



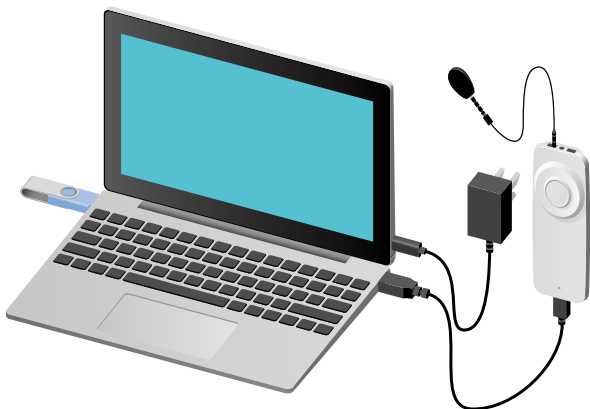
# UNEEG™ HOME DATA MANAGER

User Manual for Medical Professional and Patient





## PRODUCT OVERVIEW



**FIGURE A**

The UNEEG™ Home Data Manager (hereafter named **Data Manager system**) consists of a computer and a USB stick (**Figure A**).

The Data Manager system connects to the 24/7 EEG™ SubQ (hereafter named SubQ device). Please refer to

the specific instructions for use supplied with the SubQ device.

The data stored on the SubQ device are downloaded using the Data Manager system, which saves the data on a USB stick for easy sharing with your medical professional.

# WARNINGS AND PRECAUTIONS

## **WARNINGS**

- Only supplied accessories may be connected to the Data Manager system.
- The USB cable supplied with SubQ device may only be used with Data Manager system and SubQ device.

## **PRECAUTIONS**

When using the Data Manager system, take note of the following:

- Only use the supplied USB stick with the supplied computer.
- For medical professionals: It is recommended to have an anti-virus program installed on computers used to access USB sticks with patient data.

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# 1. INTRODUCTION

## 1.1 INTENDED USE

The intended use of the UNEEG™ Home Data Manager is transfer of EEG data from UNEEG SubQ device to portable storage media (USB stick).

## 2. DATA MANAGER SYSTEM DESCRIPTION

### 2.1 DATA MANAGER SYSTEM PARTS

The Data Manager system with the SubQ device connected to computer is illustrated in **FIGURE B**.

The Data Manager system consists of the following parts:

1 Computer	Receives and processes data from SubQ device.
2 Power adaptor	A power adaptor for the computer to be placed in a regular wall socket is supplied with the Data Manager system.
3 USB sticks	The Data Manager system is supplied with two USB sticks. During use one must be plugged into the computer. One USB stick has the capacity to store EEG data for up to 3 months.

The Data Manager System has an interface for connecting the 24/7 EEG™ SubQ (**FIGURE B**).

4 SubQ device	The SubQ device is worn to record EEG data from the implant.
5 USB cable	The USB cable connects the SubQ device to the computer. The cable is supplied with the 24/7 EEG™ SubQ system as part of the charger to the SubQ device.



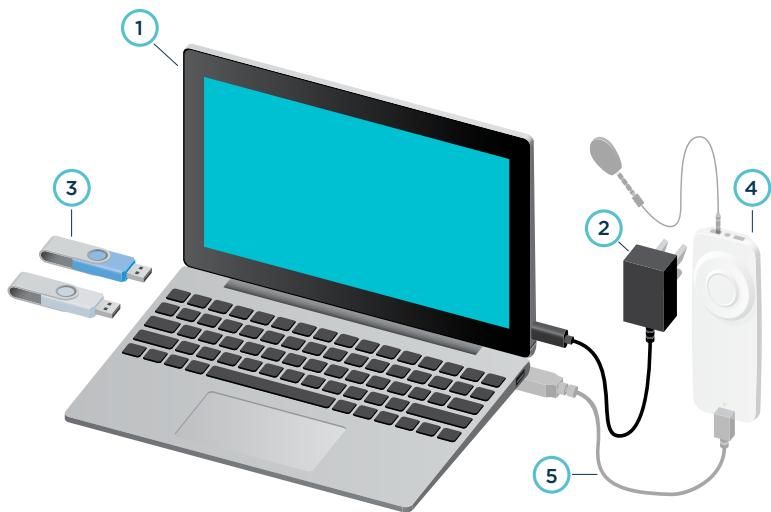


FIGURE B

**⚠ Warning**

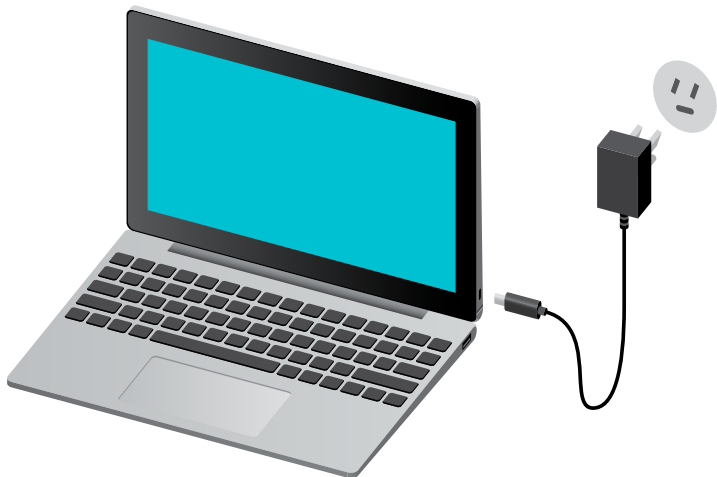
- Only connect the supplied parts to the computer.

## 3. HOW TO USE: PATIENT GUIDE

### 3.1 PLACEMENT AT HOME

1. Find a suitable level surface that can accommodate the computer and one SubQ device. Choose a spot close to a free power socket, as the Data Manager system will need power during the entire use period to function properly. Place the computer on the surface and open the lid.

### 3.2 ATTACH THE POWER ADAPTOR



**FIGURE C**

1. The computer must always remain connected to the keyboard as shown in **FIGURE C** (laptop mode).
2. Attach the power adaptor in the wall socket.
3. Plug the power cable into the computer.
4. Let the power adaptor stay connected to the computer, as the computer needs power supply during the entire period to function.

### 3.3 TURN ON COMPUTER



**FIGURE D**

1. Press and hold the power button for 2 seconds (**FIGURE D**).
2. Wait for the Data Manager system to start up.

**Note:** The computer has the following battery saving modes when screen is not activated:

- After 5 minutes the screen will turn off.
- After 1 hour on battery the computer will go in sleep mode.  
If the power cable is plugged in, the computer will not go in sleep mode.

### 3.4 CONNECT THE SUBQ DEVICE



**FIGURE E**

The computer prompts for connection to the SubQ device.

1. Use the USB cable supplied with SubQ device and connect it to the computer. If the USB cable is connected to the wall adaptor you will need to disconnect the USB cable from the wall adaptor before connecting to the computer.
2. Attach the SubQ device.

### 3.5 ATTACH USB STICK

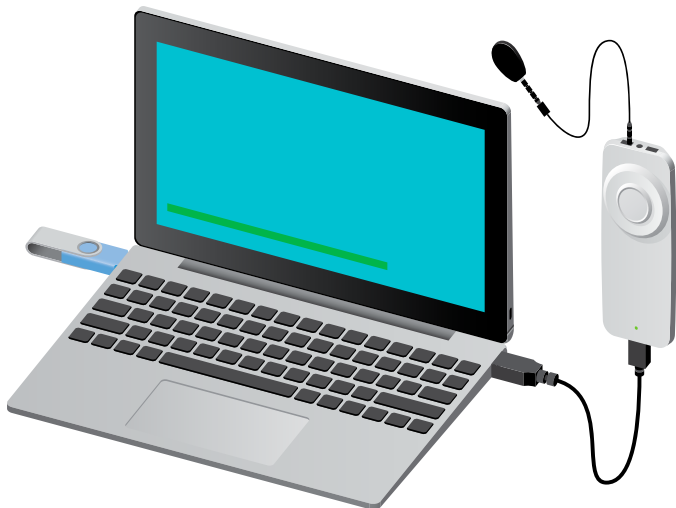


**FIGURE F**

The computer prompts for connection to the USB stick.

1. Attach the USB stick. The computer will automatically start transfer of data from the SubQ device (**FIGURE G**). If the USB stick is already mounted the Data Manager system will proceed to next step and start to transfer data.
2. Keep the USB stick connected to the computer until you send the data to your doctor as agreed. See section 3.9. Do not remove the USB stick on a daily basis.

### 3.6 TRANSFER DATA AND CHARGE YOUR SUBQ DEVICE



**FIGURE G**

When all components are connected to the Data Manager system, data is downloaded to the computer. The computer automatically processes the data and stores it on the USB stick to be reviewed later by your medical professional.

A progress bar will indicate when data is transferred.

### 3.7 DATA TRANSFERRED



**FIGURE H**

When the data is successfully transferred, the progress bar disappears and a message to leave the SubQ device plugged in until fully charged is shown.

1. Check on screen, that the data was successfully transferred. In case of an error follow the instruction displayed on the screen.
2. Leave the SubQ device connected to the computer to allow it to charge.
3. When fully charged the green light on the SubQ device stops flashing and lights solid green.



It is now safe to remove the SubQ device. You are advised to leave it plugged in until you need to wear the SubQ device. You can find the lights and sounds associated with charging and low battery levels in the Instructions for use for the SubQ device. The SubQ device should be charged whenever it is not in use. The battery life when fully charged is minimum 24 hours.

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

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

### 3.8 CHANGE SUBQ DEVICE



**FIGURE I**

If more than one SubQ device is in use, it is advised to set a daily routine for changing SubQ devices and connect the just worn SubQ device to the computer for charging and download of data.

1. Remove the SubQ device from the computer.
2. Prepare that SubQ device for wearing by attaching an adhesive pad to the disc.
3. Remove the SubQ device you are wearing.
4. Connect that SubQ device to the computer.

The Data Manager system will start to transfer data as described in 3.6.

5. Wear the prepared SubQ device as instructed in the SubQ device Instructions for use.

**Note:** *The SubQ device has a battery life of minimum 24 hours when fully charged and the capacity to store EEG data for up to 1 month.*

**Note:** *Be careful not to mix up the SubQ devices when changing. Using the same SubQ device for several days can lead to low battery level.*

### 3.9 SENDING DATA TO YOUR MEDICAL PROFESSIONAL



**FIGURE J**

After a period of time agreed with your medical professional, you can send the recorded data to your medical professional.

1. Make sure that data transfer is not in progress.
2. Find the second USB stick supplied with the Data Manager system.
3. Prepare an envelope to send the USB stick to your medical professional.

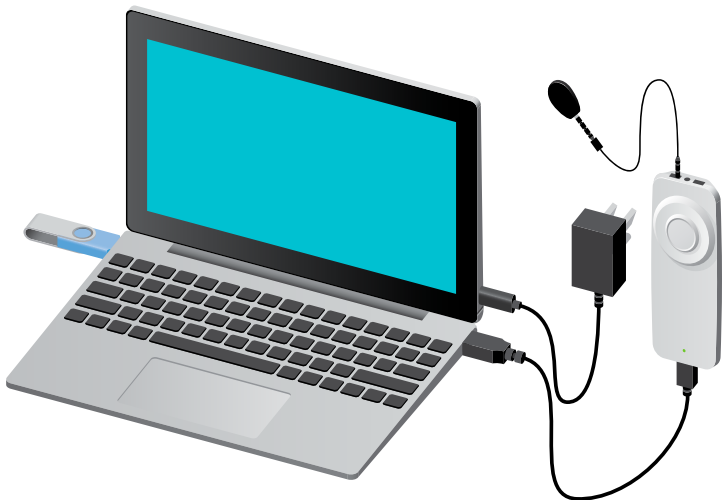
4. Remove the USB stick from the computer and place it in the envelope.
5. Place the second USB stick in the free USB port on the computer.
6. Mail the envelope containing the USB stick as agreed with your medical professional.

The medical professional can then review your EEG before your next visit.

**Note:** *Be careful not to mix up the USB sticks, as sending an empty USB stick will cause a delay in the medical professional receiving your data.*

**Note:** *When you visit your medical professional, the USB stick you sent, will be given back to you. **Do not replace the USB stick currently in use when you come home**, but wait until next time you are scheduled to send in your data.*

### 3.10 RETURNING THE DATA MANAGER SYSTEM



**FIGURE K**

When it is time to stop using the Data Manager system, you must return it to your medical professional.


The computer, the SubQ devices and the USB stick all contain data. When you return the Data Manager system make sure that the medical professional receives:

- One computer with power adaptor.
- Two USB sticks. You may already have mailed one of the USB sticks to your medical professional.
- One or more SubQ devices with wall adaptor and USB cable.
- Please return the Data Manager System components in their original packaging, if available.

## 4. HOW TO USE: MEDICAL PROFESSIONALS GUIDE

### 4.1 FIRST PATIENT VISIT

1. Hand over the Data Manager system to the patient. The patient should get one box containing a computer, power adaptor and two USB sticks.

**Note:** *It is possible to change the language on the computer to match your patients preference. Press  in the software on the computer to set the language.*

2. Consider handing out pre-addressed padded envelopes\* (which the patient can use to send the USB stick with data).
3. Fill out the address you would like to receive the USB stick at.

**\*Note:** *In order to comply with GDPR rules; Do not insert the patient name on the envelope as it will contain health data.*

### 4.2 SCHEDULE NEXT PATIENT VISIT

1. Schedule next patient visit.
2. Ask patient to send USB stick prior to visit, to allow for processing and analysis.

### 4.3 ACCESSING PATIENT DATA

When you receive the USB stick, the data is preprocessed to EDF+ files with a unique filename.

1. Connect USB stick to PC.
2. Access the EDF+ files on the USB stick as you would normally access data and transfer the files to a destination folder on the PC.
3. Delete data on the USB stick after data transfer.
4. Store the USB stick to return to patient at next patient visit.

**Note:** Please note that files are named with the implant ID.

**Note:** Please note that files from more patients can be transferred to the same destination folder.

**Note:** Make sure to delete data on the USB stick before returning it to the patient.

### 4.4 PATIENT VISIT

Remember to hand over the USB stick to the patient, to ensure continued logging.

1. Instruct the patient to change the USB stick currently connected to their computer the next time they need to send data.
2. Inform patients not to change the USB stick immediately when getting home as this would cause fragmentation of data.



## 5. MAINTENANCE

The Data Manager system is a valuable part of optimising your treatment and should be treated with care. This section contains information on how to handle it.

### 5.1 HANDLING

Make sure that the Data Manager system does not get wet or exposed to dust, dirt or excessive temperatures. See environmental conditions in '7 TECHNICAL DESCRIPTION'.

### 5.2 CLEANING

For the computer and the USB stick, normal conditions for home use electronics apply. For the SubQ device please refer to the specific user manual.

### 5.3 DISPOSAL

The SubQ device and all electronic accessories must be disposed according to the EU directive 2012/19/EU (WEEE). It is advised that the medical professional return the Data Manager system to UNEEG™ medical.

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

#### **5.4 MALFUNCTIONING DEVICES**

If the Data Manager system seems to be malfunctioning, contact your responsible medical professional.

#### **5.5 PRODUCT LIFE TIME**

The Data Manager system is designed to be used for 6 months.

During the product life time, the Data Manager system does not need service or calibration.

#### **5.6 TRAVELLING**

In addition to ensuring that you have an appropriate adapter/voltage converter when it is needed to power the Data Manager System, there are no special precautions to take.

## 6. TROUBLESHOOTING

See Table 1 for information on how to react in different situations.

**Table 1: Troubleshooting**

<b>Problem</b>	<b>Possible cause</b>	<b>Possible solution</b>
The computer informs that download failed.	SubQ device is disconnected.	Reconnect the SubQ device. See section 3.4.
	USB stick is disconnected.	Reconnect the USB stick. See section 0. If the problem persists, change the USB stick and contact your medical professional. See section 3.9.
	Other error.	Disconnect the SubQ device and contact your medical professional.
The computer informs that hard drive is full.	The storage capacity of the computer is full.	Contact your medical professional.
The computer informs that USB stick is full.	No more free storage space on the USB stick.	Replace USB stick with another UNEEG medical USB stick and contact your medical professional.

Problem	Possible cause	Possible solution
The computer screen is off.	The screen automatically turns off after 5 minutes if application is not used.	Reactivate the computer by pressing any key and the screen automatically turns on.
	The computer has been without power supply for more than one hour and is in sleep mode.	Reconnect the power adaptor for the computer and turn on the computer. See section 3.2 and 3.3.
	The power supply for the computer is disconnected.	Reconnect the power adaptor for the computer and turn on the computer. See section 3.2 and 3.3. You may need to resume the data transfer from the SubQ device. See section 3.6.
	The computer has been turned off.	Turn the computer back on by pressing and holding the power button. See section 3.3.
The computer screen informs to connect USB stick	No UNEEG USB stick is connected.	Connect the supplied UNEEG USB stick to the computer or contact your medical professional.
	Invalid USB stick not supplied by UNEEG medical is used.	Use supplied UNEEG medical USB stick or contact your medical professional.
The computer informs to connect the SubQ device.	Computer is not in laptop mode.	Position computer in laptop mode as shown on <b>FIGURE C.</b>

For further assistance regarding SubQ device use or unexpected events, contact your medical professional.

## 7. TECHNICAL DESCRIPTION

### Power Source

Only use the supplied charger to charge the computer.

### Modification

No modification of the equipment is allowed. Only the UNEEG Home Data Manager application can run on the computer.

### Repairs

The SubQ device contains no replaceable or repairable parts.

### Environmental Conditions

The following are the allowed environmental conditions for the Data Manager system and accessories:

**Relative Humidity:** 8 % to 80 %

**Temperature:** 5 °C to +35 °C

## Specifications & Characteristics

The Data Manager system consists of the following parts:

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### Computer

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Computer	<p>Computer with installed UNEEG™ Home Data Manager Software</p> <p>The software will start automatically when the computer is turned on.</p> <p>The computer will charge the SubQ device when connected.</p>
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Power adaptor	<p>A power adaptor is supplied with the Data Manager system. The power adaptor will charge and power the computer.</p>
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### UNEEG™ USB stick

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USB stick	<p>USB stick formatted to be recognised by the UNEEG™ Home Data Manager software.</p>
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## 8. SYMBOLS AND MARKINGS



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

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