



lifelines[®]
neuro



trackit T4A

MADE IN
BRITAIN



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:	51305-006
Part No:	1606
Issue:	2.2
CCN:	CCN162
Created	
Checked	
Approved	

Customer Responsibility

The Trackit T4A 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

The information in this section is subject to change without notice.

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

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

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

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

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

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

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

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

All warranties for third-party products used within the Trackit T4A 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, 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 Trackit T4A system is supplied by third-party providers recommended by the manufacturer;
- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by the manufacturer;
- the electrical installation of the relevant room complies with the appropriate requirements;
- the equipment is used by a health-care professional and in accordance with the instructions for use.

NOTE: the manufacturer has a policy of continual product improvement; hence the equipment specifications are subject to change without notice.

Check with Lifelines or your distributor if a software update is available.

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

Software and Virus Protection

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

- 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.

Contents

Disclaimers & Warranties	2
1 Overview and Technical Description.....	6
1.1 General description.....	6
1.2 Warnings and Cautions.....	7
1.3 Explanation of symbols	9
1.4 The Amplifier and its parts	10
1.5 Specifications and safety.....	11
1.6 Description of the components	12
1.7 Replaceable parts.....	14
2 Installation and Maintenance	15
2.1 Checks for completeness and integrity	15
2.2 Environmental parameters for operation	15
2.3 Power supply connections	16
2.4 Battery Operation	17
2.5 Use in the home environment.....	18
2.6 Use with other equipment	18
2.7 Interference	19
2.8 Maintenance and cleaning.....	19
2.9 Disposal of equipment.....	19
3 Connections and usage	20
3.1 Overview	20
3.2 Laptop installation and operation.....	21
3.3 Fitting the battery packs	22
3.4 Connecting the Trackit T4A Amplifier	23
3.5 Switching the Amplifier on and off	25
3.6 Bluetooth	27
3.7 SD Card	29
3.8 The T4A Bag.....	31
3.9 Remote Patient Event Thumb Switch (optional).....	32
3.10 Battery Pack Charging.....	33
4 Trackit Software - overview	36

5	The ambulatory recording.....	37
5.1	Preparing the Ambulatory Recording.....	37
5.2	Patient Instruction Sheet.....	37
5.3	Event marking.....	37
5.4	Ending a recording.....	37
5.5	Identifying a recording.....	37
	Version History.....	52

Appendices

Appendix 1: Trackit T4A Amplifier Specifications.....	38
Appendix 2: Additional Events Information.....	41
Appendix 3: Additional Bluetooth Information.....	42
Appendix 4: SD Card Information.....	44
Appendix 5: Default Setup on Amplifier.....	46
Appendix 6: Troubleshooting Guide.....	47
Appendix 7: Manufacturer’s Declaration.....	48

Illustrations

Figure 1: Connecting the Trackit T4A Amplifier – Clinical Use.....	20
Figure 2: Connecting the Trackit T4A Amplifier - Home Use.....	21
Figure 3: Battery replacement.....	22
Figure 4: Battery capacity display.....	22
Figure 5: Connecting the Trackit T4A Amplifier (PCU/front face).....	23
Figure 6: Connections and indicators on the T4A Amplifier, connector end.....	24
Figure 7: Releasing the data cable.....	25
Figure 8: Trackit T4A display.....	26
Figure 9: Bluetooth pairing.....	28
Figure 10: SD Card location.....	30
Figure 11: Patient Event Thumb Switch.....	32

1 Overview and Technical Description

1.1 General description

Indications for use

The Trackit T4A 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 T4A EEG Amplifier is intended to be used as a front-end amplifier to acquire, store and transmit electrophysiological signals (wireless or cabled).

General description

The Trackit T4A EEG amplifier is a 32-channel electroencephalograph recorder and is intended for use in ambulatory EEG and lab monitoring applications. The Trackit T4A Amplifier is intended to be used in a Professional healthcare Environment and a Home (healthcare) environment.

The Trackit T4A amplifier is powered by one or two lithium-polymer battery packs and is fitted with an internal lithium-ion backup battery. The amplifier features a local event pushbutton and has connection for an optional remote (cabled) event pushbutton. The input channels of the T4A amplifier have built-in calibration and electrode impedance measurement. Communication to a PC is through a wireless (Bluetooth) interface and a cabled (USB) interface. Recorded data is stored on a removable SD memory card. A pouch is provided to carry and protect the amplifier in ambulatory use.

The Trackit T4A amplifier is intended to be configured and set up by a trained healthcare professional. In an ambulatory situation, the EEG electrodes are fitted to the patient by the healthcare professional prior to the patient being sent home. The patient is intended to have minimal interaction with the Trackit T4A amplifier, with the only interacting being pressing the event pushbutton(s).

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

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

Two fully charged battery packs provide sufficient power to power the Amplifier for a minimum of 72 hours. The battery packs are intended to be replaced when the amplifier is not recording and not fitted to the patient. The T4A amplifier does not recharge the battery packs. The battery packs must be removed from the amplifier and recharged using a desktop charger.

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

Intended User

The intended user of the equipment is a healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice.









1.2 Warnings and Cautions








	<p>Warning sign indicates a situation or procedures that may be dangerous for the patient and/or user.</p>		<p>Caution sign indicates a situation or procedures that may cause equipment damage or its improper usage.</p>
	<p>Do not use the Trackit T4A EEG Amplifier in an MRI environment, in an oxygen rich environment or during defibrillation</p>		
	<p>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.</p>		
	<p>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.</p>		
	<p>Only use the PC and the medical-grade power supply as supplied or authorised by Lifelines.</p>		
	<p>To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.</p>		
	<p>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.</p>		
	<p>The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth conductors.</p>		
	<p>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.</p>		
	<p>Do not touch simultaneously any accessible USB or other contacts on the PC and the patient.</p>		
	<p>Strangulation hazard due to long cables. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.</p>		
	<p>Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.</p>		
	<p>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.</p>		

	Do not open or modify the equipment without the authorization of the manufacturer.
	Replace the Lithium polymer battery packs with Lifelines supplied battery packs only. Use of another battery may present a risk of fire or explosion.
	Do not touch the battery contacts (in the Trackit T4A battery housing) and the patient simultaneously.
	The lithium-polymer battery packs used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate.
	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.
	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 T4A, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the T4A Amplifier, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
	If the Trackit T4A amplifier is not to be used for some time, the battery packs should be removed.
	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
	Manufacturer
	Internal battery hazard - refer to section 1.7
	Battery pack identifier

Symbol	Meaning
	Follow operating instructions
	Input connection
	Bluetooth
	Memory card read/write
	On/Off and patient event switch
	Battery door access - refer to section 3.3
	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 Trackit T4A EEG Amplifier is a 32-channel electroencephalograph recorder intended to acquire EEG signals in an ambulatory environment. It is powered by either one or two lithium-polymer battery packs and is fitted with an internal, non-replaceable, lithium-ion backup battery. The amplifier features a local event pushbutton and has connection for an optional remote (cabled) event pushbutton.

In ambulatory applications the amplifier communicates with a host computer, wirelessly, through Bluetooth. Alternatively it can be connected to a USB port on a PC which is powered from a medically approved power supply. Refer to section 3.1 for details.



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

The Trackit T4A EEG Amplifier comprises the following components:

Component	Part Number
Trackit T4A Amplifier	1600
Trackit T4A Amplifier USB cable	1601
Trackit T4A bag and straps	1602
Trackit T4A Lithium-polymer battery pack (x2)	1603
Single bay battery charger with power supply	1604
Trackit software CD, standard	1009
Trackit T4A User Manual (<i>this document</i>)	1606
Trackit T4A Quick Start Guide	1607
Trackit T4A Patient Instruction Sheet	1608
Trackit T4/T4A Tool	1408
SD card, 16GB, Industrial Grade	1610

The T4A EEG Amplifier can be used with the following accessories:

Accessory	Part Number
Patient event switch	1353
Lenovo ThinkPad laptop computer	1389
Medical grade power supply	1390
4-Bay Battery Charger and Power supply	1605
Mains cable, UK	1066
Trackit T4A Amplifier USB cable (170mm)	1611

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

1.5 Specifications and safety

Refer to **Appendix 1** for specifications.

The Trackit T4A amplifier has been certified and complies with the following standards:

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 T4A 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 Trackit T4A Amplifier

The Trackit T4A amplifier provides 32 channels (28 referential, 4 bipolar) with built-in calibration and electrode impedance measurement. The amplifier has built in type-BF patient isolation and has a USB interface to the PC. Bluetooth wireless communication is included for ambulatory applications. EEG data is recorded to a removable SD card. The amplifier has a built-in position sensor (accelerometer) and light sensor.

Applied parts, type BF

EEG Electrodes

The amplifier connects to standard 1.5mm touchproof EEG recording electrodes arranged in a standard 10-20 pattern, attached to the patient's head.

	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.

Patient Event pushbutton

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

Lithium Polymer Battery Packs

The Trackit T4A amplifier has provision to fit two Lithium-Polymer battery packs, which provide the main power source for the amplifier. The battery packs are housed in the battery compartment of the Trackit T4A amplifier and connected in parallel, so the Trackit T4A can operate with only one battery pack fitted. The Trackit T4A does not have the capability to recharge the battery packs and the battery packs must be removed from the Trackit T4A to be recharged in a desktop charger. Details for charging the batteries are provided in Section 3.10.



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

SD Memory Card

The SD card is used to store the EEG data recorded by the Trackit T4A. Storage cards of varying capacity are available in the SD format. The Trackit T4A supports SD cards with a capacity up to 64GB with a FAT32 file system. For best performance and to ensure continued reliable recordings Industrial grade SD cards are recommended for use with the Trackit T4A. The Trackit T4A is supplied with a 16GB Industrial Grade MicroSD card (with adapter).

Bags and straps for ambulatory applications

The T4A bag houses the Amplifier when used in ambulatory application. The bag protects the amplifier from water and dust (IP22 protection).

USB Cable for connection to PC

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



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

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

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



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

The Setup and Recording Software

The Trackit setup software runs under Microsoft Windows XP, Windows Vista, Windows 7, 8 or 10 on the host PC and is used to setup and review the T4A Amplifier and to record on to the PC.

The Trackit T4A amplifier is connected to the PC via the USB cable or wirelessly with Bluetooth. The recording setup is downloaded to the device and checks can be made to verify that all the electrodes have been attached correctly. The Amplifier is then disconnected from the PC and the recording is started.

Functions of the software: *Refer to the Trackit Plus software manual*

- 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 Amplifier.
- Perform an EEG recording.
- View on-going EEG traces.

1.7 Replaceable parts

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

Internal battery replacement – service personnel only

The Trackit T4A amplifier contains a lithium ion rechargeable coin cell, type LIR2450.



Battery replacement by inadequately trained personnel could result in a hazard. It must be replaced only with the correct type. Refer to the Trackit T4A Service Instructions.

2 Installation and Maintenance

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 T4A Amplifier



Power requirements	3.7V Lithium-Polymer battery pack or 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.

Single Bay battery charger (P/N 1604)




AC/DC power adapter		Battery charging cradle	
Mains Power input:	100-240VAC, 50/60Hz, 0.35A max.	Power input:	5VDC, 1A nom.
Output:	5VDC, 1A Max. Micro-USB connector	Output:	4.2VDC, 1A max.

Four Bay battery charger (P/N 1605)

AC/DC power adapter		Battery charging cradle	
Mains Power input:	100-240VAC, 50/60Hz, 1.5A max.	Power input:	12VDC, 3.3A nom.
Output:	12VDC, 4.2A Max.	Output:	1A max (x 4).

2.4 Battery Operation

Li-Polymer battery pack

	<p>Replace the Lithium polymer battery packs with Lifelines supplied battery packs only. Use of another battery may present a risk of fire or explosion.</p>
	<p>The lithium-polymer battery packs used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate.</p>
	<p>If the Trackit T4A amplifier is not to be used for some time, the battery packs should be removed.</p>

The Trackit T4A amplifier is powered from one or two battery packs. When fully charged, two battery packs will typically power the unit for 72 hours depending on the number of channels, sample rate and wireless usage (36 hours if only one battery pack is used).

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

A desktop charger is required to recharge the battery packs. The Trackit T4A amplifier does not recharge the battery packs.

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

Li-Polymer battery pack Instructions for Use

- The battery packs are charged using the specified desktop charger. Refer to the instructions supplied with the charger.
- Operating time will be shorter than usual at low temperatures. The battery can be used between 0°C (32°F) and 45°C (113°F), but will give best performance between 10°C (50°F) and 30°C (86°F).
- If the battery packs start to give less operating times than usual, they have reached the end of their life and must be replaced. Dispose of used battery packs promptly and keep away from children.
- Since the battery packs will naturally discharge itself over a period of time, it is best to charge the battery packs a day or two before planning to use it.

Internal Li-Ion backup battery

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

The typical service life is 500 charge-discharge cycles. The backup battery is replaceable by service personnel only.

2.5 Use in the home environment

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

The laptop PC is optional in the home environment and may be used for video recordings. There is no cable connection between the PC and the T4A Amplifier unit, as all communication is accomplished wirelessly.

Keep the equipment away from sources of heat.

Do not use mobile phones.

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

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

The Trackit T4A has an internal Bluetooth radio fitted. This is an approved industry-standard type which present minimal risk of reciprocal interference with other equipment.

2.6 Use with other equipment

Defibrillators and HF surgical equipment

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

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

Other patient-connected equipment

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

Leakage current

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




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

2.7 Interference

The Trackit T4A will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of IEC60601-1-2. However, the Trackit T4A amplifier records signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. Such interference may cause signal artefacts.

The Trackit T4A has an internal Bluetooth radio fitted. This is an approved industry-standard type which present minimal risk of reciprocal interference with other equipment.

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

	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 T4A, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the T4A 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 T4A Amplifier and its accessories require no routine testing, calibration or maintenance procedures apart from occasional cleaning and checking for wear and damage to all parts including the accessories.


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

Cleaning and disinfection

Prior to each re-use of the system, all the outer surfaces of the T4A Amplifier and its bag may be cleaned, as required, with a cloth moistened with a mild detergent solution.

Disinfection of the equipment can be carried out by the use of QAC-based disinfectants. Wipes are recommended in order to prevent the ingress of any liquid into the equipment. Suitable products include Mikrozyd Sensitive Wipes (Schülke & Mayr GmbH), Microbac forte (Paul Hartmann AG), Distel Wipes (Tristel Ltd.), Mikro-Kill disinfectant wipes (Medline Industries, Inc.), Sani-Cloth HB Germicidal Wipes (PD International, Inc).


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

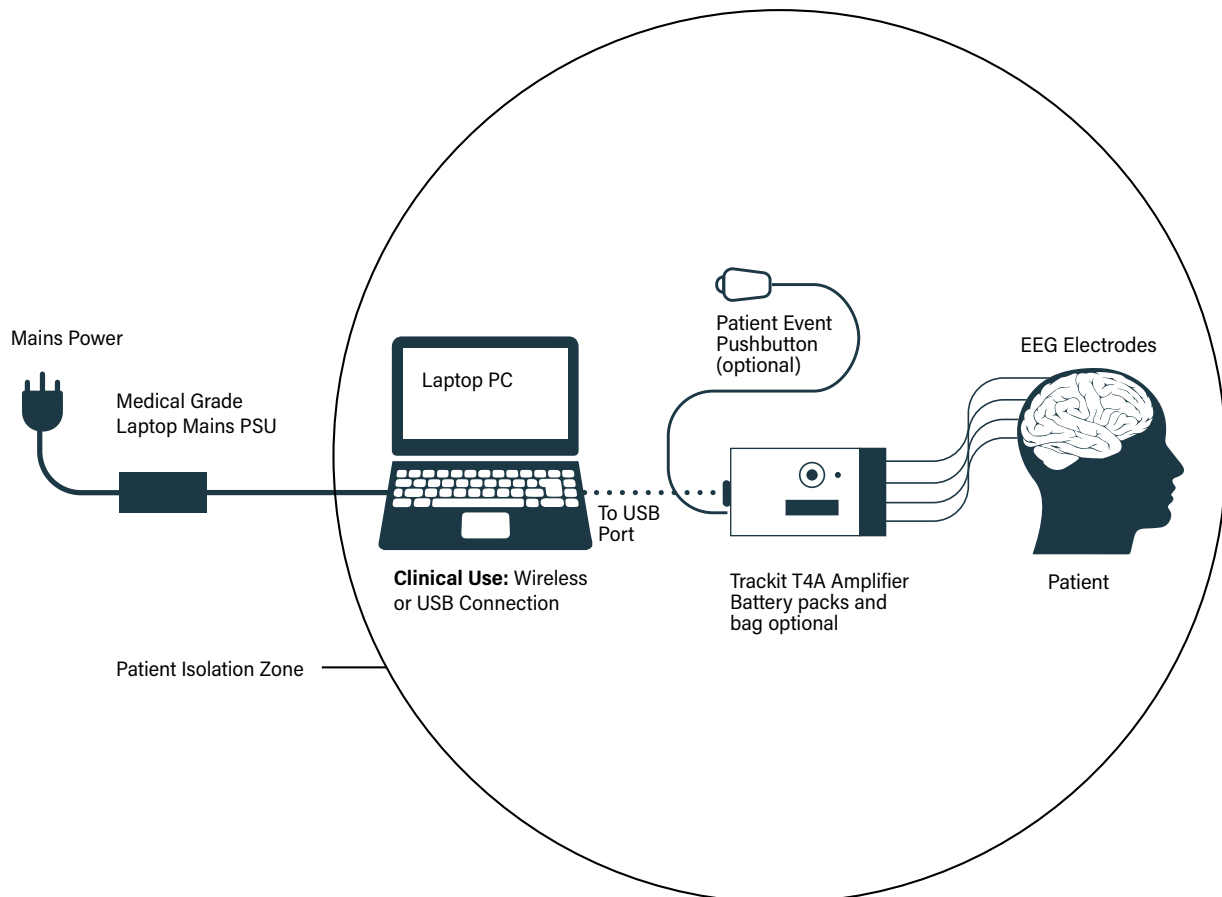


Figure 1: Connecting the Trackit T4A Amplifier – Clinical Use

Clinical Use

During Clinical use, the Trackit T4A Amplifier can be connected to a PC either using the USB cable or through a wireless Bluetooth connection (see Figure 1). Housing the amplifier in the T4A bag is optional and may be used to protect and secure the amplifier.

NOTE: In transportable, i.e. body-worn situations within the clinic, the T4A amplifier must be housed inside its bag after being disconnected from the PC, for protection against spillage of liquids, high levels of static electricity discharge and physical damage.

Where the entire Trackit T4A system including the PC is used within the patient environment, the mains leakage currents and safety and regulatory requirements are met by the use of the special medical-grade laptop power supply.

Home Use

During home use, the Trackit T4A Amplifier is battery powered and is housed inside its bag where it is protected against ingress of solid objects and water to a degree of IP22. The laptop PC is optional and may be used for video recordings. There is no cable connection between the PC and the T4A Amplifier, as all communication is accomplished wirelessly (See Figure 2).

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

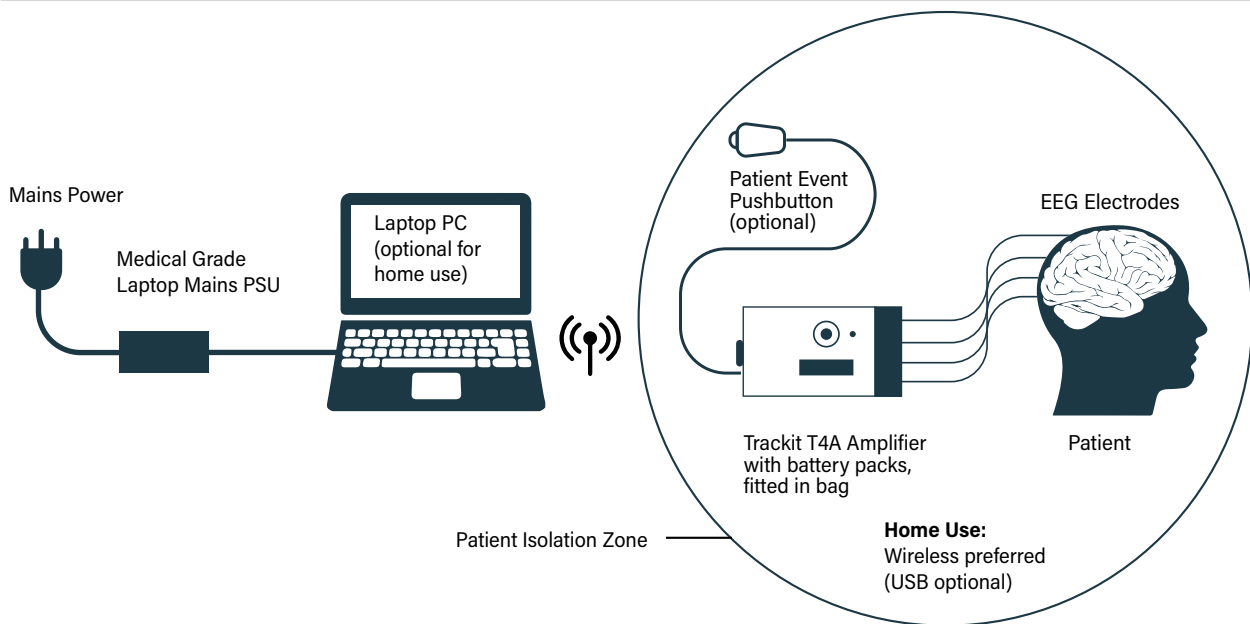


Figure 2: Connecting the Trackit T4A Amplifier - Home Use

3.2 Laptop installation and operation



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 Fitting the battery packs

	Only fit battery packs supplied or authorised by Lifelines, with the correct part number (PN 1603). Use of other battery packs may present a risk of fire or explosion.
	Do not touch the battery contacts (in the Trackit T4A battery compartment) and the patient simultaneously.
	If the Trackit T4A amplifier is not to be used for some time, the battery packs should be removed.

For ambulatory, body-worn applications the Trackit T4A is powered from the battery pack(s). The fully charged battery pack(s) should be fitted into the T4A Amplifier before setting up an ambulatory recording. If the amplifier is to be used in a Clinical environment with the USB cable, the use of the battery packs is optional as the amplifier will be powered from the USB port.

1. Flip the T4A over, so the base is facing up.
2. Using the T4/T4A Tool, open the battery door by pressing the door-release button. The battery door will spring open. See Figure 3.
3. If there are batteries in the unit, remove these first.
4. Insert the battery pack(s) (battery contacts facing down) into the amplifier. If only fitting one battery pack, fit the battery in battery location 1.
5. Gently push the battery door closed. The door will click shut and lock automatically.

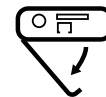


Figure 3: Battery replacement




Figure 4: Battery capacity display

While the battery door is open, and the amplifier is powered on, the display will show the remaining capacity of the fitted battery packs. If a battery pack is not fitted, the display will show two dashes, as shown above. This view will remain on the display for 10 seconds after closing the battery door. Pressing the event button will reset the display back to the status screen.

NOTE: The battery packs are not secured in the T4A while the door is open. Care should be taken while the door is open as the battery packs can fall out if the amplifier is tipped over.

3.4 Connecting the Trackit T4A Amplifier

The top face of the Trackit T4A houses the display, the patient event pushbutton  and the ambient light sensor. For display details refer to **page 26**. Pressing the pushbutton records a patient event and illuminates the back-light of the display.

Adjacent the pushbutton is a circular aperture which houses a sensor to measure the ambient light level.

EEG Electrode Connection




The Patient Connection Unit (PCU) of the amplifier is laid out in a standard 10-20 configuration, as shown in Figure 5. It accommodates standard touch-proof electrode leads fitted with DIN 42802 connectors.

The graphic and colours of the 10/20 layout on the PCU have been updated to clearly identify the location of the EEG inputs. Figure 5 shows both versions of artwork.

Any unused input can be disabled or re-assigned to the user preferences, using the supplied software. Refer to **Appendix 5** for the full channel mapping.



Figure 5: Connecting the Trackit T4A Amplifier (PCU/front face)

	<p>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.</p>
	<p>The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including Earth conductors.</p>
	<p>Cables must be routed carefully to avoid risk to the patient of entanglement and strangulation.</p>

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

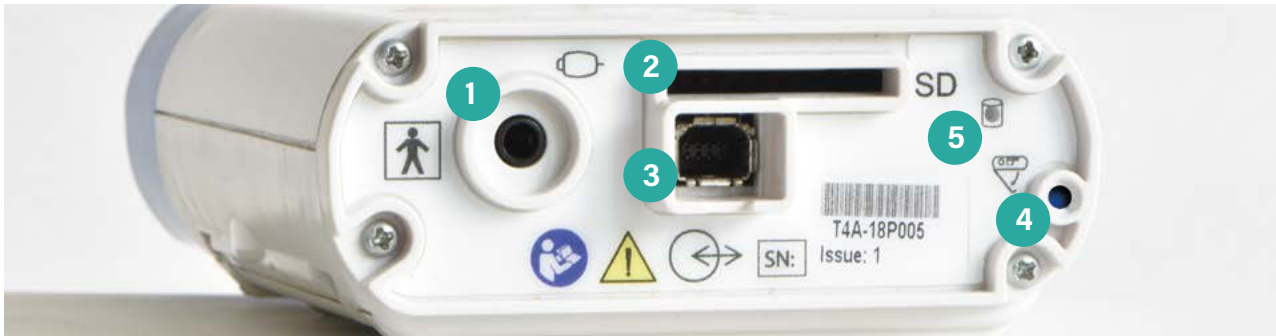


Figure 6: Connections and indicators on the T4A Amplifier, connector end

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



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

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

USB Cable Connection



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



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

If the amplifier is to be connected using a cable, the supplied USB cable (PN 1602) is plugged into the data socket (item 3, Figure 6) on the connector end of the T4A Amplifier and into any USB port on the laptop PC. When used with a cable, the amplifier can operate with or without the battery packs.

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

To release the cable:

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

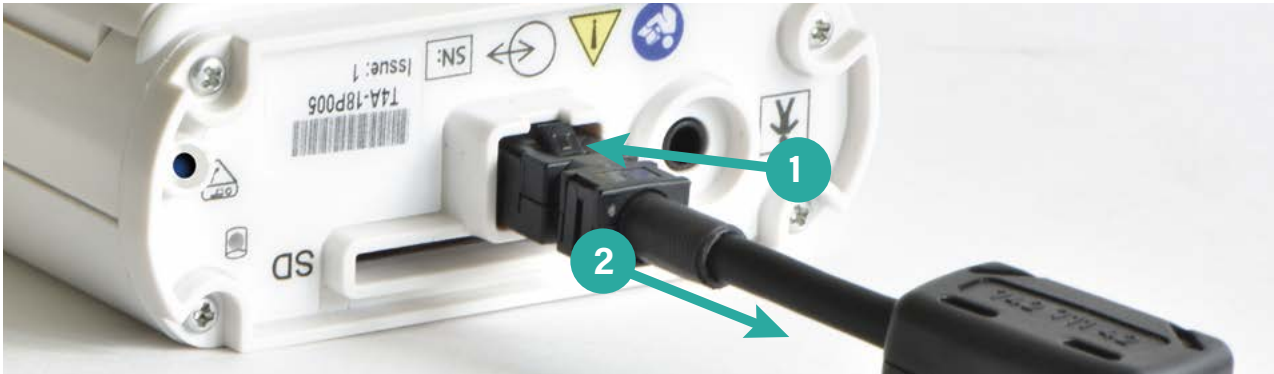


Figure 7: Releasing the data cable

Bluetooth Connection

The Trackit T4A Amplifier has built-in Bluetooth wireless capabilities, which allows the T4A to communicate, wirelessly, with a Bluetooth-enabled PC. This allows the T4A to be monitored remotely over a secure wireless link up to a range of about 100m or greater (dependent on hardware and environmental factors).

Refer to Section 3.6 for details on the Bluetooth connection and usage.

3.5 Switching the Amplifier on and off

Switching on

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

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

Switching off

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











Indicators

Trackit T4A Display



Figure 8: Trackit T4A display

The following indicators are shown on the display of the T4A:

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

Display Backlight

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

- at power-up
- when the local event button is pressed
- during Bluetooth pairing
- when the battery door is closed

SD card Indicator

The T4A amplifier is provided with an amber LED indicator on the connector panel (Figure 6, #5). This indicator will flash whenever there is any reading or writing activity on the SD card.

Buzzer

The T4A amplifier uses an audible buzzer to indicate user action feedback. A short beep will sound for the following events:

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

3.6 Bluetooth

The Trackit T4A Amplifier has built-in Bluetooth wireless capabilities, which allows the T4A to communicate, wirelessly, with a Bluetooth-enabled PC. When the T4A amplifier is used wirelessly, the amplifier must be powered by at least one battery pack.

To connect the T4A Amplifier to a PC via Bluetooth, the amplifier must first be paired with the PC.

Additional Bluetooth Information can be found in **Appendix 3**.

Bluetooth Pairing

The Bluetooth connection on the T4A uses Simple Secure Pairing (SSP) authentication. When the T4A is paired with a computer, a random code is generated and shared between the T4A and the PC. The code must be confirmed on both the PC and the amplifier in order to connect the two devices. This prevents other devices from interrupting the pairing process.

To pair to a T4A Amplifier:

1. Switch on the T4A amplifier.
2. In the Windows® Bluetooth options, search for new devices. The T4A will be shown as Lifelines T4A – xx, where xx is the serial number of the amplifier.

3. Select the desired T4A amplifier and click the "Pair" button.
4. A code will be displayed on the PC and on the T4A, as shown below.

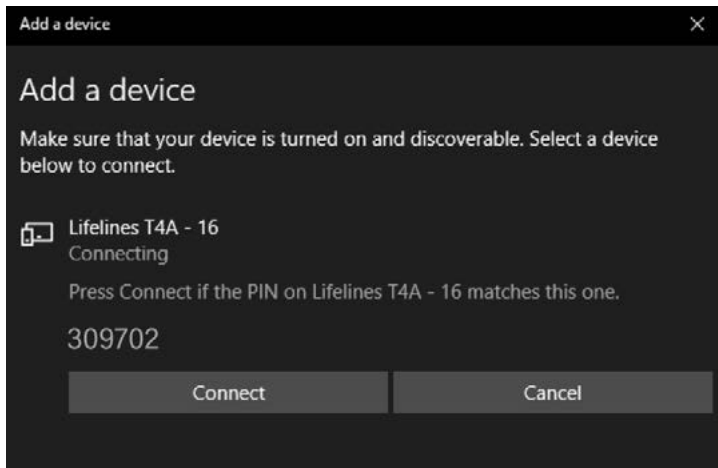


Figure 9: Bluetooth pairing

5. If the codes match, press the Event button on the T4A amplifier followed by the 'Connect' (Windows 10) or 'Next' (Windows 7) button on the PC.

NOTE: There is a 10 second timeout on the T4A amplifier. If the Event button is not pressed within 10 seconds, the pairing will fail and this process will need to be repeated.

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

Bluetooth Usage

Once paired, the Trackit T4A acts as the server and provides a serial port service to the PC, acting as a client. The Serial COM port number can be found in the Windows® Bluetooth settings.

NOTE: Windows® assigns two COM ports to the T4A. The required COM port is the 'Outgoing' port. The allocated COM port can be renamed in the Trackit software application for easy identification. To rename the COM port, open the Trackit Options window and edit the applicable COM port name (refer to the Trackit Plus software manual).

The data rate over Bluetooth is slower compared to the USB cable. When data is transmitted over Bluetooth at high sampling rates (1ksps or 2ksps), there may be some data loss between the PC and the amplifier (refer to table below). In this situation, either reduce the sample rate, reduce the number of displayed channels or revert to the USB cable.

Sample Rate	Number of channels streaming (without data loss)
250 & 500 sps	36
1000 sps	18
2000 sps	8

NOTE: The Bluetooth data rate does not affect the number of channels recorded to the SD card. For example; 32 channels can be recorded to the SD card at 1000 sps without data loss.

3.7 SD Card

SD Card Preparation

The T4A Amplifier supports SD and SDHC cards up to 32GB. Refer to **Appendix 4** to determine the capacity required for the recording. The SD card needs to meet the following requirements:

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

If these requirements are not met, the T4A Amplifier may not be able to read the card and will not be able to start the recording.

High Endurance (MLC) type SD cards are recommended for the T4A Amplifier.

NOTE: The T4A amplifier will delete all the files on the SD card before starting a recording.



Figure 10: SD Card location

Insertion and Removal

The T4A Amplifier uses a “push-push” style of SD card holder (push to insert, push to remove).

Insertion

1. To insert the card, slide the card into SD card slot (Figure 6, #2) with the SD card label facing up. The card will stop against a spring.
2. Using the T4/T4A tool (supplied), gently push the card further into the slot until it clicks into place.
3. When full inserted and locked in place, the SD card will be recessed in the card slot.

Removal

1. To remove the card, gently push the SD card with the T4/T4A tool.
2. Release the pressure on the card and the card will eject out the card slot.

The SD card can be inserted and removed while the T4A Amplifier is switched on.

When the SD card is inserted (and successfully read) or removed, an audible beep will sound. Upon card insertion, the T4A will read the card and the card capacity will be indicated on the display, accompanied by an audible beep. Upon removal, the display will show “ --- M”.

NOTE: If the T4A fails to read the card upon insertion, then remove and reinsert the card.

3.8 The T4A Bag

The T4A bag provides protection to the T4A amplifier when used in the home environment. The bag features a large zipped opening for fitting the amplifier into the bag. This opening has a fold-over hood to protect the zip from water ingress. A smaller zipped opening is provided to access the data and remote event connections. A large clear window provides a view of the LCD display and the event pushbutton.

⚠	The T4A must be housed in the bag when used in the home environment.
⚠	In transportable, i.e. body-worn situations within the clinic, the Amplifier must be housed inside its bag after being disconnected from the PC, for protection against spillage of liquids.

Fitting the amplifier into the bag

When the T4A Amplifier has been set up (battery pack(s) and SD card fitted and electrodes connected):

1. Place the amplifier into the bag.



2. Close the zips around the electrode cables



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



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

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

Fitting the bag to the patient

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



	<p>Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.</p>
	<p>Strangulation hazard due to long cables. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.</p>

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

Removing the amplifier from the bag

To remove the amplifier from the bag:

1. Fold the hood up and open the zip.
2. Open the zip on the connector end.
3. Push the amplifier out the bag from the connector end.

3.9 Remote Patient Event Thumb Switch (optional)

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

 symbol.

During recording, when the thumb switch is pressed a marker will be placed in the EEG recording.



The Remote patient event switch must be configured when setting up the recording (*Refer to the Trackit Plus software manual*).



Figure 11: Patient Event Thumb Switch

3.10 Battery Pack Charging

The battery pack(s) can be recharged using the supplied single-bay desktop charger (part number 1604) or the optional 4-bay charger (part number 1605).


	The lithium-polymer battery packs used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 100°C (212°F) or incinerate.
	Do not short circuit the contacts on the battery pack. To avoid short circuit, keep the device away from any metal objects (e.g., hair clips and keys).

NOTE: The battery pack may get hot during charging, which is normal. Handle with care.

Single bay battery charger (p/n 1604)

The single bay battery charger will only charge one battery at a time. Refer to the instruction sheet included with the charger.

- Remove the battery pack(s) from the T4A Amplifier and place in battery charger cradle.
- Connect the micro-USB plug of the power adapter into the charger cradle.
- Plug the charger's power adapter into a mains power outlet.

	The charger's power adapter serves as the mains-supply disconnect device. When connected to a mains power outlet, it should be positioned so that it's easily accessible. The power adapter can be isolated from the mains supply by unplugging it.
---	---

- When the battery pack is fully charged, remove from the charger and fit the second battery pack (if required).
- When charging is complete, unplug the mains power adapter.

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

Charging Phase	Description	LED indicator		
		Green	Orange	Red
No Charge	No battery connected, power on			ON
Pre-Charge	0V < battery voltage < 3.06V ($\pm 1\%$) pre-charge / pre-qualification / wake-up charge: I = 15mA for a max. period of 40 minutes.			FLASHES
Fast charge & Top-off charge	3.06V($\pm 1\%$) < battery voltage < 4.20V ($\pm 1\%$)		ON	
Battery Full / Standby	Battery cell full (4.2V $\pm 1\%$)	ON		
Fault	Charge time exceeding 3 hours or Battery is too hot or too cold or There is a fault with the charger.			ON
Other	Power off or charger broken	OFF	OFF	OFF

Four bay battery charger (p/n 1605)

The 4-bay battery charger is capable of charging up to four battery packs simultaneously. The battery packs are charged independently of each other. Refer to the instruction sheet included with the charger (which can be found on the Lifelines CD).

- Plug the power supply into the socket on the back of the battery charger. Use an appropriate mains lead to connect the power supply to the mains. It is recommended that when the charger is not in use that the power supply is turned off and disconnected from the mains. When the charger is powered the blue indicator on the front of the charger is illuminated.



The charger's mains cable serves as the mains-supply disconnect device. When connected to a mains power outlet, it should be positioned so that it's easily accessible. The power adapter can be isolated from the mains supply by unplugging the mains cable.

- Remove the battery pack(s) from the T4A Amplifier.
- Slide the battery packs into the charger's battery compartments (gold contacts facing the front) and ensure the battery hooks under the retaining clip.
- When the battery packs are fully charged unhook the retaining clip and remove the battery packs.

Each battery compartment has an LED indicator which shows the battery pack's state of charge, as shown in the table below:

LED indicator	Description
Off	No battery in Charge compartment
Slow Flash (once per 1.5 seconds)	The battery is charging
Fast Flash (5 per second)	Battery is too hot or too cold or There is a fault with the battery.
On (Solid)	Battery is fully charged

Charging time

If all four compartments of the charger are used then the charger itself will warm up. This causes it to slow the charge rate down. This means that charging four batteries will take longer than charging one, two or three batteries.

Approximate charge times for fully discharged batteries, assuming an ambient temperature of 20°C (60°F) are shown below:

Number of batteries being charged	Approximate charging time
One	220 minutes
Two	315 minutes
Four	360 minutes

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 T4A. Check with your distributor or Lifelines if a newer version of software is available.

The Trackit software is designed to work with both the Trackit T4A Amplifier and with the optional 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.

5 The ambulatory recording

5.1 Preparing the Ambulatory Recording

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

1. Fit one or two **fully charged** battery packs into the T4A amplifier (see Section 3.3).
 - One battery pack will record for approximately 37 hours @ 250sps
 - Two battery packs will record for approximately 74 hours @ 250sps
2. Fit a prepared SD card into the T4A amplifier. The SD card capacity should be large to record the full recording duration (See **Appendix 4**). Check the display to ensure the card has been loaded correctly (see **page 26**).
3. Connect the EEG electrodes to the patient.
4. Setup and initiate the recording (*refer to the Trackit Plus software manual*).
5. Fit the amplifier in the bag (see Section 3.8 on **page 31**).
6. Fit the bag to the patient (see **page 32**).

5.2 Patient Instruction Sheet

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

The only interaction the patient has with the T4A amplifier is to press the event button if they need to log an event.

5.3 Event marking

Once a recording has commenced, the button on the front panel of Trackit T4A acts as an event marker. Events are stored in an event file (filename.tev), from which on review the events are inserted into the displayed data.

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

The Trackit T4A can record 15 different event types. These can be seen by looking at the Trackit event types in the online event viewer. See Trackit Events (*refer to the Trackit Plus software manual*).

5.4 Ending a recording

To stop a recording:

- 1 Connect the Trackit T4A to the host software.
- 2 Click on the Stop Recording button in the Trackit control panel.

Alternatively, to stop the Trackit T4A recording in the field:

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

NOTE: This feature can be disabled in software.

5.5 Identifying a recording

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

Appendix 1: Trackit T4A Amplifier Specifications

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

EEG inputs

Number of EEG channels	28 referential (monopolar) inputs
ADC Resolution	24 bits
Sampling	250 - 2000 Hz (up to 32 channels (EEG & Bipolar)) 4000 Hz (up to 16 Channels (EEG & Bipolar)) 8000 Hz (up to 8 Channels (EEG & Bipolar))
Input impedance	>20 Mohms
Common mode rejection ratio	>110dB @ 50 and 60 Hz
Equivalent input noise	<3.5 μ Vpp
Gain	8 \pm 0.5%
Max Input Vdiff	750mVpp (including DC)
Quantisation	0.17 μ V/bit @ Gain = 8 and Bits = 22
Bandwidth (-3dB)	DC to 4193Hz
Max common mode input voltage	0.4Vpp
Input bias current	< 5nA
Front-end Calibration	8mVpp \pm 5% at 0.98Hz
Impedance Check current	24nA \pm 20% at 7.8Hz

Polygraphy inputs

Number of polygraphy inputs	4 poly (bipolar) inputs
ADC Resolution	24 bits
Sampling	250 - 8000 Hz (see sampling rate for EEG inputs)
Input impedance	>20 Mohms
Common mode rejection ratio	>110dB @ 50 and 60 Hz
Equivalent input noise	<3.5 μ Vpp
Gain	8 \pm 0.5% (AC), 2 \pm 0.5% (DC)
Max Input Vdiff	750mVpp AC setting (including DC), 3Vpp DC setting
Bandwidth (-3dB)	DC to 4193Hz
Quantisation	0.17 μ V/bit @ Gain = 8 and Bits = 22
Max common mode input voltage	0.4Vpp
Input bias current	< 5nA
Front-end Calibration	8mVpp \pm 5% at 0.98Hz
Impedance Check current	24nA \pm 20% at 7.8Hz

Connections, ports and controls

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

Bluetooth Wireless

Type	Bluetooth 4.2 Smart-ready (LE & BR/EDR)
Output power	12dBm max.
Output frequency	2.402 - 2.480 GHz, ISM band
Data rate	1.0 Mbps max.
Protocols	Standard Bluetooth - SPP, GATT, PAN
Modulation	GFSK, DQPSK. Frequency Hopping Spread-Spectrum (FHSS)
Error correction	Forward Error Correction (FEC), Automatic repeat request (ARQ).
Security	Authorization and authentication of devices, Simple Secure Pairing (SSP), proprietary Interface Protocol
Type Approvals	Europe (RE-D); US (FCC/CFR 47 part 15) FCC ID: QOQBT121; Canada (IC RSS) IC ID 5123A-BGBT121; Japan (MIC - formerly TELEC)
RE-D (2014/53/EU)	Effective use of frequency spectrum: EN 300 328 EMC: EN 301 489-1, EN 301 489-17, EN 61000-6-2
Bluetooth Qualification	Health and safety: EN 60950-1+A11:2009 +A1:2010+A12:2011+A2:2013, IEC 60950-1 V4.2

Physical characteristics

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

Safety and EMC standards

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

IEC 60601-1 and IEC 60601-2-26 IEC 60601-1-11	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.
IEC 60601-1-6 ANSI/AAMI ES 60601-1 CAN/CSA 22.2 No 601.1 M90	Collateral standard for usability. 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

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

Classification of system		
Classification	Clinical use	Home use
Degree of protection against electrical shock	Internally powered; or it can be connected to a PC which is powered by a medical grade Class I power supply.	Trackit T4A 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

Battery pack specifications (per battery pack)

Rated capacity	2300mAh min., 2400mAh typical
Nominal voltage	3.7V
Watt-Hour rating	8.9Wh
Overdischarge detection	2.40V \pm 0.035V
Overcurrent detection	3.2A to 5.2A Limited to 500mA by the T4A's internal overcurrent protection.
Temperature range	Charge: 0°C to +45°C (+32°F - +113°F) Discharge: -10°C to +60°C (+14°F - +140°F) Storage: Less than 1 month at -20°C to +60°C (-4°F - +140°F) Less than 3 months at -20°C to +45°C (-4°F - +113°F) Less than 1 year at -20°C to +30°C (-4°F - +86°F)
Humidity	65 \pm 20%RH
Certification	UN38.3, IEC 62133 ed 2, UL 2054 Listed
Dimensions	1.14cm x 3.66cm x 6.45cm
Weight	48g

Appendix 2: Additional Events Information

For the T4A EEG Amplifier, events types are as shown below.

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

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 Open	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 3: Additional Bluetooth Information

System overview

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

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

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



The displayed number is the number of invalid messages received. If the number of invalid received messages increases significantly, it will cause the Trackit application to close the connection. If the Autoconnect feature has been enabled in Options, the application will automatically attempt to reconnect to the T4A every 10 seconds.

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




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

Pre-compliant Wireless Modules

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

Interference

The T4A Amplifier will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of IEC60601-1-2. However, the amplifier records signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. Such interference may cause signal artefacts.

	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.
	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 4: SD Card Information

BDF File Format

The Trackit T4A Amplifier records EEG data to the SD card in BDF format, which is the 24-bit variation of the native EDF (European Data Format). The Trackit software and other EEG applications can view EEG data in BDF format. The table below shows the comparison between the EDF header and the BDF header. Each data sample in a BDF file is stored in 3 bytes.

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

SD Card Capacity Calculation

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

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

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

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

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

Appendix 5: Default Setup on Amplifier

Channel	Signal Type	Channel Label	Physical Signal Range		
			Min	Max	Units
1	AC Referential	Fp1-Ref	-375,000	375,000	μV
2	AC Referential	Fp2-Ref	-375,000	375,000	μV
3	AC Referential	F3-Ref	-375,000	375,000	μV
4	AC Referential	F4-Ref	-375,000	375,000	μV
5	AC Referential	C3-Ref	-375,000	375,000	μV
6	AC Referential	C4-Ref	-375,000	375,000	μV
7	AC Referential	P3-Ref	-375,000	375,000	μV
8	AC Referential	P4-Ref	-375,000	375,000	μV
9	AC Referential	O1-Ref	-375,000	375,000	μV
10	AC Referential	O2-Ref	-375,000	375,000	μV
11	AC Referential	F7-Ref	-375,000	375,000	μV
12	AC Referential	F8-Ref	-375,000	375,000	μV
13	AC Referential	T3-Ref	-375,000	375,000	μV
14	AC Referential	T4-Ref	-375,000	375,000	μV
15	AC Referential	T5-Ref	-375,000	375,000	μV
16	AC Referential	T6-Ref	-375,000	375,000	μV
17	AC Referential	A1-Ref	-375,000	375,000	μV
18	AC Referential	A2-Ref	-375,000	375,000	μV
19	AC Referential	Fz-Ref	-375,000	375,000	μV
20	AC Referential	Cz-Ref	-375,000	375,000	μV
21	AC Referential	Pz-Ref	-375,000	375,000	μV
22	AC Referential	Oz-Ref	-375,000	375,000	μV
23	AC Referential	23-Ref	-375,000	375,000	μV
24	AC Referential	24-Ref	-375,000	375,000	μV
25	AC Referential	25-Ref	-375,000	375,000	μV
26	AC Referential	26-Ref	-375,000	375,000	μV
27	AC Referential	27-Ref	-375,000	375,000	μV
28	AC Referential	28-Ref	-375,000	375,000	μV
29 +/-	AC Bipolar	29A-29B	-375,000	375,000	μV
30 +/-	AC Bipolar	30A-30B	-375,000	375,000	μV
31 +/-	AC Bipolar	31A-31B	-375,000	375,000	μV
32 +/-	AC Bipolar	32A-32B	-375,000	375,000	μV

Appendix 6: Troubleshooting Guide

COM port problems with Bluetooth communication to Trackit T4A

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

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

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

Problems starting the recording

The setup has not been sent correctly

Under T4 Status, in the Control Panel, check that Acquire Ready shows Yes. If it is not ready, acquisition cannot begin. This could be caused by incomplete transmission of the Trackit T4A setup.

Check that all channels in the Recording setup have the same sample rate. The T4A does not support multi-sample rate.

An incorrect setup has been sent

If an incompatible setup has been sent to the Trackit T4A the message; "unable to comply" will indicate that. If an incorrect setup has been sent, the Trackit Control Panel will show 'Acquire Ready: No'.

The card is not formatted correctly

If the card is not formatted with a correct 32-bit FAT, a recording cannot commence. Format the flash card using the SD Card Formatter PC utility.

The card is corrupted

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

Trackit T4A: always stop a recording 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 pre-sent', in the Status section of the Trackit Control Panel, will evidence this.

Appendix 7: Manufacturer's Declaration

EMC Compatibility

This section contains specific information regarding the device's compliance with 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 T4A, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the T4A 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
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 T4A is intended for use in the electromagnetic environment specified below. The customer or user of the T4A should assure that it is used in such an environment.


Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The T4A uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11/EN55011	Class B	The T4A is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. Note: Only the recommended or supplied PC must be used in the system to ensure compliance.
Harmonic emissions 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 T4A is intended for use in the electromagnetic environment specified below. The customer or user of the T4A should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) 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 T4A system requires continued operation during power mains interruptions, it is recommended that the T4A system be powered from an uninterruptible power supply or a battery

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 T4A, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3,5/V] \sqrt{P} : 80 \text{ MHz to } 800 \text{ MHz}$ $= 1.2 \sqrt{P}$ $d = [7/V] \sqrt{P} : 800 \text{ MHz to } 2.5 \text{ GHz}$ $= 2.33 \sqrt{P}$ 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 T4A is used exceeds the applicable RF compliance level above, the T4A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the T4A.			
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 unshielded input electrode leads 1 m in length and worst-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 unshielded input electrode leads 1 m in length and worst-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 T4A EEG System

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

The T4A is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the T4A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the T4A as recommended below, according to the maximum output power of the communications equipment.

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 T4A 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.

Version History

V 1.0 (2 May 2018)

- First release

V 1.1 (31 May 2018)

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

V 1.2 (26 Nov 2018)

- 4-bay battery charger added.
- Additional cleaning wipes added for US customers.
- Bluetooth information moved to Section 3.6.
- Added explanation that PG1 and PG2 can be reconfigured as required.
- Added warning about battery packs falling out if door is open.
- Temperature values expressed in °C and °F.
- Recommended SD card type added.
- Trackit Software Section based on software Version 2.8.1.7

V 1.3 (19 Jul 2019)

- T4A images updated with new PCU graphic
- Default setup updated (PG1 & PG2 removed)
- Status display icons updated
- EMC warnings and information updated

V2.0 (10 Oct 2019)

- New document style
- CE Number changed and EC Rep details added
- Images updated
- 't4A' changed to 'T4A'

V2.1 (13 Aug 2021)

- Updated Manufacturer's address
- Updated EC Rep address
- Updated LNC logo

V2.2 (13 Mar 2023)

- Updated "Indications for use" and "Intended use"
- Updated "Manufacturer's Declaration"



lifelines[®]
neuro

trackit T4A

Lifelines Ltd

1 Tannery House, Tannery Lane,

Woking, Surrey, GU23 7EF UK

Telephone +44 (0) 1483 224 245

www.lifelinesneuro.com

sales@lifelinesneuro.com

Imagine EEG Anywhere[®]