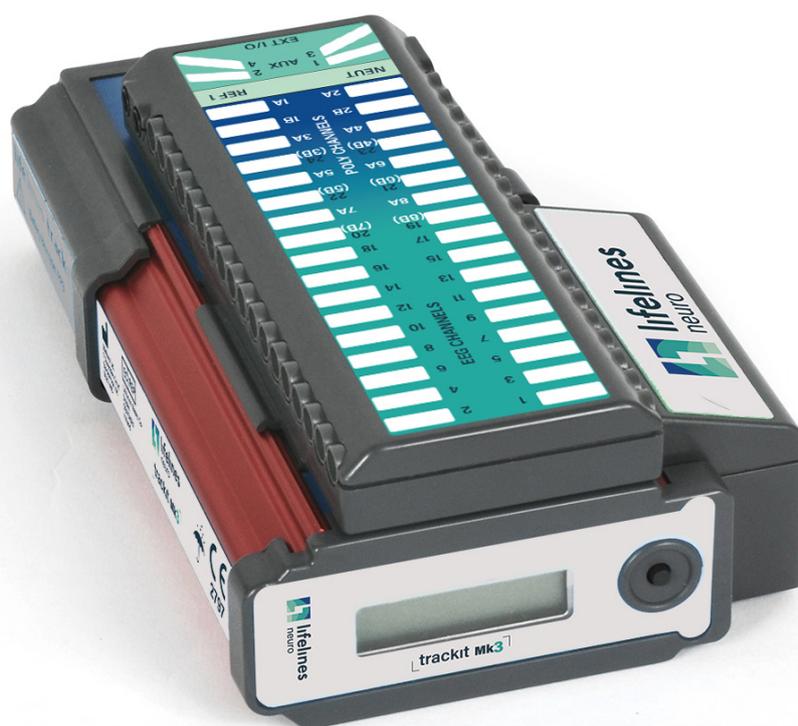




Lifelines
neuro



MADE IN
BRITAIN



trackit mk3

Ambulatory EEG Recorder

USER MANUAL

Imagine EEG Anywhere



Lifelines Ltd,

7 Clarendon Court, Over Wallop, near Stockbridge,
Hampshire SO20 8HU, UK
Telephone +44 (0)1264 782226
www.LLines.com
sales@LLines.com



Incereb Ltd.

3015 Lake Drive, Citywest
Dublin D24 DKP4, Ireland



Doc No:	51336-006
Part No:	1114
Issue:	3.0
CCN:	CCN126
Created	 Digitally signed by Geoff Salter Date: 2020.07.07 09:44:33 +01'00'
Checked	 Digitally signed by David Hulin DN: cn=David Hulin, o=Lifelines Ltd, ou=Development, email=david.hulin@llines.com, c=GB Date: 2020.07.08 09:23:29 +01'00'
Approved	 Digitally signed by Geoff Salter Date: 2020.07.09 16:57:19 +01'00'

Customer Responsibility

The Trackit Mk3 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 60601-1-2 and IEC 60601-1-11 for medical devices.

Disclaimers & Warranties

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

Except as stated below, Lifelines 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 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 Mk3 system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

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

Trademarks

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

Responsibility of manufacturer

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

- any peripheral equipment to be used with Trackit Mk3 is supplied by third-party providers recommended by the manufacturer;
- assembly operations, extensions, readjustments, modifications, or repairs are carried out by person authorised by the manufacturer;
- the electrical installation of the relevant room complies with the appropriate requirements;
- the equipment is used by a healthcare professional and in accordance with the instructions for use.

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

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

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

Software and Virus Protection

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

1. Virus protection software should be installed on every computer at risk of infection. This software should have a resident (online) shield and provide email scanning if appropriate.
2. Virus scanning should be set to manual mode or automatic if desired but at a time when the system is not being used.
3. All programs offering auto-update features, including Windows, should be set to manual or automatic if desired but at a time when the system is not being used.
4. Adopt formal departmental or organisational procedures to ensure the integrity and safe operation of the medical equipment and supporting systems.

Contents

1	System Overview	7
1.1	General description.....	7
1.2	Warnings and Cautions.....	8
1.3	Explanation of symbols	10
1.4	The Trackit Mk3 and its parts.....	11
1.5	Specifications and safety.....	12
1.6	Description of the components	13
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	Use in the home environment.....	16
2.5	Use with other equipment	17
2.6	Interference	17
2.7	Maintenance and cleaning.....	18
2.8	Disposal of equipment.....	18
3	Connections and Usage.....	19
3.1	Overview	19
3.2	Connecting the Trackit Mk3.....	20
3.3	Switching the Trackit Mk3 Recorder On and Off	21
3.4	Symbols on the display	22
3.5	Bluetooth	23
4	Trackit Software - overview	24
5	The ambulatory recording	25
5.1	Changing batteries and cards	25
5.2	Fitting the Clickon PCU.....	30
5.3	Event marking.....	32
5.4	Ending a recording	32
5.5	Identifying a recording	32
5.6	Reading an ambulatory recording.....	33
	Version History	68

Appendices

Appendix 1: Trackit Mk3 Specifications	34
Appendix 2: Advanced Trackit Settings (Defaults).....	37
Appendix 3: Trackit Mk3 Options	42
Appendix 4: Photic Stimulator and Hyperventilation.....	45
Appendix 5: Bluetooth Wireless	48
Appendix 6: Troubleshooting Guide.....	62
Appendix 7: Manufacturer's Declaration.....	64

Illustrations

Figure 1: Connecting the Trackit Mk3 – Clinical use	19
Figure 2: Connecting the Trackit Mk3 – Home Use	20
Figure 3 Connecting the Trackit Mk3 recorder	20
Figure 4 Trackit Mk3 recorder: front panel.....	21
Figure 5: The Trackit Mk3 display	22
Figure 6: Opening the rear battery box/door	25
Figure 7: Removing and replacing 9V PP3 batteries.....	26
Figure 7 Removing and replacing Lithium rechargeable battery	27
Figure 9: Closing the rear battery box/door.....	28
Figure 10: Removing and replacing the flash card	29
Figure 11: Removing the flash card.....	30
Figure 12: Clickon PCU Retaining screw location.....	30
Figure 13: Detach the PCU	31
Figure 14: Lift the PCU away from the Trackit Mk3.....	31
Figure 15: Locating the PCU	32
Figure 16: Trackit Defaults Tab 1.....	37
Figure 17: Trackit Defaults Tab 2.....	39
Figure 18 Pulse oximeter and oximeter probe	42
Figure 19: Connecting the oximeter to Trackit Mk3.....	43
Figure 20: Connecting the oximeter to the oximeter probe.....	43
Figure 21: Attaching the oximeter probe to the finger	44
Figure 22: Display of SaO2.....	44

Illustrations (contd)

Figure 23: Photic Stimulation (using Trackit Plus software).....	45
Figure 24: Photic Stimulation control window	45
Figure 25: Photic trigger signal definition.....	46
Figure 26: Hyperventilation	47
Figure 27: Hyperventilation control window	47
Figure 28: Trackit Mk3 with Internal Bluetooth Module	50
Figure 29: The Trackit Control Panel	51

1 System Overview

1.1 General description



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

Intended use

The Trackit Mk3 is intended to measure and record EEG signals.

Indications for use

The Trackit Mk3 is used as an aid in the diagnosis of neurophysiological disorders such as epilepsy.

General description

The Trackit Mk3 is a multi-channel, ambulatory, electroencephalograph recorder. It is a compact body-worn device that is battery powered and the data is stored on a Compact Flash card.

The device is suitable for use in a clinical environment and in an outpatient setting. The EEG electrodes are fitted to the patient by a trained clinician prior to the patient being sent home. No subsequent intervention is required by the patient.

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

This device is intended only as an adjunct device in patient assessment; it must be used in conjunction with other methods of patient diagnosis.

The device 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 Mk3 EEG Recorder in an MRI environment, in an explosive atmosphere 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>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.</p>		
	<p>Lifelines does not supply the Nonin sensor. Only use the 'PureLight' sensors specified by Nonin to be used with their Oximeters.</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>		
	<p>Do not open or modify the equipment without the authorization of the manufacturer.</p>		
	<p>Do not touch simultaneously any accessible USB or other contacts on the PC and the patient.</p>		
	<p>Only use the PC and the medical-grade power supply as supplied or authorised by Lifelines.</p>		
	<p>Do not plug the USB connector into any device other than the PC supplied or authorised by Lifelines.</p>		
	<p>The conductive part of connectors and transducers should not contact other conductive parts including earth. Always ensure that the transducer fitted is suitable for a connection of Type BF isolation.</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.
	Ensure that carrying bag and straps are worn over clothing to prevent any possibility of skin irritation.
	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 Mk3 EEG Recorder, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the Trackit Mk3 EEG Recorder, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to Appendix 7 for more information.
	Only use approved sensors as specified by Lifelines.
	The Trackit Mk3 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	Symbol	Meaning
	Type BF applied part		Follow operating instructions
	Input/output connection		Input connection
	Special recycling required*		Bluetooth
	Consult warnings in User Manual		Manufacturer
	Push to eject Compact Flash card		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 Trackit Mk3 and its parts

The Trackit Mk3 recorder is a multi-channel ambulatory electroencephalograph designed for use in a variety of monitoring applications, including those concerned with neurological and sleep disorders.

NOTE: Trackit Mk3 is available in a number of versions, including a 32-channel (Trackit-32/0 or Trackit-24/8), a 24-channel (Trackit 24/0) and a 12-channel (Trackit-12/0). The version is displayed on the Trackit Mk3 LCD at switch-on. This manual applies to all versions, the only difference being the number of channels.

The Trackit Mk3 recorder comprises the following components:

Component	Part Number
Recorder	
Trackit-32/0 (32 EEG)	1186
Trackit-24/0 (24 EEG)	1187
Trackit-12/0 (12 EEG)	1189
Trackit-20/4 (20 EEG, 4 POLYGRAPHIC)	1184
Trackit-18/8 (18 EEG, 8 POLYGRAPHIC)	1185
Trackit-24/8 (24 EEG, 8 POLYGRAPHIC)	1188
Recorder with internally fitted wireless Bluetooth option	
Trackit-32/0 (32 EEG)	1171
Trackit-24/0 (24 EEG)	1172
Trackit-12/0 (12 EEG)	1174
Trackit-20/4 (20 EEG, 4 POLYGRAPHIC)	1169
Trackit-18/8 (18 EEG, 8 POLYGRAPHIC)	1170
Trackit-24/8 (24 EEG, 8 POLYGRAPHIC)	1173
Patient connection unit (PCU) Clickon	
PCU-clickon Short	1181
Patient connection unit (PCU) Cabled	
PCU-cabled 24/0	1104
PCU-cabled-Extended 32/0 (universal)	1136
Cable, PCU 32ch 1m	1106
Cable, PCU 32ch 0.5m	1105
Accessories and components	
Cable, USB 3m	1277
Trackit Mk3 strap, adult	1117
Trackit Mk3 strap, child	1118
Trackit Mk3 bag with PCU-clickon	1259
Trackit Mk3 set up software	1009
Trackit Mk3 User Manual	1114
Battery Box PP3	1111
Battery Box PP3-Small	1140
Battery Box Li	1112

1.5 Specifications and safety

Refer to **Appendix 1** for specifications.

The Trackit Mk3 has been certified and complies with the following standards:

Standard	Description
IEC 60601-1 and IEC 60601-2-26	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
ANSI/AAMI ES 60601-1	AAMI Deviations from IEC 60601-1 (USA).
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	International standard for medical electrical equipment, EMC requirements, calling:
*CISPR11	Conducted Emissions, Group 1, Class B
CISPR11	Radiated Emissions, Group 1, Class B
IEC 61000-4-2	Electrostatic Discharges
IEC 61000-4-3	Immunity - Radiated RF Field
*IEC 61000-4-4	Immunity - Transients Bursts
*IEC 61000-4-5	Immunity - Surges
IEC 61000-4-6	Immunity - Conducted
IEC 61000-4-8	Immunity - Power frequency fields
*IEC 61000-4-11	Immunity - Voltage dips, interruptions
*IEC 61000-3-2	Harmonic Emissions
*IEC 61000-3-3	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 USB powered by PC using Class I or Class II mains isolated medical grade power supply. Type BF applied parts.	Trackit Mk3 recorder: Internally powered. Type BF applied parts. If a PC is supplied, the PC has no electrical connection to the recorder and has no applied parts.
Degree of protection against harmful ingress of water	Ordinary (no protection) or IP22 (recorder in bag)	IP22 (recorder 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 Mk3 recorder

The Trackit Mk3 is a multi-channel recording device designed for use in recording a patient's EEG signals. It comprises a 24-channel EEG (monopolar) recorder acquisition board, an 8-channel polygraphic acquisition board and control board with all the I/O interface for serial and patient communication. When connected to a host PC, the device has built-in isolation for patient safety. The device may be powered either by its own batteries or a PC USB port. EEG data is stored on an internal CF card. The data format is native European Data Format (EDF), allowing the EEG files to be reviewed by any EDF-compatible EEG reader.

Patient Connection Unit

The Patient Connection Unit (PCU) connects the standard 1.5mm touchproof EEG recording electrodes attached to the patient to the Trackit Mk3 unit. It is available either as a 'Cabled' type which is connected via a screened cable or a 'Clickon' type which fits on the Trackit Mk3 directly without needing a cable.

	Lifelines does not supply EEG electrodes. The PCU 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.

PC Connection Cable

For non-ambulatory applications the Trackit Mk3 can be plugged directly into a USB port on the PC.

Batteries

Three 9V/PP3 disposable alkaline batteries are optionally supplied with the Trackit Mk3 recorder. Alternatively, a rechargeable Lithium battery option and a small (single) 9V/PP3 option is available.

CF flash card

A Compact Flash ('CF') card is used to store the EEG data recorded by Trackit Mk3. Storage cards of varying capacity are available in the CF format.

Bags and straps for ambulatory applications

The Mk3 bag houses the recorder when used in ambulatory applications. The bag protects the recorder from water and dust (IP22 protection).

Trackit setup 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 Trackit Mk3 recorder for an ambulatory recording session.

The Trackit Mk3 recorder is connected to the PC via the connection cable or wirelessly with Bluetooth. The recording setup/montage, and patient information/ID is downloaded to the device, and a short review is made to verify that all the electrodes have been attached correctly.

The recorder is then disconnected from the PC and the ambulatory recording is started.

Functions of the setup software *(Refer to the Trackit Plus Software manual for full details):*

- Download the recording template. This includes which electrodes are used and the recording montage.
- Perform a calibration check of the recorder.
- Perform an Impedance check on the recorder.
- Perform an EEG recording.
- View on-going EEG traces.

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. Assembly instructions for third-party products will be found in their packing cases. It is recommended that these instructions be filed with Trackit Mk3 technical reference materials.
4. 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	+10°C to +40°C (+50°F to +104°F)	Temperature	-10°C to +50°C (14°F to +122°F)
Relative humidity	25% to 95% non-condensing	Relative humidity	10% to 95% non-condensing
Atmospheric pressure	700 hPa to 1060 hPa	Atmospheric pressure	500 hPa to 1060 hPa

2.3 Power supply connections

Trackit Mk3

Power requirements	Standard PC USB port or 9V PP3 batteries when operating independently. No Protective earth required.
Power consumption	Maximum power from USB port: 2.5W.

	The Trackit Mk3 must only be used with the USB cable provided with the unit.
---	--

2.4 Use in the home environment

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

An approved laptop PC is optional in the home environment and may be used for video recordings. There is no cable connection between the PC and Mk3 recorder unit, as all communication is accomplished wirelessly, over Bluetooth.

	Keep the equipment away from sources of heat.
	Do not use mobile phones.
	Do not allow pets or children to interfere with the sensor cables.

When the equipment is operated with or without its Bluetooth 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 optional, internal Bluetooth radio is an approved industry-standard type which presents minimal risk of reciprocal interference with other equipment.

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

2.6 Interference

Trackit Mk3 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, Trackit Mk3 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 optional, internal Bluetooth radio is an approved industry-standard type which presents 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.

	<p>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 Mk3, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.</p>
	<p>When in close proximity to the Trackit Mk3, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to Appendix 7 for more information.</p>
	<p>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.</p>

2.7 Maintenance and cleaning

The Trackit Mk3 contains no user-serviceable parts (apart from replaceable batteries). The system uses solid state components and requires no routine testing or maintenance procedures apart from occasional cleaning and checking for wear and damage to all parts including the accessories.

All the outer surfaces of the individual pieces of equipment of the Trackit system may be cleaned using a soft cloth moistened with water and a mild detergent. Each item may also be cleaned using a low-pressure airline or a vacuum cleaner.

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 Mikroqid 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).



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

2.8 Disposal of equipment

When the equipment 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.



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

3 Connections and Usage

3.1 Overview

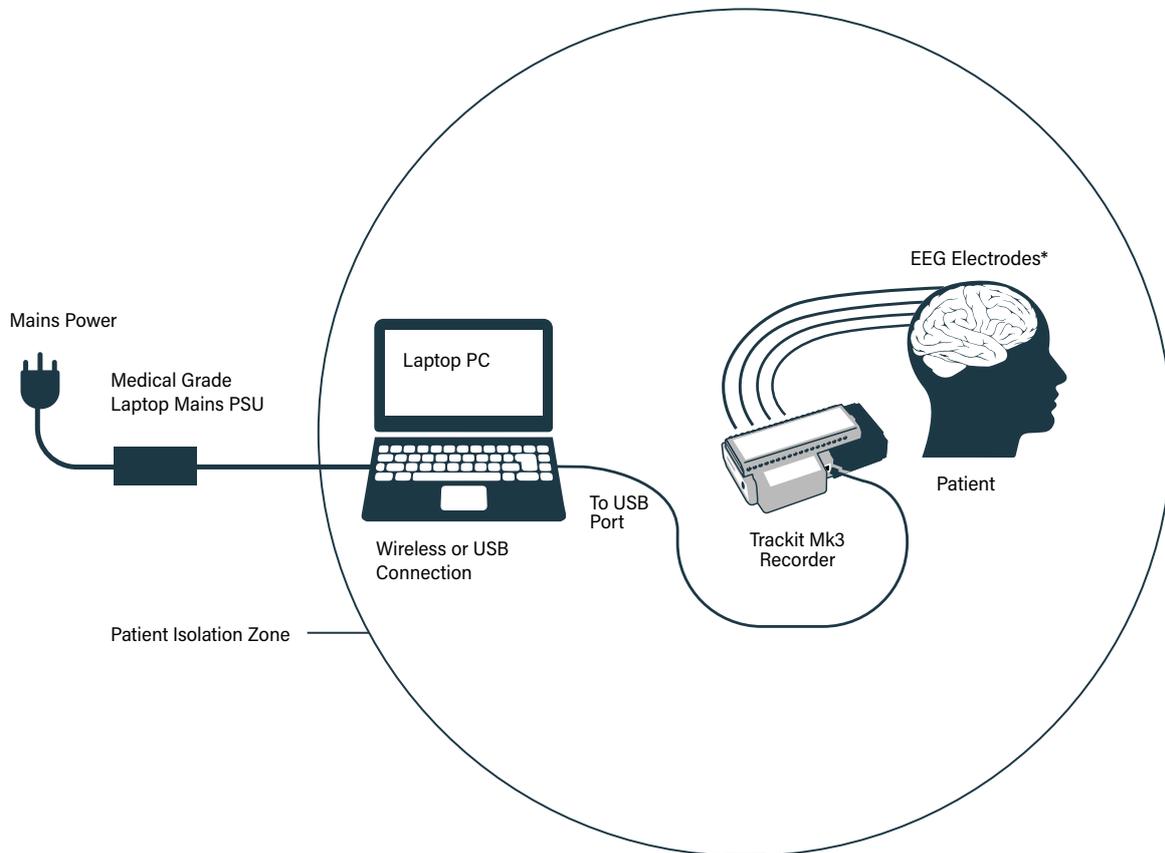


Figure 1: Connecting the Trackit Mk3 – Clinical use

List of parts supplied by Lifelines:	List of optional parts supplied by third parties:
Trackit Mk3 recorder plus bag	Host PC/laptop with power cable
Patient Connection Unit (PCU), for electrode connection	CF cards
1 x CF flash card (optional)	Batteries
3 x 9V PP3 batteries (optional)	Battery charger
PC USB cables	

Clinical Use

During Clinical use, the Trackit Mk3 Recorder can be connected to a PC either using the USB cable or through the optional wireless Bluetooth connection (see Figure 1). Housing the recorder in the Trackit Mk3 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 Trackit Mk3 recorder 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 Mk3 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 Mk3 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 Trackit Mk3, 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.

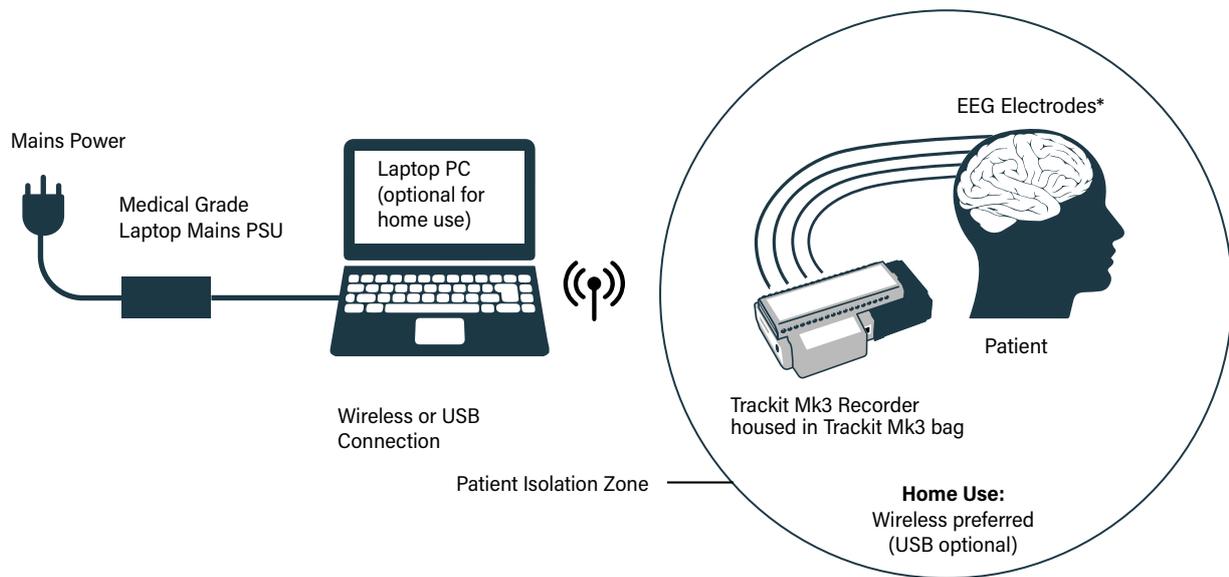


Figure 2: Connecting the Trackit Mk3 – Home Use

3.2 Connecting the Trackit Mk3

The Trackit Mk3 is simply plugged into the PC USB port using the cable supplied.



The Trackit Mk3 recorder must only be used with the USB cable (with the red tip) provided with the unit.



Figure 3 Connecting the Trackit Mk3 recorder

The necessary USB drivers will be found on the installation CD. Upon first connection of the Trackit Mk3 to the PC USB port, 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.

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



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.

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



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 Switching the Trackit Mk3 Recorder On and Off

Switching on

Turn on the unit by pressing the button on the right of the LCD display on the front panel of the recorder.



Figure 4 Trackit Mk3 recorder: front panel

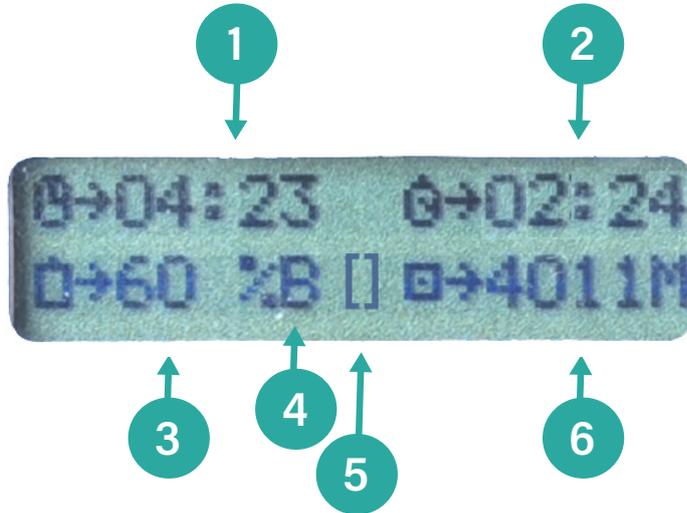
After several seconds the LCD display indicates that Trackit Mk3 is performing a self-test for system integrity. On completion of the self-test the LCD indicates the status of the Trackit Mk3 recorder.

Switching off

The Trackit Mk3 will automatically switch off (after a period of inactivity) when not recording and disconnected from the PC. The inactivity timeout is configurable in software.

Indicators

The following indicators are available depending on Trackit Mk3 status:



Key:

- 1 Time of day
- 2 Recording time
- 3 Battery capacity remaining
- 4 Internal Bluetooth on(B)/off (β)
- 5 Rear door open warning
- 6 CF Card capacity remaining

Figure 5: The Trackit Mk3 display

Time of day	The battery-backed, real time clock which is synchronized to the host during setup.
Recording time of the current recording	If not recording, '00:00' is displayed.
Disk capacity	Remaining storage capacity in MB. If there is no card present, '0' is displayed.
Battery capacity	Approximate battery capacity remaining (as % of full battery capacity).
Rear door open warning symbol	Flashes when the rear battery door is open.
Internal beeper	Warning of low battery or rear-door open

3.4 Symbols on the display

Symbol	Description
L	Low Disk Space: Displayed when recording and the remaining CF card space is low (< 8 minutes), (accompanied by auditory beep every 30 seconds).
S	Special recording 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.
R	Recording Active: Displayed when the Trackit Mk3 is recording to the CF card.
B/β	Internal Bluetooth on/off When the Internal Bluetooth option is fitted to the Trackit Mk3, the unit will display whether it is enabled or disabled with a large 'B' (enabled) or small 'β' (disabled) next to the '%' indication. To toggle the current selection the pushbutton is pressed 5 times within 3 seconds. The display will change to indicate the new state. Refer to Appendix 5 for further information on Bluetooth.

3.5 Bluetooth

The Trackit Mk3 recorder has optional built-in Bluetooth wireless capabilities, which allows the Mk3 to communicate, wirelessly, with a Bluetooth-enabled PC.

To connect the Mk3 Recorder to a PC via Bluetooth, the amplifier must first be paired with the PC.

Additional Bluetooth Information can be found in **Appendix 5**.

Bluetooth Pairing

To pair to a Mk3 Recorder

1. Switch on the Mk3 recorder.
2. Enable the internal Bluetooth By pressing the pushbutton 5 times (a large 'B' should be displayed on the LCD).
3. In the Windows® Bluetooth options, search for new devices. The Trackit Mk3 will be shown as Trackit Blue xxx, where xxx is the serial number of the Mk3 Bluetooth serial number.
4. In Windows, select the Trackit Mk3 in the list of Bluetooth devices and click the "Pair" / "Connect" button.
5. If a PIN code is required, enter the default PIN: 1.
6. The Trackit Mk3 should now be paired to the PC.

Bluetooth Usage (Trackit Plus Software)

Once paired, the Trackit Mk3 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 Mk3. 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*).

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. 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 Mk3 recorder 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 recorder 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 recorder
- 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

Once Trackit Mk3 has been set up for an ambulatory recording, and a recording has been initiated, you can change batteries and cards without interfering with the recording, so long as you observe the rules for changing batteries and cards outlined below.

5.1 Changing batteries and cards



If the Trackit Mk3 recorder is not likely to be used for some time, the batteries should be removed.

To change cards and batteries during a recording, following a low battery or card warning, carry out the following procedures.

Changing batteries

- 1 Open the Trackit Mk3 rear Battery box/door with the special tool provided. The unit's warning beeper will sound and the Door Open symbol will flash on the display.

NOTE: The Trackit Mk3 will continue recording for a couple of minutes, depending on the number of channels, before shutting down.

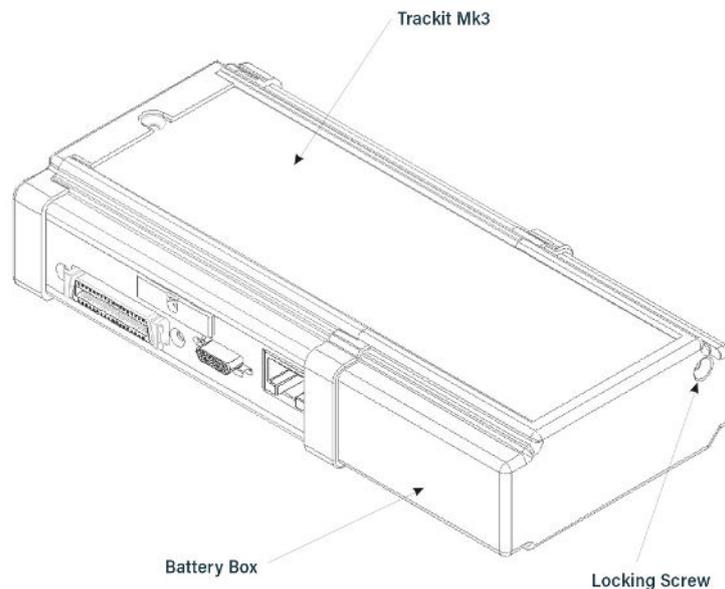


Figure 6: Opening the rear battery box/door

2 Different battery types

9V / PP3 Battery



Follow the following procedures for replacing and removing batteries.

Replacement:

Replace the batteries one at a time, making sure they are orientated correctly and firmly seated onto their terminals. Do not continue to push the battery if there is any misalignment between the mating terminals. See Figure 7.

Removal:

If 1 or 2 batteries are fitted ensure that each is removed by carefully pushing sideways at the base of each battery until the terminals disengage at the front. If 3 batteries are fitted, remove the centre one first by carefully lifting it at its base until it disengages. Now remove the remaining batteries as described above.

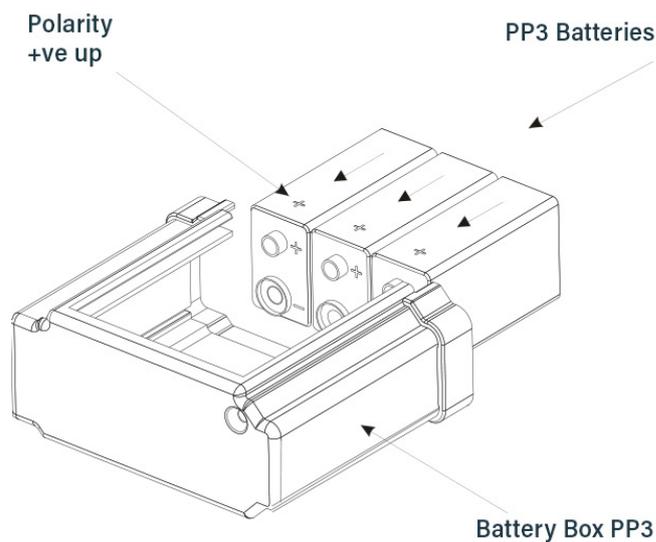


Figure 7: Removing and replacing 9V PP3 batteries

Lithium Rechargeable Battery

For the Lithium rechargeable option, firstly slide out the tray that holds the battery inside the box. To slide out the Tray, push the battery gently towards the open end of the Battery Box. This will slide out the battery and the Tray simultaneously. Now separate the battery from the Tray by pushing it sideways along the Tray to disengage the bayonet tabs.

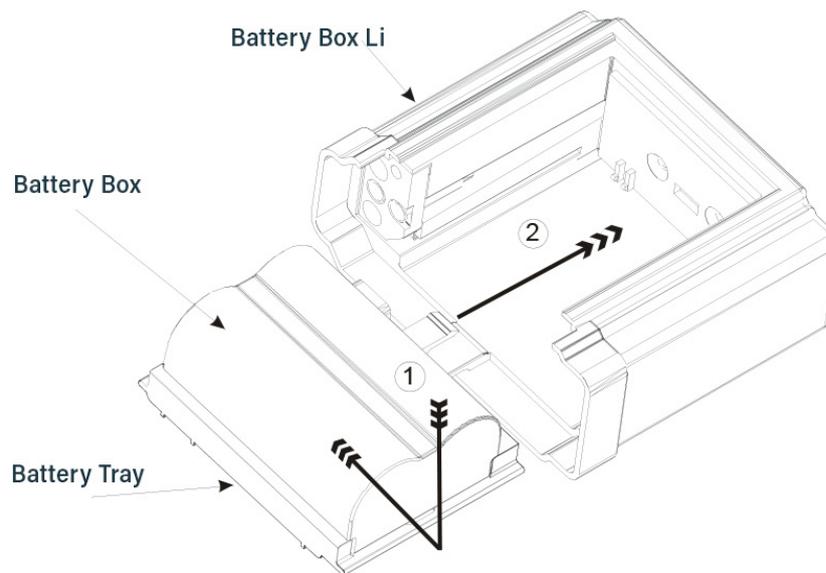


Figure 7 Removing and replacing Lithium rechargeable battery

To fit a fresh battery, either charge the original battery first or replace with another previously charged battery. Fitting is a reverse of the removal process. Firstly slide the Battery onto the Tray to engage the bayonet fittings. Then slide the entire Tray plus battery assembly back into the Battery Box by engaging the Tray slides into the slots in the Battery Box. Note that there is a tab on the Tray which engages into a slot in the back of the Battery Box.

Special Lithium Battery Instructions for Use

- The battery pack is a Canon Type BP511 and uses rechargeable lithium ion batteries. Always refer to the documentation that accompanies the battery for more information.
- The battery can only be charged outside the Trackit Mk3. Only the specific Canon charger for the BP511 must be used. Lifelines do not supply the charger; this is available from your local camera or video stockist. Always refer to the documentation that accompanies the charger for charging instructions.
- Operating time will be shorter than usual at low temperatures. The battery can be used between 0 C and 40 C, but will give best performance between 10 C and 30 C.
- If the battery starts to give less operating times than usual, it has reached the end of its life and must be replaced.
- The battery can be recharged at any time. However, since the battery will naturally discharge itself over a period of time, it is best to charge the battery a day or two before planning to use it.
- Always attach the battery terminal cover when not in use. Do not allow any metal objects to touch the battery terminals.



- Only use the Canon Type BP511 with the Trackit Mk3
- Keep the battery pack away from fire
- Do not expose the battery pack to temperatures greater than 60°C
- Do not disassemble or modify the battery pack
- Do not drop the battery pack or allow it to become wet
- Only use the specific Canon battery charger for use with the BP511 type battery

- 3 When the batteries have been replaced, and if the flash card does not need replacing, refit the rear Battery box/door and screw it down with the special tool provided. The warning beeper will stop.



Do not overtighten the locking screw – finger tight is all that is required.

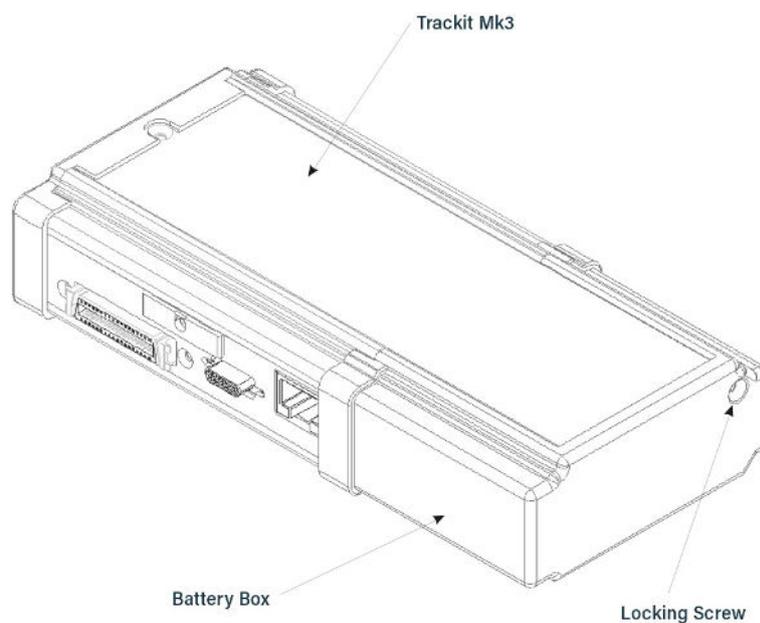


Figure 9: Closing the rear battery box/door

Changing the flash card

- 1 Open the Trackit Mk3 rear Battery box/door with the special tool provided. See Figure 23. The unit's warning beeper will sound for a few seconds and the Door Open symbol on the display will flash.
- 2 Watch the yellow Light Emitting Diode (LED) indicating CF Card activity. When it is on, this means the Trackit Mk3 is writing data to the PC Card.



Do not remove the CF Card when the LED is lit

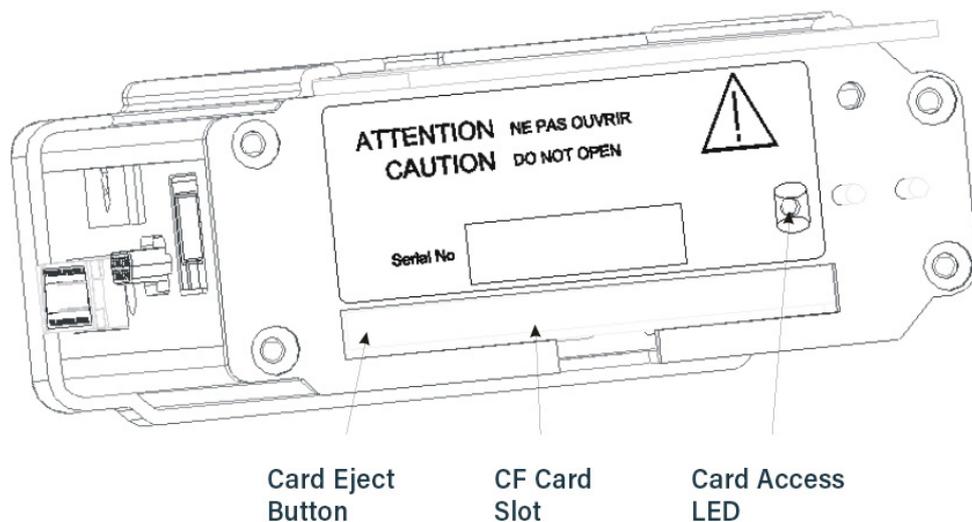


Figure 10: Removing and replacing the flash card

- 3 When the yellow LED is not lit, remove the card by carefully pressing the black eject button on the left edge of the card slot with a plastic ballpoint pen or similar. Keep the pen straight and avoid pushing at an angle or inserting too far into the unit and causing damage.



Use only a plastic ballpoint pen or similar to eject the flash card. DO NOT use the special Trackit Access Tool supplied with the unit or any similar thin, pointed object for this purpose, since it is possible to slip and damage the inside of the unit.



Figure 11: Removing the flash card

- 4 Replace the card with a blank one.
- 5 Refit the rear Battery box/door, and screw it down with the special tool provided.



Do not over-tighten the locking screw – finger tight is all that is required

5.2 Fitting the Clickon PCU

Retaining screw location



Figure 12: Clickon PCU Retaining screw location

- 1 Release the Clickon PCU by unscrewing the retaining screw as shown with the special tool provided.
- 2 Lock by screwing up the retaining screw.



Do not over-tighten the locking screw – finger tight is all that is required

Detaching the Clickon PCU

- 3 Ensure that the retaining screw is released as described above. Squeeze as shown below between fingers and thumb of each hand until the PCU moves by about 5mm and unplugs from the Trackit Mk3.



Figure 13: Detach the PCU

- 4 Lift the PCU away from the Trackit Mk3.

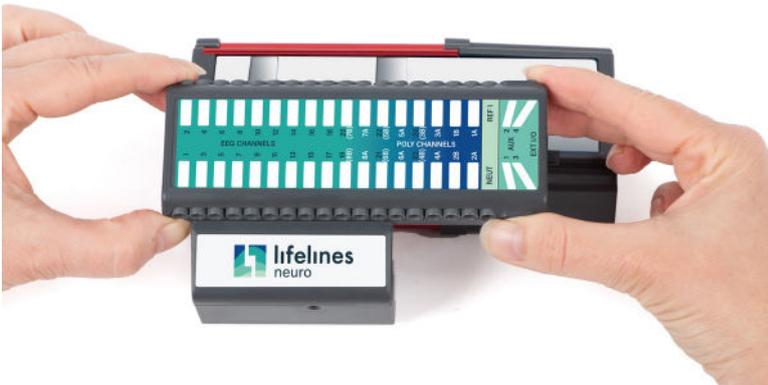


Figure 14: Lift the PCU away from the Trackit Mk3

Attaching the PCU

- 5 Position the PCU above the Trackit Mk3 as shown above in Figure 14 and lower it down ensuring that the two tabs locate fully into the slots in the top of the Trackit Mk3.
- 6 Squeeze as shown below between fingers and thumb of each hand until the PCU locates fully on the Trackit Mk3. Make sure the two tabs of the PCU are located correctly inside the slots in the top of the Trackit Mk3. Lock the PCU with the retaining screw as described above.



Figure 15: Locating the PCU

5.3 Event marking

Once a recording has commenced, the button on the front panel of Trackit Mk3 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.

You can view events before replaying the recording using your EEG review program or the Eventit.exe program that comes with the Trackit Software installation.

Trackit Mk3 can record 15 different event types. These can be seen by looking at the Trackit event types in the online event viewer. Refer to *Trackit Events in the Trackit Plus Software Manual*.

5.4 Ending a recording

To stop a recording:

- 1 Connect the Trackit Mk3 to the host software.
- 2 Click on the Stop Recording button in the Trackit control panel.

Alternatively, to stop the Trackit Mk3 recording in the field:

- Either press the button on the front panel and hold it for approximately 5 seconds;
- Or simply remove the card and do not replace it. The idle time by default is only 5 minutes and can be set in increments up to 255 minutes – see Advanced Settings in **Appendix 2**.

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 Patient ID entered during the setup procedure, and by the user-definable file name.

5.6 Reading an ambulatory recording

The Trackit Mk3 recording can be reviewed using the Trackit Software. *Refer to the Trackit Plus Software user manual for more details.*

As an alternative to the Trackit software which offers basic playback features, any EDF-compatible viewer can be used to read the standard EDF files recorded by the Trackit Mk3.

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

Lifelines currently recommends:

- Rendr
- Stratus EEG
- Nihon Kohden 1100 and 1200 EEG
- Neurotronics Polysmith Sleep software
- Nicolet One EEG
- Natus Coherence EEG (formerly Deltamed/Itmed)
- Persyst Insight EEG

Appendix 1: Trackit Mk3 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	24 monopolar touchproof inputs
ADC Resolution	16 bits
Sampling	1 to 256Hz or 25 to 200Hz rate, simultaneous sampling all channels
Differential input impedance	>20 Mohms
Common mode input impedance	>100 Mohms
Common mode rejection ratio	>100dB @ 0.16Hz to 70Hz with active ground connected
Equivalent input noise	<3.5 μ V pk-pk @ 0.16Hz to 70Hz
Hardware gain	500 \pm 2%
Max differential AC input before clipping	10mV pk-pk
Max operational DC input voltage (electrode offset)	\pm 500mV
Bandwidth	0.16Hz to 70Hz (-6dB)
Max common mode input voltage	2V pk-pk
Input bias current	< \pm 25nA
Polygraphy inputs	
Number of polygraphy inputs	8 bipolar touchproof inputs
ADC Resolution	16 bits
Sampling	1 to 256Hz or 25 to 200Hz rate, simultaneous sampling all channels
Differential input impedance	>20 Mohms
Common mode input impedance	>100 Mohms
Common Mode Rejection Ratio	>100dB @ 0.16Hz-70Hz with active ground connected
Equivalent input noise	<3.5 μ V pk-pk @ 0.16Hz to 70Hz
Hardware gain, AC setting	500 \pm 2%
Max differential AC input before clipping	10mV pk-pk
Max operational DC input voltage (electrode offset), AC setting	\pm 500mV
Hardware gain, DC setting	10.1 \pm 2%
Max differential input before clipping, DC setting	\pm 250mV
Bandwidth	0.16Hz to 70Hz (-6dB) or DC to 70Hz
Max common mode input voltage	2V pk-pk
Input bias current	< \pm 25nA
Aux. high-level DC Inputs	
Number of Aux channels	4 on Aux. connector
ADC Resolution	16 bits
Sampling	1 to 256Hz or 25 to 200Hz rate, simultaneous sampling all channels
Input impedance	47 Kohms
Hardware gain	1 \pm 2%
Max input before clipping	\pm 2.5 V
Bandwidth	DC to 70Hz (-6dB)
Modes of operation	
Impedance	< 2 to > 90 KOhm, measured with 0.075 μ A p-p, 5Hz signal. Measurement accuracy \pm 15%.
Calibration	0.5mV p-p square wave @ 1Hz at ADC input. Amplitude accuracy \pm 5%.

Connections, ports and controls

Patient Connection Unit (36 pin MDR connector)	Connector for touch-proof Patient Connection Unit (PCU), either Leaded or Clickon
Front panel pushbuttons	1 on/off pushbutton Patient Event during record
Aux. Connector 1 (RJ45 connector)	USB port (isolated from patient)
Aux. Connector 2 (15 pin Micro-D connector)	External Patient Event input Bluetooth Module I/O Nonin XPOD SaO2 probe input 4 Aux. High level DC inputs
CF card port	1 Type II socket (3.3V)
Batteries	3 type PP3/MN1604 1 type BP511 Lithium rechargeable
Internal beeper	Internal beeper sounds when: door is open battery is low card storage is low Patient Event

Backlight display

Current Time and Date
Recording Time
Battery Life remaining
Disk Storage remaining
Door open warning

Physical characteristics

Weight	500g including card and 3 PP3 batteries 450g including card and Li rechargeable battery
Size	16cm x 8cm x 3.5cm

Recording format

Native European Data Format (EDF)
Native MSDOS/Windows card data structure

Safety and EMC standards

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

IEC 60601-1 and IEC 60601-2-26	International standard for medical electrical equipment, general requirements and particular requirements for EEG systems.
IEC 60601-1-11	Collateral standard for medical electrical equipment used in the home healthcare environment.
UL60601-1	USA standard for medical electrical equipment, general requirements.
ANSI/AAMI ES 60601-1	AAMI Deviations from IEC 60601-1 (USA).
UL60601-1	USA standard for medical electrical equipment, general requirements.
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	International standard for medical electrical equipment, EMC requirements, calling:
*CISPR11	Conducted Emissions, Group 1, Class B
CISPR11	Radiated Emissions, Group 1, Class B
IEC61000-4-2	Electrostatic Discharges
IEC61000-4-3	Immunity - Radiated RF Field
*IEC61000-4-4	Immunity - Transients Bursts
*IEC61000-4-5	Immunity - Surges
IEC61000-4-6	Immunity - Conducted
IEC61000-4-8	Immunity - Power frequency fields
*IEC61000-4-11	Immunity - Voltage dips, interruptions
*IEC61000-3-2	Harmonic Emissions
*IEC61000-3-3	Voltage Fluctuations/flicker

*Note: Compliance is provided by the PC

Trackit Mk3 Classification		
Classification	Clinical use	Home Use
Degree of protection against electrical shock (when connected to host system)	Type BF	Type BF
Type of protection against electrical shock (when connected to host system)	Internally powered or USB powered by PC using Class I or Class II mains isolated medical grade power supply.	Trackit Mk3: Internally Power PC (if supplied): Class II AC power. No electrical connection to Trackit Mk3 (Bluetooth connection in use)
Degree of protection against harmful ingress of water	Ordinary (no protection) IP22 (Recorder in bag)	IP22 (Recorder in bag)
Mode of operation	Continuous	Continuous
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not suitable	Not suitable

Appendix 2: Advanced Trackit Settings (Defaults)

Set Trackit Defaults

[> Advanced Operations > Settings > Set trackit Defaults]



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

Trackit Defaults Tab 1

This menu item activates a control dialog that adjusts how the Trackit Mk3 behaves during a recording. See Figure 16.

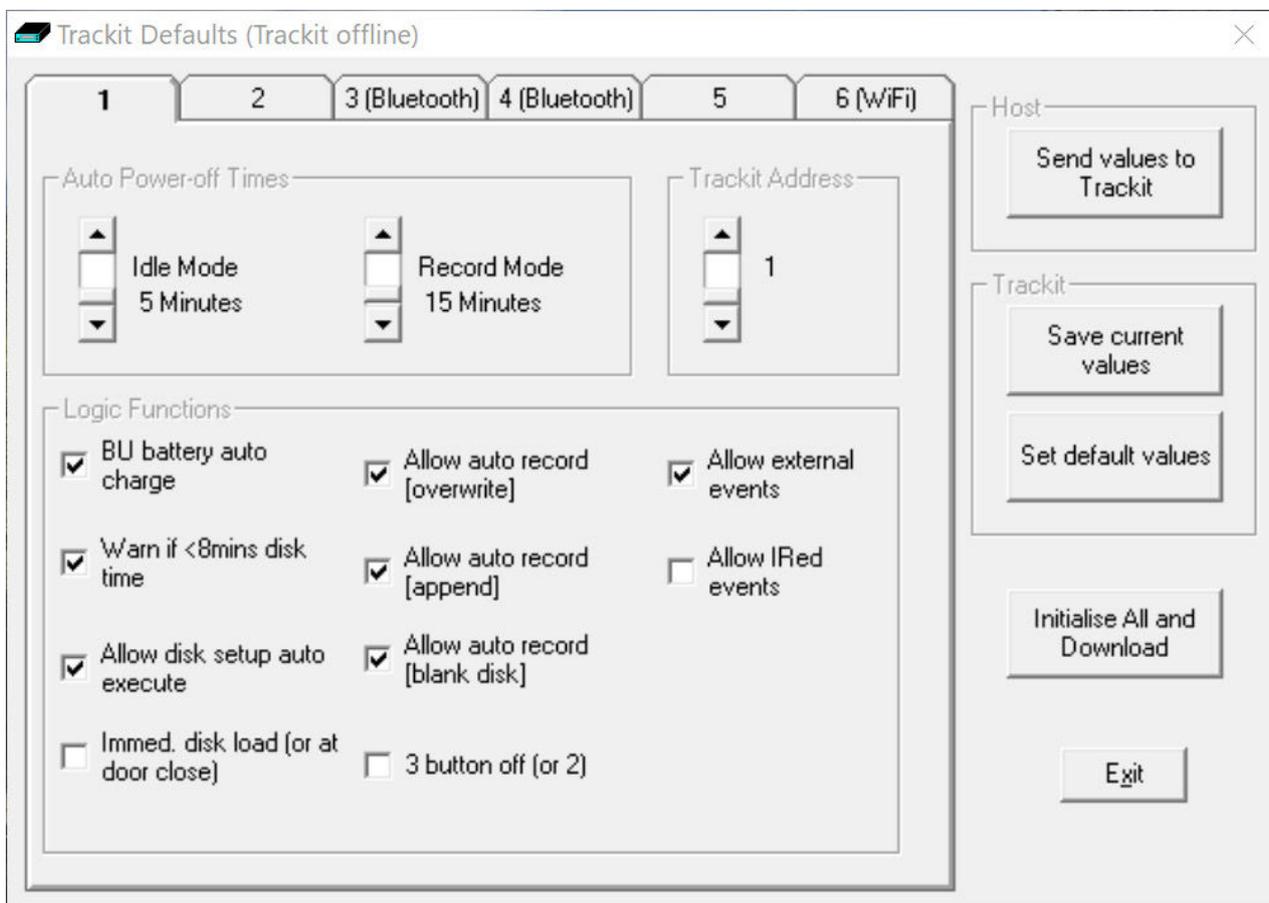


Figure 16: Trackit Defaults Tab 1

To save new defaults to Trackit Mk3, press 'Send these values to Trackit', followed by 'Save current values'.

The following functions are supported:

Idle Mode: Trackit Mk3 turns itself off after a defined period when not recording.

Record Mode: Trackit Mk3 turns itself off after a defined period after having recorded. Trackit Mk3 waits for a defined period for a card to be reinserted to append to an existing file which is <24 hours old. Otherwise it starts a new recording on a blank card. 60 minutes is enough for a user to remove a card, read it and reinsert it to continue recording until the card is full.

Trackit Address: sets the serial address of the Trackit Mk3 if a simple serial network is configured with several Trackits connected to one PC.

BU battery auto charge: enables fast charging of the backup battery when the Trackit Mk3 is connected to its external power supply.

Warn if <8 mins card time: the Trackit Mk3 starts beeping when the card has room for only another 8 minutes of recording.

Allow card setup auto execute: allows a setup to be stored onto a flash card for a recording to start automatically only when the Trackit Mk3 is switched on. See Ways to start a recording, in Step 8.

Allow auto record (overwrite): when this box is checked the Trackit Mk3 automatically overwrites any data on a card inserted during a recording (e.g. when changing cards during a recording).

Allow auto record (append): if a card is inserted with a file which has the same patient name and is less than 24 hours old, Trackit Mk3 appends to rather than overwrites the data. This is a very useful feature if a recording is interrupted, say for a quick review of the data. Trackit Mk3 waits in record mode, and when the card is reinserted it carries on recording to the existing file on the card.

Allow auto record (blank card): check the box if you routinely want recordings to take place over several blank cards. This is a very useful feature if a recording over several days is required.

Allow external events: an external event marker can be attached to the Aux. port.

Allow IRed events: the optional Trackit infra-red event marker (**Trackit Mk 1 only**) can be used to annotate a recording.

Immed. card load (or at door close): off by default, allowing the card to be loaded only when the rear door is shut. Leave this box unchecked if you want to make recordings over several cards on a regular basis.

3 button Off (or 2): unchecked by default. **Trackit Mk 1 only.**

All new Trackits have all the logic functions enabled by default except Immed. card load and 3 button Off. To update the logic functions in the Trackit Mk3 recorder when changes are made, click on *Send values to Trackit*, followed by *Save current values*. This saves the values in the Trackit Mk3's non-volatile memory. See Figure 16 above.

Trackit Defaults Tab 2 (Mk2 and Mk3 only)

The Trackit Mk2 and Mk3 have additional optional parameters. These are accessed via Tab 2 of Trackit Defaults, as shown in Figure 17 below.

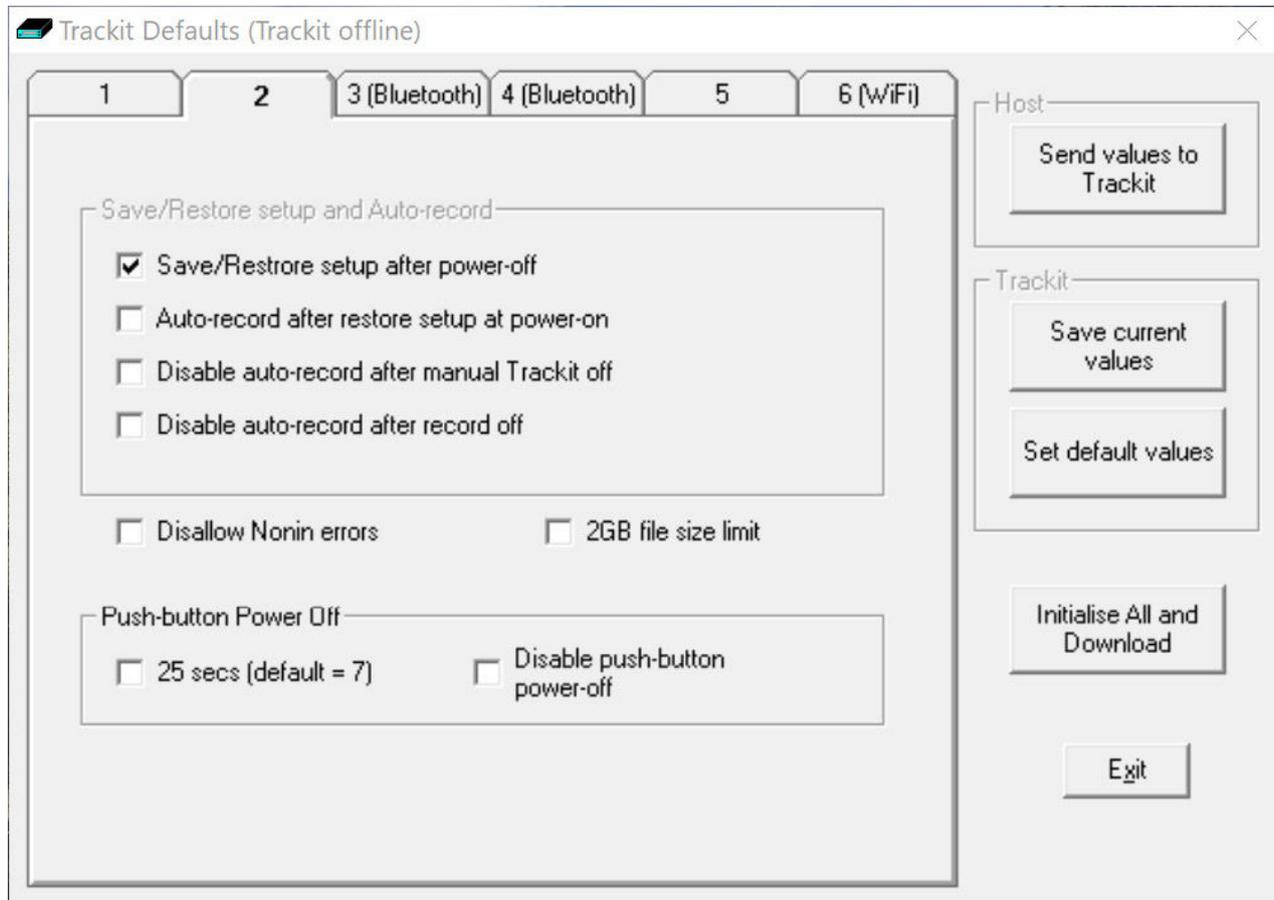


Figure 17: Trackit Defaults | Tab 2

Save/Restore setup and Auto-record

The Trackit Mk2 and Mk3 have much increased internal non-volatile memory. This memory allows it to save its entire Setup before powering off. When next powered on, it is able to restore its last saved Setup. This feature can significantly speed-up the download of a Setup to the Trackit because the Host software automatically determines if the Trackit is already set up correctly.

Another benefit to this save/recall of Setup is that the Trackit can resume recording in exactly the same state it was in the last time it was powered off. This is especially useful if, during a recording, the User takes a long time to replace the batteries. To control this feature, the following options are available:

- **Save/Restore setup after power-off.** When checked, this enables the Trackit Mk3 to save its entire Setup including Patient Name and Recording ID after power-off and recall it at power-on. Note that the Patient Name and Recording ID are only retained for 15 minutes after power-off (refer below).
- **Auto-record after restore setup at power-on.** When checked, this enables the Trackit Mk3 to continue recording if it was recording the last time it was powered off, using the recalled Setup and Patient Name and Recording ID, but only if it has been powered off for 15 minutes or less. If the Trackit Mk3 has been powered off for longer than 15 minutes, then the Patient Name and Recording ID are overwritten with defaults (the current Setup remains) Note that the parameter above must also be checked to use this feature.
- **Disable auto-record after manual Trackit off.** When checked, this causes a potential Auto-record situation to be cancelled whenever the Trackit Mk3 is powered off either from its own front panel pushbutton or from the Host.
- **Disable auto-record after record off.** When checked, this causes a potential Auto-record situation to be cancelled whenever the Hosts instructs the Trackit Mk3 to stop recording.

Note that in all these Auto-record situations, the same rules apply to data storage on the flash card as defined in the User Manual for the current Trackit Default Options | Tab 1. To summarise these rules:

- The Trackit Mk3 will not record over a data file on the card which is less than 24 hours old.
- The Trackit Mk3 will append new data, if enabled, if the data file on the flash card is less than 24 hours old and the Trackit Mk3's Setup and Patient Name and Recording ID are identical to that on the card.
- The Trackit Mk3 will overwrite data on the flash card, if enabled, if the data on the card is more than 24 hours old.
- The Trackit Mk3 will write new data to a blank flash card, if enabled.

Disallow Nonin Errors

This is a feature available to all Trackits running firmware Vx.13.x or later. Normally, the SaO2 data stored to the flash card is set to an invalid value (127) to mark any of the following Nonin errors

1. Sensor disconnected
2. Out of track
3. Low perfusion
4. Marginal perfusion
5. Bad pulse

Errors 1 and 2 are serious and do cause invalid data. However, short-term errors 3 to 5 are not so serious and the Nonin device is still able to produce meaningful data. The available option is as follows:

- **Disallow Nonin Errors.** When checked, all errors 1 – 5 produce invalid data (127). When unchecked, it is only errors 1 and 2 which cause the data to be marked as invalid, otherwise the Nonin data is unmodified.

Get Card Info

[> *Advanced Operations > Settings > Get Card Info*]

Selecting Get Card Info opens a dialog showing the current status of the flash card, including the file name and any error codes ('Disk OK' is displayed to indicate a properly functioning card). Should any problem occur with the flash card, copy and paste this dialog and send it to your Lifelines distributor.

To format a flash card:

- 1 Insert the flash card into the Trackit Mk3 and connect to the host computer. See Step 6 Connect Trackit for Setup.
- 2 Open the Get Card Info dialog box.
- 3 Choose Format Disk from the Disk Utilities Menu.
- 4 Click on the Format button.
- 5 Wait for the format complete message to appear. A 1GB card will take around 5 seconds to format, larger cards will take longer to format.



In normal operation, flash cards rarely require formatting. If formatting is done on the PC it is easy to inadvertently create the wrong card format.

Earlier Trackits with V4.19 firmware and earlier use FAT16 cards only (referred to in Windows as 'FAT'). If for any reason you wish to format a flash card, make absolutely certain you know what you are doing! It is easy to convert from FAT16 to FAT32, but very difficult to convert the other way (the card has to be manually repartitioned and reformatted). In the rare circumstances that it is necessary to format a flash card, use the inbuilt Trackit format utility.

Later Trackits fitted with firmware V4.21 and later use FAT16 or FAT32 cards and there are format facilities in the Trackit to support both types.

Factory Settings

[> *Advanced Operations > Settings > Factory Settings*]

Factory settings are protected by a password (via Other Options in the View Menu). Only trained support staff should have access to factory settings.

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

Configuration

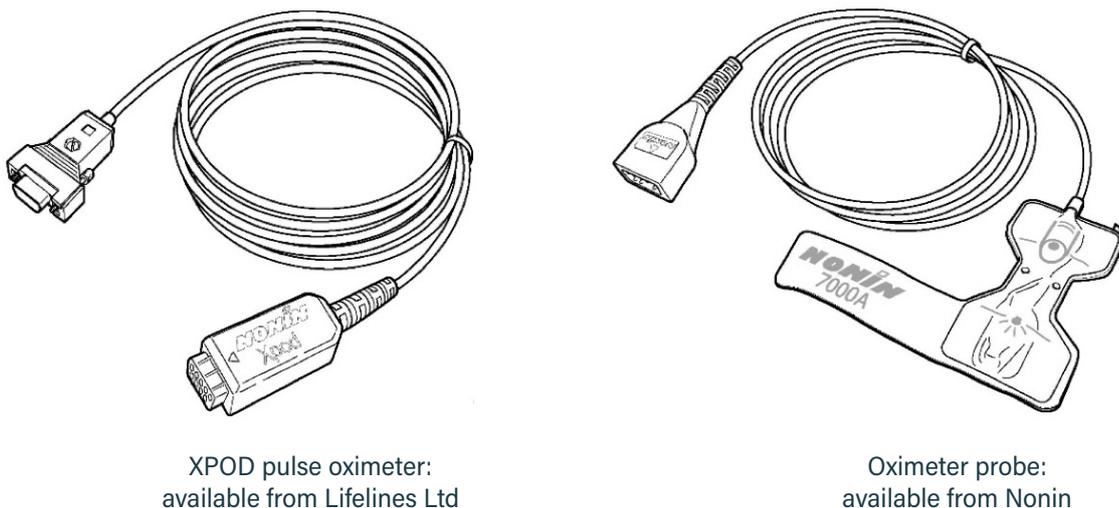
[> *Advanced Operations > Settings > Configuration*]

Configuration gives access to the optional pulse Oximeter and the independent sample rate and headbox mode features. The code displayed can be copied and emailed to Lifelines for an activation code to be sent back.

Appendix 3: Trackit Mk3 Options

Nonin XPOD pulse oximeter

The Nonin XPOD is an in-line pulse oximeter that connects to the second serial port on the side of the Trackit Mk3, or the optional AUX input box. Finger probes may be purchased locally from Nonin.



XPOD pulse oximeter:
available from Lifelines Ltd

Oximeter probe:
available from Nonin

Figure 18 Pulse oximeter and oximeter probe

Trackit Mk3 takes the digital output from the XPOD, and displays it as a DC-analogue signal, along with a realtime numeric display of O₂ saturation and pulse rate. The data stored is displayed in the range 0-100%.

Additionally, for the Trackit Mk2 and 3 only, an enhanced XPOD will be available that offers Plethysmographic pulse data.

NOTE: The XPOD oximeter and Probe take power from the Trackit Mk3 and the typical recording time will be reduced by approximately 22%. The later version of the XPOD which is coloured blue instead of grey, is lower power and only reduces the recording time by approximately 13%.

Ideal applications

The XPOD pulse oximeter can be used extensively in sleep studies while monitoring patients who suffer from sleep apnoea. The pulse oximeter is used to correlate the corresponding dip in the blood's O₂ saturation with an apnoea attack.

Pulse oximetry is also used in a wide variety of applications such as hypoxia in children with central breathing disorders, hypoxic events during epileptic seizures, etc.

Ordering information

Description	XPOD pulse oximeter
Requires	Version 2.1.x EPROMS, and will work with all Trackit variants. Will also work with optional AUX Input Box.
Part Number	1022 or enhanced 1119 (Plethysmographic data for Trackit Mk2 only)

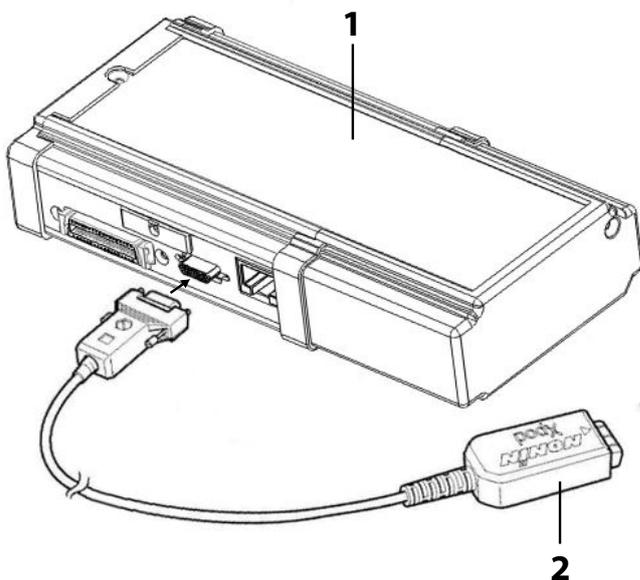
Operation

To enable the pulse oximeter:

- 1 Open the Trackit Control Panel (in the Trackit Plus Software).
- 2 Click on Advanced Operations.
- 3 Choose Configuration from the Settings Menu.
- 4 Copy the code displayed in the configuration dialog and email it to your nearest Lifelines distributor.
- 5 You will receive by return an unlock code that will enable this feature.

Setup as follows:

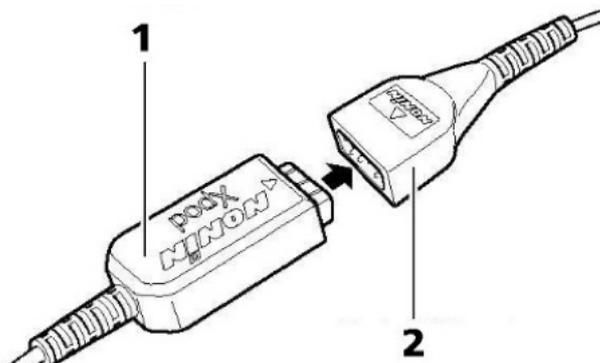
- 1 Locate the 15 pin EXT IO connector on the Trackit Mk3. If the Click-on PCU is attached, this connector is located on the PCU. If the Click on PCU is not attached, the 15-pin connector is located on the side of the Trackit Mk3. Connect the pulse oximeter to this 15-pin EXT IO connector (see Figure 19).



1 Nonin XPOD oximeter
2 Nonin 7000A oximeter probe

Figure 19: Connecting the oximeter to Trackit Mk3

- 2 Connect the oximeter probe, which can be purchased from Nonin via their local distributors - <http://www.nonin.com/sensors.html>.



1 Nonin XPOD oximeter
2 Nonin 7000A oximeter probe

Figure 20: Connecting the oximeter to the oximeter probe

- Remove the paper backing from the oximeter probe (see 1 in Figure 21). Attach the probe to the index finger of the patient's non-dominant hand, as shown below.

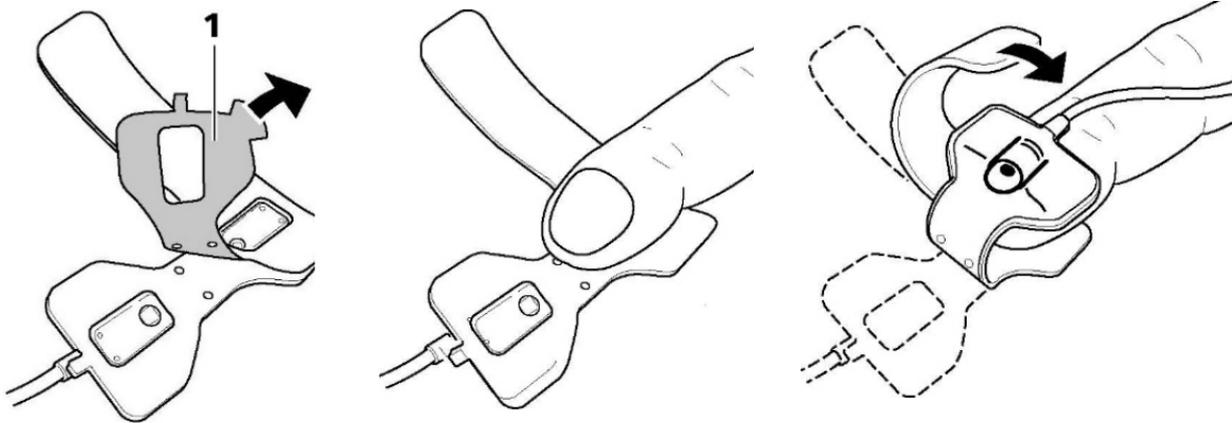


Figure 21: Attaching the oximeter probe to the finger

- Include the SaO₂ signal in the recorder setup using one of the AUX inputs and create a recording channel as per normal.
- Connect the Trackit Mk3 to the host PC. Switch on, and click on Connect in the Trackit Control Panel.
- Observe the display of SaO₂ and pulse rate on the Trackit Control Panel. Probe off, and XPOD disconnect information is displayed. See Figure 22.
- Start the recording. SaO₂ is stored as an analogue DC signal with a scale 0-100%.
- To display O₂ Saturation values on the trace display, under the channel label, click the SaO₂ channel label, and put a checkmark by Numeric.

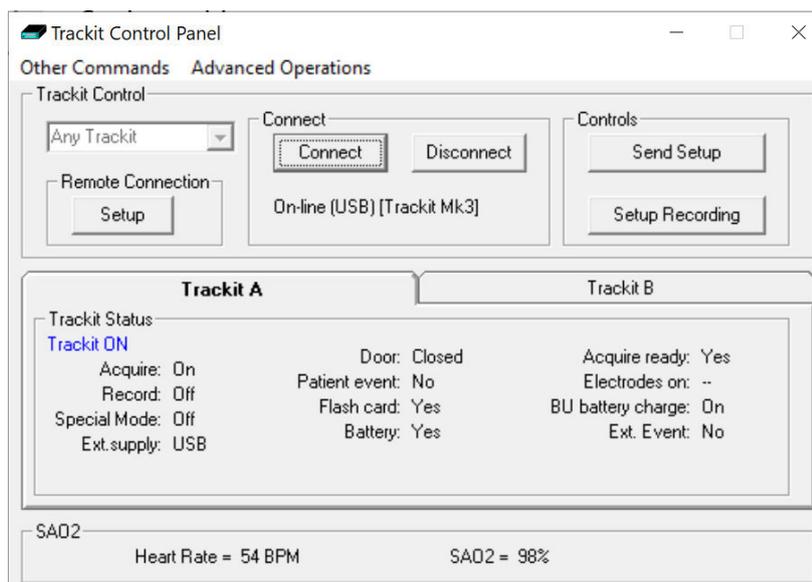


Figure 22: Display of SaO₂

Appendix 4: Photic Stimulator and Hyperventilation

NOTE: The following appendix shows Photic Stimulation and Hyperventilation using Trackit Plus Software. If using other EEG acquisition software please refer to the relevant user manual.

Photic Stimulation

An optional Lifelines Photic Stimulator is available which can be used with the Trackit Mk3 to assess patient photosensitivity in EEG studies. For a detailed description of operation, connection and specifications please refer to the separate documentation Lifelines Photic User Manual and the Trackit Plus Software manual.

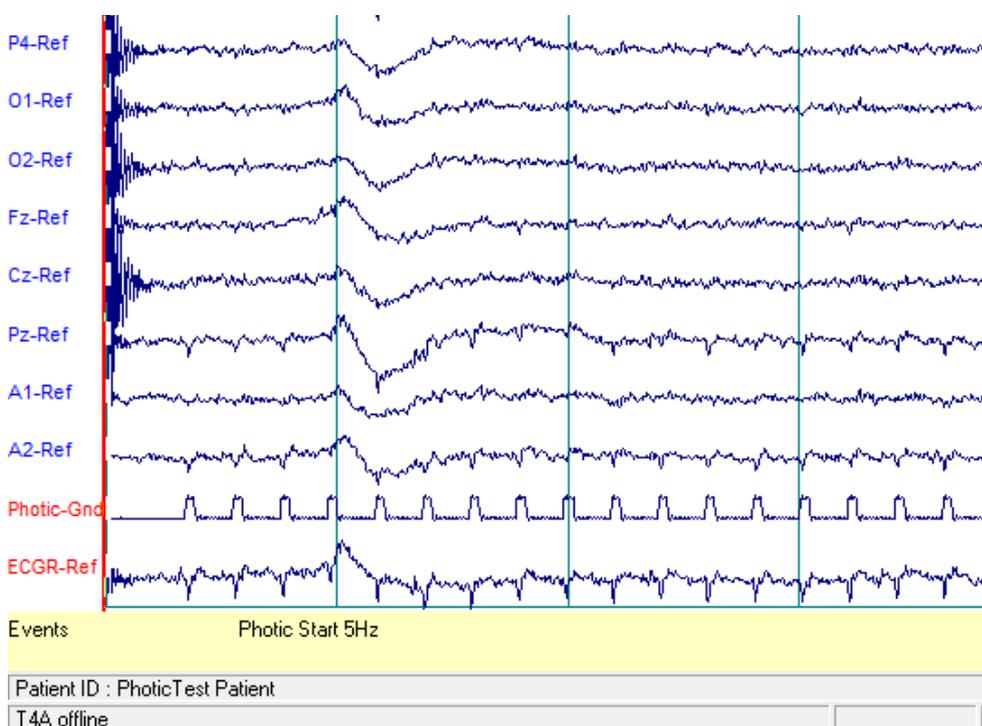
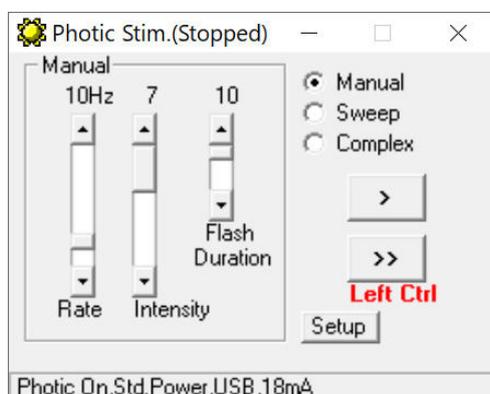


Figure 23: Photic Stimulation (using Trackit Plus software)



Click on the Photic Stimulation icon in the home toolbar to bring up the Photic Stimulation control panel.



The Photic Control panel, shown in Figure 24, allows single, manual, sweep and complex sequences of Photic stimulation to be produced. Photic start/stop events are recorded as shown above. By using the Trigger output from the Photic Stimulator and connecting to an Aux input on the Trackit Mk3, the actual Photic flash 'ticks' are produced in the recording, as shown in Figure 23.

Figure 24: Photic Stimulation control window

NOTE: Refer to the Trackit Plus Software manual to set up a Photic Trigger signal definition. Define a signal with a name "Photic," set it to type DC, units mV and Physical Signal Amplitude of + - 1000mV/V. Set the sensitivity to non-master and 10mV/mm.

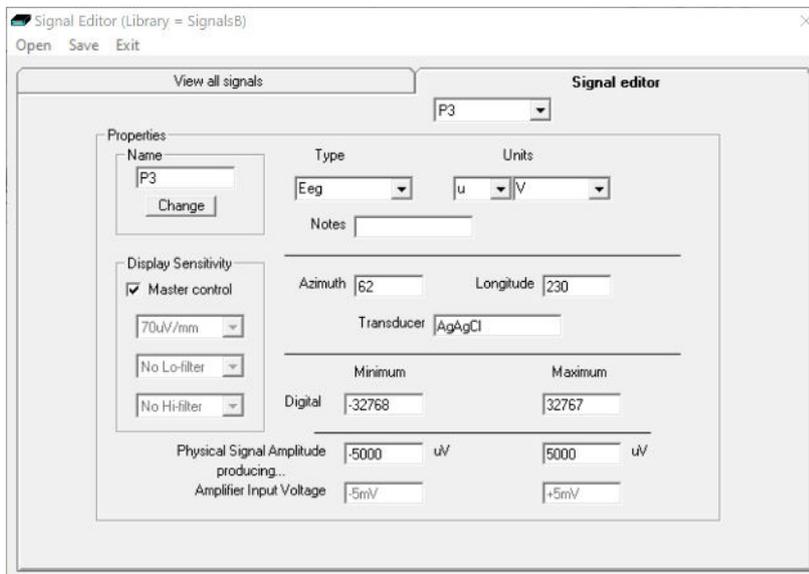


Figure 25: Photic trigger signal definition

Hyperventilation

A method of timing and marking a Hyperventilation and post-Hyperventilation activation sequence is provided.

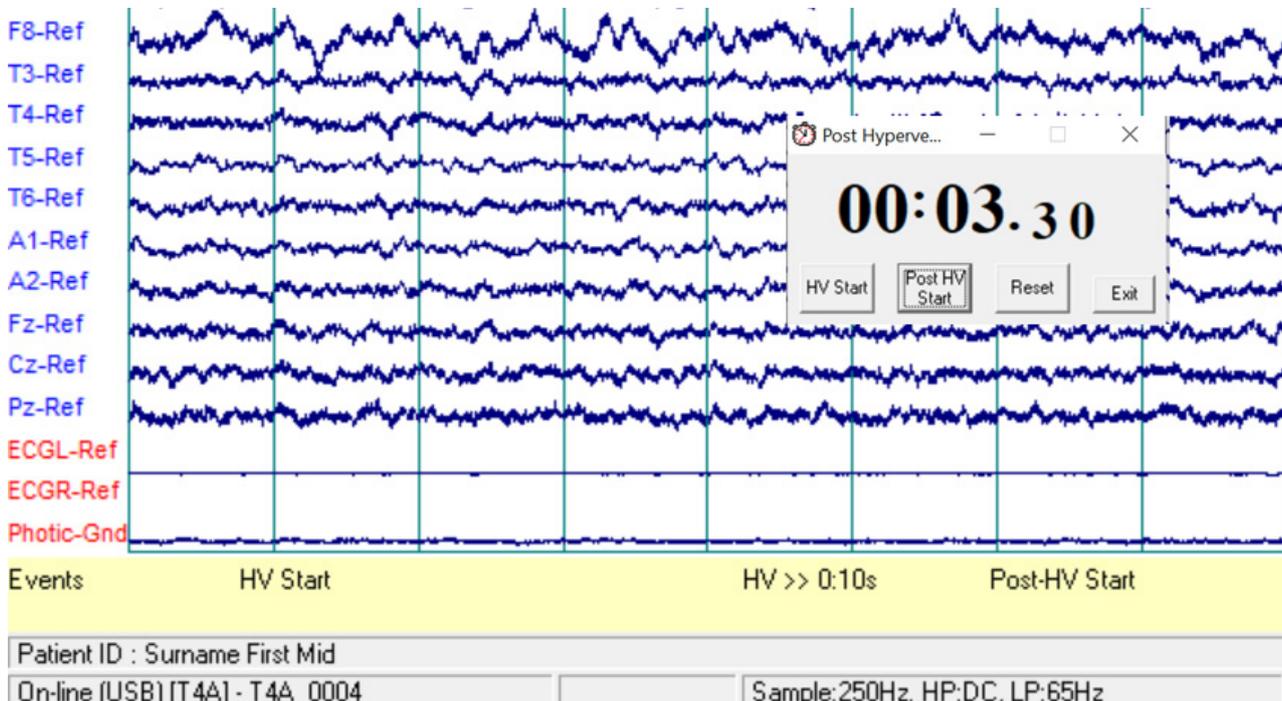


Figure 26: Hyperventilation



Figure 27: Hyperventilation control window

This provides a digital timer, which is used as follows:

- Click on HV Start to start the HV period and the timer starts running. An 'HV Start' event is recorded.
- Thereafter an 'HV' event is automatically generated every 10 seconds.
- Click on Post HV Start to start the post HV period. A 'Post HV Start' event is recorded.
- Thereafter a 'Post HV' event is automatically generated every 10 seconds.
- Click on Reset or Exit to end the hyperventilate activation.

NOTE: The Post HV Start will not work unless HV is in progress. Likewise, HV Start will not work if Post HV is in progress.

Appendix 5: Bluetooth Wireless

Introduction

Using a single plug-in Bluetooth interface module on the Trackit Mk3, wireless connections can be established with it from any Bluetooth-enabled PC, Laptop or PDA. This allows the Trackit Mk3 to be controlled or monitored remotely over a secure wireless link up to a range of about 100m or greater (dependent on hardware and environmental factors).

Bluetooth primer

It is not intended here to provide a full introduction to Bluetooth technology, how it works and how to use it. There is a huge amount of information elsewhere that is available for this purpose. Nevertheless, a short description will be given to identify some of the common terms that will be used later in the document.

The term "Bluetooth" refers to a worldwide standard for the wireless exchange of data between two devices.

In order to exchange data, two Bluetooth devices must establish a connection. Before a connection is established, one device must request a connection with another. The second device accepts (or rejects) the connection.

The originator of the request is known as the client. The device that accepts (or rejects) the request is known as the server. Many Bluetooth devices can act as both client and server.

A client Bluetooth device runs a software program that requests a connection to another device as part of its normal operation. For example, the program may request a connection to a remote computer, a printer, a modem or a Trackit Mk3.

Becoming a Bluetooth client normally requires an action by the device operator, such as an attempt to browse a remote computer, print a file, dial out on a modem or connect to a Trackit Mk3.

Every Bluetooth device that provides a service must be prepared to respond to a connection request. Bluetooth software is normally running in the background on the server, ready to respond to connection requests.

Specification Summary

- The devices in a piconet share a common communication data channel. The channel has a total capacity of 1 megabit per second (Mbps). Headers and handshaking information consume about 20 percent of this capacity.
- In the United States and Europe, the frequency range is 2,400 to 2,483.5 MHz, with 79 1 MHz radio frequency (RF) channels.
- A data channel hops randomly 1,600 times per second between the 79 RF channels.
- Bluetooth can transmit up to 721 kilobits per second (Kbps) in one direction, with 57.6 Kbps in the other. If the use calls for the same speed in both directions, a link with 432.6-Kbps capacity in each direction can be made.
- Each channel is divided into time slots 625 microseconds long.
- A piconet has a master and up to seven slaves.
- Packets can be up to five time slots wide.
- Data in a packet can be up to 2,745 bits in length.
- There are currently two types of data transfer between devices: SCO (synchronous connection oriented for voice and audio) and ACL (asynchronous connectionless).
- In a piconet, there can be up to three SCO links of 64,000 bits per second each.
- Masters can support up to three SCO links with one, two or three slaves.
- Slots not reserved for SCO links can be used for ACL links.
- One master and slave can have a single ACL link.
- ACL is either point-to-point (master to one slave) or broadcast to all the slaves.
- ACL slaves can only transmit when requested by the master.
- A Class 1 device has a maximum output power of 100mW (20dBm) and has a range of about 100m.
- A Class 2 device has a maximum output power of 2.5mW (4dBm) and has a range of about 20m.
- A Class 3 device has a maximum output power of 1mW (0dBm) and has a range of about 10m.

System overview

The system and its parts

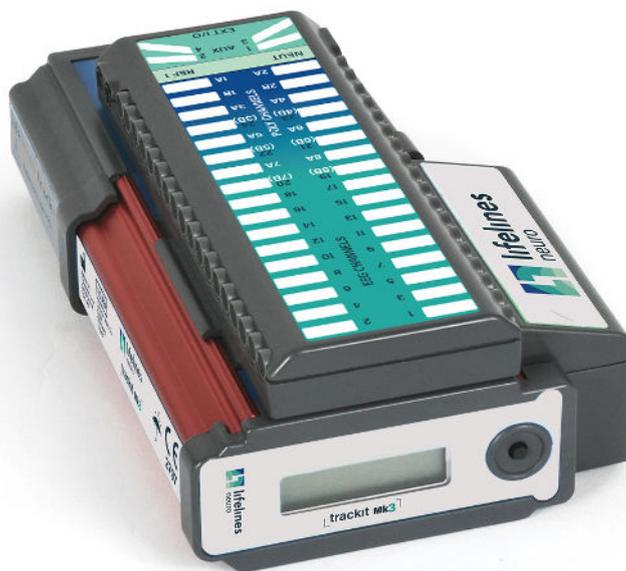


Figure 28: Trackit Mk3 with Internal Bluetooth Module

Internal Bluetooth

Trackit Mk3 has built-in Bluetooth capability which can be ordered as an option. When present there is a small 'β' on the display as shown in Figure 5 on page 22. This internal Bluetooth can be enabled by pressing the pushbutton 5 times within 3 seconds whereupon the display will change to a 'B'. Note that when enabled, the normal serial cable communication with the host PC becomes inoperative. At any time the Bluetooth can be disabled by again pressing the pushbutton 5 times within 3 seconds. This will restore the serial cable communication.

The module is qualified against Bluetooth specification V1.1 or V2.0 (later modules) and it will communicate with any similarly qualified Bluetooth device elsewhere. This means that the Bluetooth host (client) can be any standard qualified Bluetooth peripheral device bought off-the-shelf. Lifelines does not supply the device at the host end and the User can make his own choice from the wide range available. Note that to achieve the maximum transmission range, this Bluetooth device should be of the High Power (Class 1) type to match the Trackit Module. Lower power devices (Class 2 and Class 3) will still work, but the range will be less. The receiver sensitivity should also be as good as possible because this also helps to maximise the transmission range. Look for a sensitivity figure of at least -80 dBm (for 0.1% BER) or better.

These standard qualified Bluetooth devices are available as USB converters, PC-card or CF-card converters, Serial Port converters and even built-in to PDA devices, Laptops and desktops. The Trackit Mk3 will communicate with all these devices through the standard Trackit Setup or Wizard Setup programs that have been enhanced to provide transparent Bluetooth functionality. These programs will work over a direct connection, over a Bluetooth wireless connection or over a network or even over a combination of connections.

What you can do with a Trackit Bluetooth link:

- Connect wirelessly to any Trackit within range equipped with a Bluetooth Module
- Control the Trackit wirelessly (Acquire on/off, Ongoing on/off, Impedance Check on/off, Recording on/off, Calibration on/off etc.)
- Send setups to the Trackit wirelessly
- Review the Trackit status wirelessly (general system status as well as Trackit time, recording time, battery level, disk level, SaO2 level, heartrate etc.)
- Monitor the Trackit Ongoing traces wirelessly
- Acquire wirelessly and record on a PC (this is using the Trackit as a wireless Headbox)
- Connect wirelessly as a second user (a Guest) and review Trackit status and also monitor Ongoing traces, Imp. Check, Events etc.
- Mark an event over the wireless link
- Optionally configure the Trackit to automatically record locally whenever the wireless link is lost
- Connect wirelessly and directly to several Trackits simultaneously from the same PC. These Trackits are also simultaneously available for Guest connections

Connection and use

The Trackit Setup and Trackit Wizard programs have been enhanced to provide transparent Bluetooth support. All the functionality of the programs is available over a direct connection or a Bluetooth connection. Note that the Trackit should be fitted with V2.10.x or later firmware.

Figure 29 below shows the new Trackit Control Panel with the additional Bluetooth features.

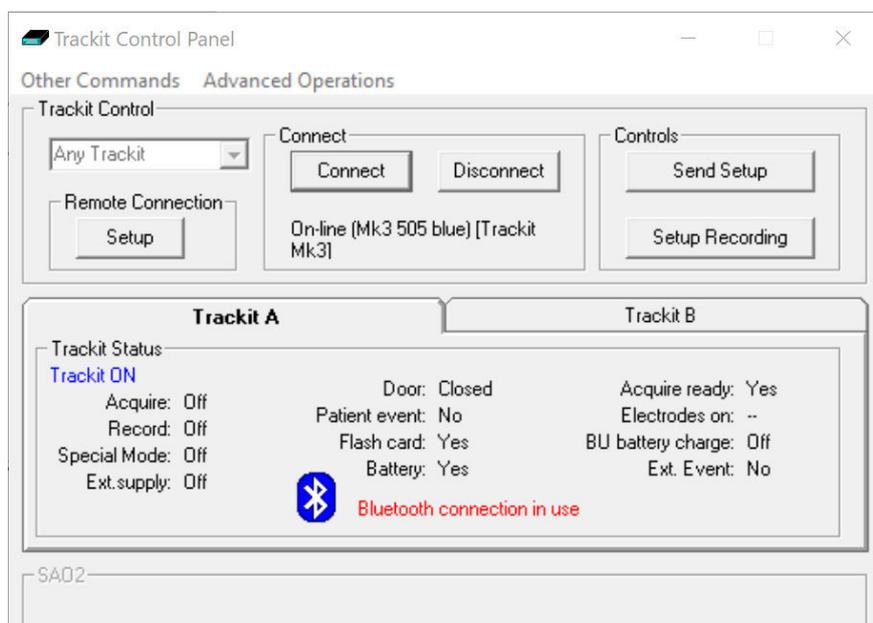


Figure 29: The Trackit Control Panel

Refer to the Trackit Plus software manual for more details on Trackit Bluetooth connection and usage.

Trackit Bluetooth Battery Power Consumption

The Trackit Bluetooth Module takes its power from the Trackit's main batteries. All the circuitry has been designed to consume as little power as possible and to utilise low-power modes whenever possible, however certain parts of the module are always on in order that searches and connection requests from other devices are serviced. In the tables below will be found an approximate indication of the reduction in battery life according to the Trackit main operating modes.

The Trackit modes are as follows :

1. Trackit Idle (not recording)
2. Trackit Acquire On (not recording) in Headbox mode
3. Trackit Recording
4. Trackit recording with Ongoings on

The Bluetooth modes are as follows :

1. No Bluetooth
2. Bluetooth power-down (discoverable and connectable) – only applicable to original module
3. Bluetooth normal not connected (discoverable and connectable)
4. Bluetooth normal connected
5. Bluetooth normal connected and transmitting

4th Generation Bluetooth Module (OBS433i) Internal (Trackit Mk3)

Trackit operating mode	Battery life reduced to %	Typical battery life (1 alkaline) Hours
	Trackit Mk3	Trackit Mk3
Trackit idle (not recording), no Bluetooth	100	20.2
Trackit idle (not recording), Bluetooth not connected	90	18.1
Trackit idle (not recording), Bluetooth connected	54	11.0
Trackit acquire (not recording), Bluetooth connected, Headbox on	63	7.2 [#]
Trackit (recording), no Bluetooth	100	12.0 [#]
Trackit (recording), Bluetooth not connected	95	11.4 [#]
Trackit (recording), Bluetooth connected	72	8.6 [#]
Trackit (recording), Bluetooth connected, ongoings on	60	7.2 [#]

NOTES:

1. Acquisition: 24 channels at 200 Hz using a Trackit T18/8 variant (fitted with 8 Poly Channels).
Add approximately 10% to battery life if internal 8 Poly Channels not fitted (T24/0 and T12/0)
2. Connected/not connected refers to wireless Bluetooth connection present or not present
3. When using the New Generation 3 and 4 Bluetooth Modules (OEMSPA332i and OBS433i) there is no benefit to using low power mode, so the option should be left off.

Bluetooth Range

The latest 4th Generation Bluetooth Module has a significantly longer range than all the earlier modules. The biggest benefit is achieved when a similarly high-performance Bluetooth device is used at the PC end of the wireless link. The typical range figures here were obtained with the following types of Bluetooth device installed in the PC:

1. Internal Class 3 fitted to laptop
2. External Class 1 USB-type fitted to laptop (this is the type with an external rotateable antenna approximately 60mm long)
3. External Class 1 USB-type (long range) fitted either with a stub antenna, manufactured by Sena (Parani UD100 USB/Bluetooth device)
4. As above (long range) but fitted with long range 180mm dipole antenna, manufactured by Sena (DAT5-G01R)

The best results are obtained when the PC-end antenna is orientated at 45 degrees to the horizontal.

Range (typical) direct line-of-sight, no obstacles

Trackit and Module type	PC Bluetooth device type			
	1 Class 3 Internal laptop	2 Class 1 external with 60mm antenna	3 Class 1 long-range with stub antenna	4 Class 1 long-range with 180mm antenna
Trackit Mk2 + 3rd Generation Bluetooth module	10m	44m	60m	110m
Trackit Mk3 + 4th Generation module	12m	85m	90m	190m

Trackit and Bluetooth Module Setup

The Trackit and the Bluetooth Module are setup from the Trackit Defaults screens. Refer to the Trackit Plus software manual for Trackit Bluetooth module setup.

Trackit Bluetooth Module Specifications

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

There are several versions of the Bluetooth Module: Type 1 is designed to be connected to the Trackit Mk1 or Mk1+ and Type 2 the Trackit Mk2. These have a 9-pin and 15-pin micro-D connector fitted respectively. Additionally, there are two versions of the internal Bluetooth circuitry: Original (OEMSPA33i) and 3rd Generation (OEMSPA332i) and the latest 4th Generation (OBS433i). The 3rd and 4th generations are significantly smaller and lower power consumption than the Original. The 3rd Generation was introduced in May 2006, the 4th in January 2012.

These versions are identified as follows:

1. Original Type 1 for Trackit Mk1. Part number marked on cable 6738-000. Lifelines part 1048.
2. Original Type 2 for Trackit Mk2. Part number marked on cable 6738-100. Lifelines part 1121.
3. 3rd Generation Type 1 for Trackit Mk1. Part number marked on cable 6738-200. Lifelines part 1048.
4. 3rd Generation Type 2 for Trackit Mk2. Part number marked on cable 6738-300. Lifelines part 1121.
5. 3rd Generation Internal for Trackit Mk2 and Mk3 only.
6. 4th Generation Internal for Trackit Mk3 only.

NOTE: The 4th Generation module has a much improved range, refer below.

Parameter Data

Original (OEMSPA33i)	
Bluetooth Module manufacturer:	connectBlue AB, Sweden
Bluetooth radio:	Infineon/Ericsson PBD 313 02 (MIRIAN)
Bluetooth base band controller:	Infineon/Ericsson PBM 990 90 (BLINK)
RF output power:	Class 1, min -28dBm, max +16dBm
Note:	0 dBm = 1 mW, 20 dBm = 100 mW
Receive sensitive level:	-80dBm (0.1% BER)
Receive input level (max):	Max +15 dBm
Output frequency:	2.402 -2.480 GHz, ISM band.
Point to multi-point operation:	Yes
Bluetooth stack:	Embedded host stack
Bluetooth qualification:	1.1

3rd Generation (OEMSPA332i)	
Bluetooth Module manufacturer	connectBlue AB, Sweden
Bluetooth radio	Philips BGB203
Bluetooth base band controller	Philips BGB203
RF output power	Class 1, min -28dBm, max +16.9dBm (49mW)
Note	0 dBm = 1 mW, 20 dBm = 100 mW
Receive sensitive level	-89dBm (0.1% BER)
Receive input level (max)	Max +16dBm
Output frequency	2.402 -2.480 GHz, ISM band.
Point to multi-point operation	Yes
Bluetooth stack	Embedded host stack
Bluetooth qualification	2.0

4th Generation (OBS433i)

4th Generation (OBS433i)	
Bluetooth Module manufacturer	connectBlue AB, Sweden
Bluetooth radio	ST-Ericsson STLC2500DB
Bluetooth base band controller	ST Microelectronics STM32F10x
RF output power	Class 1, min -28dBm, max +17dBm (50mW)
Note	0 dBm = 1 mW, 20 dBm = 100 mW
Receive sensitive level	-94dBm EIRP (0.1% BER)
Receive input level (max)	Max +5dBm
Output frequency	2.402 -2.480 GHz, ISM band.
Point to multi-point operation	Yes
Bluetooth stack	Embedded host stack
Bluetooth qualification	2.1 + EDR

Regulatory

Original (OEMSPA33i)	
R&TTE Directive 1999/5/EC	EN 300 328-2 V1.1.1 (2000-07)
EMC Directive: 89/336/EEC	EN 301 489-1 V1.3.1 (2001-09) EN 301 489-17 V1.1.1 (2000-09) EN 61000-6-2 (1999)
Low Voltage Directive: 73/23/EEC	EN 61131-2
Medical Electrical Equipment	IEC 60601-1-2

3rd Generation (OEMSPA332i)	
R&TTE Directive 1999/5/EC	EN 300 328 V1.6.1 (2004-11)
EMC Directive: 89/336/EEC	EN 301 489-1 V1.4.1 (2002-08) EN 301 489-17 V1.2.1 (2002-08) EN 61000-6-2 (2001)
Safety Compliance	EN 60950-1:2001 and/or IEC 60950-1:2001 (1st Edition) EN 60950-1/A11:2004 + Corrigendum:2004
Medical Electrical Equipment	IEC 60601-1-2 (2001)

4th Generation (OBS433i)	
R&TTE Directive 1999/5/EC	EN 300 328 V1.7.1 (2006-05)
EMC Directive: 89/336/EEC	EN 301 489-1 V1.8.1 (2008-04) EN 301 489-17 V1.3.2 (2008-04) EN 61000-6-2 (2005)
Safety Compliance	EN 50371:2002 EN 60950-1:2006 and/or IEC 60950-1:2005 (2nd Edition)
Medical Electrical Equipment	IEC 60601-1-2 (2007)

If the module is used within EU a notification must be made to each of the national authorities responsible for radio spectrum management of the intention to place radio equipment that uses frequency bands whose use is not harmonized throughout the EU, on its national market.

More information at: <http://europa.eu.int/comm/enterprise/rtte/gener.htm>

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

IC Compliance

Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been designed to operate with an antenna having a maximum gain of 8dBi. Having a higher gain is strictly prohibited per regulations of Industry Canada. The required antenna impedance is 50 ohms.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website www.hc-sc.gc.ca/rpb

Labelling Requirements for End Product

For an end product using the OEM Serial Port Adapter or the OEM Bluetooth Enabler there must be a label containing, at least, the following information:

Original (OEMSPA33i)	
This device contains	
FCC ID	PVH070201

3rd Generation (OEMSPA332i)

3rd Generation (OEMSPA332i)	
This device contains	
FCC ID	PVH090202L
IC	5325A-090202L

4th Generation (OBS433i)

4th Generation (OBS433i)	
This device contains	
FCC ID	PVH0939
IC	5325A-0939

The label must be affixed on an exterior surface of the end product such that it will be visible upon inspection in compliance with the modular approval guidelines developed by the FCC.

RF-exposure Statement

This portable modular transmitter MUST have a separation distance of at least 2.5cm between the antenna and the body of the user or nearby persons, excluding hands, wrists, feet, and ankles.

Bluetooth Qualification

Original (OEMSPA33i)

The Serial Port Adapter has been qualified according to Bluetooth 1.1 specification, QPLN reference GRA 001 03, qualification date 2003-01-31.

The following Bluetooth profiles are supported (covered functionality):

- Generic Access Profile
- Serial Port Profile
- Dial-up Networking Profile
- LAN Access Profile

3rd Generation (OEMSPA332i)

The Serial Port Adapter has been qualified according to Bluetooth 2.0 specification, QPLN reference B02993, qualification date 2006-03-17.

The following Bluetooth profiles are supported (covered functionality):

- Generic Access Profile
- Serial Port Profile
- Dial-up Networking Profile

4th Generation (OBS433i)

The Serial Port Adapter has been qualified according to Bluetooth 2.1+EDR specification, QDID reference B016927 combined with B015102.

The following Bluetooth profiles are supported (covered functionality):

- Generic Access Profile
- Serial Port Profile
- Dial-up Networking Profile
- Personal Area Networking Profile

Guidelines for Efficient and Safe Use

Read this information before using your Serial Port Adapter.

For any exceptions, due to national requirements or limitations, when using your Serial Port Adapter, please visit www.bluetooth.com.

Product Care

- Do not expose your product to liquid or moisture.
- Do not expose your product to extreme hot or cold temperature
- Do not expose your product to lit candles, cigarettes, cigars, open flames, etc.
- Do not drop, throw or try to bend your product since rough treatment could damage your product.
- Do not attempt to disassemble your product. Doing so will void warranty. The product does not contain consumer serviceable or replaceable components.
- Do not paint your product as the paint could prevent normal use.
- If you will not be using your product for a while, store it in a place that is dry, free from damp, dust and extreme heat and cold.

Radio Frequency Exposure

The Serial Port Adapter contains a small radio transmitter and receiver. During communication with other Bluetooth products the Serial Port Adapter receives and transmits radio frequency (RF) electromagnetic fields (microwaves) in the frequency range 2400 to 2500 MHz. The output power of the radio transmitter is very low.

When using the Serial Port Adapter, you will be exposed to some of the transmitted RF energy. This exposure is well below the prescribed limits in all national and international RF safety standards and regulations.

Electronic Equipment

Most modern electronic equipment, for example, in hospitals and cars, is shielded from RF energy. However, certain electronic equipment is not. Therefore:

NOTE: This equipment emits RF energy in the ISM (Industrial, Scientific, Medical) band.

Please ensure that all medical devices used in proximity to this device meet appropriate susceptibility specifications for this type of RF energy.

Potentially Explosive Atmospheres

Turn off your electronic device when in any area with potentially explosive atmosphere. It is rare, but your electronic device could generate sparks. Sparks in such areas could cause an explosion or fire resulting in bodily injury or even death.

Areas with a potentially explosive atmosphere are often, but not always, clearly marked. They include fuelling areas, such as petrol station, below deck on boats, fuel or chemical transfer or storage facilities, and areas where the air contains chemicals or particles, such as grain, dust, or metal powders.

Bluetooth Knowledge Base

1. The list of adapter hardware used by Lifelines so far is as follows :
 - Belkin Bluetooth USB adapter F8T001
 - Ezurio/TDK Bluetooth USB adapter "go blue"
 - Newlink Bluetooth USB adapter USBBTC1A-N-CDL
 - Anycom Bluetooth Compact Flash Card CF-2001
 - Bluemonkey Bluetooth Compact Flash Card BlueCF
 - Linksys USBT100
2. It has been found that some 3rd party Bluetooth adapters will drop a connection for no apparent reason. This effect can be tested by connecting to the Trackit and switching ongoings on. This produces a lot of predominantly one-way traffic. The connection should never be dropped. This effect has been found using the Belkin F8T001 Bluetooth USB Adapter. The problem has been fixed by installing a later version of the WidcommSdk.dll in the system32 folder. Version 1.4.1.6 or later seems to fix the problem.
3. It has been found that some 3rd party Bluetooth adapters will drop a connection when the Trackit Bluetooth is set up for multi-drop support, even when there is only one connection. This effect has been found using the Belkin F8T001. The solution is to either disable multi-drop on the Trackit Bluetooth Module or to make the Belkin device Undiscoverable AND Unconnectable. This effect has not been found on other devices so far - the TDK and Newlink adapters are ok.
4. It has been found that some 3rd party Bluetooth adapters will not support several simultaneous connections. This has been found on the Belkin F8T001 which only seems to support a single connection. The TDK adapter does allow several simultaneous connections. In any event, you should expect data transfers to slow when using several simultaneous connections.
5. Sometimes it may appear that your Bluetooth connections in **My Bluetooth Places** or **Entire Bluetooth Neighbourhood** seem to be forgotten when the Bluetooth adapter is unplugged or after a power-off. Also, you may find that you cannot allocate a Comm Port to your connection (each Trackit Blue x connection needs its own Comm Port). The reason for this is that you have set up a temporary connection in **Entire Bluetooth Neighbourhood** rather than a shortcut reference in **My Bluetooth Places**. Here, connection definitions are permanent and you can allocate Comm Ports at will. When setting up a Trackit connection for the first time, you should use the proper Wizard or other method as provided by the adapter manufacturer. If you find that you can allocate a Comm Port to a connection, but there are not enough virtual Comm Ports to select from in the list, check in Device Manager that there are enough ports called "Bluetooth Communications Port (COM x)" for your use. If not, either use your adapter application to add some more or use the Windows Add/Remove Hardware Wizard to add "Ports (COM & LPT)" followed by WIDCOMM.
6. There can be problems installing Bluetooth adapters in **Windows XP SP2** computers. Refer to the article in the following link for more information: <http://support.microsoft.com/?kbid=840635>. Basically, rename the %WINDIR%\inf\Bth.inf file to Bth.bak before installing the Bluetooth adapter.

Appendix 6: Troubleshooting Guide

COM port problems with Bluetooth communication to Trackit Mk3

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 Trackit Status, in the Control Panel, check that Acquire Ready shows Yes. If it is not ready, acquisition cannot begin. This could be caused by incomplete transmission of the Trackit setup. Try to adjust the transmission delay for serial communication in the Trackit software as described above.

An incorrect setup has been sent

If an incompatible setup has been sent to the Trackit the message; "unable to comply" will indicate that. The usual cause for this is if a T36 or T24P setup has been sent to a Trackit 24: the presence of poly channels resulting in the setup being rejected. 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 16-bit FAT, a recording cannot commence. Format the flash card using the inbuilt Trackit format utility under Get Card Info. See 'Get Card Info' in 5.5 Advanced Settings.



Do not attempt to do a low-level format, or do a standard format using a SCSI or USB card reader.

The card is corrupted

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

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

Card reader: make sure the device is stopped, in Card Services, before removing the Card. This is especially important in Win2000 systems using a USB card reader, where the activity LED stays on for several seconds after deleting an old file. If the card is removed when this LED is on, the card will be corrupted and a reformat will be necessary. Always stop and eject the card using the icon in the Windows system tray before physically ejecting it.

The card is not inserted correctly

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

File review problems

The card is not formatted in FAT16

When a recording is made on a card formatted in FAT32 it will appear to be severely truncated and most probably unreadable. If you know a recording has a duration of >24 hours but it only shows up as several minutes in review, the most likely cause is that the card is not formatted in FAT16.

NOTE: This problem does not occur if the format has been performed using the inbuilt Trackit format utility.

NOTE: Trackit software detects corrupted or incorrectly formatted cards prior to recording.

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.
	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 Mk3, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the Trackit Mk3, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.
	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.

Accessory name	Type	Length	Description
PCU cable 32ch	IEEE 1284 C-C shielded	1 m	Shielded IEEE 1284 C-C cable
USB Interface Cable	USB	2.8 m	USB shielded cable
RJ45 cable	Cat 5 UTP Patch Cable	2 m	Cat 5 UTP Patch Cable
Input electrodes	EEG disc electrodes	1 m	Unshielded EEG disc electrodes
Aux. Connector cable	Shielded	1 m	Shielded cable

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

EN 60601-1-2

The Trackit Mk3 is intended for use in the electromagnetic environment specified below. The customer or user of the Trackit Mk3 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The Trackit Mk3 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 Trackit Mk3 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.
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 Trackit Mk3 is intended for use in the electromagnetic environment specified below. The customer or user of the Trackit Mk3 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	+/- 6 kV: Contact +/- 15kV: Air	+/- 6 kV: Contact +/- 15kV :Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. In home environments and portable or transport situations, the Trackit should be housed in the Trackit bag to protect it from high ESD disturbances.
Electrical fast Transients/burst IEC 61000-4-4	+/- 2 kV:AC mains +/- 1 kV:Signal lines	+/- 2 kV:AC mains +/- 1 kV:Signal lines.	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	+/- 2 kV:Common mode +/- 1kV:Differential mode	+/- 2 kV:Common mode +/- 1kV:Differential mode	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	<5% 230 V (>95% dip in 230 V) for 0.5 cycle 40% 230 V (60% dip in 230 V) for 5 cycles 70% 230 V(30% dip in 230 V) for 25 cycles <5% 230 V(>95% dip in 230 V) for 5 sec	<5% 230 V(>95% dip in 230 V) for 0.5 cycle 40% 230 V(60% dip in 230 V) for 5 cycles 70% 230 V(30% dip in 230 V) for 25 cycles <5% 230 V(>95% dip in 230 V) for 5 sec	Mains power should be that of a typical commercial and/or hospital environment. If the user of the Trackit Mk3 system requires continued operation during power mains interruptions, it is recommended that the Trackit Mk3 system be powered from an uninterruptible power supply or a battery

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m, 30A/m	3 A/m See Note e.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF Electromagnetic Fields IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6V in ISM Bands 3 V/m 80 MHz to 2.5 GHz 10V/m (Home Environment)	1 Vrms 1 V/m See Note f.	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Trackit Mk3, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = [3.5/E] \sqrt{P}$</p> <p>Note: using unshielded input leads</p> <p>$d = [3.5/E] \sqrt{P} : 80 \text{ MHz to } 800 \text{ MHz}$</p> <p>$d = [7/E] \sqrt{P} : 800 \text{ MHz to } 2.5 \text{ GHz}$</p> <p>Note: using unshielded input leads</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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 Trackit Mk3 is used exceeds the applicable RF compliance level above, the Trackit Mk3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Trackit Mk3.			
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 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 unshielded input electrode leads 1 m in length and worse-case coupling, including any resonances across the frequency band. The interference is less when the polarisation plane of the interference source is not in the same plane as the electrode leads.			
e The Trackit Mk3 does not contain magnetic components and is not susceptible to power frequency magnetic field interference.			
f The conditions of intended use justify lower immunity test levels. The hazards and risk analysis associated with these lower limits have been documented in the Risk Management file			

Recommended separation distance between portable and mobile RF communications equipment and the Trackit Mk3 EEG System

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

The Trackit Mk3 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Trackit Mk3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Trackit Mk3 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 Mk3 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

V1.8 (28 January 2010)

- Virus protection recommendations added, Page 5.
- Lifelines logo adjusted, Page 3.
- References to Windows 98 and ME removed, Sections 1.4 and 4.
- Check with distributor for later software version added, Section 4.
- Picture of latest main Toolbar updated, Figure 16, and table below updated.
- Picture of main ongoing display window updated, Figure 23.
- Appendix 3 added, Photic and Hyperventilation. Photic refers to separate documentation. Old Appendix 3 now Appendix 4.
- Appendix 4 added, Trackit Plus and Plus with Video Software. Both refer to separate documentation. Old Appendix 4 now Appendix 5.
- Appendix 5 added, Bluetooth Wireless. Refer to separate documentation. Old Appendix 5 now Appendix 6.

V2.0 (April 2010)

- Reformatted to A4 page size
- Added full documentation to Appendix 4:
 - Section 1 Record to PC
 - Section 2 Network Connection
 - Section 3 Video
- Added full documentation to Appendix 5: Bluetooth Wireless
- Appendix 7: Troubleshooting guide moved to Appendix 8
- Appendix 8: Manufacturer's Declaration moved to Appendix 9
- Added Appendix 7: Trackit Setup Wizard

V2.1 (June 2010)

- Added Bluetooth indicator to Figure 6
- Added 'Internal Bluetooth' paragraph to Appendix 5
- Minor amendments to section 5.7 'Reading an ambulatory recording'
- Minor amendments to Appendix 4 'Network Connection'

V2.2 (September 2011)

- Trackit Mk3 introduced: USB Interface detail added to Sections 1.2, 1.3, 3.1, 3.2 and 4.2.
- Large memory cards (FAT32) added in Section 5.6.
- Aux Box 2 added in Appendix 2.
- More Setup parameters added to Appendix 5.
- Quick Setup Guide adjusted in Appendix 6.
- Troubleshooting adjusted in Appendix 8.

V2.3 (May 2014)

- Latest 4th Generation internal Bluetooth details added in Appendix 5
- Bluetooth recording times and range details added
- Latest version low-power XPOD Pulse Oximeter details added in Appendix 2

V2.4 (February 2018)

- Added disinfection information in section 2.7.
- Changed N.B. to 0086 (BSI).

V2.5 (August 2019)

- EMC warnings and information updated

V3.0 (June 2020)

- Updated with new design and images
- Trackit Software section moved to separate User manual
- Advanced Trackit Settings (Defaults)' moved to Appendix 2.
- Changed N.B. to 2797 (BSI Netherlands)
- Added EC Rep details
- Removed Bluetooth module setup information (now located in Trackit Plus Software manual).



Lifelines
neuro

trackit Mk3

Ambulatory EEG Recorder

Lifelines Ltd,

7 Clarendon Court, Over Wallop, near Stockbridge,
Hampshire SO20 8HU, UK

Telephone +44 (0)1264 782226

www.LLines.com

sales@LLines.com

Imagine EEG Anywhere