24/7 EEG™ SUBQ

USER MANUAL FOR PROFESSIONALS

24/7™
EEG SubQ

PRODUCT OVERVIEW

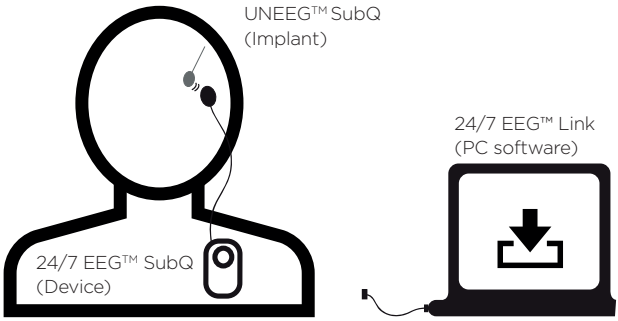


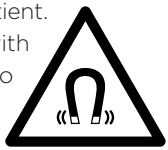
FIGURE A

The 24/7 EEG™ SubQ (hereafter named **device system**) consists of implantable and non-implantable device parts (**Figure A**).

The implantable part, the UNEEG™ SubQ (hereafter named **implant**), measures the subcutaneous electroencephalogram (EEG) from two bipolar channels with a common reference.

It communicates with a non-implantable part, the 24/7 EEG™ SubQ (hereafter named **device**), which supplies the implant with power, and receives and stores recorded EEG. This runs through an inductive link (wireless), which requires a close transcutaneous alignment between the device and the implant to function.

The device exists in two variants; one with a magnet inside (M1) and one without (C1). Please be aware of which variant you have supplied your patient. The M1 variant is marked with the magnet-symbol seen to the right. Patients with other active implantable devices sensitive to magnets are advised to use the C1 variant, since the magnet in the M1 variant might disturb other active implants.



The M1 variant is attached to clothing using the supplied attachment magnet, while the C1 variant is attached to clothing using a plastic clip.

The stored data are downloaded using dedicated computer software; the 24/7 EEG™ Link (hereafter named **PC software**), which parses the data to standard EDF+ file format.

WARNINGS AND PRECAUTIONS

IMPORTANT: Additional warnings and precautions may appear in this user manual.

⚠ WARNINGS

- Seek medical guidance before entering environments that could adversely affect the implant. This includes, but is not limited to:
  - Hospital areas with restricted access for patients.
  - High-power radio-frequency transmitters (e.g. military radar installations, radio/TV transmitters).
- The implant is not compliant with the following medical procedures. The implant must be explanted before receiving any of the following treatments:
  - MRI scan. The implant is MR unsafe.
  - Therapeutic ionizing radiation induced close to the implant (e.g. radiation therapy for cancer).
  - Therapeutic ultrasound induced close to the implant.
  - Electrical current induced close to the implant (e.g. electro knife, electroconvulsive therapy).
- The following medical procedures are safe to use with the implant:
  - Diagnostic ionizing radiation (e.g. x-ray, CT).
  - Diagnostic ultrasound.
- Usage of the device closer than 30 cm to other electronic equipment (including radio-frequency communications equipment) might result in improper operation. If such use is necessary, check that the device is functioning.
- Only supplied accessories may be connected to the device.
- Keep device and accessories out of reach of childeren.

PRECAUTIONS

Subjects using the device should take note of the following:

- The implant can be damaged if exposed to physical impact. Do not take part in combat sports such as boxing, and wear a helmet in activities such as skiing, mountain bike riding, or horseback riding.
- The implant can be damaged if exposed to extreme pressure variations. Do not take part in extreme sport activities such as parachute jumping or diving deeper than 5 metres.
- In case the implant site has been exposed to physical injury, contact the responsible medical professional.
- Hold mobile phone to the opposite ear from the implant site.
- The device contains personal data. Take precautions not to lose the device.
- Do not wear the device in the shower or when swimming.
- Avoid dropping the device.
- Do not use water or cleaning solutions to clean the device. See User Manual for Home Use.
- Do not sink the device into any liquid, including alcohol.
- Do not try to open or repair the device.

CONTENT

1. INTRODUCTION

1.1 INTENDED USE

Measuring and recording of electrical activity of the brain (EEG) through electrodes implanted subcutaneously in the tissue between the skull and the skin. Intended for subjects where single-location, continuous, ultra long-term (more than two weeks) EEG recordings are indicated to aid in monitoring and diagnosis of diseases or conditions that alter the EEG.

The intended users of the product are males and females, age 18 and above.

IMPORTANT: The subject should receive regular follow-up related to the system from the responsible medical professional.

1.2 CONTRAINDICATIONS

The device system is not intended in case of any of the following:

- Subjects with cochlear implant(s).
- Subjects involved in therapies with medical devices that deliver electrical energy in the area around the implant.
- Subjects at high risk of surgical complications, such as active systemic infection and hemorrhagic disease.
- Subjects who are unable (i.e. mentally or physically impaired patients), or do not have the necessary assistance, to properly operate the device system.
- Subjects who have an infection at the site of device implantation.
- Subjects who operate MRI scanners.
- Subjects with a profession/hobby that includes activity imposing extreme pressure variations (e.g. diving or parachute jumping). NB: diving/snorkelling is allowed to 5 metres depth.
- Subjects with a profession/hobby that includes activity imposing an unacceptable risk for trauma against the device or the site of implantation (e.g. martial art or boxing).

1.3 SIDE EFFECTS

General side effects normally associated with any surgical implantation procedure or local anaesthesia also apply to the placement of the implant.

Specifically, the following side effects may be associated with implantation and use of the device system:

- Formation of haematoma or seroma near the implant site following the surgical procedure (for a period up to 3 weeks).
- Temporary pain, headache, infection and discomfort (including soreness, inflammation, swelling, irritation and itching) at the implant site following the surgical procedure, for a period up to 3 weeks.
- Skin ischemia potentially inducing necrosis at the implant site due to pressure and compromised local circulation.
- Infection, swelling, soreness, irritation or itching of the skin at the implant site.
- Occasional headache or pain during long-term use of the device.

Note: *3M™ Cavilon™ or similar barrier film product can be used to protect against stress from the adhesive pad.*

1.4 IMPORTANT SUBJECT INFORMATION

Below is a list of important information for subjects using the 24/7 EEG™ SubQ.

- Inform subjects of risks, warnings and precautions for using the device as part of subject inclusion, see 'WARNINGS AND PRECAUTIONS' in the beginning of this user manual.
- Instruct subjects in the use of the device (see User Manual for Home Use for this information).

Note: *The device will only collect data when it is turned on and connected to the implant. Disconnection will result in lacking data.*

- Demonstrate the different feedback patterns of the device to the subject, see '4.7 Demonstrate Use'.
- Be sure that the subjects receive the User Manual for Home Use as well as all accessories necessary for using the device system (see User Manual for Home Use for information on the accessories).

1.5 IMPLANTATION

To use the device system, subjects need a UNEEG™ SubQ implanted first. The implant consists of two parts, as seen on **FIGURE B**.

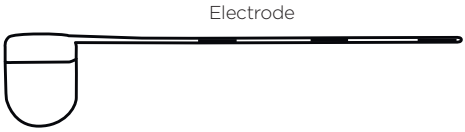


FIGURE B

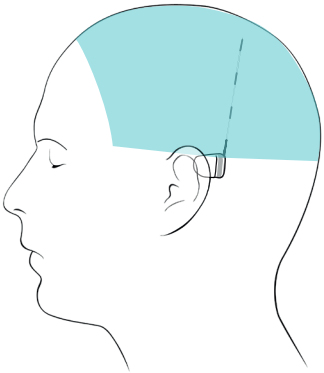


FIGURE C

- The house is implanted subcutaneously behind the ear, as indicated by **FIGURE C**.
- The electrode is tunnelled subcutaneously from behind the ear in any direction within the blue area indicated by **FIGURE C**. The electrode has three contact points located 35, 65, and 95 mm from the house and is inserted using a supplied needle called the introducing aid.

The implantation procedure takes approximately 15-30 minutes and is conducted using local anaesthesia.

IMPORTANT: The surgeon is required to hold an MD with specialisation in a surgical area relevant for the implantation and explantation procedure, such as plastic surgery. The procedure is described in the "UNEEG™ SubQ User Manual - Surgical Procedure" (hereafter named **Surgical Procedure**).

Note: *The responsible medical professional must coordinate with the surgeon in which direction the electrode should be implanted.*

When implanting in the direction of the temple, the electrode cannot be implanted in its full length. Therefore, the surgeon must adjust the length of the electrode by bending it around the house. This might induce rotation of the house over time, potentially displacing the electrode towards the temple. This has no influence on the data quality. Approximately 1-2 weeks after the implantation, the stitches can be removed and the device system can be used.

1.6 STERILITY

The implant has been sterilised using ethylene oxide.

The introducing aid (see Surgical Procedure) has been sterilised using irradiation.

⚠ WARNINGS

- After use, implant and introducting aid are not to be re-sterilised or re-used. Single-use only.
- In the event of damage to the sterile packaging, the content must not be used.

2. HOW TO USE 24/7 EEG™ SUBQ

For instructions on the daily use of the device, see the User Manual for Home Use provided separately.

To prepare the device for use, first connect it to a PC with EEG Link installed to synchronise the internal clock of the device. See ‘4.1 Connect Device to PC’.

If using one device for several subjects, it is recommended to clear the memory of the device in between the uses. See ‘4.4 Clear Memory’.

For instructions on how to demonstrate to the subject the various feedback patterns of the device, see ‘4.7 Demonstrate Use’.

3. HOW TO INSTALL 24/7 EEG™ LINK SOFTWARE

3.1 PC SYSTEM REQUIREMENTS

Before installing the PC software, make sure the computer meets the requirements listed in **TABLE 1**.

3.2 INSTALL 24/7 EEG™ LINK

Please be aware that the installation process will always be in English. Below is a description of how to complete the installation:

1. Insert the installation USB memory stick into the PC and start the installer.
   Setup – 24/7 EEG™ Link:
2. Click 'Next'.
   Installation Folder:
3. Select the location for the installation of the PC software.
4. Click 'Next'.
   License Agreement:
5. Select 'I accept the license'.
6. Click 'Next'.
   Start Menu shortcuts:
7. Select a start menu folder for the shortcut to the PC software.
8. Click 'Next'.
   Select Start up Language:
9. Select preferred language.
10. Click 'Next'.
    Ready to Install:
11. Click 'Install'.
    Installing 24/7 EEG™ Link:
    Please wait while the PC software is installed.
    Completing the 24/7 EEG™ Link Wizard:
12. Click 'Finish'.

TABLE 1: PC SYSTEM REQUIREMENTS.

Operating system	Microsoft Windows 7 SP1 (32/64-bit) Microsoft Windows 8.1 (32/64-bit) Microsoft Windows 10 (32/64-bit)
CPU	Minimum: 2 GHz (multicore)
Memory	Minimum: 4 GB RAM
Disk space	Minimum: 1 physical hard drive Minimum: 30 GB available space
Graphics hardware	DirectX 9 compatible graphics device with WDDM 1.0 or higher driver
Display	Screen resolution minimum 1280x1024 or 1440x900
Other	Minimum: 1 available USB 2.0 compatible port PC should have antivirus program. PC must be IEC 60950-1 compliant

4. HOW TO USE 24/7 EEG™ LINK SOFTWARE

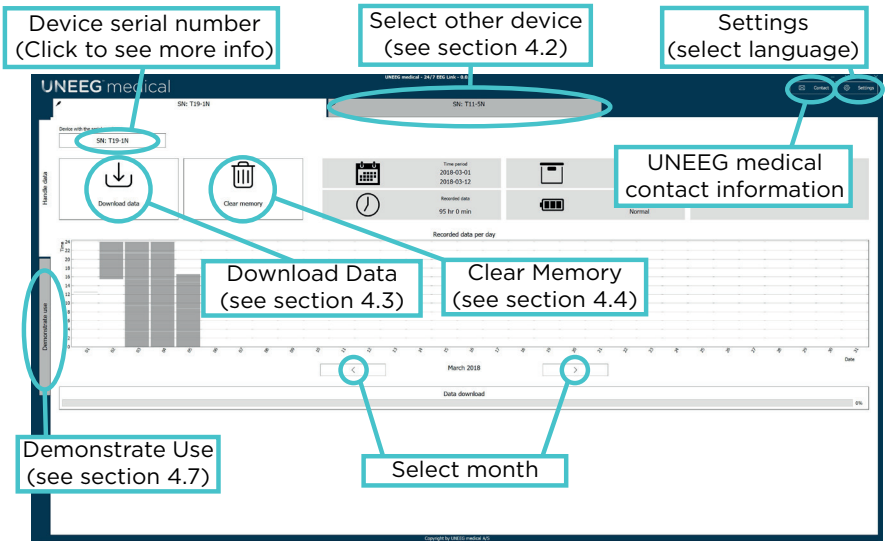


FIGURE D

To extract the data from the device, the 24/7 EEG™ Link (hereafter named **PC software**) is required.

This chapter explains how to use the PC software.

FIGURE D shows the different functions available from within the software.

WARNING

- Never touch (physically) the subject and the computer or computer power supply simultaneously.

4.1 CONNECT DEVICE TO PC

Apart from the accessories for the subject, which are described in the User Manual for Home Use, the device system also comes with a special USB cable. The USB cable is needed to connect the device to the PC.

WARNING

- Only use the supplied USB cable to connect the device to the PC.

1. Start the PC software using the start menu shortcut created during installation.
2. Insert the USB cable into the PC and into the device.

Note: *When the device is connected to the PC, the internal clock of the device is synchronised with the PC. To make sure that data are correctly time stamped, the clock shall be synchronised within 30 days prior to data collection start.*

Note: *Make sure that the PC's clock is correct when the device is connected to the PC.*

Note: *The device cannot record data while it is connected to the PC.*

The feedback patterns of the device when connected to the PC are illustrated in '7 FEEDBACK PATTERNS'.

4.2 CONNECT MULTIPLE DEVICES

To handle data from several devices at the same time, it is possible to connect up to five different devices simultaneously while using the PC software.

1. To select another device, click the tab with the corresponding serial number (see **Figure D** on page 17).

4.3 DOWNLOAD DATA

When the device has collected data from a subject, data can be downloaded to the PC.

Note: *Data take up approximately 1 GB of storage per week of recording.*

1. Connect device to PC (see '4.1 Connect Device to PC').
2. Click 'Download data'.
3. Select the destination folder and a filename prefix for the data.
4. Click 'Start data download' and wait for the data to download.
   Note: *Do NOT disconnect the device or turn off the PC while downloading data.*
5. When data are downloaded, select whether to clear the memory of the device. To do this at another time, see '4.4 Clear Memory'.
6. To go directly to the downloaded data, click 'Open Folder'.

4.4 CLEAR MEMORY

The memory storage allows for minimum 30 days of recording. When the storage is full, the device will stop recording.

To clear the memory of the device, follow these steps:

1. Connect the device to the PC (see '4.1 Connect Device to PC').
2. Click 'Clear memory'. The PC software will inform about the last data download time.
   Note: *Make sure that all data are downloaded before clearing memory of device.*
3. Click 'Clear memory' and wait for the device to clear the memory
   Note: *Do NOT disconnect the device or turn off the PC while clearing the memory of the device.*
4. When the device has finished clearing the memory, it is safe to disconnect the device

Error or Data storage full

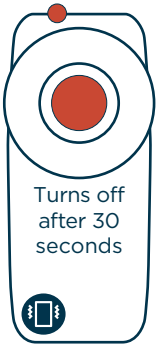


FIGURE E

4.5 DEVICE ERROR - RESET DEVICE

If the device has entered the 'Error or Data storage full' state (**FIGURE E**) it might be necessary to use the PC software to reset the device.

1. Connect the device to the PC (see '4.1 Connect Device to PC').
2. If the device has encountered an error, the PC software will state "An error has occurred". In this case, it is necessary to reset the device and send a system report to UNEEG™ medical.
3. Download data from the device to the PC (see '4.3 Download Data').
   Note: *It is not possible to reset the device before data have been downloaded.*
4. When download has finished, click 'Reset device'.
   Note: *Do not disconnect the device or turn off the PC while the device is resetting.*
5. When reset has finished, click 'OK'.
6. Click 'Open folder'.
7. Find the system report ("...Systemreport.zip") in the folder. The system report must be sent to UNEEG™ medical. Contact the following email address for information on how to send the file: **technicalsupport@uneeg.com**

Note: *A system report must be sent to UNEEG™ medical every time the device has encountered an error.*

4.6 UPDATE DEVICE

The PC software will automatically detect any available firmware updates for the device.

1. Before updating the device, the memory must be cleared. Either download data (see '4.3 Download Data') or clear the memory of the device (see '4.4 Clear Memory').
2. After the memory has been cleared, the PC software will ask whether to update the firmware of the device. Click 'Yes'.
3. Wait for the device to update.
   Note: *Do not disconnect the device or turn off the PC while the device is updating.*
4. When update is finished, click 'Continue'.

4.7 DEMONSTRATE USE

To demonstrate the sounds and lights of the device, use the demonstration mode of the PC software.

1. Connect the device to the PC (see '4.1 Connect Device to PC').
2. Click 'Demonstrate use'. The power button of the device will blink white twice to show that demo mode is activated.
3. To demonstrate the feedback pattern of one of the scenarios, click the corresponding button (e.g. "Low battery").

4.8 SYSTEM REPORT

A system report (...Systemreport.zip) is automatically generated every time data are downloaded from the device (see '4.3 Download Data').

In case the device has encountered an error (see '4.5 Device Error - Reset Device'), please send the system report to UNEEG™ medical. For information regarding implant model and year of manufacture, send the system report to UNEEG™ medical and request the details.

4.9 DISCONNECT DEVICE FROM PC

1. Make sure that the device is not downloading data (see '4.3 Download Data'), clearing memory (see '4.4 Clear Memory'), resetting (see '4.5 Device Error - reset Device') or updating (see '4.6 Update Device').
2. Pull the USB cable out of the device. It is not necessary to 'eject device'.

5. DATA INFORMATION

5.1 EDF+ FILES

EEG data are parsed into EDF+ files. These files are annotated with status checks (short button presses) and diary check marks (double button presses) performed by the subject. See the User Manual for Home Use for information about status check and diary check mark.

Be aware that the supplied PC Software is only capable of downloading the data from the device to the PC. To utilise the data, a third-party software program capable of handling EDF+ files must be installed.

Note: *In case of any suspicion that the data are wrong/bad, verify the data with another measuring system.*

5.2 AUXILIARY DATA

The device records auxiliary data in a proprietary file format that, if provided to UNEEG™ medical, can be interpreted to accelerometery recordings to support future product development.

5.3 METADATA

Metadata are contained in the filename of the downloaded data. To make sure that the correct data are being analysed, it might be necessary to look at the metadata – e.g. to determine the serial number of the implant from which the data have been collected.

1. After data download (see '4.3 Download Data'), open the folder containing the data.

The downloaded files will be named after this pattern:

EEG data file (EDF+):
Prefix_Device_Implant_StartDate_FN_EEGdata.edf

System Report:
Prefix_Device_Period_SystemReport.zip

Where the following applies:

Prefix: Set by user

Device: 24/7 EEG™ SubQ Serial Number

Implant: Implant Serial Number

StartDate: Session start date [year, month, day]

Period: Start date and end date of data recording

FN: File Session Number*

* A new file session is started when:
  - The device is turned ON.
  - The device is disconnected from an implant and connected to a new implant.
  - The device has recorded for 6 hours.

5.4 DATA SPECIFICATIONS

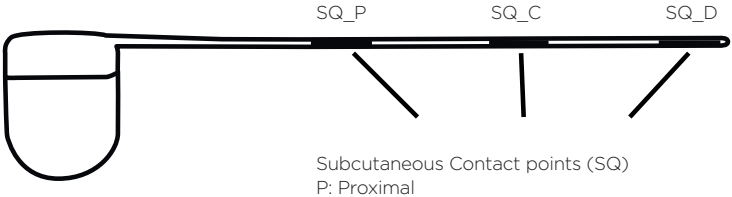
Specifications for the data are found in **TABLE 2.**

TABLE 2: DATA SPECIFICATIONS.

Sampling frequency	Bandwidth	Resolution	Accuracy	Dynamic range
207 Hz	0.5-48 Hz	< 1 µV	+10% at 50 µV for all frequen-cies within 1 Hz to 48 Hz	+350 µV

The EEG data are measured in µV and split into two channels:

- „EEG SQ_D-SQ_C“ – measured from SQ_C to SQ_D
- „EEG SQ_P-SQ_C“ – measured from SQ_C to SQ_P.



Subcutaneous Contact points (SQ)
P: Proximal
C: Central
D: Distal

6. MAINTENANCE

See User Manual for Home Use for information on cleaning.

6.1 STORAGE AND HANDLING

Store the device within a temperature range of +5°C to +30°C.

Make sure that the device does not get wet, and, if necessary, dry it thoroughly with a cloth or similar.

PRECAUTION

- Do not expose the device to water or other liquids.
- Avoid dropping the device.

6.2 LIFETIME OF IMPLANT

The implant has a lifetime of 15 months after implantation. Before this period expires, the implant must be explanted.

The implant does not require service or calibration during its lifetime.

6.3 MAINTENANCE OF DEVICE

The device does not need service or calibration during its lifetime.

6.4 DISPOSAL

The device and all electronic accessories must be disposed of in accordance with the (WEEE) EU directive 2012/19/EU.

This means that the device and all electronic accessories should be handed in for recycling rather than discarded with household waste.

6.5 MALFUNCTIONING DEVICES

If a device is malfunctioning, first try to reset the device, see '4.5 Device Error - Reset Device'. If this does not work, the malfunctioning device shall be returned to UNEEG™ medical.

In case an implant is not performing as expected, it is recommended that UNEEG™ medical is consulted before explanting the implant. The malfunctioning implant shall be returned to UNEEG™ medical.

PRECAUTION

- Never try to open or repair the device.

7. FEEDBACK PATTERNS

Feedback patterns of the device when connected to the PC are shown in **FIGURE F**.

For feedback patterns during use of the device, see User Manual for Home Use.

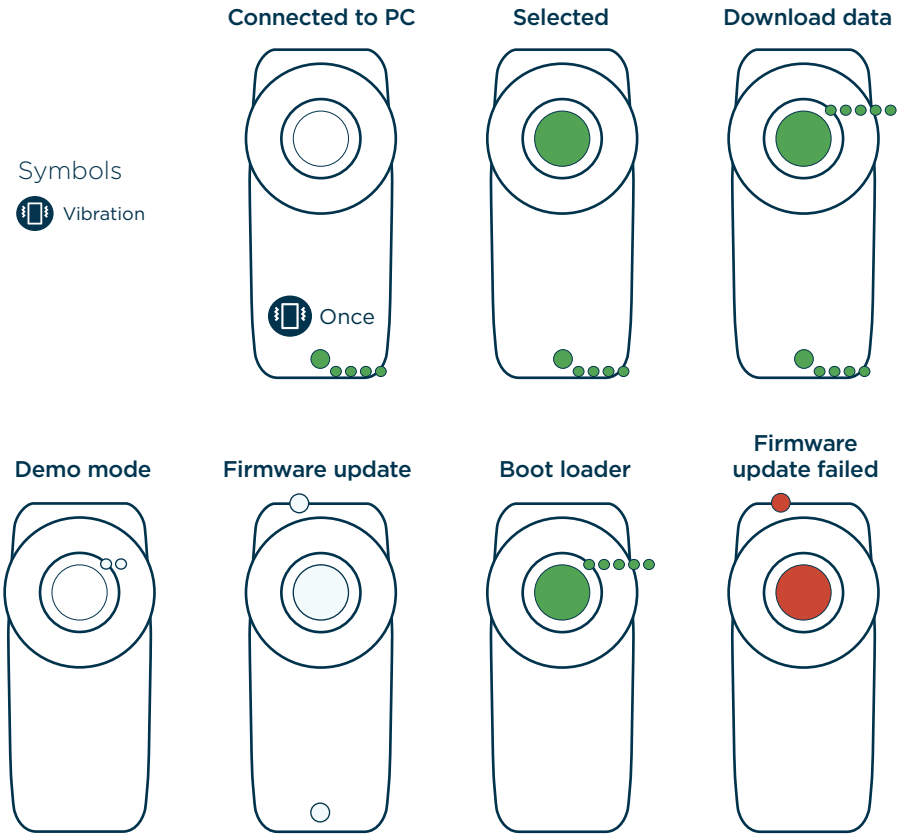


FIGURE F

8. TROUBLESHOOTING

See **TABLE 3** for information on how to react in different situations.

TABLE 3: TROUBLESHOOTING.

Problem	Possible cause	Possible solution
The power button and charging light are blinking yellow.	The device is low on battery.	Charge the battery. See User Manual for Home Use.
The power button and connection light are red.	The device is facing an error.	Reset the device. See section '4.5 Device Error - Reset Device'.
	Data storage is full.	Clear memory of device. See section: '4.4 Clear Memory'.
The device does not turn on.	The device is facing an error.	Reset the device. See section '4.5 Device Error - Reset Device'.
	The device is low on battery.	Charge the battery. See User Manual for Home Use.

9. TECHNICAL DESCRIPTION

Intended Performance
The 24/7 EEG™ SubQ records EEG.

Power Source
The device may only be charged by an IEC 60950-1 compliant power source. Only use the provided charger or USB cable to charge the device.
The charger and USB cable are considered accessories to the medical device.

Modification
No modification of the equipment is allowed.

Repairs
The device contains no replaceable or repairable parts.

Environmental Conditions
The following are the allowed environmental conditions for the device and accessories:

Pressure: 70 kPa (3000 m above sea level) to 150 kPa (5 m below sea level)

Relative Humidity: 10 % to 95 %

Temperature (transport): -10 °C to +55 °C (max 2 weeks)

Temperature (storage): +5 °C to +30 °C

Temperature (use): 0 °C to +40 °C

Ingress: IP24; protection against object > 12.5 mm and splashed water.

Emissions

PHENOMENON	TEST METHOD	CLASS	GROUP
Conducted RF emissions	EN 55011	Class B	Group 1
Radiated RF emissions	EN 55011	Class B	Group 1
Harmonic current emissions	EN 61000-3-2	Class A	-
Voltage changes, voltage fluctuations and flicker emmisions	EN 61000-3-3	-	-

Immunity

PHENOMENON	TEST METHOD	IMMUNITY TEST LEVEL
Electrostatic discharge immunity	EN 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air
Electrostatic discharge immunity - patient coupling ports	EN 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air
Electrostatic discharge immunity - I/O SIO/SOP ports	EN 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air
Radiated RF electromagnetic field immunity	EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM 2 Hz
Immunity to proximity fields from RF wireless communication equipment	EN 61000-4-3	385 MHz, 27 V/m, 18 Hz PM (50% duty cycle square wave). 450 Mhz, 28 V/m, FM +/- 5 kHz dev.,1 kHz sine. 710 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave). 745 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave). 780 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave). 810 MHz, 28 V/m, 18 Hz PM (50% duty cycle square wave). 870 MHz, 28 V/m, 18 Hz PM (50% duty cycle square wave). 930 MHz, 28 V/m, 18 Hz PM (50% duty cycle square wave). 1720 MHz, 28 V/m, 217 Hz PM (50% duty cycle square wave). 1845 MHz, 28 V/m, 217 Hz PM (50% duty cycle square wave). 1970 MHz, 28 V/m, 217 Hz PM (50% duty cycle square wave). 2450 MHz, 28 V/m, 217 Hz PM (50% duty cycle square wave). 5240 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave). 5500 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave). 5785 MHz, 9 V/m, 217 Hz PM (50% duty cycle square wave).
Electrial fast transient/ burst immunity - AC power ports	EN 61000-4-4	+/- 2 kV +100 kHz repetition frequency
Electrial fast transient/ burst immunity - DC power ports	EN 61000-4-4	Not applicable
Electrial fast transient/ burst immunity - I/O SIO/SOP ports	EN 61000-4-4	Not applicable
Surge immunity - AC power ports	EN 61000-4-5	Line-to-line: +/- 0.5, 1 kV line to line Line-to-ground: Not applicable, the system is a Class II device
Surge immunity - DC power ports	EN 61000-4-5	Not applicable
Surge immunity - I/O SIO/SOP ports	EN 61000-4-5	Not applicable

PHENOMENON	TEST METHOD	IMMUNITY TEST LEVEL
Immunity to conducted disturbances induced by RF fields - AC power ports	EN 61000-4-6	3 V (6 V in ISN bands and amateur radio bands[a] 0.15-80 MHz 80% AM 2 Hz
Immunity to conducted disturbances induced by RF fields - DC power ports	EN 61000-4-6	Not applicable
Immunity to conducted disturbances induced by RF fields - I/O SIO/ SOP ports	EN 61000-4-6	Not applicable
Immunity to conducted disturbances induced by RF fields - Patient coupling ports	EN 61000-4-6	Not applicable
Power frequency magnetic field immunity	EN 61000-4-8	30 A/m 50 Hz
Voltage dips, short interruptions and voltage variations immunity	EN 61000-4-11	0% U_T: 0.5 cycle at 0°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle at 0° 70% U_T: 10 cycle at 0° 0% U_T: 25 cycle at 0°
Electrical transient conduction along supply lines	ISO 7637-2	Not applicable

[a] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz. 3.5 MHz to 4.0 MHz. 5.3 MHZ to 5.4 MHz. 7 MHZ to 7.3 MHz. 10.1 MHz to 10.15 MHz. 14 MHz to 14.2 MHz. 18.07 MHz to 18.17 MHz. 21.0 MHZ to 21.4 MHz. 24.89 MHz to 24.99 MHz. 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Specifications & Characteristics

The device system consists of the following parts:

24/7 EEG™ SubQ	
Device	Length: 89.9 mm Width: 37.5 mm Thickness (without Attachment Magnet): 10.9 mm Thickness (with Attachment Magnet): 15.6 mm Polycarbonate/Acrylonitrile Butadiene Styrene (PC ABS) Material grade: Sabic CYCOLOY HC1204HF. Weight (without Attachment Magnet and wire): 37.1 g
Disc	Diameters: 15.9x20.4 mm Thickness: 3 mm Moulded in epoxy Weight (with wire): 2.9 g
Wire	Length: 360 mm Outer diameter: 1.452 mm Cable: silicone Bend reliefs: Polyamide (PA)

UNEEG™ SubQ (implant)	
House	24x17x3.3 mm Ceramic, titanium, silicone, tungsten, gold and ruby feed through overload
Electrode variants	Length: 103 mm Material: Silicone Number of contact points: 3
Contact points	Outer diameter: 1.1 mm Length: 10 mm Pt-Ir

Charger	
Manufacturer	ARTESYN
Model	DA5-050EU

Device RF reception specifications:	
Fc	1.0606 MHz
RBW	30 kHz

Device RF transmission specifications:	
Fc	1.0606 MHz
Modulation	Load modulation (ASK)
Data	8,3k bit/s Manchester encoded
OBW	25 kHz
ERP	73 dBm

10. SYMBOLS AND MARKINGS

Explanation of symbols found on products and on packaging:

Manufacturer

Date of manufacture

Use-by date

Batch number

Catalogue number

Serial number

CE marking: Declaration that the product meets all the safety, health, and environmental protection requirements for CE marking and can be sold throughout the EEA.

Not for general waste

Warning: Messages with this heading indicate serious adverse reactions, potential safety hazards and inadequate performance of device.

Consult instructions for use

Temperature limits

Humidity limits

Do not use if package is damaged

Do not re-sterilise

Do not re-use

Sterilised using ethylene oxide

Sterilised using irradiation

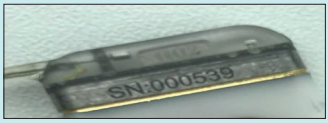
Open here

Open by hand

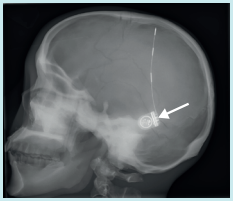
BF type applied part

Warning: Magnetic field. Do not bring device near implants sensitive to magnetic fields.

Markings found on implant:



Serial number (SN)



Model tag (x-ray readable)

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CE

0344
2019

2022/04
Rev. LTX10020-13