



# trackit <sup>M</sup>

EEG SYSTEM

## SYSTEM MANUAL

**M** is for Mobile



Imagine EEG Anywhere

DM00003 Rev D

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# 1 Attention

No part of this document may be copied or reproduced in any form or by any means without prior written consent of Lifelines Neuro Company, LLC.

## 1.1 Customer Support Info

In case of issues, requests, or for technical support, contact:

**Address:**

Lifelines Neuro Company, LLC  
900 E. Main Street, Suite 300  
Louisville, KY 40206

**Telephone:**

866.889.6505

24/7/365

Normal Business hours 7:30 a.m. - 5:00 p.m. CT

Afterhours 5:00 p.m. - 7:30 a.m. CT, weekends and holidays

**E-mail:**

support@LifelinesNeuro.com

During normal business hours you can expect a response within 2 hours.

Outside normal business hours or holidays, please be advised that it may take up to 48 hours to respond.

For more information, visit [www.lifelinesneuro.com](http://www.lifelinesneuro.com)

A digital copy of this manual can be accessed through the Rendr Acquisition by clicking 'Help' on the main menu.

**Caution:**

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

## 2 Customer Responsibility

The Trackit M EEG System 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 60601-1-1, IEC 60601-1-2, IEC 60601-2-40 for medical devices.



## 3 Abbreviations

Abbreviation	Description
EEG	Electroencephalogram
EM	Event Marker
ESU	Electro Surgical Unit
ME	Medical Electrical
MRI	Magnetic Resonance Imaging
EMC	Electromagnetic Compatibility
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization







## 4 Safety

Read this manual carefully before using the Trackit M for the first time to familiarize yourself with its operation. This manual is part of the product and must be available anytime. Use the device only for the intended purpose. Pay attention to all warnings, advice, and notes provided in this manual. To avoid the possibility of injury to the patient or user, damage to your system or data loss, always observe these safety precautions during the system operation.

Two signs are used to define potentially harmful conditions, or conditions or procedures capable of causing damage.

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

### 4.1 Warnings for the Trackit M

	This system should only be operated by personnel having a sufficient amount of training and experience according to all local regulations and guidelines.
	This system should only be used for patient examination by personnel who have fully familiarized themselves with the system and the processes and procedures contained in this manual, including all warnings and caution statements.
	The Photic Stimulator is classified as a Group 2 instrument under ISO 15004-2. In the event of an electrical failure that turns the Photic Stimulator on at full brightness and at continuous wave stimulation (i.e., the photic stimulator turns on and remains on for more than 16 seconds), the light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 36 minutes.
	All use of this system with a photic stimulator must be under the supervision of a physician, as photic stimulation can result in seizure activity in the patient. Stop all photic stimulation if abnormal seizure waveforms are detected to prevent the patient from having a seizure.
	Do not perform studies involving hyperventilation techniques with patients having severe heart, respiratory, or cerebrovascular disease.
	To ensure patient safety, connect the patient electrodes only after the system is fully turned on.

	To ensure patient safety, disconnect all electrodes from the patient before the system is turned off.
	Connect patient electrodes only to corresponding inputs of the Headbox. Connection to any other devices or sockets may cause injuries.
	Only connect floating (non-ground referenced) sensors to the differential inputs. Use of grounded sensors could result in electric shock of the patient. Do not use differential inputs to connect EEG sensors or the channel may be subject to increased noise levels.
	Any devices connected to the Trackit M should be certified by Lifelines Neuro for safety and compatibility according to the relevant safety standards, and connected according to the instructions provided in this manual. Connection of non-approved equipment may result in harm to the patient or operator, or malfunction of the system.
	Only connect Lifelines Neuro approved cables and accessories to Trackit M input/output ports. Use of non-approved cables and accessories could cause shock hazards to the patient or operator, or result in malfunction of the system.
	Only use Lifelines Neuro approved power cords and power supplies. Use of non-approved cords could result in shock hazards to the patient or operator, or malfunction of the system. Power supplies are specified as part of ME equipment.
	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	Only connect external monitors that are IEC 60950-1 class I certified or equivalent. Use of non-approved equipment could result in shock hazards to the operator.
	Never use this device in the presence of flammable gas or high oxygen concentration environments. Failure to comply may result in an explosion or fire.
	An approved Separation Device (isolation device) is required when connecting an external monitor to the Trackit M. The requirement for the Separation Device is defined in IEC 60601-1- 1 and in IEC 60601-1, edition 3, clause 16.
	This device is not designed for use during defibrillation. Remove all electrodes and sensors from the patient before using a defibrillator. Failure to comply may result in serious electric shock or burn to the patient or operator.











	This device is not intended for use in conjunction with or in the presence of an electrical surgical unit. Use of this device in the presence of an electrical surgical unit may cause noise or device malfunction due to high frequency noise from the electrical surgical unit. Use of this device in conjunction with an electrical surgical unit may result in shock and burn hazards to the patient or operator, as well as damage to the device. Completely disconnect the device from the patient before using an electrical surgical unit.
	This Trackit M is not designed for use in or near MRI equipment. Failure to remove all sensor leads before performing an MRI can result in burn hazards to the patient. Using this equipment in or near an MRI can result in equipment malfunction due to magnetic noise from the MRI.
	Do not connect the Neutral electrode or the Negative connection of any differential sensor to any grounded connection, as this could result in the electrical shock of the patient.
	Ensure that the connector port dust cover is properly installed on the system whenever the connectors are not connected to prevent damage to the system. Check the connector area for debris before connecting cables to ensure that they seat properly.
	Unauthorized modification of the Trackit M is strictly prohibited, and may result in additional hazards to the patient and operator.
	The Trackit M needs special precautions regarding EMC and needs to be put into service according to the EMC information provided in this manual.
	Portable and mobile RF communications equipment can affect the Trackit M.
	Using accessories other than those specifically certified by the manufacturer for use with the Trackit M may result in increased emissions or decreased immunity.
	The Trackit M should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Trackit M should be observed to verify normal operation in the configuration in which it will be used.








## 4.2 Cautions for the Trackit M

	Proper usage of this system depends on careful reading of all instructions and labels.
	A power interruption that occurs during an EEG recording session may cause non recoverable data loss. If you experience frequent power interruptions, Lifelines Neuro recommends usage of an Uninterruptible Power Supply (UPS). To minimize the risk of data loss, follow all the requirements of the UPS operation manual including the timely replacement of the batteries.
	Do not autoclave or sterilize, except for aseptic techniques on cabling and electrodes, any parts of Trackit M.
	Do not use acetone or other solvents for cleaning the components of the system. Cleaning the system without first turning it off may result in electric shock or system malfunction.
	Installation of additional software on the unit other than those explicitly approved for use on the device may result in system malfunction. Do not delete or modify any system files as this may also result in system malfunction.
	Do not run other applications while conducting a study with the Rendr Acquisition Software or the system may not function correctly.
	Data collected during electrostatic discharge to the system may contain spike noise artifact.
	Data collected within environments containing high frequency noise may be subject to such noise. In such cases, the traces may appear thicker.
	Always disconnect all cables, turn off the device, and close the screen before transportation of the Trackit M to avoid injury and system damage. Also, to avoid system damage, only transport the system using approved packaging.
	Adjusting the date and time of the system before conducting a study will affect the date and time information associated with the study. Ensure that the date and time of the system is correct before beginning a study. Do not change the date or time while performing a study.
	Do not enable the screen saver or turn off the system while performing a study. Only turn off the system according to the procedure outlined in this manual.
	Do not expose the system to large magnetic fields or it may result in lost data or system malfunction.
	Do not block the fan vents on the back and rear of the device or it may overheat, leading to system malfunction.
	The manufacturer does not recommend the use of extension cords when powering the Trackit M or its accessories, as it may result in decreased noise performance or an electrical safety hazard.

## 5 Explanation of Symbols

The following signs are used for marking the Trackit M and accessories:

Symbol	Meaning
	BF-type Applied Part
	Class II Equipment
	Manufacturer name and address
	Date of Manufacture
	Product serial number
	Product Reference /Catalog Number
	Product Lot / Batch Number
	Refer to instruction manual

Symbol	Meaning
	Alternating Current
	Direct Current
	Power / Stand-by
	Do not dispose with other household wastes at the end of working life*
	European Authorized Representative
	Consult instructions for use
	Caution

\*To prevent possible harm to the environment or human health from uncontrolled waste disposal, separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

## 6 Getting to Know the Trackit M

### 6.1 Intended Use

The electroencephalographic system "Trackit M" (hereinafter referred to as the Trackit M) is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing electrodes on the patient scalp.

The Trackit M is intended to be used for such studies as electroencephalogram (EEG) and video EEG recording to aid in diagnosis. The Trackit M does not draw any diagnostic conclusions.

The Trackit M's software package allows performing an advanced computerized analysis of the EEG on the internalized notebook including recording, displaying, digital filtering, montage reformatting, measuring and streaming data and video to the cloud.



The Trackit M hardware does not directly contact the patient. Accessories that contact patients, such as electrodes or sensors, should comply with their respective requirements and be duly approved.

The Trackit M is not sterile.

The Trackit M is intended for use in clinical and research environments.

The Trackit M is intended for use by qualified medical personnel only.

The Trackit M is intended to be used in conjunction with the cables, electrodes and accessories supplied by Lifelines Neuro. Any deviation of this or introduction of outside, third party accessories, may impact the reliability and quality of the data received from the Trackit M.

	The Trackit M does not feature defibrillator protection.
	The Trackit M includes neonate to adult patient population only.

## 6.2 Parts List

### 6.2.1 Standard Kit

The following parts are provided as part of the Trackit M.

Part Number	Description	Qty
PL00000	Trackit M	1
DP00277	Wireless mouse	1
DP00597	Trackit M EEG Power Cord (US)	1
PL00016	Trackit M Connector Dust Cover	1
PL00003	Custom EEG Headbox	1
PL00005	Event Marker Cable	1
PL00001	Photoc Stimulator	1
DP00851	Peripheral Power Supply and Interchangeable Plug	2
PL00006	Peripheral Cable	1
PL00015	Video and IR Illuminator Assembly	1
DP00282	Tripod Tilt Arm	1
DP00812	USB 2.0A to Mini-B Cable, 6.0 ft	1
DP00275	Tripod	2
PL00012	Carrying Case	1
PL00017	10-20 EEG Electrode Kit	1

## 6.2.2 Patient Sensor Leads

Part Number	Description	Qty
PL00008-32.00-34.75-37.50-G PL00008-60.00-60.00-60.00-G	Midline Sensor Cable Gold, Long Length, Graduated Midline Sensor Cable, Long Length, Single Length	1
PL00009-26.75-29.5-32.25-35.00-37.75-G PL00009-60.00-60.00-60.00-60.00-60.00-G	Parasagittal Sensor Cable Gold - Long Length, Graduated Parasagittal Sensor Cable Gold, Long Length, Single Length	2
PL00010-29.00-31.75-33.00-35.50-G PL00010-60.00-60.00-60.00-60.00-G	Temporal Sensor Cable Gold - Long Length, Graduated Temporal Sensor Cable Gold - Long Length, Single Length	2
PL00011-60.00-W-G	Single Sensor Cable Gold - Long Length, White	1
PL00011-60.00-Gr-G	Single Sensor Cable Gold - Long Length, Green	1
PL00011-60.00-R-G	Single Sensor Cable Gold - Long Length, Red	2

*Note: Lead type delivered will be configured at sale.*

## 6.2.3 Optional Accessories

Part Number	Description	Qty
DP00278	HDMI Mini Cable (6 ft max)	1
DP00279	Ag-AgCl Cup Sensors (for D clip leads)	500
DP00290	Ambu® Sleepmate CannuTherm (814310-100)	1
DP00291	Ambu® Sleepmate Respiratory Effort Belt (813236-100)	1
PL00019	PTZ, IR Video Kit	1
PL00020	Standard 10/20 Headbox	1

### 6.3 Understanding the Trackit M System Connections

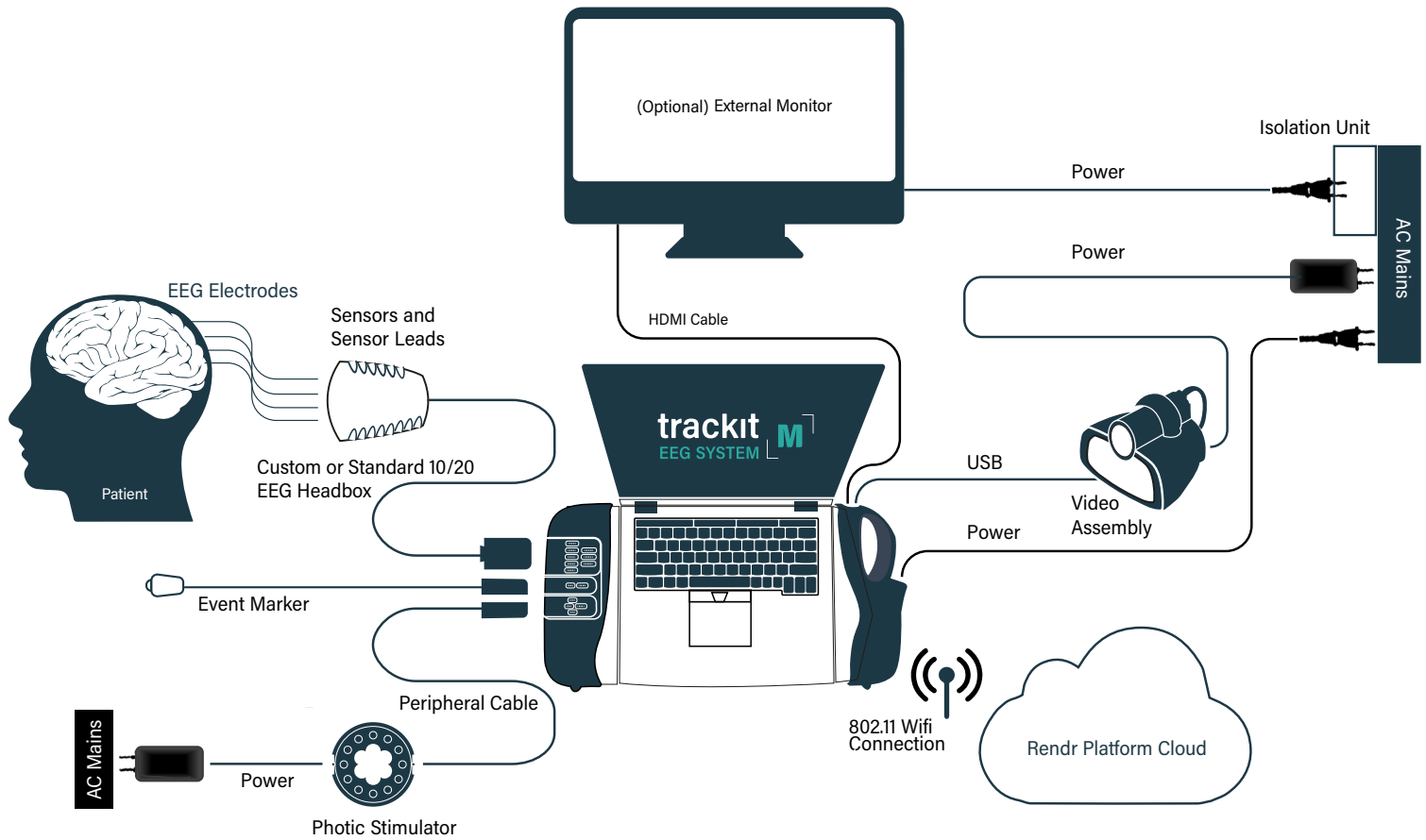


Fig 1: Trackit M with accessories

## 6.4 Indicator Lights

### 6.4.1 Trackit M Indicator Light

Color	Status
Green	Powered On, Ready for use.
No Light	Powered Off

### 6.4.2 Photic Stimulator Light

Color	Status
Green	Powered On, Ready for use.
Yellow	Powered On, Caution, prompt response from operator required.
Yellow (flashing)	System boot, initial configuration. Error if this state lasts for more than 2 seconds.
No Light	Powered Off

### 6.4.3 Camera Indicator Light

Color	Status
Green	Powered On, Initializing.
Green (flashing)	Powered On, Ready for use.
Yellow	System boot / Caution, Camera not connected.
No Light	Powered Off



## 6.5 Understanding the Custom EEG Headbox

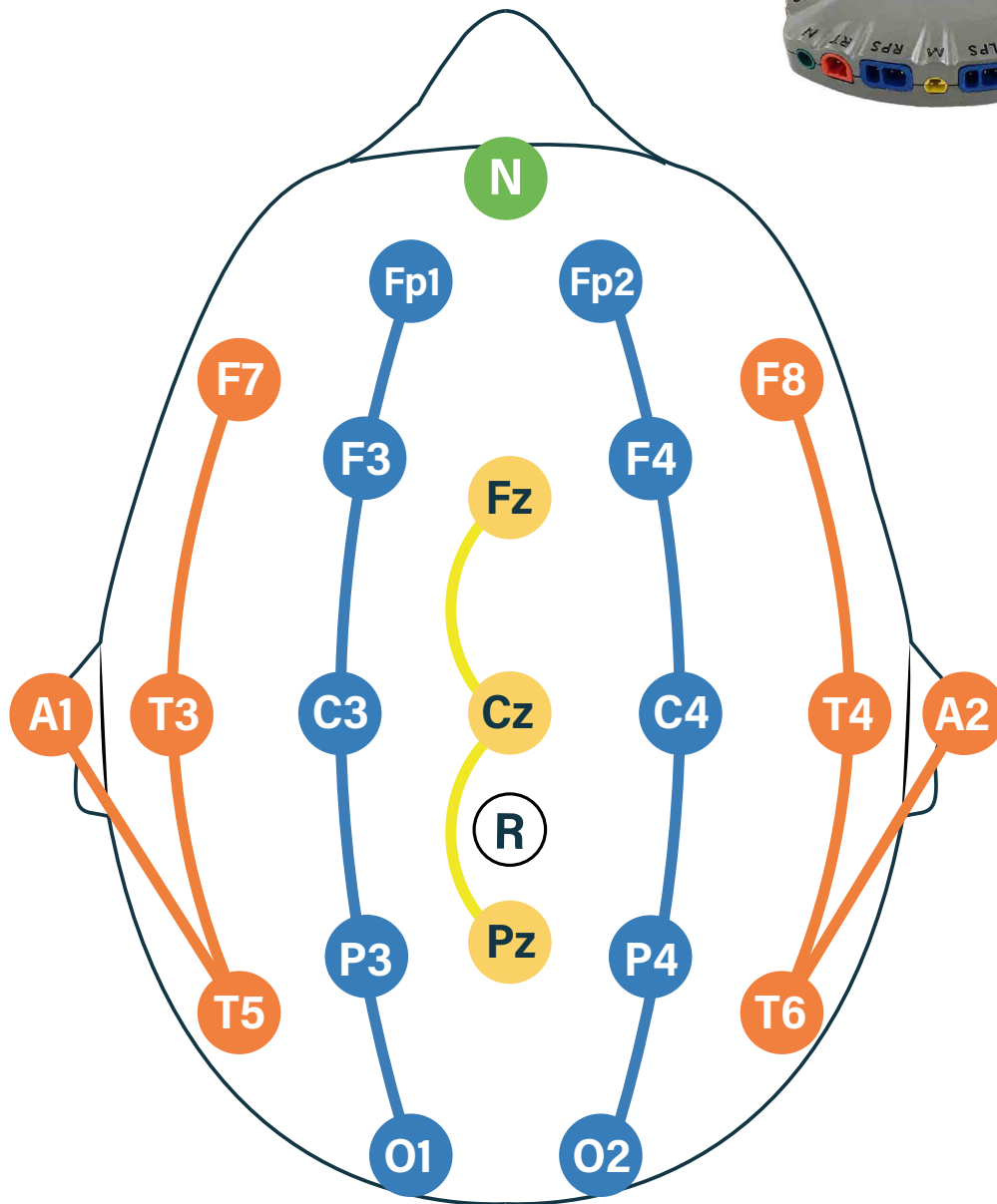


Fig 2: 10/20 Sensor Positions on Head

## 6.5 Understanding the Custom EEG Headbox

The Trackit M has two options for the Headbox cable (the Custom EEG Headbox and the Standard 10/20 EEG Headbox). The Custom EEG Headbox utilizes the Headlines Electrode System. Each sensor lead in the Headlines system is color-coordinated based on its location on the head, as shown on previous page.

Color	Sensor	Description
Orange	Temporal	Used for electrode placement in the temporal region, including on the earlobes (4 leads) All measurements are taken with respect to the Reference Sensor
Blue	Parasagittal	Used for electrode placement in the parasagittal region (5 leads) All measurements are taken with respect to the Reference Sensor
Yellow	Midline	Used for electrode placement in the midline region (3 leads) All measurements are taken with respect to the Reference Sensor Must be on the head in order to initiate the impedance measurement
White	Reference	Used for common mode sensing Should be placed between Cz and Pz along the midline. Must be on the body for all measurements performed, since all measurements are taken with respect to the Reference sensor
Green	Ground/Neutral	An "active ground" electrode that uses the Reference electrode to eliminate noise on the body, and brings the Trackit M to a neutral potential with respect to the body Can be placed on either the forehead (Fpz) or the left or right mastoid Is not a protective earth ground connection, and is protectively isolated from earth ground. Must be on the body for all measurements performed
Red	X1 - X8	Additional monopolar sensors that can be placed as needed and mapped in software Can be used for various bio-potential signals, and are all measured with respect to the Reference sensor
Red and Black	D1 - D3	Differential Pair channels that can be used for floating differential sensors such as the Ambu® Sleepmate CannuTherm and Sleepmate Respiratory Effort Belt (not for use as EEG channels).





Monopolar sensor leads of the same color are interchangeable. However, after placement on the patient, leads must be plugged into their respective connectors on the custom EEG Headbox. The connections are labeled as follows on the custom EEG Headbox:

Label	Sensor
LT	Left Temporal
LPS	Left Parasagittal
MID	Mid-Line
RPS	Right Parasagittal
RT	Right Temporal
REF	Reference
N	Ground/Neutral

Within each sensor bundle, the sensor wires have varying lengths to avoid any misplacement of electrodes, with the longest wire in each bundle to be placed towards the front of the head (anterior). Uniform length versions are also available.

Three differential channels are available that can be used with external passive differential sensors, such as a respiratory belt or cannula temperature sensor. See "Connecting the Sensor Leads" for more.

Sensors and sensor leads are important components of the EEG system. All sensors and sensor leads should comply with Trackit M requirements. Lifelines Neuro recommends using Lifelines Neuro branded sensors in order to achieve optimum results.

	Recommendations for maintenance and disinfection of sensors should be strictly followed.
	Only connect floating (non-ground referenced) sensors to the differential inputs. Use of grounded sensors could result in electric shock of the patient. Do not use differential inputs to connect EEG sensors or the channel may be subject to increased noise levels.
	Do not connect the Neutral electrode or the Negative connection of any differential sensor to any grounded connection, as this could result in the electrical shock of the patient.
	Usage of noncertified sensors may cause damage of the EEG system components.



## 6.6 Understanding the Standard 10/20 EEG Headbox

The Standard 10/20 EEG Headbox uses individual DIN 42-802 connections for each sensor lead. The cable includes 29x EEG channels. Unlike the Custom EEG Headbox, the Standard 10/20 EEG Headbox provides 2x passive differential sensor connections (D1-D2) for a total of 31 sensor channels (whereas the Custom EEG Headbox provides 3x passive differential sensor connections for a total of 32 sensor channels). See "Connecting the sensor leads" for more. A 25 pin D-Sub connector is also available for connection to electrode caps.

Label	Description
REF	Used for common mode sensing. Should be placed between Cz and Pz along the midline. Must be on the body for all measurements performed, since all measurements are taken with respect to the Reference sensor
G (GND/ NEUTRAL)	An "active ground" electrode that uses the Reference electrode to eliminate noise on the body, and brings the Trackit M to a neutral potential with respect to the body. Can be placed on either the forehead (Fpz) or the left or right mastoid. Is not a protective earth ground connection, and is protectively isolated from earth ground. Must be on the body for all measurements performed.
X1-X8	Additional monopolar sensors that can be placed as needed and mapped in software. Can be used for various bio-potential signals, and are all measured with respect to the Reference sensor.
D1-D2	Differential Pair channels that can be used for floating differential sensors such as the Ambu® Sleepmate CannuTherm and Sleepmate Respiratory Effort Belt (not for use as EEG channels)

Sensors and sensor leads are important components of the EEG system. All sensors and sensor leads should comply with Trackit M requirements. Lifelines Neuro recommends using Lifelines Neuro branded sensors in order to achieve optimum results.

	Recommendations for maintenance and disinfection of sensors should be strictly followed.
	Only connect floating (non-ground referenced) sensors to the differential inputs. Use of grounded sensors could result in electric shock of the patient. Do not use differential inputs to connect EEG sensors or the channel may be subject to increased noise levels.
	Do not connect the Neutral electrode or the Negative connection of any differential sensor to any grounded connection, as this could result in the electrical shock of the patient.
	Usage of noncertified sensors may cause damage of the EEG system components.

## 6.7 Understanding the Rendr Acquisition Software

The Rendr Acquisition Software manages the Trackit M hardware, collects and processes data, displays and prints reports, stores data, and provides the user interface. The Rendr Acquisition Software includes the following features:

- Data acquisition and graphing
- Streaming data to Rendr Cloud
- Photoc stimulator controls (controlled intervals/synchronization)
- Video EEG with synchronization
- Event markers
- Notes and measurements
- Patient data entry and synchronization with the Rendr Cloud
- Data review and reporting
- Montage / filter selection and customization




Refer to the **Rendr Acquisition Software Manual** for a full description of all functionality and options.

## 7 Setting Up the Trackit M

### 7.1 Before You Begin

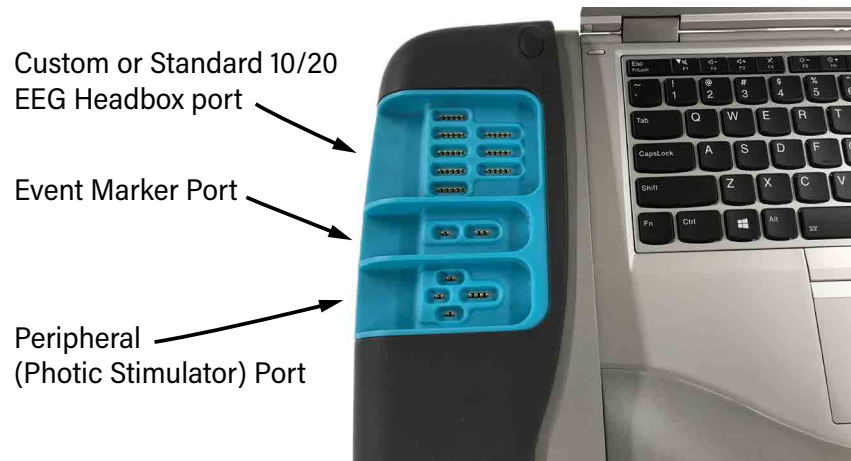
Before beginning the setup process, read this manual thoroughly.

Check that all components from the parts list in section 7.2 are included. If any components are damaged, do not use them and contact Customer Support for replacement. Arrange the system components observing safety requirements specified in this manual.

	Do not open the Trackit M casings if they are connected to the power supply unit due to risk of electric shock. Only Lifelines Neuro personnel should service the unit.
	The operator should ensure that the Trackit M Main Unit is setup outside of the patient environment, so as to prevent the patient from touching the main unit. Failure to do so may result in risk of electric shock and decreased noise performance.
	There are no parts internal to the Trackit M that should be maintained by the user.

The Trackit M, accessories and peripherals can be connected in different ways depending on the goals of the EEG investigation. Typical system connection diagrams are shown in this manual.

## 7.2 Setting Up the Trackit M Main Unit



*Fig 3: Trackit M Connector Bay*



*Fig 4: Trackit M Main Unit—Rear View*

To get started with the Trackit M, set up the Trackit M main unit and connect the EEG cable and event marker.

### To set up the Trackit M main unit, EEG cable, and event marker

1. Remove the Trackit M main unit from the case.
2. Connect the power cord to the unit and plug it into an electrical outlet.
3. Open the Trackit M display, then press the power button to turn it on.
4. Remove the Trackit M dust cover from the left side of the chassis to expose the connectors.



*Fig 5: Trackit M Custom Headbox and Cable (left) and Standard 10/20 Headbox and Cable (right)*

5. Remove the EEG cable and Headbox from the case. Connect the magnetized connector to the EEG cable port on the Trackit M.



*Fig 6: Event Marker Cable*

6. Remove the event marker from the case. Connect the magnetized connector to the event marker port on the Trackit M.



### 7.3 Setting Up the Video and IR Illuminator Assembly



*Fig 7: Video assembly*

Next, mount the video camera assembly on the tripod.

#### To set up the video camera

1. Unfold and assemble the video tripod.
2. Remove the video assembly from the case. Slide it onto the tripod, then tighten the rail lock.
3. Use the USB 2.0A to Mini-B cable (DP00812) to connect the assembly to the USB port on the back of the Trackit M. Connect the camera to power using the provided power supply.

#### To set up the PTZ camera

1. Unfold and assemble the video tripod.
2. Remove the PTZ camera from the case. Screw the camera to the tripod by rotating the camera base. Ensure a secure fit.
3. Use the network cable in combination with the Ethernet to USB adapter to connect the camera to the USB port on the back of the Trackit M. Connect the camera to power using the provided PTZ camera power supply.



*Fig 8: PTZ Camera Assembly*

## 7.4 Setting Up the Photic Stimulator



*Fig 9: Photic Stimulator*

The photic stimulator is used in conjunction with the EEG reading to investigate brain activity triggered by flashing lights. Set up the photic stimulator as shown below.

### To set up the photic stimulator

1. Unfold and assemble the photic stimulator tripod.
2. Rotate the boom parallel to the ground by loosening the bolt, pulling up, then tightening the bolt.
3. Remove the photic stimulator from the case and screw it to the end of the boom using the screw connector, rotating the stimulator until it is tight.



*Fig 10: Photic Stimulator—Ports*

4. Remove the photic stimulator cable from the case. Connect the magnetized connector to the stimulator port on the Trackit M, and plug the other end into the back of the photic stimulator.

5. Plug in the power cord to the back of the photic stimulator, then plug the other end into an electrical outlet.



*Fig 11: Photic Stimulator Cable*



The Photic Stimulator is classified as a Group 2 instrument under ISO 15004-2. In the event of an electrical failure that turns the Photic Stimulator on at full brightness and at continuous wave stimulation (i.e., the photic stimulator turns on and remains on for more than 16 seconds), the light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 36 minutes.

## 7.5 Setting Up an External Monitor

The Trackit M also can be used with an external monitor.

### To set up an external monitor

1. Use the provided HDMI mini to HDMI cable to connect an external monitor to the HDMI port on the back of the Trackit M.



*Fig 12: Trackit M Main Unit—Rear View*



External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 or IEC 62368-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.

Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

An approved Separation Device (isolation device) is required when connecting an external monitor to the Trackit M. The requirement for the Separation Device is defined in IEC 60601-1-1 and in IEC 60601-1, edition 3, clause 16.

## 8 Operating the Trackit M

### 8.1 Windows Login

In order to use Trackit M, you must log into Windows through one of the following methods

- Local User Account
- Domain Account on Windows Server 2003 Active Directory or later

### 8.2 Network Configuration

To configure a network connection, click the wireless icon in the Windows system tray and connect to a wireless network. The following network protocols are supported:

- 802.11 a/b/g/n/ac Wireless Network
- WPA2 security recommended

### 8.3 Opening the Software

1. On the Trackit M, enter your Windows username and password.
2. Double click the Rendr Acquisition Software desktop icon.

A new study may be initiated by clicking "New", selecting a patient profile, and connecting to the amplifier hardware. During a study, you may run impedance measurement, run calibration, record EEG data, control the photic stimulator, run a hyperventilation sequence, mark events, and take notes and measurements.

Detailed instructions for software operation, along with all associated features and functions used to perform and EEG study, are located in the Rendr Acquisition Software Manual. Refer to the **Rendr Acquisition Software Manual** for a full description of how to perform an EEG study. This manual can be accessed through the software help.

## 8.4 Connecting the sensor leads using the Custom EEG Headbox.

### To connect the sensors and sensor leads

#### 1. Using D Clip snap in leads

Connect the Ag-AgCl cup sensors to the sensor leads for all EEG channels. A snap should be heard when the cup is fully seated.

#### Using Fixed Cup leads

Fixed Cup leads are ready to use.

#### Using Alligator Clip leads

Alligator clip leads may be used for A1 and A2 sensors. Place one alligator clip on each earlobe. Ensure that the wired side of the clip is oriented furthest from the mid-line.

2. Add conductive paste inside each of the sensor cups.
3. Connect the sensors on the patient's head as shown on page 13.
4. If using the Custom EEG Headbox, connect each sensor lead to the appropriate color-coded jack on the custom EEG Headbox. Begin with the shortest leads in the back of the head, and work toward the front (cables are sized to length), using the following order:
  - a. Midline (yellow)
  - b. Reference (white)
  - c. Ground/Neutral (green)
  - d. Parasagittal (blue)
  - e. Temporal (orange)

**NOTE:** Reference and Ground must be connected to collect EEG data. Fz, Cz, and Pz (Midline) must be connected to begin impedance measurement. If the correct sensors are not connected, the midline sensor icons flash and show the impedance gauges at high impedance.



Fig 13: Custom EEG Headbox

## 8.5 Connecting the sensor leads to the Standard 10/20 EEG Headbox

### To Connect Single Electrodes

1. Using standard DIN 42-802 sensor leads: For all typical single electrode sensor leads (including snap-in, fixed cup, alligator clip, etc.), a single connector is provided for each lead on the Standard 10/20 EEG Headbox.
2. Add conductive paste inside each of the sensor cups.
3. Place the sensors on the patient's head according to the standard 10/20 system.
4. Connect each sensor individually to the corresponding jack on the Headbox.

### To Connect E-Caps

1. Flip open the E-cap connector cover on the Standard 10/20 EEG Headbox.
2. Place the E-Cap on the patient in accordance with the 10/20 system and manufacturer's instructions.
3. Connect the E-Cap to the Standard 10/20 EEG Headbox E-Cap connector (25 pin d-sub), either directly or through the use of an adapter (check with the manufacturer of the E-Cap). The pin-out should be compatible with the below diagram.



**NOTE:** Reference and Ground must be connected to collect EEG data. Fz, Cz, and Pz (Midline) must be connected to begin impedance measurement. If the correct sensors are not connected, the midline sensor icons flash and show the impedance gauges at high impedance.

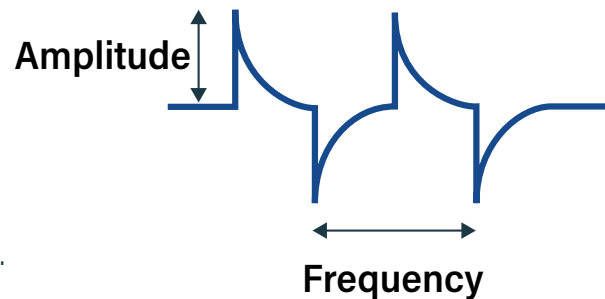


## 8.6 Calibration Waveform Settings

The internal calibration signal can be customized in Rendr Acquisition Software system settings. The following parameters can be adjusted (Refer to Rendr Acquisition Software Manual for more details):

**Amplitude:** Select the amplitude for calibration waveform.

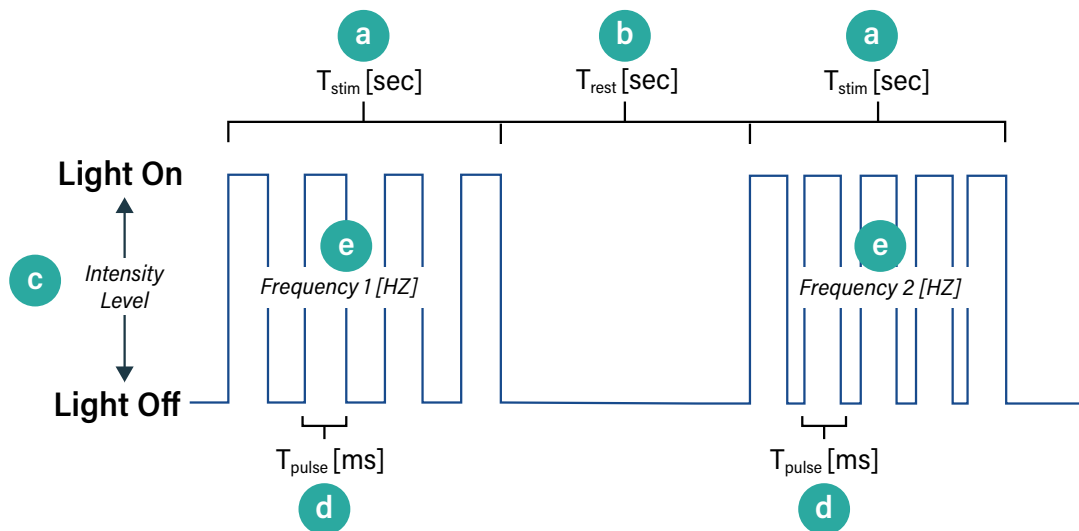
**Frequency:** Select the frequency for the calibration waveform.



## 8.7 Photoc Stimulation Pattern

The following parameters can be customized in Rendr Acquisition Software settings (Refer to Rendr Acquisition Software Manual for more details):

- Stimulation Duration:** The duration for how long the light pulses during stimulation.
- Rest Duration:** Select the length for the rest period between pulses.
- Simulation Intensity Level:** The brightness of the photic stimulator light (where 1 is the dimmest and 10 is the brightest).
- Pulse Width:** The duration for each photic stimulation pulse in milliseconds.
- Program Frequencies:** The stimulation frequencies to be used by the photic simulator.



## 8.8 Accessing Help

At any time, click  to access the Trackit M User Manual.

Users experiencing an issue that cannot be solved may contact a Lifelines Neuro representative using the contact information provided in the front of this manual.



## 9 Maintenance and Care

### 9.1 Setup and Teardown

#### 9.1.1 Powering the System

If it becomes necessary to disconnect the Trackit M from mains power, simply disconnect the Trackit M power cable.

The device should be powered down when not in use. To power the device down, disconnect the EEG cable, close all applications and choose 'Shut Down' from the operating system. Alternatively, close all applications and hold down the power button for 3-5 seconds. Simply pressing the power button or closing the lid may put the device into stand-by and not fully shutdown the device. The device may automatically shut down upon a sufficiently low battery condition. To prevent this, connect the power cable to charge the battery.

The photic stimulator is powered when connected to the provided 12V power adapter. To power down, simply disconnect the power cable.

To power the camera, connect the provided power supply. Camera power is indicated by an LED. To power down the camera, disconnect the power supply.

#### 9.1.2 Inspection of Parts

Before using Trackit M, examine all components and cables for damage. If you notice any damage to a component, cable insulation, or connector contacts, do not use the component. Contact the manufacturer for replacement parts.

Do not use limited life parts, like sensor leads, for longer than the specified number of uses or it may result in degraded performance due to regular wear and tear of the electrode cup plating.

#### 9.1.3 Dust Cover Installation

Always install the dust cover to protect the connectors when cables are not connected to the Trackit M. When removing the dust cover, inspect the connector area for any particles that might keep the magnetic connectors from seating properly.

#### 9.1.4 Cable Management

Always disconnect cables by gripping as close to the connector as possible. When storing cables, do not coil the cable too tightly as this may cause damage over time.

#### 9.1.5 Storage and Transport

Stow the Trackit M in the Trackit M carrying case when not in use. Never transport the system unless properly stowed in the carrying case.

If the device must be moved, it is recommended that the operator first disconnect all cables, install the dust cover, power down the device, and close the screen. This protects the device from possible hazards while being maneuvered. The device may be carried using the handle on the right side of the device.



#### 9.1.6 Service and Maintenance

The warranty will be voided if the user removes any of the Trackit M screws. Please contact Lifelines Neuro Customer Support for service and mechanical maintenance.

## 9.2 Cleaning Instructions

### 9.2.1 Sanitization and Wipe Down

To clean the device, it is recommended to use 70% isopropyl alcohol (IPA) or a 2%-3.14% Chlorhexidine / 70% IPA mixture with a lint free cloth. Do not soak or submerge the device, use only enough solution to sanitize the surface. Always clean with the dust cover installed. Always allow the device to fully air dry before use.

	Do not autoclave or sterilize, except for aseptic techniques on cabling and electrodes, any parts of Trackit M.
	Do not use acetone or other solvents for cleaning the components of the system. Cleaning the system without first turning it off may result in electric shock or system malfunction.

Use similar methods to sanitize cables and accessories. Always allow cables to fully air dry before connecting them.

### 9.2.2 Connectors

Avoid placing cable magnetic connectors near metal particles or parts. If any debris is found to be on cable connectors or the connector area of Trackit M, it must be removed or the cables may not connect properly. It is advised to wipe the area with a lint free cloth, and to clean the area thoroughly using compressed air. Periodically clean the connector sockets on the device using 70% Isopropyl Alcohol and lint-free swabs to remove debris. Ensure that all liquid has evaporated before connecting the cables. Ensure that all debris is removed before connecting the cables. Proper use of the dust cover will help protect the device from debris.

### 9.2.3 Fan Vents

The fan vents on both the bottom and rear of the device must not be blocked or obstructed. Always ensure that the device has air-flow clearance in these areas, or the device may overheat and shut down.

Clean the air vents with a vacuum and/or canned air to clear away any dust that may accumulate during normal use.

## 9.3 Data Management

The Rendr Acquisition Software automatically syncs Patient data, Studies and Settings when connected to the internet. Study data that has already been synced will automatically be removed from local storage to create disk space for new study recordings. If the device is unable to sync, old studies cannot be automatically removed from local storage. In order to free disk space for new recordings, perform one of the following steps:

- Connect the device to the internet and allow it to sync.
- Manually delete old studies (data will be lost) or export them to a network share.

Data management and archival settings can be adjusted in Rendr Acquisition Software settings. Refer to the Rendr Acquisition Software Manual for details.

## 9.4 Battery Management

The Rendr Acquisition Software has built in battery monitoring. If a low battery condition is detected, the operator will be notified. If the battery becomes sufficiently low, the device will halt all data collection to avoid lost data, and will not allow a study to continue until the Trackit M power cable is connected.

To maximize battery life, always allow the system to fully charge. Do not subject the device to temperatures outside of the recommended temperature ranges. For long term storage, ensure that the Trackit M battery is around 40% charged.

## 9.5 Systems Check

The Trackit M automatically performs a functional systems check when the device is powered on. If there is a system fault detected, the user will be notified in the Rendr Acquisition Software.

## 9.6 Limited Use Items

Do not use limited life parts, like sensor leads, for longer than the specified number of uses or it may result in degraded performance due to regular wear and tear of the electrode cup plating. Contact the manufacturer for replacement parts. Always clean conductive gel from electrodes and electrode clips before storage or reuse.

## 10 Troubleshooting

To troubleshoot common issues with the Trackit M, follow the steps below.

If the problem cannot be solved, contact a Lifelines Neuro representative using the contact information provided in the front of this manual.

Problem	Solutions
Device does not power on	Make sure that the power cord is plugged into the Trackit M and then into a wall outlet.
Device powers on, but does not show the log in screen	Turn off the Trackit M, then turn it back on.
Rendr Acquisition Software does not load	Force quit on the application. Turn off the Trackit M, then turn it back on.
Trackit M amplifier won't connect to Rendr Acquisition Software	Turn off the Trackit M, then turn it back on.
Graphing is inaccurate on Graph screen	Review the Impedance & Placement screen to help identify the proper electrode positions and spacing. Clean the patient's scalp where electrodes are placed. Apply more conductive gel to electrodes. Make sure the proper montage is selected in the Montage field at the top of the Graph screen. An event marker label will be placed on the graph when the montage is changed.
Graph does not detect low or high frequency data	Filter settings could be too narrow; adjust the filter settings to a wider range and see if the data begins to appear.
Graph does not display data such as eye blinks, teeth grinding, etc	Adjust the Sensitivity at the top of the Graph screen, or pinch and zoom on the touch screen. Adjust the Time Base at the top of the Graph screen.
Device does not register a mated connector and/or device connections behave erratically	Clean the connector sockets on the device using 70%+ Isopropyl Alcohol and lint-free swabs to remove debris. Ensure that all liquid has evaporated before connecting the cables.

Problem	Solutions
Graph does not display data	<p>Make sure the EEG cable is properly and securely attached to the Trackit M.</p> <p>Make sure the leads are plugged into the EEG cable Headbox properly.</p> <p>Make sure the electrodes are properly attached to the scalp of the patient.</p>
Graphed data is not being recorded	<p>Make sure the Record button at the bottom of the Graph screen has been selected. Data will not be recorded until the Record button is selected. An event marker will be placed on the graph at the point where the recording begins.</p>
Video and data are not synchronized	<p>Close the video feed, then open it again. Once relaunched, the video should start recording automatically and sync back up with the data.</p>
Video and IR Illuminator window does not appear on the Graph screen when the button is clicked	<p>Make sure the Video and IR Illuminator is plugged in via USB to the Trackit M.</p> <p>Make sure the Video and IR Illuminator is powered.</p>
Video and IR Illuminator will not record	<p>Make sure the Record button at the bottom of the Graph screen has been selected. The video feed will show up in the window on the Graph screen, however, it will not begin recording until Record is clicked.</p> <p>Make sure the Video and IR Illuminator is plugged in via USB to the Trackit M.</p> <p>Make sure the video camera is turned on.</p>
Data is not being streamed to the cloud	<p>Make sure there is a proper internet connection.</p> <p><b>Note:</b> If an internet connection exists, a syncing icon will appear in the lower right hand portion of the Graph screen. If an internet connection exists and the Trackit M is recording data, the icon will be glowing. If an internet connection is not available, the sync icon will be greyed out, which means the recorded data will be stored locally on the device.</p>

Problem	Solutions
Photic stimulator is not flashing	<p>Make sure the peripheral cable is properly and securely attached to the Trackit M.</p> <p>Make sure the peripheral cable is plugged into the photic stimulator.</p> <p>Make sure the power cable is plugged into the photic stimulator.</p> <p>Make sure the Start button has been selected on the Photic Controls window on the Graph screen.</p> <p>Check Photic protocol to ensure at least one frequency is selected.</p>
Test will not end	<p>Make sure the Stop button is selected on the Graph screen. An event marker will be placed on the graph when the recording has ended. Data may still be scrolling on the graph until the electrodes are unhooked, but that data will not be recorded.</p> <p>Click Yes on the popup window that asks if you are sure that you want to stop recording.</p>
Unable to locate an archived study	<p>On the Home screen, select Open Existing Study.</p> <p>Search for the study by patient name, birth date, ordering doctor, patient ID number, or social security number.</p>
Unable to locate notes that were made during the study	<p>Navigate to the Event list (List icon on the Graph screen) that stores all the events and notes made during the study.</p> <p>View the scrubber under the graph on the Graph screen, which shows a highlighted mark on the timeline where an event or note was placed.</p>

# 11 Technical Specifications

## 11.1 Trackit M

Category	Specification
Computer Manufacturer	Lenovo®
Computer Model	ThinkPad™ Yoga Family
Screen Size (Touch Capable)	13.3"
Maximum Screen Resolution	1920 x 1080 pixels
Battery Capacity	51 Wh
Processor	8th Generation Intel® Core™ i7 - quad core or better
Hard Drive Capacity	512 GB or better
RAM	8 GB
<b>Wireless Network Devices</b>	
• Wi-Fi	802.11 ac
• Bluetooth	Bluetooth 4.1
<b>Nominal Power Input</b>	
• Voltage / Frequency / Current	100-240 VAC / 50-60 Hz / 2.0-1.0 A
<b>Additional I/O Connections</b>	
• USB	1x USB 3.0 port
• HDMI	1x HDMI port
Ingress protection	IP 2X
Weight	7.7 lbs
Dimensions	10.6" x 20.9" x 1.8"
Operating Temperature	5°C - 33.5°C
Storage Temperature	5°C - 43°C
Relative Humidity	8% - 80%
Atmospheric Pressure (Operating)	79.5kPa (2000 m/6561 ft) to 106 kPa (sea level 0 m / 0ft)

Category	Specification
Atmospheric Pressure (Storage & Transport)	69.7kPa (3,048 m/10,000 feet) to 106 kPa (sea level 0 m / 0ft)

## 11.2 Amplifier

Category	Specification
<b>Number of Channels</b>	
• Total	32 (Custom EEG Headbox) 31 (Standard 10/20 EEG Headbox)
• EEG Channels	29
• Differential Channels	3 (Custom EEG Headbox) 2 (Standard 10/20 EEG Headbox)
Analog to Digital Converter Resolution	24 bits
Sampling Rate	500 Hz
EEG Amplifier Noise (0.5 – 60Hz)	<2.5 $\mu$ Vp-p <0.3 $\mu$ Vrms
CMRR	>100 dB
Maximum DC Offset	$\pm$ 300 mV

## 11.3 Impedance Measurements

Category	Specification
Measurement Current (Max)	1.5 $\mu$ A
Measurement Voltage (Max)	0.3 V
Measurement Frequency (Nominal)	27 Hz
<b>Impedance Range</b>	
• Minimum	200 $\Omega$
• Maximum	100,000 $\Omega$
• Accuracy	$\pm$ 200 $\Omega$



## 11.4 Degree of Accuracy of On-Screen Measurements

### 11.4.1 Visual Degree of Accuracy

Visual measurements are measurements taken using the on-screen legend in software. The accuracy of these measurements is a function of screen size, screen resolution, and user adjustable software settings like sensitivity and time-base. These values assume a resolution of 1920x1080.

Category	Specification
Voltage Resolution [uV/px]	(0.114128 * x) Where x is sensitivity in uV/mm
Time Resolution [sec/px]	(y / 1830) Where y is timebase in seconds

### 11.4.2 Software Measurement Tool

The built in software measurement tool reports measurement data based on the actual data array, and is limited by the hardware resolution and sampling rate.

Category	Specification
Voltage Resolution	12.7 nV
Time Resolution	2 ms

## 11.5 Event Marker

Category	Specification
Minimum Required Pulse Duration	2 ms

## 11.6 Photic Stimulator

Category	Specification
Power Requirements	
• Voltage	12 Vdc
• Current	2 A
Recommended Distance from Patient	20 cm
Stimulation Light Intensity	
• LVL 1 Setting (Nominal)	3,000 lux
• LVL 10 Setting (Nominal)	10,000 lux
Stimulation Frequency	
• Minimum	1 Hz
• Maximum	60 Hz
• Resolution	1 Hz
Stimulation Pulse Width	
• Minimum	0.1 ms
• Maximum	12.8 ms
• Resolution	0.1 ms
Stimulation Duration (Per Frequency)	
• Minimum	1 second
• Maximum	16 seconds
• Resolution	1 second
Rest Duration (Between Frequencies)	
• Minimum	1 second
• Maximum	16 seconds
• Resolution	1 second

## 11.7 Video Assembly

Category	Specification
Camera Manufacturer	V.I.O
Camera Model	Stream
Resolution (Max)	1280 x 720 pixels
Framerate (Nominal)	24 frames/second
Illumination (Minimum)	20 lux
<b>Power Requirements</b>	
• Voltage	12 VDC
• Current	2A
Weight	1.8 lbs
IR Sensitivity	850 nm
<b>Optional PTZ camera specs</b>	
Manufacturer	Amcrest
Model	IP4M-1051B
Resolution (Max)	1280x720
Framerate (Nominal)	20 frames/second
Illumination (Minimum)	1.08lux/F2.0
<b>Power Requirements</b>	
• Voltage	5.0 VDC
• Current	2A
Weight	0.77lbs
IR sensitivity	850nm

## 12 Technical Description

### 12.1 Sensing Channels

The Trackit M is a 32-channel electroencephalographic system comprised of 29 EEG sensors and three differential sensing channels.

The 29 EEG sensors are organized into 6 groups of signals. Five of the groups correspond to rostral to caudal lines within the standard 10/20 system (Left Temporal, Left Parasagittal, Midline, Right Parasagittal, and Right Temporal). The remaining EEG sensors are grouped as "X" sensors, and are available for additional recording locations. They can be dynamically assigned within the Rendr Acquisition Software.

The three differential channels are able to interface to various passive floating differential sensors. These differential channels share a common negative reference and should only be connected to floating sensors. Lifelines Neuro recommends using Ambu respiratory sensors and cannula temperature sensors. The differential channels cannot provide power to external devices, and therefore would be incompatible with active sensors, unless they are otherwise powered and provide floating outputs. Only 2 differential channels are available on the Standard 10/20 EEG Headbox.

### 12.2 Analog Circuit and Amplification

The input circuit for each EEG channel consists of an RFI filter, a buffer, differential amplification, and a low frequency filter. Each EEG channel is initially measured with respect to the Reference sensor, with montages calculated afterward in the Rendr Acquisition Software.

The input circuit also includes overcurrent and overvoltage protection, as well as a multiplexor circuit that allows each EEG channel to interface to the impedance measurement and calibration circuits.

The differential channels have a similar input circuit, but are processed independently of the EEG channels and are therefore not dependent on the Reference or Neutral sensors. The differential sensors are not able to be connected to the impedance measurement circuit.

### 12.3 Analog to Digital Conversion

The Trackit M features a 32-channel delta-sigma Analog to Digital Conversion scheme, meaning each channel is independently sampled, allowing for a truly synchronized simultaneous sampling of each sensor. Each sample is 24 bits, providing excellent voltage resolution, and is sampled at a data rate of 500 Hz.

### 12.4 Differential Accessories

The Trackit M can interface to several passive differential sensors. Lifelines Neuro recommends using the following compatible Ambu® products:

**Ambu® Sleepmate CannuTherm (814310-100)**

Recommended Filter Settings	
Low Frequency Filter	0.1 Hz

**Recommended Filter Settings**

High Frequency Filter	15 Hz
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**Ambu® Sleepmate Piezo Effort Sensors (813236-100)****Recommended Filter Settings**

Low Frequency Filter	0.2 Hz
High Frequency Filter	3 Hz

## 12.5 Common Mode Noise Rejection

The Trackit M employs an active ground to increase the common mode rejection ratio and reduce overall signal noise. The circuit uses the Reference sensor to measure the common mode voltage on the body, which is then inverted and applied back onto the body using a current limited driver through the Neutral connection. It is recommended that careful consideration be given to the environment within which an EEG is performed to reduce overall noise.

## 12.6 Impedance Measurement

The Trackit M impedance measurement circuit measures the complex bio-impedance of the sensor-skin interface. It injects a very small current through each electrode and measures the resulting voltage across the load. Although the system measures the complex-impedance, only the magnitude of the impedance is reported in the Rendr Acquisition Software. Factory default thresholds are:

- **Green** 0 to 5 k $\Omega$
- **Yellow** >5 to 10 k $\Omega$
- **Red** >10 k $\Omega$

At least three EEG sensors (Fz, Cz, and Pz) must be applied to the head before the impedance measurement can begin. If the user begins the impedance measurement using the Rendr Acquisition Software before these sensors have been applied, the software will cycle through these three sensors, waiting for them to be applied. If these sensors are removed from the head after impedance measurement has been initiated, the displayed results will be inaccurate until the Rendr Acquisition Software detects that they are no longer on the head. Once the Rendr Acquisition Software determines that the first three electrodes are on the head, it will cycle through the other sensors in a pre-determined order. The electrodes will flash as they are being updated in the Rendr Acquisition Software.

## 12.7 Filtering

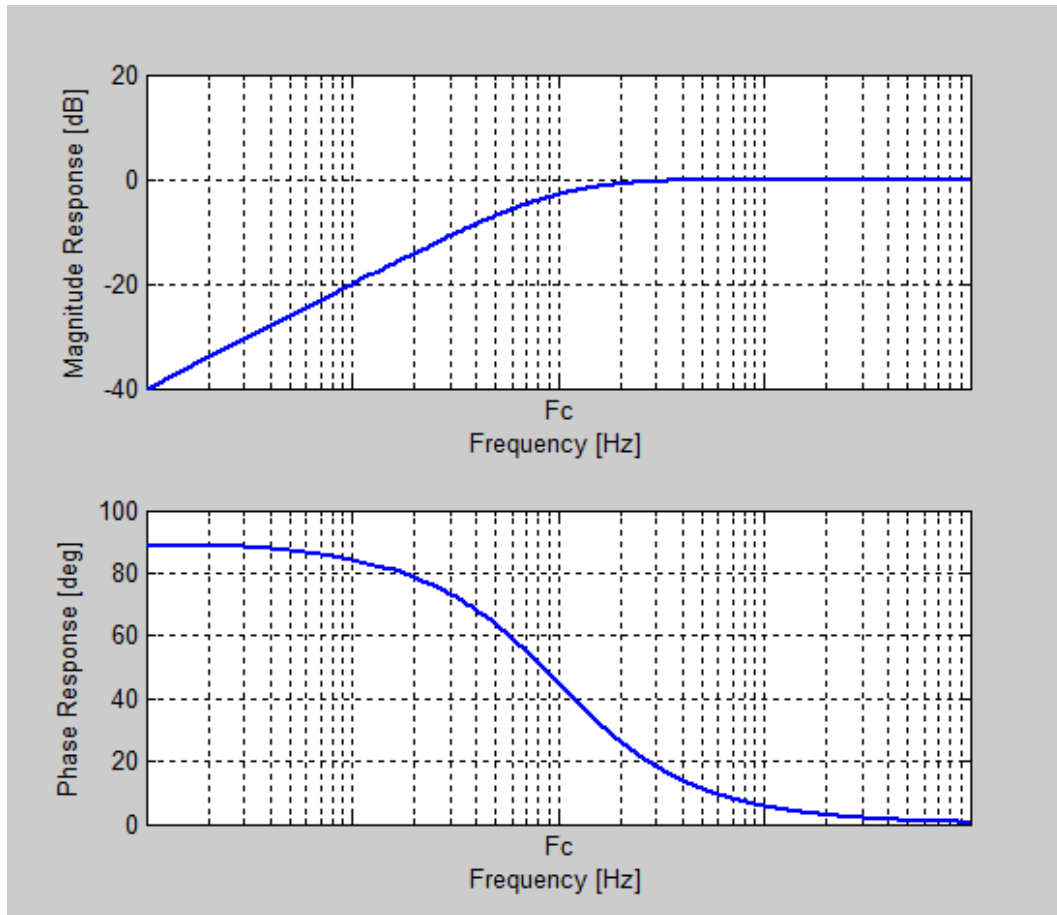
The Trackit M utilizes a minimal amount of hardware filtering to allow the maximum amount of flexibility for a given application. Hardware filtering consists of an RFI filter to eliminate high frequency RF noise, a Low Frequency (High Pass) Filter to eliminate very low frequency DC components, and an anti-aliasing filter at the Analog to Digital Converters.

The Rendr Acquisition Software has additional filters that can be configured by the user:

- Low frequency filter

- High frequency filter
- Notch filter

The characteristics of each filter are shown below.



*Fig 14: Low Frequency Filter*

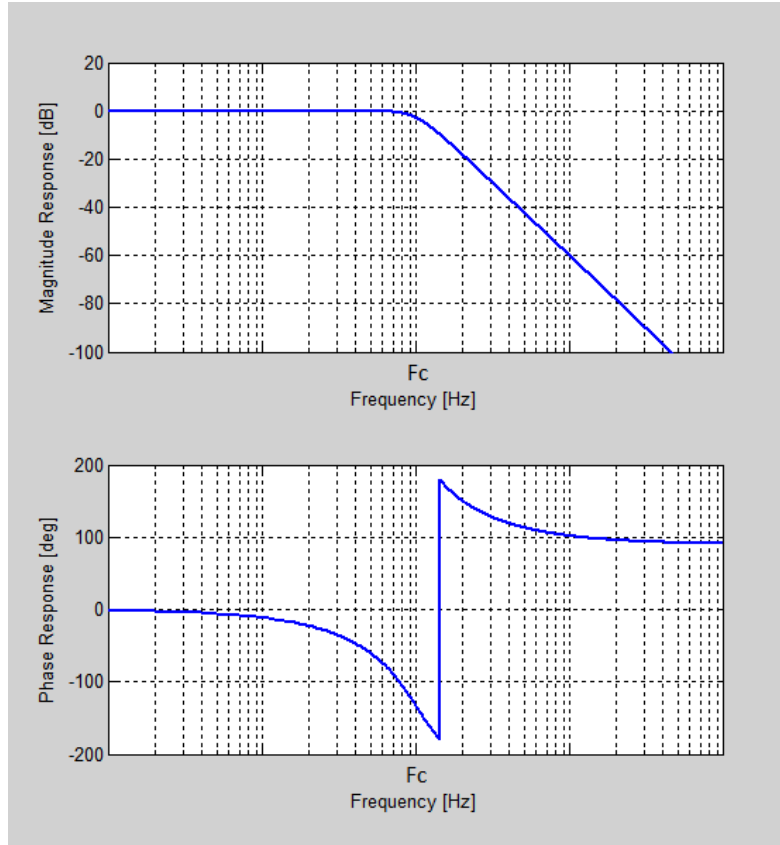


Fig 15: High Frequency Filter

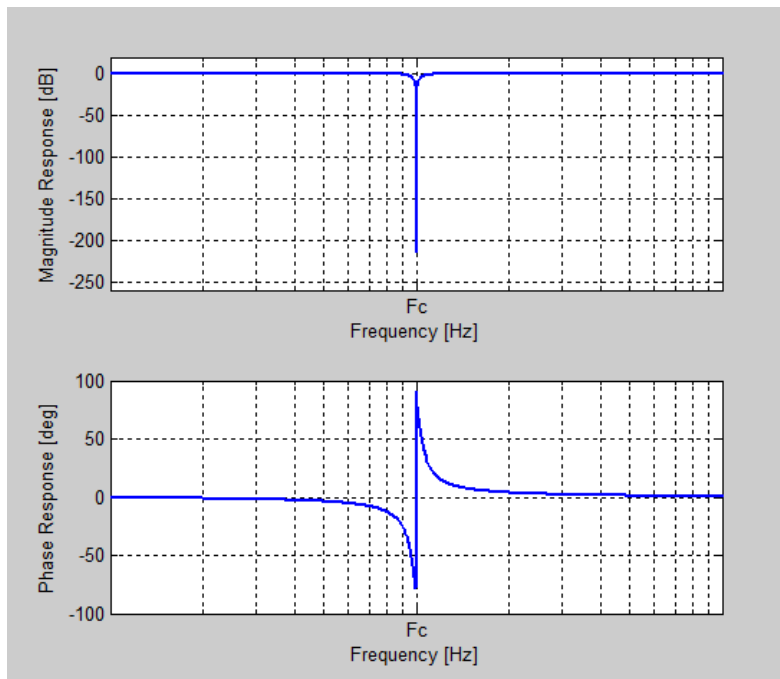


Fig 16: Notch Frequency Filter

## 12.8 Montages

The Trackit M measures each sensor with respect to the Reference electrode. The software then calculates all montages from the original referential montage.

### 12.8.1 Default Montages

Bio-Calibration	Average Reference	Cz Reference	Circumferential	Ipsilateral Ear	Linked Ear	Longitudinal Bipolar	Transverse Bipolar
F7 - Ref	F7 - Avg	F7 - Cz	T3 - F7	F7 - A1	Fp1 - LE	Fp1 - F7	F7 - Fp1
A1 - Ref	A1 - Avg	A1 - Cz	F7 - Fp1	T3 - A1	Fp2 - LE	F7 - T3	Fp1 - Fp2
T3 - Ref	T3 - Avg	T3 - Cz	Fp1 - Fp2	T5 - A1	F3 - LE	T3 - T5	Fp2 - F8
T5 - Ref	T5 - Avg	T5 - Cz	Fp2 - F8	Fp1 - A1	F4 - LE	T5 - O1	F7 - F3
Fp1 - Ref	Fp1 - Avg	Fp1 - Cz	F8 - F4	F3 - A1	C3 - LE	Fp1 - F3	F3 - Fz
F3 - Ref	F3 - Avg	F3 - Cz	T3 - T5	C3 - A1	C4 - LE	F3 - C3	Fz - F4
C3 - Ref	C3 - Avg	C3 - Cz	T5 - O1	P3 - A1	P3 - LE	C3 - P3	F4 - F8
P3 - Ref	P3 - Avg	P3 - Cz	O1 - O2	O1 - A1	P4 - LE	P3 - O1	T3 - C3
O1 - Ref	O1 - Avg	O1 - Cz	O2 - T6	Fz - A1	O1 - LE	Fz - Cz	C3 - Cz
Fz - Ref	Fz - Avg	Fz - Cz	T6 - T4	Pz - A2	O2 - LE	Cz - Pz	Cz - C4
Cz - Ref	Cz - Avg	Cz - Cz	Fp1 - F3	Fp2 - A2	F7 - LE	Fp2 - F4	C4 - T4
Pz - Ref	Pz - Avg	Pz - Cz	F3 - C3	F4 - A2	F8 - LE	F4 - C4	T5 - P3
Fp2 - Ref	Fp2 - Avg	Fp2 - Cz	C3 - O1	C4 - A2	T3 - LE	C4 - P4	P3 - Pz
F4 - Ref	F4 - Avg	F4 - Cz	Fp2 - F4	P4 - A2	T4 - LE	P4 - O2	Pz - P4
C4 - Ref	C4 - Avg	C4 - Cz	F4 - C4	O2 - A2	T5 - LE	Fp2 - F8	P4 - T6
P4 - Ref	P4 - Avg	P4 - Cz	C4 - O2	F8 - A2	T6 - LE	F8 - T4	T5 - O1
O2 - Ref	O2 - Avg	O2 - Cz	Fz - Cz	T4 - A2	Fz - LE	T4 - T6	O1 - O2
F8 - Ref	F8 - Avg	F8 - Cz	Cz - Pz	T6 - A2	Cz - LE	T6 - O2	O2 - T6
A2 - Ref	A2 - Avg	A2 - Cz			Pz - LE		
T4 - Ref	T4 - Avg	T4 - Cz					
T6 - Ref	T6 - Avg	T6 - Cz					

### Abbreviated Formulas

Abbv	Formula
Avg	$(Fp1+Fp2+F3+F4+C3+C4+P3+P4+O1+O2+F7+F8+T3+T4+T5+T6+A1+A2+Fz+Cz+Pz)/21$
LE	$(A1+A2)/2$



## 12.9 Guidance and manufacturer's declaration

### 12.9.1 Electromagnetic emissions

#### Guidance and manufacturer's declaration - Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Trackit M 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 CISPR 11	Class A	The Trackit M is suitable for use in all establishments other than domestic 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	

## 12.9.2 Electromagnetic Immunity

### Guidance and manufacturer's declaration - Electromagnetic Immunity

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


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Trackit M requires continued operation during power mains interruptions, it is recommended that the Trackit M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1 UT is the a.c. mains voltage prior to application of the test level.

NOTE 2 Essential performance for the Trackit M includes the ability to perform without any non-recoverable fault related to data and video acquisition, photic stimulation, impedance measurement, internal test signal injection, or battery charging, as well as all basic safety requirements per the applicable specifications.

### Guidance and manufacturer's declaration - Electromagnetic Immunity

The Trackit M is intended for use in the electromagnetic environment specified below. The customer or the user of the Trackit M should assure that it is used in such an 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	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Trackit M, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  

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

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

<sup>a</sup> Field strengths 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 M is used exceeds the applicable RF compliance level above, the Trackit M should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Trackit M.

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

### Recommended separation distances between portable and mobile RF communications equipment and the Trackit M

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

Rated maximum output power of transmitter <i>W</i>	Separation distance according to frequency of transmitter <i>m</i>		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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 1 At 80 MHz and 800 MHz, the separation distance for 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.

## trackit EEG SYSTEM

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