trackit SOLO

MADE IN BRITAIN

USER MANUAL

lifelines® neuro

Imagine EEG Anywhere

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Customer Responsibility

The Trackit Solo 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.

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 representative and for any malfunctions caused by any parts that have been damaged or modified by anyone other than a qualified Lifelines representative.

The owner of this system has the sole responsibility for the connection of this product to other systems which do not satisfy the electrical safety requirements of standards IEC 60601-1 and IEC 60601-1-2 for medical devices.

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

Disclaimers & Warranties

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

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

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

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

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

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

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

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

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

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

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Trademarks

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

Responsibility of manufacturer

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

- any peripheral equipment to be used with the Trackit Solo 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 in accordance with the instructions for use.

NOTE: Equipment specifications are subject to change without notice.

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. Please note the following recommendations which should be supported by your internal IT/Computing department procedures and practices:

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

General Security Policies

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

Networked Environments

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

Warnings and Cautions

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

	The Trackit Solo EEG system, including the EEG amplifier, must be operated by a healthcare professional who is familiar with EEG equipment and practice. This user manual must be read in its entirety before the equipment is used.
	Do not modify this equipment without the authorization of the manufacturer.
	The use of accessories and cables other than those specified, with the exception of accessories and cables sold by the manufacturer of the equipment, may result in increased emissions or decreased immunity of the equipment.
	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.
	Do not connect any external equipment to the Trackit Solo if the EEG amplifier is connected to the Solo via a USB cable.
	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 Solo, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the Trackit Solo and the EEG amplifier do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.
	Do not allow any liquid to enter the case of the Trackit Solo. Do not use acetone on any of the instruments.
	The Trackit Solo EEG System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

Contraindications

There are no known contraindications to the use of this equipment.

Residual Risks and Side Effects

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

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Appendices

Illustrations

1 Overview and Technical Description

1.1 General Description

Intended Use

The Trackit Solo is intended to be used in combination with a compatible Lifelines EEG amplifier for the collection and display of video and EEG data in EEG studies.

Intended User

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

Trackit Solo Setup and Description

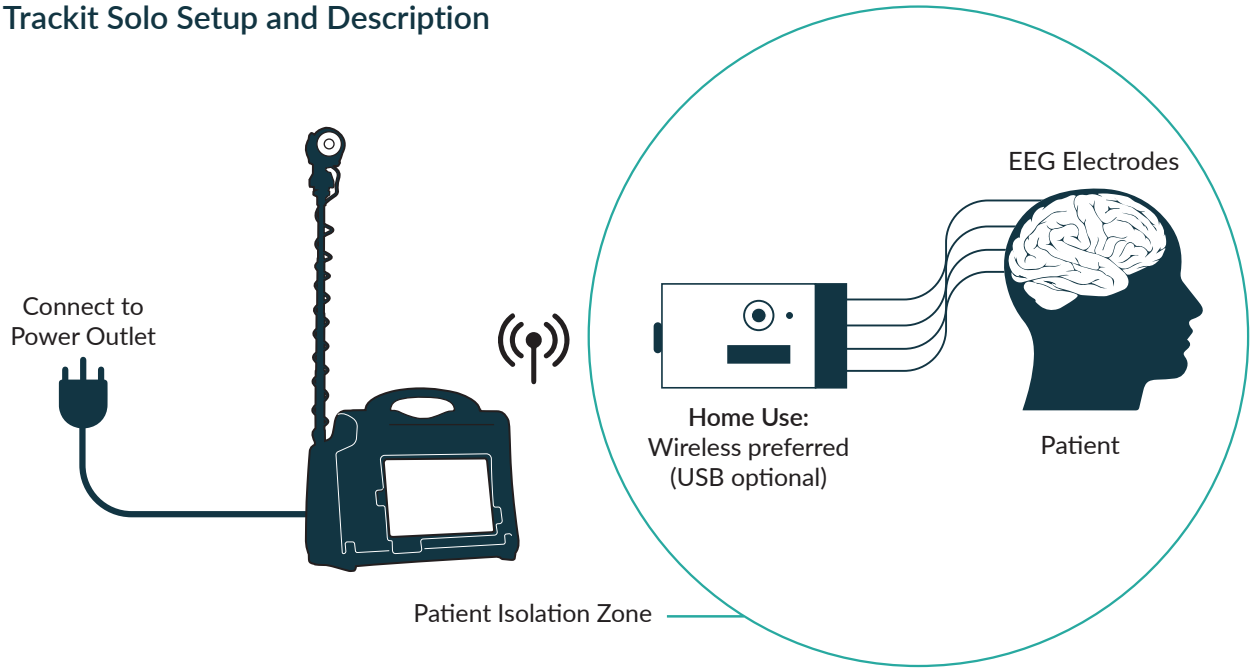


Figure 1 Trackit Solo Patient Environment setup

The Trackit Solo is an optional accessory that can be used as a component with compatible Lifelines EEG amplifiers (e.g. Trackit T4A or Trackit T4) as part of an EEG recording. The Trackit Solo is a portable data acquisition and communications system that works in tandem with the EEG amplifier to allow EEG and video data to be recorded locally and monitored remotely. The Trackit Solo wirelessly receives data from the EEG amplifier (via Bluetooth) and relays that data, along with video data acquired from the onboard camera, via the EEG software package which runs locally on the Trackit Solo. The data can then be relayed to an approved cloud-based software (e.g. Stratus iEEG), which allows clinical staff to access and monitor the data from any compatible device. Alternatively, the data, which is recorded locally as well, can be accessed via a remote desktop application (e.g. Teamviewer).

The Trackit Solo comprises a 10” tablet PC with a high-definition, infra-red camera. The system is powered with a medical grade power supply to ensure patient safety. The HD camera is fitted to a retractable extension pole. The Trackit Solo feature a Lithium-ion battery power source and can run on battery for up to 3 hours (EEG software dependant).

The EEG System contains several wireless connections, including Bluetooth from the Trackit Solo to the amplifier, as well as WiFi and LTE from the Trackit Solo to a remote network for data upload to the cloud-based software. The Trackit Solo contains an infrared camera that can be manually repositioned to keep the patient in view. This camera is mounted to the Trackit Solo. The Trackit Solo has additional USB & Network ports available for the connection of additional or different approved cameras.

The Trackit Solo is lightweight and durable. It possesses a shoulder strap and a handle that allows it to be carried. This allows the Trackit Solo to be moved with the patient. The Trackit Solo is designed such that it can be wirelessly connected to an ambulatory amplifier by clinical personnel, and then used by the patient for the duration of an EEG study in their home or clinical environment. After the study is completed, clinical personnel can disconnect the patient from the amplifier and retrieve the Trackit Solo.

1.2 Explanation of symbols

Symbol	Description
	Follow operating instructions
	Keep dry
	Manufacturer
	European Representative
	Special recycling required, do not dispose of in landfill. This product contains batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. When this equipment has reached the end of its useful life, follow all local laws and regulations for the proper recycling and disposal of such equipment. Contact your local distributor for information..

Storage and transport symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Temperature limits		Fragile		Keep dry
	Relative humidity limits		Barometric pressure limits		

1.3 Component and Part Numbers

Component	Part Number
Trackit Solo	1700xx-L1 (xx = US, UK or EU)

2 Installation and Maintenance

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

⚠	This 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.

2.1 Checks for completeness and integrity

1 Remove the equipment from the packaging case(s).

2 Use the parts list to check that all ordered items have been received.

3 Check for signs of damage that may have occurred during transit or storage. If any damage is found, do not use the instrument; contact your distributor.

2.2 Environmental parameters for operation

The operational and storage/transportation environmental conditions are as follows:

Operation The instrument is designed to operate within the following ranges:		**Storage and transport** When the instrument is in store or being transported, the following ranges are tolerated:	
Temperature	-10°C to +45°C (+14°F to +113°F)	Temperature	-20°C to +70°C (-4°F to +158°F)
Relative humidity	0% to 90% non-condensing	Relative humidity	0% to 95% non-condensing
Atmospheric pressure	700mB to 1060mB	Atmospheric pressure	500mB to 1060mB

⚠	**Do not obstruct any cooling slots. Position the instrument so that air flows freely.**

2.3 Power supply connections

Power requirements	100-240V~, 50-60Hz
Power consumption	60W (Maximum)

2.4 Use with other equipment

EEG amplifier

The patient will be connected to an EEG amplifier during the EEG examination. The EEG amplifier will be connected to the Trackit Solo via Bluetooth or USB to record the data acquired by the EEG amplifier.

Always refer to the relevant EEG Amplifier User Manual.

Other patient-connected equipment

The Trackit Solo has no patient-applied parts and so 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 be used as part of a Medical System which complies 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.

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

2.5 Interference

The Trackit Solo and EEG Amplifier will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of IEC 60601-1-2. However, EEG systems record signals of very low amplitude, and these signals themselves are not immune to the effects of RF, ESD and low-frequency magnetic field interference. Such interference may cause signal artefacts.

The Trackit Solo has internal Wifi, Bluetooth and LTE (4G) radios fitted. There are approved industry-standard types which present minimal risk of reciprocal interference with other equipment.

However, while in use other devices in the vicinity should be moved away or turned off to reduce the likelihood of interference to the equipment or by the equipment.

⚠	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit Solo, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
⚠	When in close proximity to the Trackit Solo, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
⚠	Medical Systems needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

2.6 Maintenance and cleaning

The Trackit Solo and its accessories require no routine testing, calibration, or maintenance procedures apart from cleaning and occasional checking for wear and damage to all parts including the accessories.

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

Cleaning and disinfection

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

Disinfection of the equipment can be carried out by the use of QAC-based disinfectants. Wipes are recommended to prevent the ingress of any liquid into the equipment. Suitable products include Mikrozid Sensitive Wipes (Schülke & Mayr GmbH), Microbac forte (Paul Hartmann AG), Distel Wipes (Tristel Ltd.), 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 any instrument or connector. Do not use acetone on any of the instruments.

2.7 Disposal of equipment

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

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

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

3 Operation

3.1 Overview

Figure 2 Front of Trackit Solo

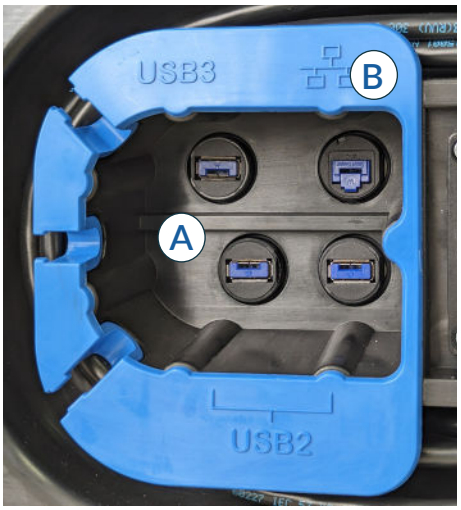
Indicators

Battery LED –

- Flashing blue LED while charging,
- Solid blue LED when not charging (while plugged in) or discharging (while unplugged)
- Flashing orange LED when battery is low (< 25%, less than 1-hour operating time remaining).

Power LED

- Solid blue LED when powered on
- Flashing orange LED when in standby mode.



Input/Output Ports

A. USB 3.0 Ports (x3)

B. LAN Port

C. SIM card slot for LTE/4G modem

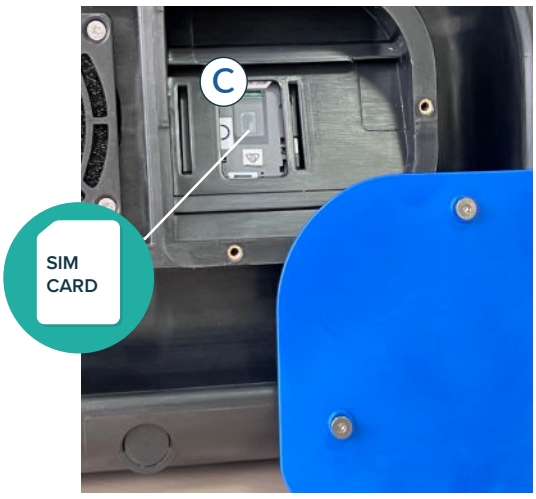


Figure 3 Back of Trackit Solo

3.2 Setting up the Trackit Solo

- Position the Trackit Solo on a solid, sturdy surface, off the ground (e.g. a coffee table).
- Unwrap the power cord fully and plug it in to a power source.
- Fully extend the camera pole and position the camera and Trackit Solo so that the patient is in view of the camera.

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

3.2.1 Switching On & Off

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

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

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

NOTE:	When the system is locked using the iEEG / Stratus EEG Acquisition “lock screen”, the Windows button and Windows menu are disabled. This prevents the patient from inadvertently turning off the system.
NOTE:	Avoid using the Power Button to turn off the tablet—this form of hardware shutdown is intended to be a means of recovery from lockups, and not as normal operation. Should the Solo lockup, press and hold the power button for 4 seconds to initiate a hard reset.

3.2.2 Connecting an EEG Amplifier

Bluetooth

The Lifelines EEG amplifier will need to be paired to the Trackit Solo in order to connect over bluetooth. Use the Windows Bluetooth settings to add a new Bluetooth device and follow the instructions in the EEG amplifier's user manual on how to pair the amplifier. Once paired, the EEG software will be able to connect to the amplifier.

USB

To connect the EEG Amplifier to the Trackit Solo via a cable, use the USB cable supplied with the EEG amplifier. Connect the cable to the amplifier and plug the USB connector into one of the three USB connectors on the back of the Solo.

ⓘ	**Do not connect any external equipment to the Trackit Solo if the EEG amplifier is connected to the Solo via a USB cable.**

3.2.3 Connectivity

Networking

The Trackit Solo is supplied with three methods of network and internet connectivity, namely:

- Wireless networking (802.11ac WLAN)
- Wired network (1000Mbps LAN)
- LTE / 4G Mobile connectivity (see Section 4).

Device Connectivity

The Trackit Solo offers three USB3.0 ports for device connectivity. These ports can be used to connect an HDMI monitor to the device, using a USB3.0-HDMI adapter (not included).

ⓘ	**Do not connect any external equipment to the Trackit Solo if the EEG amplifier is connected to the Solo via a USB cable.**

3.2.4 Screen Brightness & Control

The screen brightness can be controlled using the up and down arrows on the right side of the screen.

Pressing the “Display Off” button, at the bottom of the screen (see Figure 2), sets the screen brightness to the minimum level. This can be used for overnight recordings to minimize the light from the screen.

The screen can be turned back on by pressing Brightness up arrow.

Note:	**When turning off the screen for a long period of time (overnight) ensure the Trackit Solo is plugged into an AC power outlet.**

3.2.5 Camera operation

The camera should be configured with the preferred EEG application.

Extend the camera pole as required to ensure the patient is within view of the camera.

Note: **the camera can rotate 90 degrees left and right and tilt up and down.**

When carrying or transporting the Trackit Solo retract the camera pole back down first.

3.2.6 Battery Operation and Charging

The Trackit Solo uses a 90Wh battery which provides approximately 3 hours of battery operation. Keep the Trackit Solo plugged in to an AC power source to ensure that the battery does not discharge during a recording.

The Trackit Solo requires approximately 6 hours to fully recharge the battery.

The Battery LED on the left of the screen provides an indication of the charging state.

LED Colour	Status
Blue (Flashing)	Battery Charging
Blue (Solid)	Fully charged (when plugged into an AC Power source) Discharging (when unplugged from an AC Power source)
Orange (Solid)	Battery is low (< 25%, less than 1-hour operating time remaining).
Red (Flashing)	Charging stopped due to battery over-temperature.

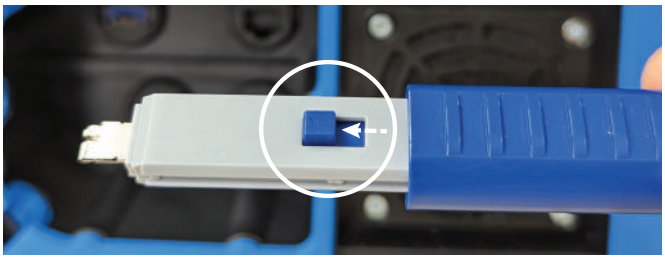
If the charging stops due to over temperature, check that the Trackit Solo is not near a heat source or in direct sunlight and check that the air vents are not blocked. Move the Trackit Solo to a cooler location.

3.2.7 Ports Locks

The Trackit Solo is supplied with port locks for the USB ports and the RJ45 port. These can be used to prevent the patient or unauthorised persons from tampering with the Trackit Solo and connecting unauthorised devices. Three USB port locks, one RJ45 port lock and a removal key are provided.

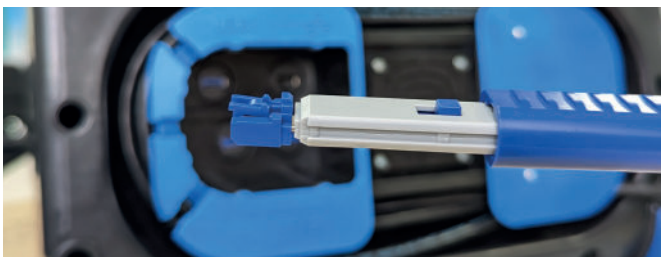
How to Use the Port Lock Key

To expose the key header, slide the cover until you hear a click.



1. Press the button forward to put the key into Insert Mode before engaging or releasing the port lock.

2. Insert the key into the port lock.



3. Pull the button back to engage the port lock. The port lock can now be removed.

Port Lock Installation

USB Port Locks

Insert the USB Port Lock by hand by pressing inwards with your fingers.

RJ45 Port Lock

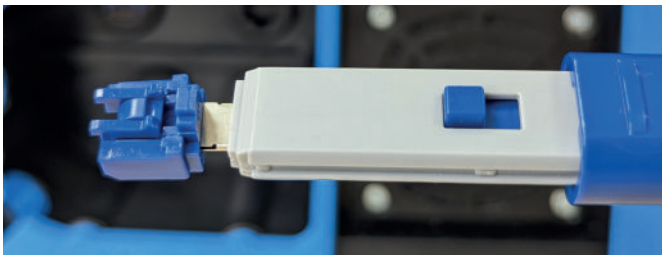
Insertion

The RJ45 port lock can only be installed while in the unlocked position. Insert by holding the sides so that it does not go into the locked position during installation.

> Note: **In case the lock is in the locked position, use the Lock Key to unlock it. Insert the key, slide the button back and holding the port lock, pull the key back until it's in the unlocked position.** (See *STEP 1, on previous page*)

Fit the RJ45 Port Lock into the port (as shown, left) and press the front part of the lock until it clicks into place.

Removal



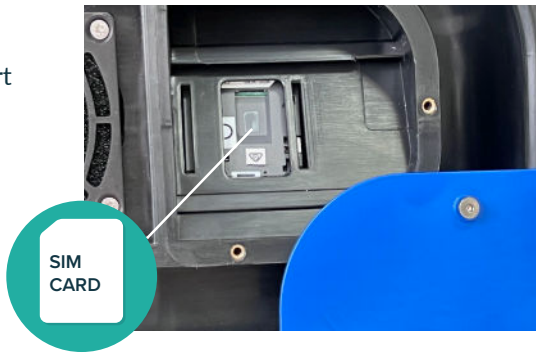
Follow the steps shown on the previous page, then, once the port lock is removed from its port, release the lock from the key by pressing the button forward.

4 LTE / 4G Mobile connectivity

4.1 SIM card

The Trackit Solo uses an LTE/4G modem to provide mobile data connectivity. The modem uses a nano-SIM card. Access to the SIM card is provided on the rear of the Solo, under the blue cover. Insert the SIM card as follows:

- Remove the cover by unscrewing the 3 x Torx screws using a T10 Torx driver (provided).
- Slide the SIM card upwards into the SIM card slot (gold contacts face towards the Solo)
- Replace the cover and refit the 3 x Torx screws.



4.2 Activating / Deactivating LTE

The LTE/4G (mobile data) connectivity should be enabled in the operating system when mobile data is required. The mobile data connection will be established when WiFi is disconnected, provided an active SIM card has been fitted.

> Note: When activated, the Mobile data connection takes priority over the wired network connection. If the wired network connection is required, the LTE modem should be disabled first.

Hold down the Function "Fn" Button while pressing the “Display On/Off” button to enable and disable the LTE Modem.

The LTE modem can also be enabled and disabled by double clicking on the LTE Modem icon (right) on the Windows Desktop.

4.3 Web User Interface (UI)

The LTE Modem uses a web User Interface (UI) to manage and monitor the mobile data network activity. When the LTE Modem is enabled and WiFi is disconnected, the web UI can be accessed from the Chrome browser on the Solo, via the URL http://my.usb or http://192.168.1.1. The Web UI allows the user to access device information, including Internet status/sessions and modem/network specifications as well as device settings.

The Web UI home page is shown in Figure 4. Click the arrow in the bottom-right corner of a panel to access pages with further information and options.

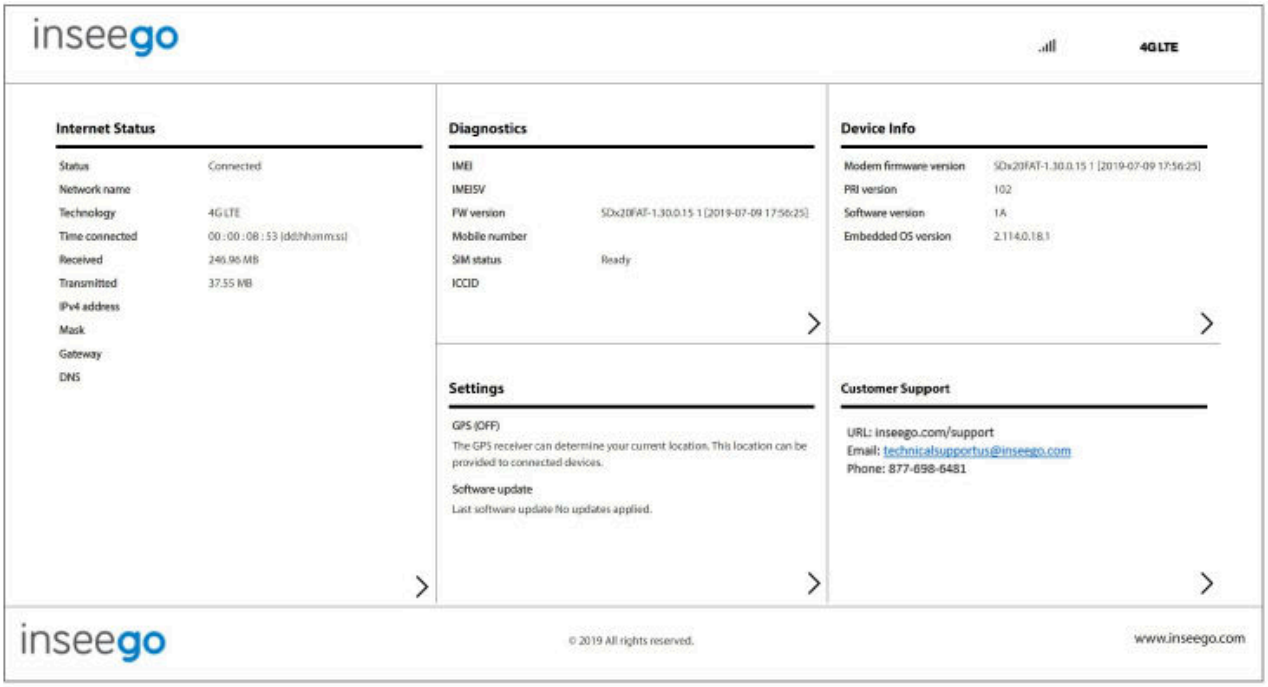


Figure 4: LTE Modem Web User Interface

Appendix 1: Trackit Solo Specifications

Overview	
CPU	Intel® Core™ i7-1165G7, 4-Core, up to 4.7 GHz (*Solo Issue 1*) Intel® Core™ i7-1355U, 10-Core, up to 5.0 GHz (*Solo Issue 2 onwards*)
RAM	16 GB
Storage	512GB Flash
Operating System	Windows 10 Enterprise or Windows 11 Enterprise
Display	10.1” LED-backlight, high-brightness (800 nits) capacitive touch screen
Display Resolution	1920 x 1200
Controls	1 power button, 3 function buttons, 2 brightness control buttons.
Indicators	1 x Battery indicator 1 x Power Indicator
I/O Ports	3 x USB 3.0, 1 x RJ45 Ethernet
Speaker	Built in Speaker
Battery Pack	8000mAh Li-ion battery.

Power Input	
AC Input	100 – 240 VAC, 50 – 60Hz
Max Input Current	1.5A
Wattage	60W
Safety	
Dielectric Withstand Voltage	4000VAC
Touch Current	20µA max.
Earth Leakage Current	300µA max. NC/SFC
Means of Protection	2 x MOPP
Earth Protection	Class I

Networking & Wireless	
Ethernet	1000Mbps
WLAN	Wi-Fi 802.11ax; 2.4GHz/ 5GHz dual band
LTE / 4G	
Model	**Inseego MC800**
Chipset	QUALCOMM® SDX20
Technology	LTE CAT 18, 480 Mbps LTE Max Throughput
Bands	B1/B2/B3/B4/B5/B7/B12/B13/B14/B17/B18/B20/B28/B29/B30/B66 HSPA+/UMTS: B1/B2/B4/B5/B8
SIM	4FF (Nano SIM)
Approvals	FCC (US), ISED (CAN), CE (EU), RCM (AUS), RSM (NZ), PTCRB; GCF
BLUETOOTH	
Standard	v4.0 low energy and v2.0, v2.1 wireless technologies
TX Output Power	9.8dBm
Rx Sensitivity	-86 dBm

Camera	
Maximum Resolution	1920 x 1080, 2.0 Megapixel
Night vision	IR LED x 10, 650nm IR wavelength
Audio	Single channel digital microphone
Swivel Tilt mount	180° swivel, 170° tilt,
Extension Pole	700mm (27.6in) from the base

Mechanical and Environmental	
Weight	5.5kg (12.12lb)
Dimensions	414.5mm x 325.6mm x 181.1mm (16.3in x 12.8in x 7.13in)
Operating temperature	-10°C to 45°C (14°F to 113°F) *During battery charging: -10°C – 30°C (14°F to 86°F)
Storage temperature	-20°C to 70°C (-4°F to 158°F)
Humidity	0% to 90% non-condensing

Classification	
Degree of protection against electrical shock:	No patient-applied parts, no accessible metalwork
Type of protection against electrical shock:	Class I device
Degree of protection against harmful ingress of water:	Ordinary (no protection).
Mode of operation:	Continuous.
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide:	Not suitable

Appendix 2: EMC Compliance

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

	The use of accessories and cables other than those specified, with the exception of accessories and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.
	Medical Systems needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here.
	The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Trackit Solo, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
	When in close proximity to the Trackit Solo, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields.

Guidance and Manufacturer's Declaration

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

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

Electromagnetic Emissions

Emissions Test	Compliance	Guidance
RF emissions Conducted & Radaited CISPR 11 / EN55011	Group 1, Class B	The Trackit Solo 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. The Trackit Solo 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. However, a separation distance of 30 cm (12 in) shall be maintained.
Voltage fluctuations/ Flicker emissions, IEC 61000-3-3	Complies	
Harmonic emissions, IEC 61000-3-2	Class A	

Electromagnetic Immunity

Immunity Test	IEC60601 Test Level	Compliance Level	Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	+/- 8 kV: Contact +/- 15kV: Air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transients/ burst IEC 61000-4-4	± 2 kV for AC-power ± 1 kV for LAN port	Complies	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	Complies	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	U_T = 0% (0.5 cycle) U_T = 70% (25 cycles) U_T = 0% for 5 s U_T = AC Input Voltage prior to application of the test level	Complies	Mains power should be that of a typical commercial and/or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 150 kHz and 80 MHz. 80% AM at 1 kHz	3 V 6V in ISM and amateur radio bands between 150 kHz and 80 MHz.	Portable and mobile RF communications equipment should be used no closer to any part of the Trackit Solo, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = [3.5/V] √P : 80 MHz to 800 MHz = 1.2 √P
Radiated RF Electromagnetic Fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	d = [7/V] √P : 800 MHz to 2.5 GHz = 2.33 √P Note: using unshielded input leads
Proximity Fields from RF Wireless Equipment IEC 61000-4-3	Refer to Table 9 of IEC 60601-1-2:2014	As per Table 9 of IEC 60601-1-2:2014	Where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from struc-tures, objects and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Trackit Solo is used exceeds the applicable RF compliance level above, the Trackit Solo should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Trackit Solo.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Trackit Solo.

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
W	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

Version History

V1.0 (November 2023)

- First release

V2.0 (November 2024)

- Updated EMC Declaration

V2.1 (April 2025)

- Corrected Earth Protection Class
- Updated CPU, Operating System and USB specifications
- Updated LTE/4G Modem instructions

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