# trackit T4A

## USER MANUAL

lifelines®
neuro

Imagine EEG Anywhere

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| Doc No: | 51305-006 |
| Part No: | 1606 |
| Issue: | 3.2 |
| Date: | August 2026 |

## Customer Responsibility

The Trackit T4A 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 T4A 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

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.

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### Trademarks

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## Responsibility of manufacturer

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

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

**NOTE:** 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.

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# 1 Overview

## 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.

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

### General description

The Trackit T4A EEG amplifier is a 32-channel electroencephalograph recorder intended for use in professional and home healthcare environments for ambulatory EEG and lab monitoring applications.

The Trackit T4A has the following features:

- Type-BF patient isolation to applied parts.
- 28 EEG inputs and 4 Bipolar polysomnography inputs.
- Built-in electrode Impedance measurement and Calibration Check.
- USB or wireless communication to the Trackit Solo or Acquisition PC.
- Powered by two lithium-polymer battery packs for 72-hour recording with internal backup battery.
- Powered via USB when used with USB cable.
- Patient Event push button, with connection for optional remote pushbutton.
- Storage on removable SD card.
- Waterproof pouch provided for home use.
- The recorded data is reviewed using review and analysis software on a PC.
- Built-in position sensor and light sensor.

The Trackit T4A amplifier is intended to be configured and set up by a trained healthcare professional. The patient should have minimal interaction with the Trackit T4A beyond pressing the event button.

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 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).

### 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

Pediatric to adult. The patient profile has no influence over the EEG signal acquisition.

### Clinical benefit

The expected clinical benefit for the Trackit T4A EEG 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 T4A amplifier does not directly affect outcome; the collected EEG activity will allow the physician to decide on diagnosis and treatment.

### Essential performance

Essential performance of the Lifelines Trackit T4A 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 T4A EEG Amplifier specification in Appendix 1.

Users should note the following:

1. the accuracy and integrity of recorded EEG data is dependent on correct device setup and operation in accordance with the device Instructions for Use and correct electrode application in accordance with standard EEG practices and relevant instructions for use.
2. the accuracy and integrity of acquired EEG data is critical to clinical interpretation. Factors such as electromagnetic interference, poor electrode contact or incorrect electrode placement may affect signal quality and could impact clinical assessment (refer to Section 2). Always verify signal quality using the built-in Calibration Check and Impedance Check functions prior to recording (refer to Section 3.6).

## 1.2 Warnings and Cautions

### 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 T4A EEG Amplifier. Please take note of the Warnings and Cautions before using the Trackit T4A EEG Amplifier.

| | | | |
|---|---|---|---|
| ! | **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 Trackit T4A EEG Amplifier in an MRI environment, in an oxygen rich environment or during defibrillation |
| ! | This equipment is intended to be used by a healthcare professional and in accordance with these instructions for use which must be read in their entirety before the device is used. |
| ! | This equipment in intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis. This equipment is not to be used for the determination of brain death. |

| | |
|---|---|
| ! | To avoid the risk of electric shock, only use the PC and the medical-grade power supply as 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. |
| ! | 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. |
| ! | To avoid the risk of electric shock to the patient, ensure all patient-connected parts are Type BF isolated as specified. |
| ! | The conductive part of electrodes and their connectors, including the Neutral electrode, should not contact other conductive parts including earth conductors. |
| ! | 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 Trackit Solo or PC. |
| ! | Do not touch any accessible conductive parts of the PC and the patient simultaneously. |
| ! | Do not allow the patient to touch accessible conductive parts of the PC or other non-patient-isolated equipment simultaneously. |
| ! | 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. |
| ! | 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. |

| | |
|---|---|
| ⚠ | 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 accuracy and integrity of recorded EEG data is critical to clinical interpretation. Poor electrode contact, electromagnetic interference, or incorrect device setup may degrade signal quality and could contribute to an incorrect clinical assessment. Always perform the Impedance Check and Calibration Check before each recording. |
| ⚠ | 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. |

## 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 |
| BT1 | Internal battery hazard<br>- refer to section **1.5** |
| 1 2 | Battery pack identifier |
| SN | Manufacturer's serial number.<br>First 2 digits of serial number indicate year of manufacture. |
| | Consult electronic instructions for use (eIFU). |

| Symbol | Meaning |
|---|---|
| | Follow operating instructions |
| | Input connection |
| | Bluetooth |
| | Memory card read/write |
| | On/Off and patient event switch |
| | Battery door access<br>– refer to section **3.3** |
| EU REP | European Representative |
| MD | Medical device |
| UDI | Unique Device Identifier code |
| REF | Manufacturer's Part Number |

* 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 T4A Supplied 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 *(Brand: Mascot)* | 1616 |
| Trackit software, standard | 1009 |
| Trackit T4/T4A Tool | 1408 |
| SD card, 16GB, Industrial Grade | 1610 |
| Mains Power Cable, 2-pin, 1.8m (for single bay battery charger). Regions: US, UK, EU or AUS | 1617xx (xx = EU, UK, US or AUS) |

### Trackit T4A optional components & compatible accessories:

| Optional Components | Part Number |
|---|---|
| Patient event switch | 1353 |
| Single bay battery charger with power supply *(Brand: RRC Power Solutions)* | 1604 |
| 4-Bay Battery Charger and Power supply | 1605 |
| Trackit T4A Amplifier USB cable (170mm) | 1611 |

| Compatible Accessories | Part Number |
|---|---|
| Trackit Solo | 1700xx (xx = EU, UK, or US) |

## 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. |

### Patient Event pushbutton

The Patient Event Pushbutton is used by the patient to mark an event.

## Lithium Polymer Battery Packs

Two 2.4Ah Lithium-Polymer battery packs are used as the main power source for the amplifier. The battery packs are housed in the battery compartment of the Trackit T4A. Refer to Section **2.5**.

| | |
|---|---|
| ! | 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

Recorded EEG data is stored on a removable SD card. The Trackit T4A is supplied with a 16GB Industrial Grade MicroSD card (with adapter). This card should be used to ensure the best performance and continued reliable recordings.

A 16GB card is sufficient for 10 days of recording at 250sps, with a typical 10-20 setup. A 72-hour recording at 250sps with 24 channels uses 4.7 GB of storage.

The Trackit T4A supports SD cards with a capacity up to 64GB using the FAT32 file system.

**NOTE:** An Industrial SD card is recommended for the T4A Amplifier

## Bags and straps for ambulatory use

The T4A bag houses the Trackit T4A 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. |

### Setup and Recording Software

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

*Refer to the Trackit Plus software manual*

### 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 for Acquisition 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 PC supplied or authorised by Lifelines.<br>Only use the medical-grade mains power supplied or authorised by Lifelines. |

## 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 Trackit T4A contains a lithium-ion rechargeable coin cell, type LIR2450.

| | |
|---|---|
| BT1 | 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 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 T4A

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|---|---|
| Power requirements | 3.7V Lithium-Polymer battery pack or Standard USB port (5V) |
| Power consumption | Maximum power from USB port: 2.5W. |

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

### Trackit Solo

| | |
|---|---|
| Power requirements | 100-240VAC, 50/60Hz, 1.5A max. |
| Power consumption | 60W |

### Medical grade AC mains power supply module for Acquisition PC

| Medical grade AC mains power supply module for Acquisition 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 computer must only be connected to the medical-grade laptop power supply supplied or authorised by Lifelines. Do not use a standard laptop power supply.<br>Only use the PC supplied or authorised by Lifelines. |

### Battery chargers

| Easypack Single bay charger (RRC Power solutions) (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. |

| Single bay charger (Mascot) (p/n 1616) | |
|---|---|
| Mains Power input: | 100-240Vac, 50-60Hz, max 0.25A |
| Output: | 4.2Vdc, 1.5A max. |

| Four bay charger (p/n 1605) | | | |
|---|---|---|---|
| AC/DC power adapter | | Battery charging cradle | |
| Mains Power input: | 100-240VAC, 50/60Hz, 1.3A max. | Power input: | 5.2Vdc, 4.0A |
| Output: | 5.2Vdc, 4.0A | Output: | 4.2VDC 1A max (x 4). |

## 2.4 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.<br>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 power cord serves as the mains-supply disconnect device. When connected to a mains power outlet, it should be positioned so that it's easily accessible.

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

| | |
|---|---|
| ! | Do not touch any accessible conductive parts of the PC and the patient simultaneously.<br>If the USB cable is used in the home, the laptop and power supply must be placed 1.5m away from the patient. |

## 2.5 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 in to a power source.
3. Fully extend the camera pole and 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 the supply mains disconnect device. When connected to a mains power outlet, the 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".

*For full instructions for use, please refer to the Trackit Solo User Manual.*

## 2.6 Battery Operation

### Li-Polymer battery pack

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|---|---|
| ! | Replace the Lithium polymer battery packs with Lifelines supplied battery packs only. Use of another battery may present a risk of fire or explosion. |
| ! | 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. |
| ⚠ | If the Trackit T4A is not to be used for some time, the battery packs should be removed. |

The Trackit T4A 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.

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. Refer to Section **3.10**.

The healthcare professional is intended to replace the battery pack(s) 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 give fewer operating times than usual, they have reached the end of their life and must be replaced. Properly dispose off used battery packs and keep away from children.

### Internal Li-Ion backup battery

The internal backup battery will enable the unit to continue operating for a short period of time (approx. 30 min) 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 typical service life is 500 charge-discharge cycles. The backup battery is replaceable by service personnel only.

## 2.7 Use in the home environment

Where the equipment is used in the home:

- The Trackit T4A 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 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.

## 2.8 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.

## 2.9 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 records signals of very low amplitude, and such interference may cause signal artefacts.

The Trackit T4A 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 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. |

## 2.10 Maintenance and cleaning

The Trackit T4A requires 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 T4A and its bag may be cleaned with a cloth moistened with a mild detergent solution.

Disinfection of the equipment can be carried out using QAC-based disinfectants. Wipes are recommended in order 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. |

## 2.11 Useful life

The Trackit T4A EEG amplifier has an expected useful life of at least 5 (five) years.

## 2.12 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

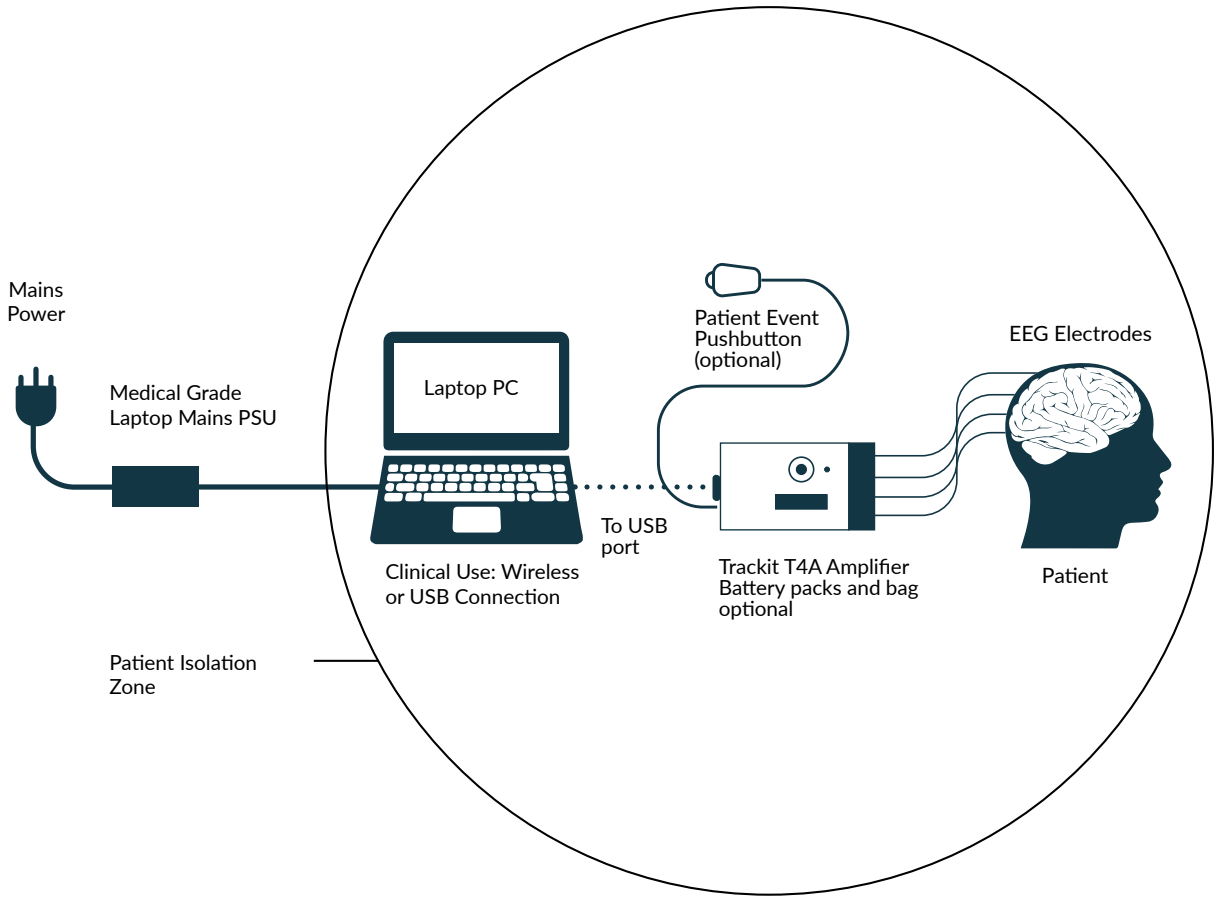


*Figure 1: Connecting the Trackit T4A Amplifier – Clinical Use*

### Clinical Use

During Clinical use, the Trackit T4A 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:** For mobile use within the clinic, the Trackit T4A 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 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 a medical-grade power supply.

## Home Use

During home use, the Trackit T4A 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 Trackit Solo or laptop PC is optional and may be used for video recordings. There is no cable connection between the Trackit Solo or PC and the Trackit T4A (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.

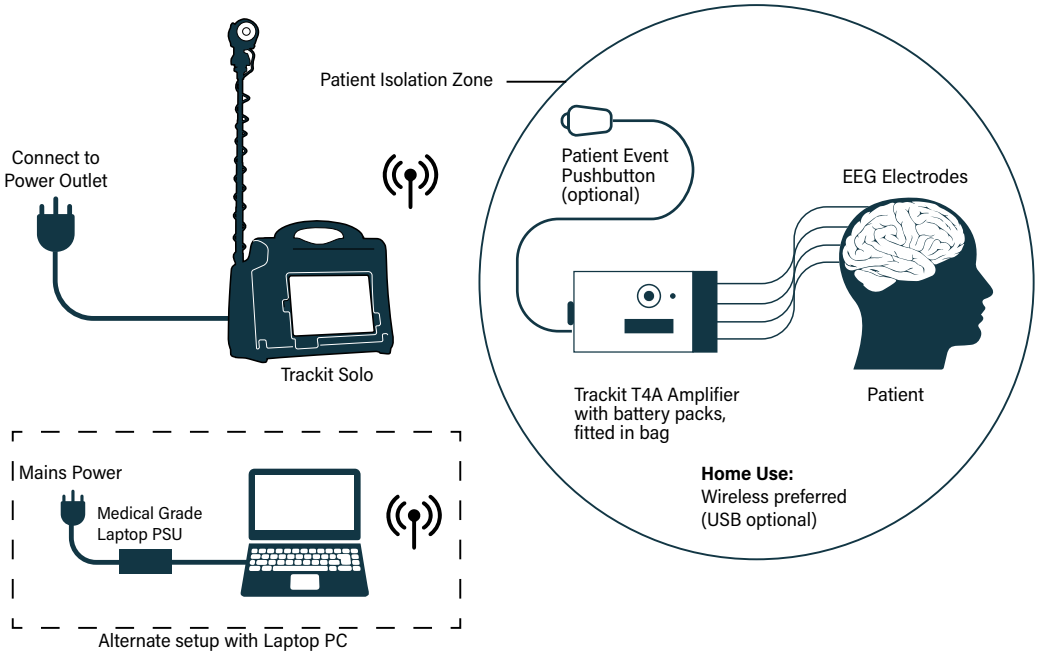


*Figure 2: Connecting the Trackit T4A - Home Use*

## 3.2 Recording Procedure

### Starting a Recording

1. Fit one or two fully charged battery packs into the Trackit T4A (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 the SD card into the Trackit T4A (Section 3.7).
3. Connect the Trackit T4A to the Trackit Solor or Acquisition PC over Bluetooth (Section 3.4).
4. On the Acquisition software, set up the recording and electrode configuration *(refer to the appropriate software manual)*.
5. Connect the EEG electrodes to the patient (Section 3.4).
6. Perform an Impedance check, if necessary (Section 3.6).
7. Start the recording via the Acquistion software (refer to the appropriate software manual).
8. The Trackit T4A will beep and show "RECORD STARTED" on the display.
9. Fit the amplifier in the bag (Section 3.8).
10. Fit the bag to the patient (Section 3.8).

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 Trackit T4A is to press the event button if they need to log an event.

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

### Event marking

Once a recording has started, the button on the front panel of Trackit T4A 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 T4A 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 |
| Door Open | Battery compartment door opened |

| Event Name | Description |
|---|---|
| Door Closed | Battery compartment door closed |
| Host On | Connection to host PC established |
| Host Off | Connection to host PC lost |
| Low Battery | Remaining Battery level is low. Trackit T4A has switched to backup battery. |
| OK Battery | Change in power source to either main battery packs or USB power bank |
| 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 |
| Disk Event | Error writing to SD card. |

## Resuming the recording

If the Trackit T4A switches off during a recording, the recording will resume when the T4A is switched on again. This must be within 18 hours of the amplifier switching off. The recording will create a new EEG data and event file at the point it resumes.

## Ending the recording

To stop a recording:

1. Ensure the Trackit T4A is connected to the Acquisition software.
2. Stop the recording using the “Stop Recording” button in the Acquisition software
3. The Trackit T4A will beep and show “RECORD STOPPED” on the display.

## Reviewing the recording

The recorded EEG data and events can be reviewed using the Trackit software or other supported 3rd party software (iEEG, StratusEEG or Persyst). Remove the SD card from the Trackit T4A and copy the data onto the Review PC, as per the Review software procedure.

When copying the recorded data into the review software, ensure that all the BDF and TEV files are copied.

## 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 is not to be used for some time, the battery packs should be removed. |

The fully charged battery pack(s) should be fitted into the Trackit T4A before setting up an ambulatory recording.

**NOTE:** If the Trackit T4A is to be used with the USB cable, the battery packs are 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. Insert the battery pack(s) (battery contacts facing down) into the amplifier. If only fitting one battery pack, fit the battery in battery location 1.
4. Gently push the battery door closed. The door will click shut and lock automatically.

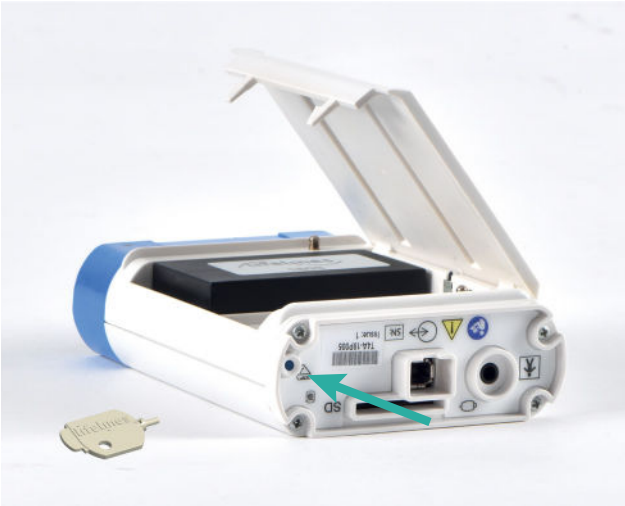

*Figure 3: Battery replacement*

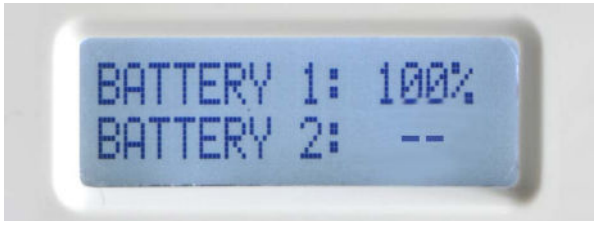


*Figure 4: Battery capacity display*

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

The top face of the Trackit T4A houses the display, the patient event pushbutton and the ambient light sensor. Pressing the pushbutton records a patient event and illuminates the back-light of the display.

### 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 EEG Electrodes with touch-proof DIN 42802 connectors.

Any unused input can be disabled or re-assigned to the user preferences, using the supplied software.

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

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

The end panel of the Trackit T4A has the following connections:

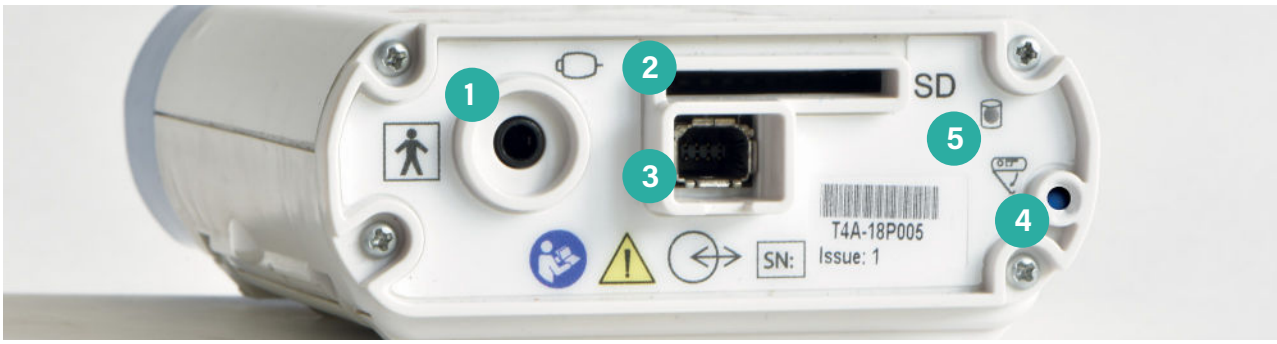


*Figure 6: Connections and indicators on the Trackit T4A, connector end*

1. Patient Event connection for optional Patient Event Button.

| | |
|---|---|
| ⚠ | Only the Patient Event Button provided by Lifelines should be plugged into this connector. |

2. SD memory card slot.
3. USB 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. |

Connect the USB cable (PN 1602) into the data socket (item 3, Figure 6) and into a USB port on the acquisition PC. When fully connected, the connector on the cable will latch into the socket on the amplifier.

| |
|---|
| **NOTE:** When used with the USB cable, the amplifier can operate with or without the battery packs. |

### 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.

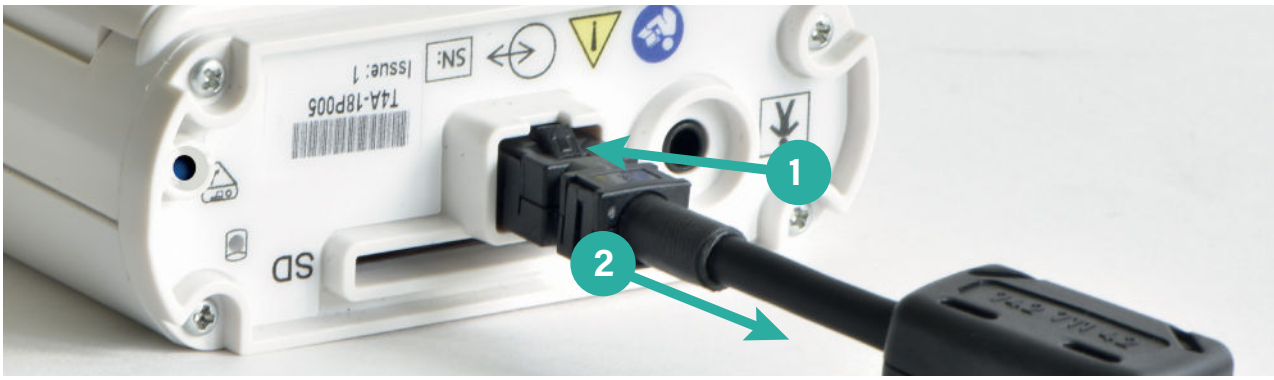


*Figure 7: Releasing the data cable*

## Bluetooth

The Trackit T4A has built-in Bluetooth for wireless communication with recording software on the Acquistion PC. Wireless mode requires at least one battery pack.

## Bluetooth Pairing

To connect the Trackit T4A to a PC via Bluetooth, the amplifier must first be paired with the PC. The Bluetooth connection on the amplifier uses Simple Secure Pairing (SSP) authentication.

To pair to a Trackit T4A:

1. Switch on the Trackit T4A.
2. In the Windows® Bluetooth options, search for new devices. The Trackit T4A will be shown as Lifelines T4A – xx, where xx is the serial number of the amplifier.
3. Select the desired amplifier and click the “Connect” button.
4. A code will be displayed on the PC and on the T4A, as shown below (Figure 8).
5. If the codes match, press the Event button on the Trackit T4A followed by the ‘Connect’ button on the PC

**NOTE:** There is a 10 second timeout on the amplifier. If the codes are not confirmed 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 paring process will be complete.

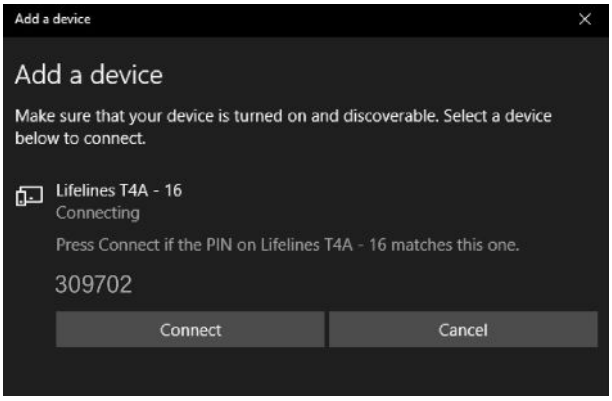

*Figure 8: Bluetooth pairing*

### Bluetooth Usage

Refer to the Acquisition Software user manual for Bluetooth connection with the software.

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 by 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.

## 3.5 Switching the Amplifier on and off

### Switching on

To switch on, press and hold the Patient event button for 2 seconds. The display's backlight will turn on and an audible beep will sound. The status screen (Figure 9) will be displayed when the Trackit T4A 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

### Trackit T4A Display

*Figure 9: Trackit T4A display*

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

| Symbol | Description |
|---|---|
| | **Clock:** Represents the time of day in HH:MM format.<br>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).<br>If there is no SD card in the amplifier, "--- M" is displayed.<br>If the disk capacity reaches zero during a recording, "FULL" is displayed.<br>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.<br>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.<br>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.<br>If the T4A is powered from a USB Data Source (i.e. a computer) the word "USB" is displayed.<br>If the T4A is powered from an approved USB power bank the word "EXT" is displayed. |
| | **Backup Battery icon:** This icon replaces the battery icon and is displayed when the T4A is operating from the backup battery. The icon will flash and the word "LOW" is displayed. |
| | **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. |
| R | **Recording Active:** Displayed when the amplifier is recording to the SD card. |
| S | **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. |
| L | **Low Disk Space:** Displayed when recording and the remaining SD card space is low (< 8 minutes), (accompanied by auditory beep every 30 seconds). |

### SD card Indicator

The SD card activity indicator (Figure 6, #5) will flash whenever there is any reading or writing activity on the SD card.

### Buzzer

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 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 T4A 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 Trackit T4A is configurable. The default waveform is an 8mVp-p square wave @ 1 Hz.

**NOTE:** The Calibration Check does not validate the connection from the from the patient electrode to the T4A Electrode input.

### 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 Trackit T4A is recording or not.

The Trackit T4A 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.

## 3.7 SD Card

*Figure 10: SD Card location*

### Insertion and Removal

The Trackit T4A 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 10) with the SD card label facing up.
2. Using the T4A tool (supplied), gently push the card further into the slot until it clicks into place.
3. When fully inserted and locked in place, the SD card will be recessed in the card slot.
4. The T4A display will show the available card capacity.

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

#### Removal

1. To remove the card, gently push the SD card with the T4A tool.
2. Release the pressure on the card and the card will eject out the card slot.
3. The display will show " --- M".

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

When the SD card is inserted (and successfully read) or removed, an audible beep will sound.

### Recorded Files

During an Ambulatory or Dual recording, the Trackit T4A will record the EEG data and events in two files on the SD card. The EEG data is stored in a BDF format, which is the 24-bit variation of the native EDF (European Data Format). The events are stored in a Trackit Event file (*.TEV). The two files will have the same file name, which is set by the Acquisition software.

The Trackit T4A supports a maximum file size of 4GB. If the recording exceeds 4GB, the data will span over multiple files. The file name for the additional files shall be sequentially numbered. Each BDF file will have a corresponding TEV event file, with the same file name and number.

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

## 3.8 The T4A Bag

The T4A bag features a large zipped opening with a fold-over hood for fitting the amplifier into the bag. 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 Trackit 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 Trackit T4A 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.

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.

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

### Fitting the bag to the patient

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

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

**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 Button (optional)

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

symbol.

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

The Remote patient event button 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 numbers 1604 or 1616) or the optional 4-bay charger (part number 1605).

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

### Single bay battery chargers

Two variants of the single bay battery charger can be used with the Trackit T4A. Refer to the safety and instruction leaflet provided with the charger.

| EasyPack Battery Charger (RRC Power Solutions) (p/n 1604) | | Single Bay Battery Charger (Mascot Electronics) (p/n 1616) | |
|---|---|---|---|
| *Figure 12: EasyPack Single Bay Charger* | | *Figure 13: Mascot Single Bay Charger* | |
| **LED indicator** | **Description** | **LED indicator** | **Description** |
| Red | No battery connected | Green flashing | Battery not connected |
| Red flashing | Pre-Charge | Yellow | Battery Charging |
| Orange | Fast charge / Top-off charge | Yellow flashing | Battery nearing end of charge cycle (90%-100%) |
| Green | Battery Full / Standby | Green | Charge complete / Standby |
| Red | Charge stopped due to temperature or fault. | Red flashing | Error (refer to charger instruction leaflet) |
| Connect the micro-USB plug of the power adapter into the charger cradle.<br>Plug the charger's power adapter into a mains power outlet (red LED on charger should be on). | | Connect the supplied 2-pin mains cable (p/n 1617xx) to the charger and plug into a mains power outlet (LED will flash green) | |
| ! | The power cable / 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. | | |
| • Remove the battery pack from the Trackit T4A and place in battery charger cradle.<br>• The charge cycle should start automatically. Monitor the LED to determine the charge status (see table above)<br>• When the battery pack is fully charged, remove from the charger and fit the second battery pack (if required).<br>• When charging is complete, unplug the charger from mains power. | | | |

## Four bay battery charger (p/n 1605)

The 4-bay battery charger can charge up to four battery packs simultaneously

- Connect the round DC plug of the power adapter into the charger cradle and plug the power adapter into a mains power outlet. The blue indicator on the front of the charger indicates the unit has power.
- 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.

*Figure 14: 4-Bay Battery Charger*

| | |
|---|---|
| ! | The 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. |

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<br>There is a fault with the battery. |
| On (Solid) | Battery is fully charged |

When the charger is not in use, disconnect the unit from the mains power.

## Charging time

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 | 110 minutes |
| Two | 158 minutes |
| Four | 180 minutes |

Refer to the instruction sheet included with the charger and available on the Lifelines Neuro Technical Support website (https://lifelinesneuro.com/eeg-customer- support/).

| | |
|---|---|
| ! | 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.

# Appendix 1: Trackit T4A Specifications

## EEG inputs

| | |
|---|---|
| Number of EEG channels | 28 referential (monopolar) inputs |
| ADC Resolution | 24 bits |
| Sampling | 250 – 2000 Hz (up to 32 channels (EEG & Bipolar))<br>4000 Hz (up to 16 Channels (EEG & Bipolar))<br>8000 Hz (up to 8 Channels (EEG & Bipolar)) |
| Input impedance | >20 Mohms |
| Common mode rejection ratio | >110dB @ 50 and 60 Hz |
| Equivalent input noise | <3.5µVpp |
| Gain | 8±0.5% |
| Max Input Vdiff | 750mVpp (including DC) |
| Quantisation | 0.17uV/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 ±5% at 0.98Hz |
| Impedance Check current | 24nA ±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 | <3.5µVpp |
| Gain | 8 ±0.5% (AC), 2 ±0.5% (DC) |
| Max Input Vdiff | 750mVpp AC setting (including DC), 3Vpp DC setting |
| Bandwidth (-3dB) | DC to 4193Hz |
| Quantisation | 0.17uV/bit @ Gain = 8 and Bits = 22 |
| Max common mode input voltage | 0.4Vpp |
| Input bias current | < 5nA |
| Front-end Calibration | 8mVpp ±5% at 0.98Hz |
| Impedance Check current | 24nA ±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 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 Dual Mode (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);<br>US (FCC/CFR 47 part 15) FCC ID: QOQBT121;<br>Canada (IC RSS) IC ID 5123A-BGBT121;<br>Japan (MIC - formerly TELEC) |
| RE-D (2014/53/EU) | Effective use of frequency spectrum: EN 300 328<br>EMC: EN 301 489-1, EN 301 489-17,<br>EN 61000-6-2<br>Health and safety: EN 60950-1+A11:2009 +A1:2010+A12:2011+A2:2013, IEC 60950-1 |
| Bluetooth Qualification | V4.2 |
| Bluetooth Range | Approx 100m (Line of sight)<br>Dependent on PC hardware and environmental factors. |

## 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<br>IEC 80601-2-26 | International 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** | **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:<br>Internally powered.<br>Type BF applied parts.<br><br>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 |
| Over discharge detection | 2.40V ±0.035V |
| Overcurrent detection | 3.2A to 5.2A<br>Limited to 500mA by the T4A's internal overcurrent protection. |
| Temperature range | Charge: 0°C to +45°C (+32°F – +113°F)<br>Discharge: -10°C to +60°C (+14°F – +140°F)<br>Storage: Less than 1 month at -20°C to +60°C (-4°F – +140°F)<br>Less than 3 months at -20°C to +45°C (-4°F – +113°F)<br>Less than 1 year at -20°C to +30°C (-4°F – +86°F) |
| Humidity | 65 ± 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: 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 & Manufacturer's Declaration

The Trackit T4A 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 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.<br>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<br>+/- 15kV: Air | +/- 8 kV: Contact<br>+/- 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<br>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<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>6V in ISM and amateur radio bands between 150 kHz and 80 MHz.<br><br>80% AM at 1 kHz | 6 Vrms<br><br>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.<br><br>**Recommended separation distance**<br><br>$d = [3.5/V]\sqrt{P}$ : 80 MHz to 800 MHz<br>$= 1.2\sqrt{P}$<br><br>$d = [7/V]\sqrt{P}$ : 800 MHz to 2.5 GHz<br>$= 2.33\sqrt{P}$<br><br>Note: using unshielded input leads |
| Radiated RF Electromagnetic Fields<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.7 GHz<br>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).<br><br>Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. |
| Proximity Fields from RF Wireless Equipment<br>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 struc-tures, 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 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 equip-ment and the Trackit T4A EEG System

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

The Trackit T4A is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Trackit 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 | | |
|---|---|---|---|
| W | 150 kHz to 80 MHz<br>$d = 1.17 \sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.17 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

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

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

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