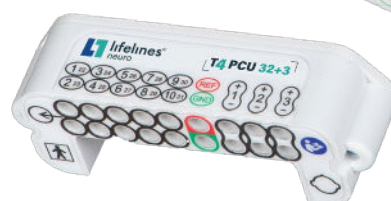




trackit T4



USER MANUAL



Imagine EEG Anywhere

**Lifelines Ltd**

1 Tannery House, Tannery Lane,
Woking, Surrey, GU23 7EF UK
Telephone +44 (0) 1483 224 245
www.lifelinesneuro.com
sales@lifelinesneuro.com

**Incereb Ltd.**

6 Charlemont Terrace, Crofton Road,
Dun Laoghaire, Dublin, A96 F8W5. Ireland.



Doc No:	51285-006
Part No:	51285-006
Issue:	3.0
Date:	April 2025

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 80601-2-26, IEC 60601-1-11, IEC 60601-1-2 for medical devices.

NOTE: Any serious incident that has occurred in relation to the Trackit T4 should be reported to the manufacturer and, where applicable, the competent authority of the EU Member State in which the user and/ or patient is established.

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 Trackit T4 system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

This document contains proprietary information that is protected by copyright. All rights are reserved. No part of this document may be photocopied, reproduced in any other form or translated into another language without the prior written consent of Lifelines.

Trademarks

Microsoft and Windows 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 Trackit 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: Equipment specifications are subject to change without notice.

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.

General Security Policies

- Prevent physical access to the system from unauthorized persons.
- Make frequent backup of the system. Store the backup on a safely stored device.
- The user should lock the system manually if they leave it unattended.
- Short inactivity timeouts are always active and lock the system when the timeout expires.
- Do not install any 3rd party software which is not intended for use with the application. An unknown software can possess a potential security risk.
- Encrypt system drives which contain local databases and temporarily store data files/reports.

Networked Environments

- Connect the system on secured networks only.
- Using the system on a wide-open network is not recommended.
- Keep the network software updated with latest patches.
- Use encrypted data communication over "less safe" network segments (ipsec, VPN).
- All resources within the network can only be accessed by authenticated users.

Contents

Disclaimers & Warranties	2
1 Overview	5
1.1 General description	5
1.2 Warnings and Cautions	7
1.3 Explanation of symbols	9
1.4 Components and Accessories	10
1.5 Replaceable parts	12
2 Installation and Maintenance	13
2.1 Checks for completeness and integrity	13
2.2 Environmental parameters for operation	13
2.3 Power supply connections	14
2.4 Battery Operation	15
2.5 Use in the home environment	15
2.6 Use with other equipment	15
2.7 Interference	17
2.8 Maintenance and cleaning	17
2.9 Disposal of equipment	17
3 Connections and usage	18
3.1 Overview	18
3.2 Recording Procedure	20
3.3 Laptop Installation and operation	20
3.4 Trackit Solo	20
3.5 Connecting the Trackit T4 Amplifier	21
3.6 Switching the Amplifier on and off	24
3.7 Battery replacement & charging	26
3.8 Micro-SD Card	27
3.9 Bluetooth	29
3.10 Connection Checks	30
Appendix 1: Trackit T4 Specifications	31
Appendix 2: Manufacturer's Declaration	34

1 Overview

1.1 General description

The Trackit T4 EEG Amplifier is a multi-channel electroencephalograph designed for use in routine EEG, lab monitoring and ambulatory applications. The two variants of the Trackit T4 EEG Amplifier are:

- Trackit T4-32, providing 24 referential + 8 polygraphic channels.
- Trackit T4-68, providing 64 referential + 4 polygraphic channels.

The Trackit T4 Amplifier has the following features:

- Type-BF patient isolation to applied parts
- Up to 64 EEG inputs and 8 Bipolar polysomnography inputs.
- Interchangeable Patient Connection Units, providing connections to touch-proof electrodes and headcaps.
- One Aux DC inputs
- Sampling rates up to 2000 Hz with 24-bit analog conversion.
- Built-in electrode Impedance measurement and Calibration Check.
- Interface to Nonin XPOD module for SpO2, heart rate and Plethysmograph capture
- Connection for optional remote pushbutton
- USB or wireless interface to the acquisition PC
- Powered via USB cable or USB Power Bank
- Digital Trigger input
- Storage on removable microSD card

Standard 1.5mm touch-proof electrode connections are provided through plug-on Patient Connection Units (PCUs), in the following variants:

- T4-PCU 24+8 provides 32 touchproof inputs (24 referential + 8 polygraphic channels.)
- T4-PCU 64+4 provides 68 touchproof inputs (64 referential + 4 polygraphic channels).
- T4-PCU 32+3 provides 21 EEG channels on an Electrocap D-type connector plus an additional 10 referential and 3 polygraphic channels.

The Trackit T4 Amplifier is intended to be connected to a USB port on the Trackit Solo or a PC which is powered from a medical-grade power supply. It can also be battery powered in ambulatory applications.



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

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.

Indications for use

The Trackit T4 EEG Amplifier is used as an aid in the diagnosis of neurophysiological disorders such as epilepsy.



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

Intended Use

The Trackit T4 EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

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.

Intended patient population

Paediatric to adult. The patient profile has no influence over the EEG signal acquisition. The patient has no interaction with the device.

Clinical Benefit

The expected clinical benefit for the Lifelines T4 amplifier is as an aid in measuring electrical brain activity and in diagnosing brain disorders, such as epilepsy and other seizure disorders.

Recording EEG with the T4 amplifier does not directly affect outcome; the collected EEG activity will allow the physician to decide on diagnosis and treatment. Treatment directed by data recorded with the T4 amplifier may result in better outcomes than treatment informed solely by data from clinical assessment.

Essential Performance

Essential performance of the Lifelines T4 EEG Amplifier is identified in the standard IEC 80601-2-26.

Essential performance relates to the quality and accuracy of the signal recorded from the amplifier. Specific essential performances are (1) accuracy of amplitude and rate of variation, (2) dynamic range and differential offset voltage, (3) input noise level, (4) frequency response, and (5) common mode rejection. The definitions of these essential performances can be found in the standard. Refer to the Trackit T4 EEG Amplifier specification in [Appendix 1](#).

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 is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. This equipment is not to 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. To ensure patient safety, the electrodes used must be approved to the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 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 Trackit Solo or 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.

Residual Risks and Side Effects

There are no known residual risks or side effects for procedures performed with the Trackit T4 EEG Amplifier. Please take note of the Warnings and Cautions before using the Trackit T4 EEG Amplifier.

1.3 Explanation of symbols

Symbol	Meaning	Symbol	Meaning
	Type BF applied part		Follow operating instructions
	Input/output connection		Input connection
	Special recycling required*		Bluetooth
	Consult warnings in User Manual		Nonin Xpod Pulse Oximeter
	Remote event pushbutton		Memory card read/write
	On/Off and patient event switch		European Representative
	Manufacturer		Medical device
	Internal battery hazard - refer to section 1.5		

* Do not dispose of in landfill. This product includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. When this equipment has reached the end of its useful life, follow all local laws and regulations for the proper recycling or disposal of such equipment. Contact your local distributor for information.

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 Components and Accessories

Trackit T4 Components:

Component	Part Number
T4-32 Amplifier	1506
T4-68 Amplifier	1502
T4-PCU 24+8	1552
T4-PCU 64+4	1553
T4-PCU 32+3	1556
T4 bag and straps	1562
Trackit tool	1115
Amplifier USB cable	1277
Trackit software standard	1009
Trackit T4/T4A Tool	1408

Trackit T4 optional components/compatible accessories:

Optional Component/Accessory	Part Number
Patient event switch	1353
USB Power Bank battery 10Ah	1581
USB Power Bank battery 20Ah	1582
T4 Battery cable	1561
Nonin Xpod Pulse Oximeter	1327
Trackit Solo	1700xx (xx = EU, UK, or US)

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

Applied parts, type BF

EEG Electrodes

The amplifier connects to EEG electrodes with standard 1.5mm touchproof DIN 42802-style connectors.

	Lifelines does not supply EEG electrodes. To ensure patient safety, the electrodes used must be approved to the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 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.

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 Trackit T4.

Bags and straps for ambulatory applications

The Bag houses the Amplifier and battery and protects them from water and dust (IP22 protection).

Trackit Solo

The Trackit Solo can be used as the acquisition system (in place of a PC) and can include recording video during the EEG study. The Trackit Solo includes a medical grade power supply.

Refer to the Trackit Solo User Manual.

Medical grade AC/DC mains power supply module for Laptop PC

To control the mains power leakage current in the patient environment, the Acquisition PC must use a medical-grade mains power supply.



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 is used to setup the Trackit T4 and to review the recorded EEG data. The software also allows for recording on to the PC.

Refer to the Trackit Plus software manual.

1.5 Replaceable parts

Lifelines 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 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. Refer to the Trackit T4 Service Instructions.

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 if assistance is 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.

Trackit Solo

Power requirements	100-240 Vac 50/60Hz, 1.5A max
Power consumption	60W

Medical grade AC mains power supply module for Laptop PC

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

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. Estimating the precise recording time of the battery is difficult as it depends on the number of channels, whether Bluetooth is 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.

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 (approx. 15 mins) 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. The backup battery is replaceable by service personnel only.

2.5 Use in the home environment

Where the equipment is used in the home:

- The Trackit T4 and power bank should be operated in its bag where it is protected against ingress of solid objects and water to a degree of IP22.
- Keep the equipment away from sources of heat.
- Do not use near mobile phones.
- Do not allow pets or children to interfere with the equipment or sensor cables.
- When the equipment is operated with or without Bluetooth connected, other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment.

2.6 Use with other equipment

Defibrillators and HF surgical equipment

The equipment is not defibrillator proof and should not be used in situations where a defibrillator is likely to be used. The equipment should not be used with, or in the presence of, high frequency surgical equipment.

Other patient-connected equipment

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

Leakage current

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

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

2.7 Interference

The Trackit 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 IEC 60601-1-2. However, the Trackit T4 amplifier records signals of very low amplitude, and such interference may cause signal artefacts.

The Trackit T4 has an approved industry-standard Bluetooth radio. This presents minimal risk of reciprocal interference with other equipment. 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 Trackit 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 Trackit T4 Amplifier require no routine testing, calibration or maintenance procedures apart from occasional cleaning and checking for wear and damage to all parts, including any accessories.

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

Cleaning and disinfection

Prior to each re-use of the system, all the outer surfaces of the Trackit 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 using QAC-based disinfectants. Wipes are recommended to prevent the ingress of any liquid into the equipment.

	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, follow all local laws and regulations for the proper recycling or disposal of electronic equipment.

Dispose off 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

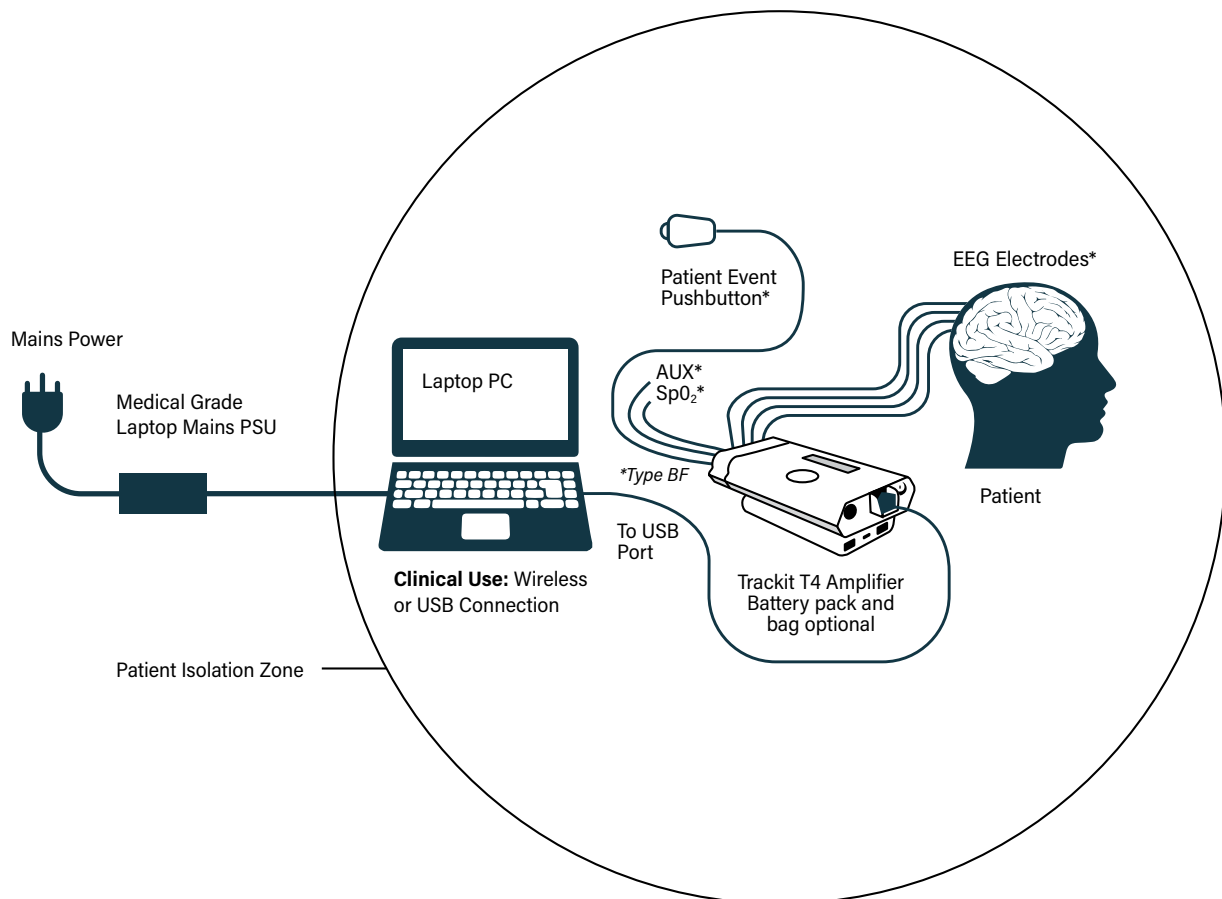


Figure 1: Connecting the T4 Amplifier – Clinical Use

Clinical Use

During Clinical use, the Trackit T4 can be connected to a PC either using the USB cable or through a wireless Bluetooth connection (see Figure 1). Housing the amplifier in the T4 bag is optional and may be used to protect and secure the amplifier.

NOTE: For mobile use within the clinic, the Trackit T4 amplifier must be housed inside its bag after being disconnected from the PC, for protection against spillage of liquids and physical damage.

Where the entire Trackit T4 system including the PC is used within the patient environment, the mains leakage currents and safety and regulatory requirements are met using the medical-grade laptop power supply.

Home Use

During home use, the Trackit 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 acquisition PC (Trackit Solo or laptop) is optional and may be used for video recordings. There is no cable connection between the PC and the T4 Amplifier (see Figure 2).

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

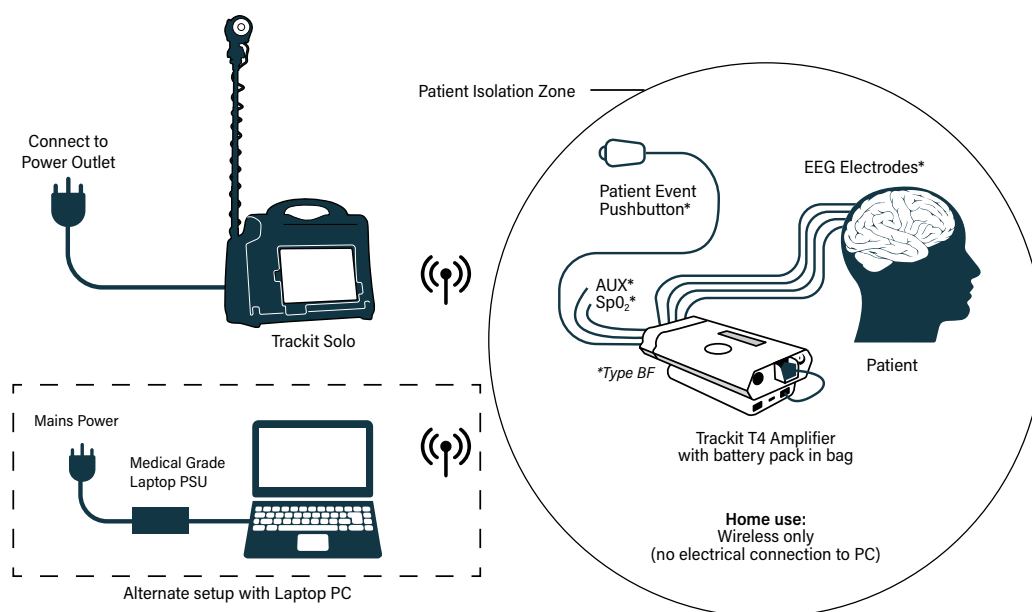


Figure 2: Connecting the T4 Amplifier - Home Use

3.2 Recording Procedure

- Set up the Trackit Solo or laptop, as per Section 3.3 & 3.4
- Connect the Power bank to the Trackit T4, if required.
- Fit the micro-SD card into the Trackit T4, if required.
- Connect the Trackit T4 to the Trackit Solo or acquisition PC via USB or Bluetooth (Section 3.9).
- Launch the EEG acquisition software. Refer to the appropriate software manual for further information.
- Fit the required PCU and connect the electrodes to the patient.
- Perform an Impedance check, if necessary (Section 3.10)
- Start the recording via the acquisition software (refer to the appropriate software manual).

Once the recording is completed, stop the recording using the acquisition software. If recording to the micro-SD memory card, then remove the card to review the recording on a PC.

3.3 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.

3.4 Trackit Solo

Setting up the Trackit Solo

1. Position the Trackit Solo on a solid, sturdy surface, off the ground (e.g. a coffee table).
2. Unwrap the power cord fully and plug it into a power source.
3. Position the camera and Trackit Solo so that the patient is in view of the camera.

NOTE: The Trackit Solo's power cord serves as a power disconnect device. When connected to a mains power outlet, the Trackit Solo should be positioned so that the power plug is easily accessible. The Trackit Solo can be isolated from the mains supply by unplugging the power cord.

Switching the Trackit Solo On and Off

To power on the Trackit Solo, push and release the Power Button. The display will come on in a few seconds.

To put the Trackit Solo in Standby mode, push and quickly release the Power Button. To exit Standby push and quickly release the Power Button again.



To turn the Trackit Solo off Press the Windows Button or the Windows start menu (on the touch screen) and press “Shutdown”.

Refer to the Trackit Solo User Manual.

3.5 Connecting the Trackit T4 Amplifier



Carefully route cabling to avoid the risk of patient entanglement or strangulation

The top face of the Trackit T4 houses the display, the patient event pushbutton and ambient light sensor. Pressing the pushbutton records a patient event and illuminates the backlight of the display.

USB Cable Connection

Connect the USB cable (PN 1277) into the RJ45 socket on the rear panel of the Trackit T4 Amplifier (item 5, [Figure 5](#)) and into a USB port on the acquisition PC.



Do not plug the USB cable into any other equipment other than the acquisition PC (Trackit Solo or laptop) provided with the system.



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

EEG Electrode connections



To ensure patient safety, the EEG electrodes used must be approved to the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745 in Europe or FDA cleared for use in USA.



Carefully route patient cabling to avoid the risk 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 Patient Connection Units (PCU) are 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**), as shown below. These accommodate standard EEG electrodes with touchproof DIN 42802 connectors.



Figure 3: T4 amplifiers and PCUs

T4-PCU 32+3 Connections

The T4-PCU 32+3 has a 25-way D-type Electrocap socket providing 21 EEG channels, which maps the 10-20 EEG locations (Fp1 – Pz) 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. Three bipolar channels are also provided on the PCU.

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 end panel of the Trackit T4 has the following connections:

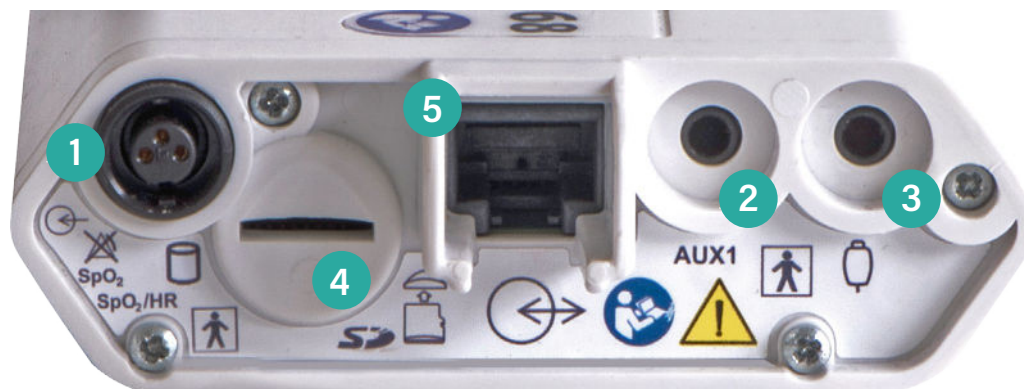


Figure 5 Connecting the T4 Amplifier (back face)

1. Nonin Xpod connector for connection of a Nonin Xpod pulse oximeter for measuring SpO₂. The appropriate Nonin sensor is plugged into the Xpod module. Note: Lifelines does not supply Nonin 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 with the Xpod.

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 connection for option Patient Event button.



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 USB Data connection (RJ45 socket).

3.6 Switching the Amplifier on and off

Switching on

To switch on, press the Patient event button. The display's backlight will turn on and an audible beep will sound. The status screen will be displayed when the Trackit T4 is ready to use.

NOTE: The amplifier will switch on when connected to a PC with the USB cable.

Switching off

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

Indicators

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



Figure 6: Trackit T4 Amplifier display indicators

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.
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.

3.7 Battery replacement & charging

For ambulatory, body-worn applications the Trackit T4 is powered from a USB Power Bank. The Trackit T4 plugs directly into the USB port on the Power Bank. After connection, press the pushbutton on the side of the battery to turn it on.



Figure 7: Battery removal



Figure 8: Battery replacement

- | | |
|--|--|
| <ul style="list-style-type: none">a. Open zip at bottom of bag to access batteryb. Unplug cable from batteryc. Withdraw discharged battery from bagd. Do not connect cable to any other equipment | <ul style="list-style-type: none">a. Insert charged battery into bagb. Plug cable into batteryc. Turn battery on using button on sided. Close zip |
|--|--|



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

- Do not short circuit the power bank. To avoid short circuit, keep the device away from any metal objects (e.g. keys).
- The power bank may get hot during use; this is normal.
- This power bank is not user repairable.
- Do not heat the power bank or throw it into a fire.
- Do not drop or place the power bank 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 power bank for approximately 9 hours before use.
- Keep the USB output port and micro-USB input port clean and free of obstruction.

Battery Charging

Connect the micro-USB charging cable supplied to the USB Power bank 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 when the equipment is in use or whilst it is connected to the Trackit T4 amplifier.

3.8 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
- 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 read the card and not 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:

1. Insert the card into the SD card slot (Figure 5, #4) with the gold contacts facing down until it stops against a spring.
2. Use the T4/T4A tool to push the card further until it clicks.
3. The card will be recessed when fully inserted.

To remove:

1. Push the card gently with the T4/T4A tool.
2. Release pressure and the card will eject.

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 Trackit T4 will read the card and display the card capacity, accompanied by a 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 Trackit T4 will record the EEG data and events in two files on the micro-SD card with the same name: a *.BDF file for EEG data and a *.TEV file for events. The file name can be set in the software to use the Patient ID or a user-defined file name. The file name will be 8 characters or less (8.3 format).

The Trackit T4 uses a FAT32 file system and splits data into multiple files if the recording exceeds 4GB, named sequentially like "FILENAME.BDF", "FILENA_1.BDF", etc. Each BDF file has a matching TEV file. When reviewing data, ensure all BDF and TEV files are loaded as per the review software instructions.

Event marking

Once a recording has started, the button on the front panel of Trackit T4 acts as an event marker. Patients can press this button to log an event, which will be saved in an event file on the SD Card. On review, the events are inserted into the displayed EEG data.

The Trackit T4 records the following events to the Trackit Event file. The recorded events can be viewed in the Trackit software, the Trackit Event viewer or supported review software.

Event Name	Description
Stop recording	Recording stopped
Start recording	Recording started
Host On	Connection to host PC established
Host Off	Connection to host PC lost
Imp. Check Mode	Impedance Check mode started
Calibrate Mode	Calibration Check mode started
Normal Mode	Normal EEG mode started / resumed
Patient Event	Patient event button pressed
External Event	Remote patient event button pressed

3.9 Bluetooth

The Trackit T4 has built-in Bluetooth, allowing it to connect wirelessly to a Bluetooth-enabled PC. When used wirelessly, the amplifier must be powered by a USB power bank or a USB connection to the PC. To connect the Trackit T4 via Bluetooth, pair it with the PC first.

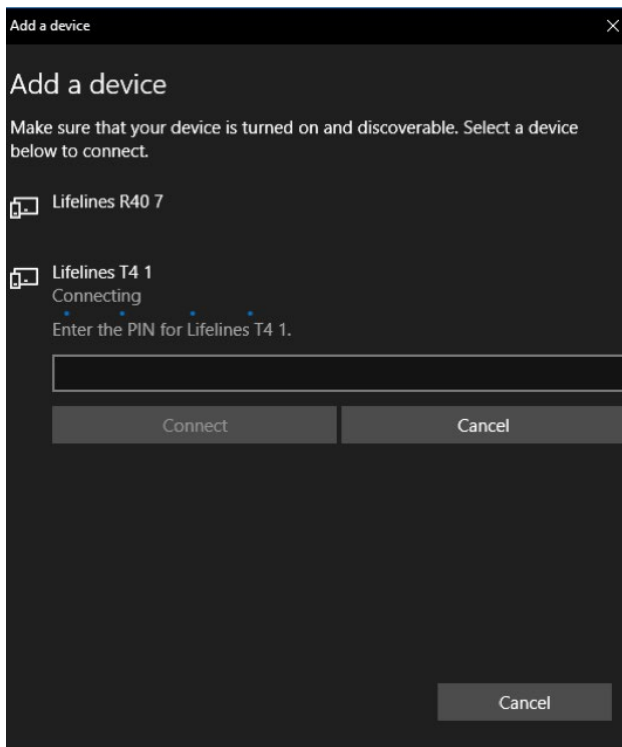


Figure 9: Bluetooth pairing

Bluetooth Pairing

The Bluetooth connection on the Trackit T4 requires authentication and is password protection. 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.

To pair to a T4 Amplifier

1. Switch on the T4 amplifier.
2. In the Windows® Bluetooth options, search for new devices. The T4 will be shown as Lifelines T4 - xx, where xx is the serial number of the amplifier.
3. Select the desired T4 amplifier and click the "Pair" button.
4. Enter the password Enter the password (default password is '1') and press 'Connect'.
5. Windows will show a notification to confirm successful pairing.

3.10 Connection Checks

Calibration Check

The Calibration Check performs a channel test on all inputs to verify the integrity of the signal processing from the Trackit T4 input to the display on the PC. This allows the user to examine the waveforms on the screen to see if all the channels are functioning correctly. The calibration check waveform for the T4 is configurable. The default waveform is an 8mVp-p square wave @ 1 Hz.

NOTE: The Calibration Check does not validate the connection from the PCU to the T4 amplifier or from the patient electrode to the PCU.

Impedance Check

An Impedance Check can be performed to ensure the electrode contact with the patient is satisfactory. The Impedance check can be performed any time during a study, regardless of whether the T4 Amplifier is recording or not.

The T4 Amplifier can perform an impedance check on all the referential EEG channels and the REF input.

NOTE: Impedance check cannot be performed on channels configured as Poly channels.

Appendix 1: Trackit T4 Specifications

Product specifications may change without notice.

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 test signal	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 test signal	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 Bluetooth Qualification	IEC 60601-1-2 V4.0

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 80601-2-26 IEC 60601-1-11	International standard for medical electrical equipment, general requirements and particular requirements for EEG systems. Collateral standard for medical electrical equipment used in the home healthcare environment.
ANSI/AAMI ES 60601-1 CAN/CSA 22.2 No 601.1 M90	AAMI Deviations from IEC 60601-1 (USA). 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

*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: 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 Trackit T4, 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 & Manufacturer's Declaration

The Trackit T4 is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Electromagnetic Emissions

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

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

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%.
Electrical fast Transients/ burst IEC 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment. If the user of the 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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 150 kHz and 80 MHz. 80% AM at 1 kHz	6 Vrms 80% AM at 1 kHz	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
Radiated RF Electromagnetic Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 10 V/m (Home Environment)	10 V/m	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 .
Proximity Fields from RF Wireless Equipment IEC 61000-4-3	Refer to Table 9 of IEC 60601-1-2:2014	As per Table 9 of IEC 60601-1-2:2014	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.			

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 Trackit T4 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Trackit T4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Trackit 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		
	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 $d = 2.33 \sqrt{P}$
W			
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.

trackit T4

Lifelines Ltd,

1 Tannery House, Send, Woking GU23 7EF

United Kingdom

Telephone +44 (0)1483 224 245

www.lifelinesneuro.com

sales@lifelinesneuro.com



Imagine EEG Anywhere