24/7 EEG™ SUBQ

USER MANUAL

24/7™

EEG SubQ

PRODUCT OVERVIEW

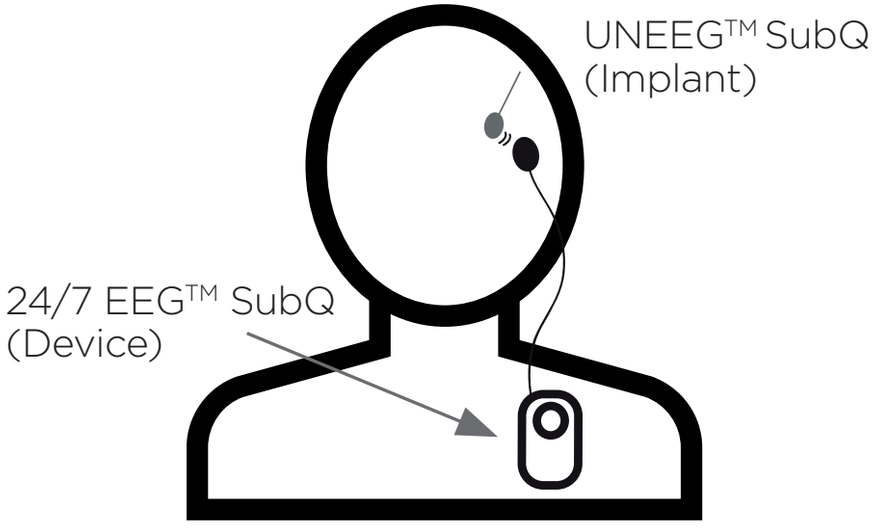

FIGURE A

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

The implantable part, the UNEEG™ SubQ (hereafter named **implant**) is implanted under the skin and measures the electroencephalogram (EEG).

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 the

recorded EEG data. The data are sent through a wireless link.

The device exists in two variants; one with a magnet inside (M1) and one without (C1). Please be aware of which variant you have been supplied with. The M1 variant is marked with a magnet-symbol **(FIGURE B)**.
Subjects with other active implantable devices must consult their responsible medical professional before using the M1 variant.
The M1 variant is attached to clothing using the supplied attachment magnet, while the C1 variant is attached to clothing using a plastic clip.

In addition to EEG, the device measures and stores 3D acceleration to support future product development. These data are encrypted and are only readable if sent to UNEEG™ medical.

FIGURE B

WARNINGS AND PRECAUTIONS

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

⚠ WARNINGS

- 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.

- 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).
- 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 children.

PRECAUTIONS

When you use the device, 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 dam-

aged if exposed to extreme pressure variations. Do not take part in extreme sport activities such as parachute jumping or diving deeper than 5 metres.

- If 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 ‘4.2 CLEANING’.
- Do not sink the device into any liquid, including alcohol.
- Do not try to open or repair the device.

CONTENTS

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

1.2 CONTRAINDICATIONS

The system should not be used in the following cases:

- If you have cochlear implant(s).
- If you receive therapy with medical devices that deliver electrical energy in the area around the implant.
- If you are at high risk of surgical complications, such as active systemic infection

and hemorrhagic disease.
- If you, for mental or physical reasons, cannot or do not have the necessary assistance, to properly operate the system.
- If you have an infection where the implant should be placed.
- If you operate MRI scanners.
- If you have 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.
- If you have a profession/ hobby that includes activity imposing a high risk of 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, you may experience the following side effects with the implantation and use of the system:

- Up to 3 weeks after the surgical procedure, haematoma or seroma may appear near the implant.
- Temporary pain, headache, infection and discomfort (including soreness, inflammation, swelling, irritation and itching) may appear around the implant up to 3 weeks after the surgical procedure.
- Damaged blood circulation and pressure to the skin around the implant may result in damaged tissue.
- Infection, swelling, soreness, irritation or itching of the skin around the implant.
- Occasional headache or pain during long-term use of the system.

1.4 AFTER THE SURGERY

Do not shower or touch the operated area the first 24 hours after the implantation.

Ensure that the area of the implant is inspected for signs of infection daily. The following might be signs of infection:

- Redness
- Heat
- Pain
- Swelling

If one or more of these signs of infection appear, or if you are in doubt whether everything is as it should be, please contact the responsible medical professional.

Approximately 1-2 weeks after the implantation, the stitches can be removed, and the device can be used.

2. DEVICE DESCRIPTION

2.1 DEVICE PARTS

The device consists of several parts (**FIGURE C**).

1	Disc	Receives EEG data from the implant.
2	Connection light	Indicates if the disc is connected to the implant.
3	Power button	Long press (3 sec): turn on/off device. Double press: diary check mark. Short press: check device status.
4	Charging light	Indicates if the device is charging.
5	Charger port	Insert the charger here.
6	Attachment clip (only for C1)	Used for attaching the C1 device on the clothes.
7	Attachment magnet (only for M1)	Used for attaching the M1 device on the clothes.

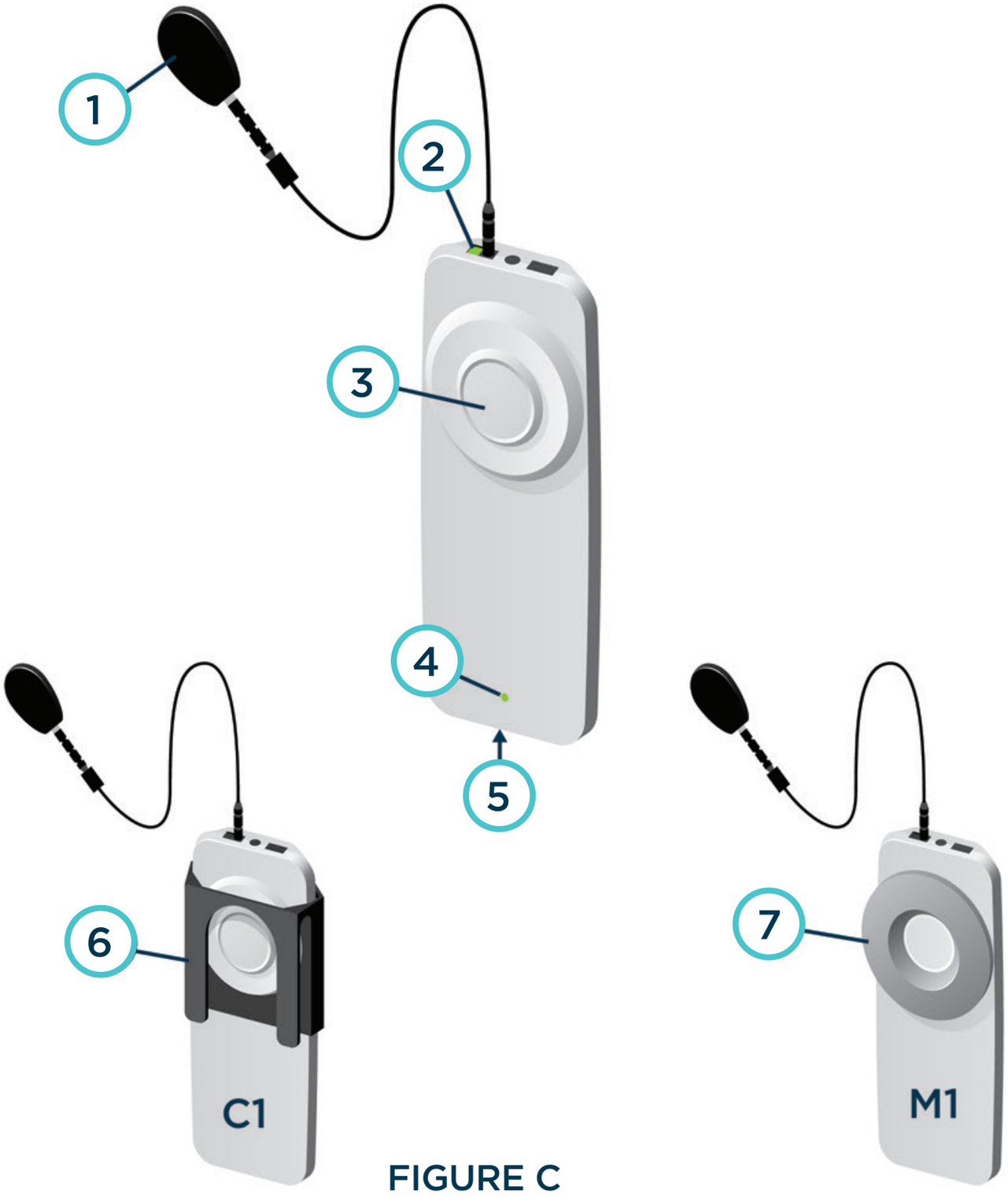

FIGURE C

2.2 ACCESSORIES

Besides the device and this manual, the following accessories are supplied:

- Charger, consisting of
  - Wall adapter
  - USB cable, 150 cm, with long-tip (8 mm) micro USB connector
- Cleaning cloth
- Adhesive pads

⚠ WARNING

- Only connect the supplied accessories to the device.

3. HOW TO USE

3.1 TURN ON THE DEVICE

1. Press and hold the power button for approx. 3 seconds until the ‘turning-on sound’ plays and the power button blinks green **(FIGURE D)**.

Until you have attached the disc, the connection light blinks white, and the device vibrates and plays the ‘disconnected sound’ every 10 seconds **(FIGURE E)**.

Turning on/off

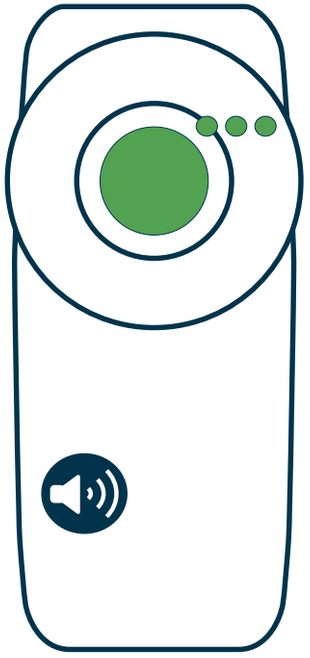

FIGURE D

Disconnected

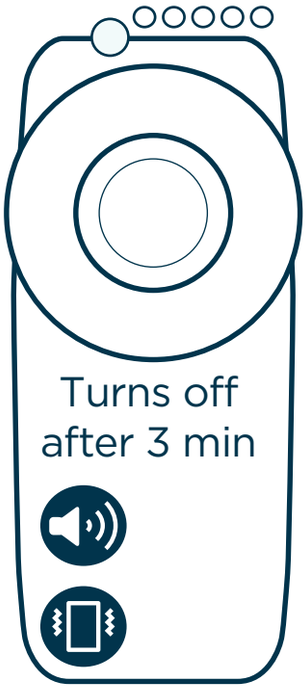

FIGURE E

3.2 MOUNT DEVICE ON CLOTHES

- The device exists in two variants; M1 and C1.
- M1 contains a magnet inside and is marked with a symbol **(FIGURE F)**.
- C1 does not contain a magnet.
- M1 is attached to clothing using a second magnet, while C1 is attached to clothing using a plastic clip.

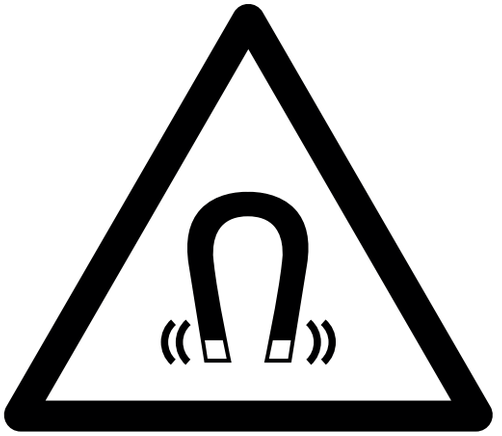

FIGURE F

⚠ WARNING

- The magnetic field from the M1 device might disturb other active implantable devices (e.g. pacemakers). If you have another active implantable device, consult your responsible medical professional before use.

3.2.1 MOUNT WITH ATTACHMENT CLIP
(only applicable for the C1 variant)

1. Choose an appropriate place on your clothes, e.g. shirt collar or bra strap.
2. Slide the device onto your clothes using the clip-arms **(FIGURE G).**

Note: *The clip version is non-magnetic and is safe to mount near implantable devices.*

FIGURE G

3.2.2 MOUNT WITH ATTACHMENT MAGNET
(only applicable for the M1 variant)

1. Remove the attachment magnet from the device.
2. Choose an appropriate place on your clothes, e.g. shirt collar or bra strap.
3. Place the device on one side of the clothes and attach the attachment magnet from the other side **(FIGURE H).**

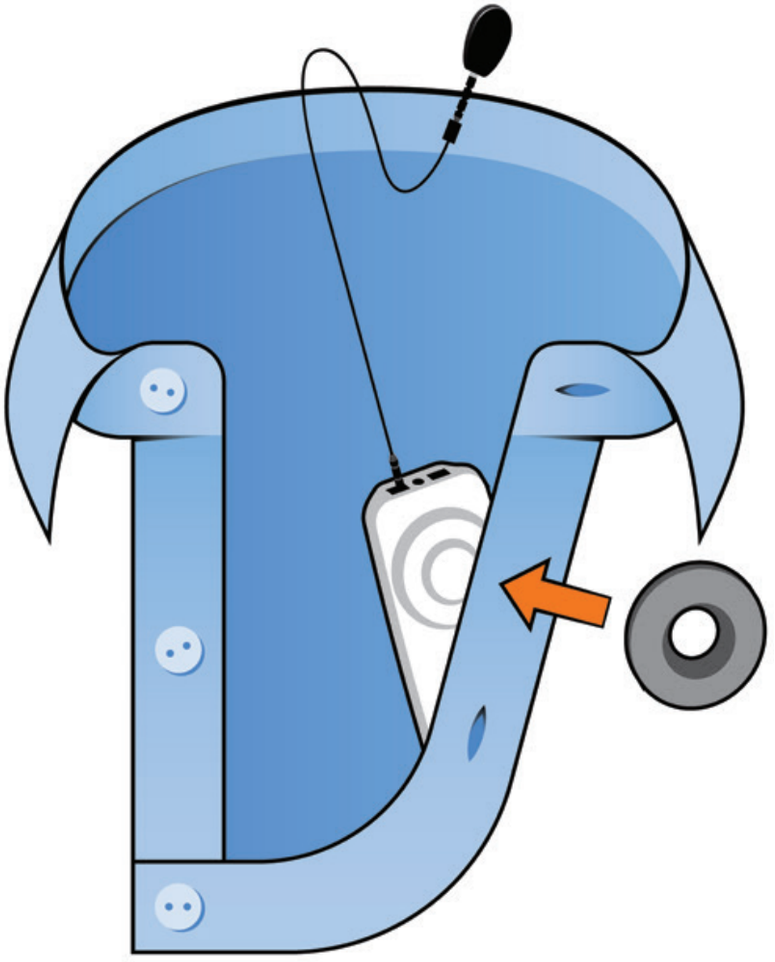

FIGURE H

3.3 ATTACH ADHESIVE PADS

1. Wipe the skin of the implant site with a dry cloth.
2. Take an adhesive pad from the sheet **(FIGURE I)**. Be careful to get both the adhesive pad and the protective paper. If the adhesive pad does not let go, use a fingernail or similar.
3. Attach the adhesive pad to either side of the disc **(FIGURE J)**.
4. Remove the protective paper from the adhesive pad **(FIGURE K)**. Make sure that the adhesive pad stays on the disc.

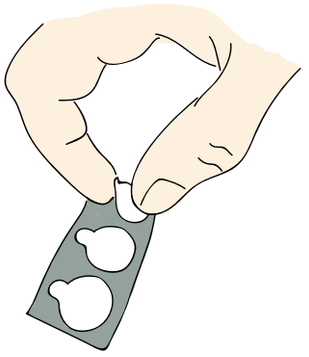

FIGURE I

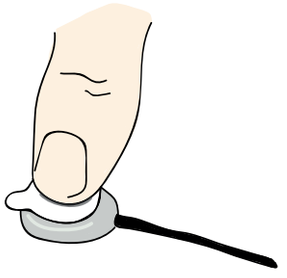

FIGURE J

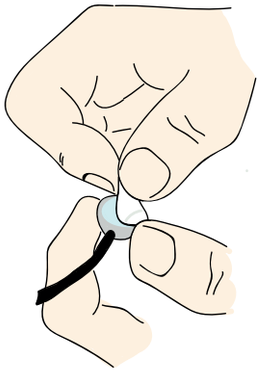

FIGURE K

Do not use the adhesive pad for more than 24 hours.

Only use each adhesive pad once.
When you remove the disc from the skin, the adhesive pad may still be attached. Use a fingernail to remove the adhesive pad from the disc. For any glue residue on the disc, see ‘4.2 CLEANING’.

For any difficulties attaching the adhesive pad to the skin, try cleaning the skin with an alcohol swab.

Note: *The device and supplied adhesive pads are made of non-allergenic materials. Nonetheless, in rare cases, skin irritation may occur. Contact your responsible medical professional if the problem is persistent.*

3.4 ATTACH AND CONNECT THE DISC

1. Hold the disc over the implant site WITHOUT attaching it to the skin **(FIGURE L)**. When at the correct position, the connection light turns green for 10 seconds, and the 'connection sound' plays **(FIGURE M)**.
2. Attach the disc to the skin.
3. Make sure that you can freely move your head. If the wire is too short, try moving the device.

Note: *the device is silent with no lights while recording EEG* ***(FIGURE N)****.*

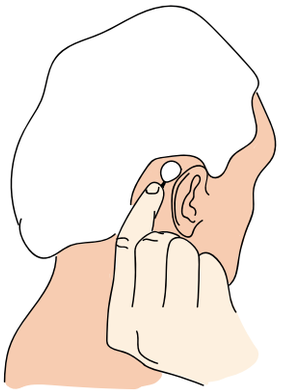

FIGURE L

Connected

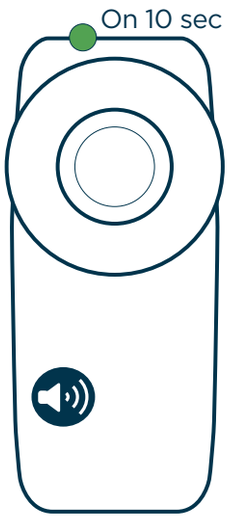

FIGURE M

Recording

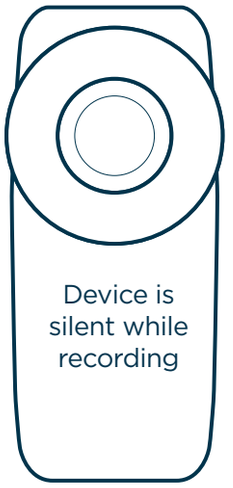

FIGURE N

3.5 TURN OFF THE DEVICE

1. Press and hold the power button for approx. 3 seconds until the device turns off. The ‘turning-off sound’ plays, and the power button blinks green once **(FIGURE O)**.

Turning on/off

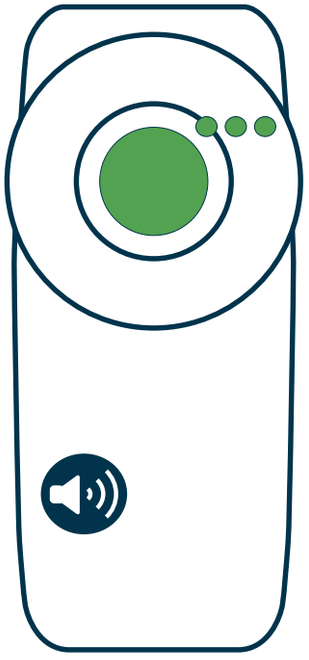

FIGURE O

3.6 CHARGE THE DEVICE

⚠ WARNING

- Only use the supplied charger for charging the device.
- Do not wear the device while it is charging.

To charge the device, use the provided charger.

1. Insert the charger into the device charger port.
2. Insert the other end of the charger into a regular power socket.

You can find the lights and sounds associated with charging and low battery levels in **TABLE 1.**

The device should be charged whenever it is not in use. The battery life when fully charged is minimum 24 hours.

Note: *If the device is not fully charged at least every 30 days, the internal clock might become incorrect.*

Note: *The device will turn off while charging.*

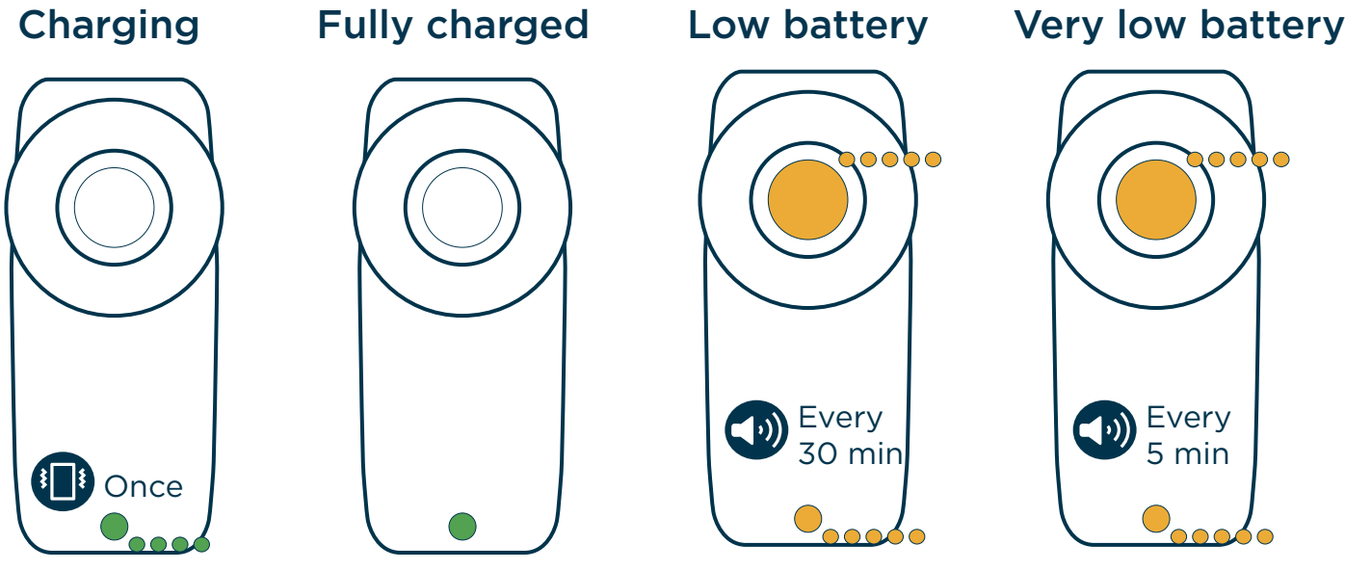

FIGURE P FIGURE Q FIGURE R FIGURE S

TABLE 1: CHARGING AND BATTERY LEVEL

Charging	The charging light blinks green **(FIGURE P)**.
Fully charged	The charging light is solid green **(FIGURE Q)**.
Low battery	Power button and charging light blink yellow. The 'low-battery sound' plays every 30 minutes **(FIGURE R)**.
Very low battery	Power button and charging light blink yellow. The 'low-battery sound' plays every 5 minutes **(FIGURE S)**.

3.7 CHECK STATUS

To check that the device works correctly:

1. Short press the power button.
2. Check device, see **TABLE 2.**

For more detailed status information, see **FIGURE T**.

Note: *The device only works when it is correctly connected to the implant. Loss of connection results in missing data.*

TABLE 2: STATUS

Turned on and connected to implant	The connection light is green for 4 seconds. The 'connection sound' plays.
Low battery	The power button and charging light are yellow for 4 seconds. The 'connection sound' plays.
Turned off	No sound or lights

Symbols: Sound Vibration

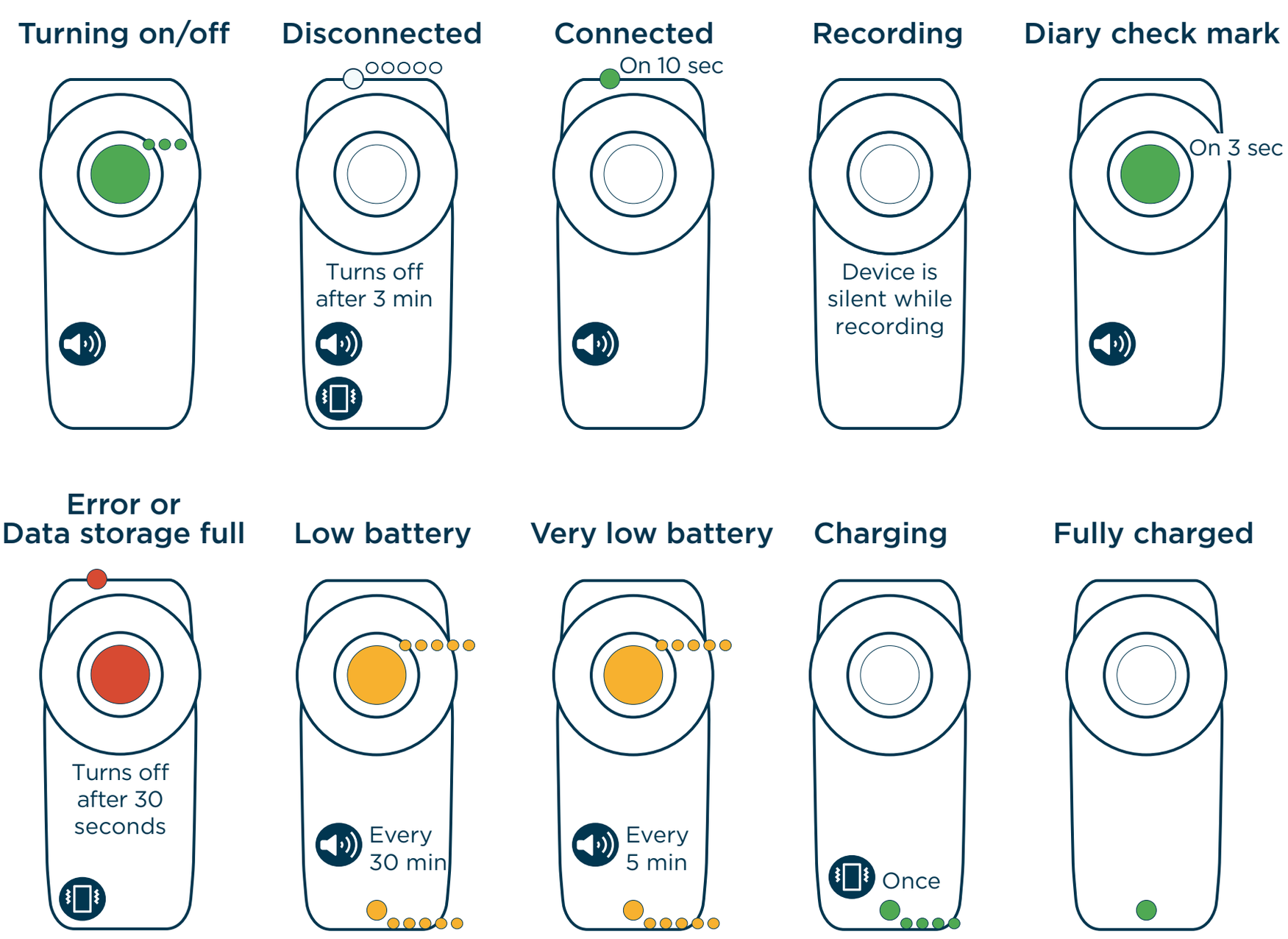

FIGURE T

3.8 DIARY CHECK MARK

To mark an event in the EEG data as advised by your medical professional:

1. Double press the power button.

Note that diary check mark is only possible when device is turned on, see **TABLE 3**.

Diary check mark

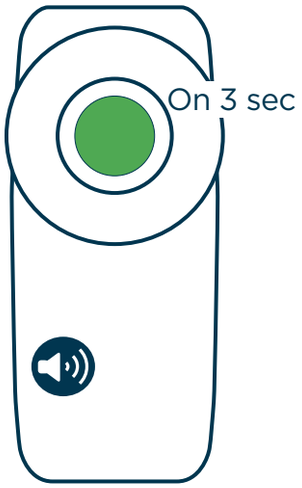

FIGURE U

TABLE 3: DIARY CHECK MARK

Turned on	The power button is green for 3 seconds. The 'diary check mark sound' plays **(FIGURE U)**.
Turned off	Not possible to mark an event

4. MAINTENANCE

The device is a valuable medical device and should be treated with care. This section contains information on how to handle it.

4.1 HANDLING

Make sure that the device does not get wet, and dry it thoroughly with a cloth or similar after heavy perspiration, e.g. after intense physical activity.

See environmental conditions in ‘6 TECHNICAL DESCRIPTION’.

PRECAUTION

- Do not wear the device in the shower or when swimming.
- Avoid dropping the device.

4.2 CLEANING

To keep the device hygienic, it is recommended to clean it at least once per week.

PRECAUTION

- Never use water or cleaning solutions.
- Never sink the device into any liquid, including alcohol.

For cleaning the device, you can use the following:

- Denatured alcohol/ethanol
- Hand disinfection gel
- Provided cleaning cloth

The cleaning process is as follows:

1. Make sure that the device is turned off, that the disc has been removed from the head, and that the adhesive pad has been removed.
2. Apply alcohol to the cleaning cloth.
3. Rub all surfaces of the device, including the cable and disc.
4. Wait for the device to dry before use.

4.3 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.

4.4 MALFUNCTIONING DEVICES

If the device seems to be malfunctioning, contact your responsible medical professional.

PRECAUTION

- Do not try to open or repair the device.

4.5 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.

4.6 MAINTENANCE OF DEVICE

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

4.7 TRAVELLING

It is okay to move through metal detectors and full-body scanners with the implant, but the device should be unmounted and turned off before you move through a metal detector. Treat the device as electronic hand luggage when you go through any security checks.

You can use the device during flight, but the airline company's guidelines for electronic equipment should be followed. This might mean that you should turn off the device during take-off and landing. If in doubt, ask the flight staff for their policy on electronic equipment.

5. TROUBLESHOOTING

See **TABLE 4** for information on how to react in different situations.

For further assistance regarding device use or unexpected events, contact the responsible medical professional.

TABLE 4: 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 '3.6 Charge the device'.
The power button and connection light are red.	The device has encountered an error.	Contact the responsible medical professional.
	Data storage is full.	Contact the responsible medical professional.
The device does not turn on.	The device is either low on battery OR has encountered an error.	First, try charging the battery. See '3.6 Charge the device'. If the device still does not turn on, contact the responsible medical professional.
The connection light is blinking white.	The device is not properly connected to the implant.	Connect the device to the implant. See '3.4 Attach and connect the disc'

6. 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 supplied charger to charge the device. The charger is considered an accessory 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: 0 °C to +40 °C

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

Specifications & Characteristics

The 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: 15.9 x 20.4 mm. Thickness: 3 mm. Moulded in epoxy Weight (with wire): 2.9 g.
Wire	Length: 360 mm. Outer diameter: 1.4 mm Cable: silicone. Bend reliefs: Polyamide (PA).

UNEEG™ SubQ (implant)	
House	24x17x3.3 mm. Ceramic, titanium, silicone, tungsten, gold and ruby feed.
Lead	103 mm. Silicone. 3 contact points.
Contact points	Outer diameter: 1.06 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

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).

PHENOMENON	TEST METHOD	IMMUNITY TEST LEVEL
Electrical fast transient/ burst immunity - AC power ports	EN 61000-4-4	+/- 2 kV +100 kHz repetition frequency
Electrical fast transient/ burst immunity - DC power ports	EN 61000-4-4	Not applicable
Electrical 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
Immunity to conducted disturbances induced by RF fields - AC power ports	EN 61000-4-6	3 V (6 V in ISM 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

PHENOMENON	TEST METHOD	IMMUNITY TEST LEVEL
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 13.5 67 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.

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 emissions	EN 61000-3-3	-	-

7. 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

IP24 Ingress protection rating

BF type applied part

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

UNEEG medical A/S
Borupvang 2
DK-3450 Allerød

www.uneeg.com

CE

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