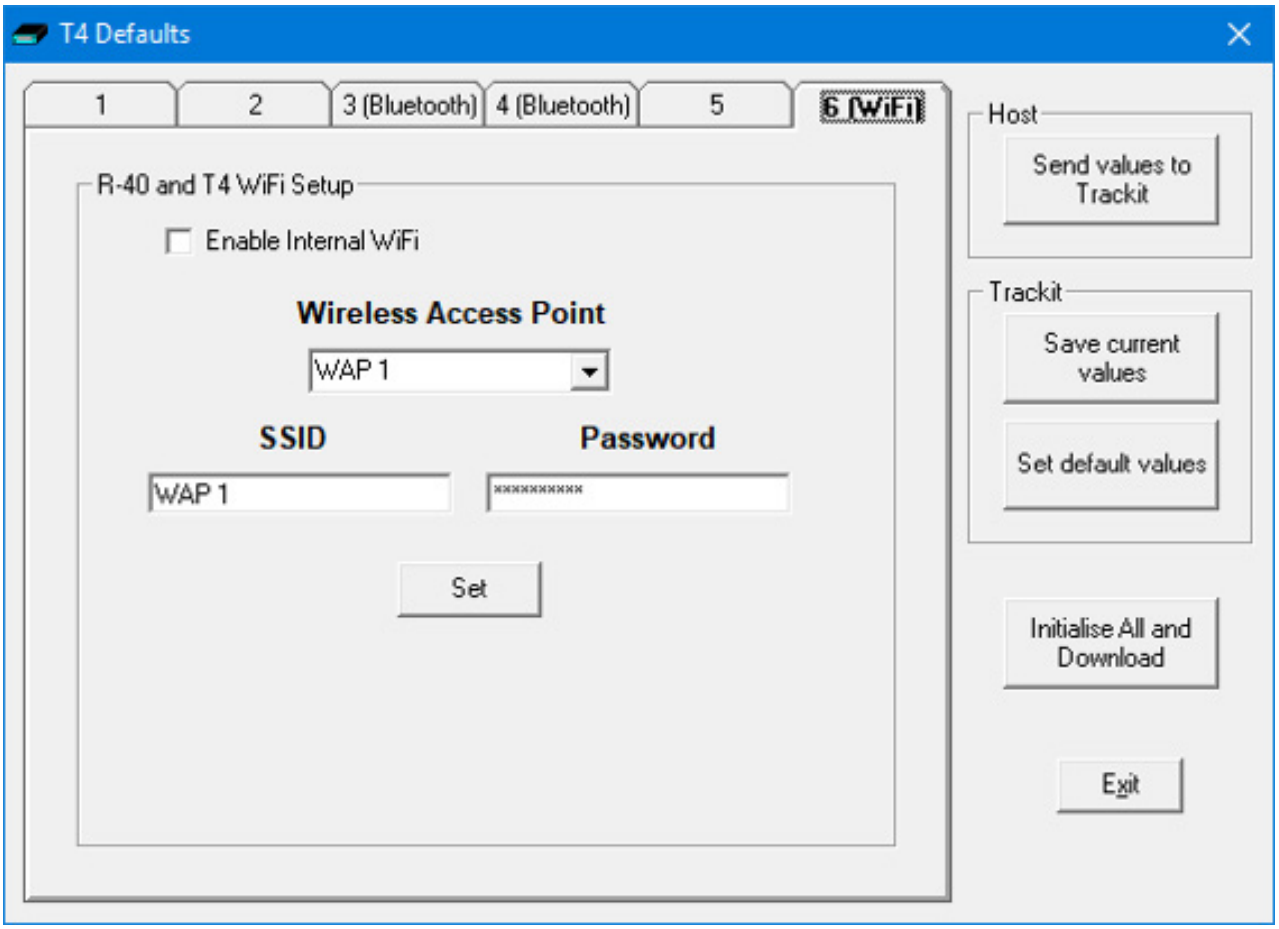


Figure 13: WiFi setup

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.

Figure 14: Unsecure network error message

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.

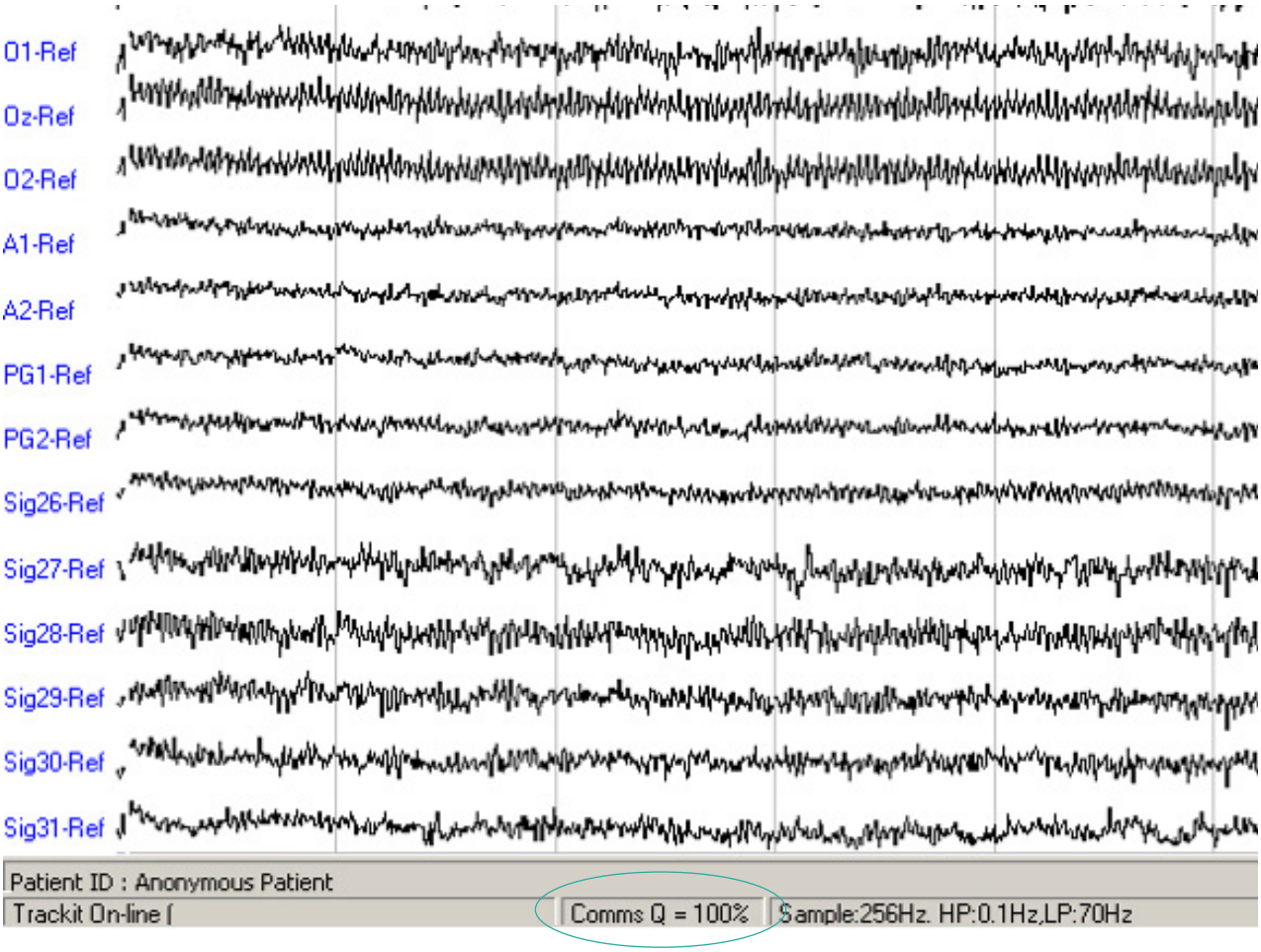


Figure 15: Bluetooth connection quality monitor.

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. WiFi 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 narrow-band 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.

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

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

Appendix 5: 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 T4 Status, in the Control Panel, check that Acquire Ready shows Yes. If it is not ready, acquisition cannot begin. This could be caused by incomplete transmission of the Trackit T4 setup.

Check that all channels in the Recording setup have the same sample rate. The T4 does not support multi-sample rate.

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 Card Formatter PC utility.

The card is corrupted

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

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

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

The card is not inserted correctly

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

Appendix 6: Manufacturer's Declaration

EMC Compatibility

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

	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.
	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here.
	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.
	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.
	When in close proximity to the T4 Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.

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

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

IEC 60601-1-2 / EN 60601-1-2

The Trackit 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 IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

IEC 60601-1-2 / EN 60601-1-2

The 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) IEC 61000-4-2	+/- 8 kV: Contact +/- 15kV: Air	+/- 8 kV: Contact +/- 15kV :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 IEC 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commer-cial and/or hospital environment
Surge IEC 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commer-cial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/ or hospital environment. If the user of the T4 system requires continued operation during power mains interruptions, it is recommended that the T4 system be powered from an uninterruptible power supply or a battery

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m, 30A/m	3 A/m See Note e.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical com-mercial and/or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF Electromagnetic Fields IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6V in ISM Bands 3 V/m 80 MHz to 2.5 GHz 10V/m (Home Environment)	3 Vrms 3 V/m See Note f.	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** d = [3.5/V] $\sqrt{P}$: 80 MHz to 800 MHz = 1.2 $\sqrt{P}$ d = [7/V] $\sqrt{P}$: 800 MHz to 2.5 GHz = 2.33 $\sqrt{P}$ Note: using unshielded input leads 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 reorienting 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 Trackit T4 EEG System

IEC 60601-1-2 / 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		
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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

V2.0 (28th November 2019)
- New document style
- Software section moved to Trackit Plus Software manual

V2.1 (07 December 2021)
- Updated Manufacturer's address
- Updated EC Rep address
- Updated LNC logo
- Updated section 1.7

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