

UNEEG™ MYCONNECT

USER MANUAL - HEALTHCARE PROFESSIONAL



UNEEG™ medical

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1. INTRODUCTION

1.1 INTENDED USE

The intended use of UNEEG™ MyConnect is to transfer data from a UNEEG recorder to the UNEEG™ Cloud.

1.2 INDICATIONS

Not applicable for this product.

1.3 INTENDED USER AND POPULATION

UNEEG™ MyConnect is aimed to be used by lay persons and healthcare professionals.

1.4 CONTRAINDICATIONS

There are no known contraindications with the use of UNEEG™ MyConnect.

1.5 WARNINGS AND PRECAUTIONS

No warnings or precautions have been identified.

1.6 SIDE EFFECTS

There are no known side effects related to the use of UNEEG™ MyConnect.

2. PRODUCT DESCRIPTION

UNEEG™ MyConnect ensures that recorded data from a recorder is transferred via a cloud-based solution to the healthcare professional.

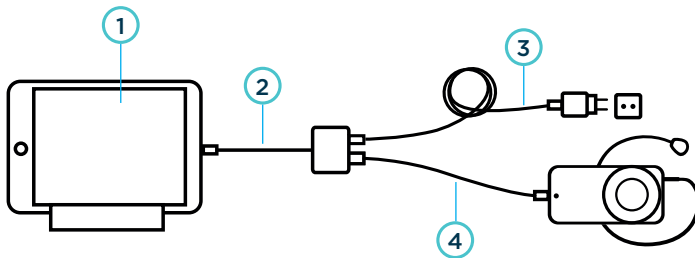
2.1 REQUIREMENTS FOR USING UNEEG™ MYCONNECT

To use UNEEG™ MyConnect the following criteria must be met:

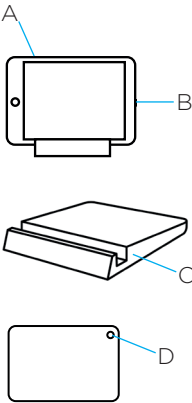
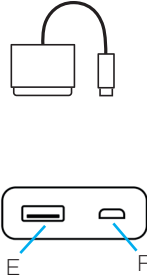
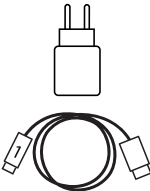
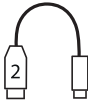
- Wi-Fi must be available to set up UNEEG™ MyConnect for a patient.
- UNEEG EpiSight (version 1.11 or newer) or UNEEG EpiSight Analyzer (version 2.0 or newer) must be installed and available. From now on referred to as the EEG review software.
- The patient must have an inserted UNEEG implant and a UNEEG recorder.

2.2 UNEEG™ MYCONNECT DEVICE DESCRIPTION




The figure shows the assembled UNEEG™ MyConnect with a UNEEG recorder and power supply.



The components included in UNEEG™ MyConnect are described in the table below.













NO.		ITEM NUM-NAME BER	DESCRIPTION
①		20002 Tablet	Device for using the UNEEG™ MyConnect app. The tablet can only be used with the preinstalled app.
		Power button (A)	Button to turn the tablet on and off.
		Connection port (B)	To connect the USB hub.
		Holder (C)	Enables the tablet to be placed in an upright position.
②		20021 USB hub	Connects tablet to connector cable and power supply.
		USB A port (E)	To connect the recorder.
		Micro USB port (F)	To connect the power supply.
③		20002 Power supply	For charging the tablet. Consist of a power adaptor and a cable.
④		20020 Connector cable	Connects the recorder to the USB hub.

2.3 COMPATIBLE PRODUCTS

PRODUCT	PART	DESCRIPTION
	24/7 EEG™ SubQ	Records EEG data. Referred to as 'recorder' in this user manual.
	UNEEG™ EpiSight UNEEG™ EpiSight Analyzer	Computer-assisted review system for EEG data. Available to healthcare professionals only.
	UNEEG™ Cloud	Transfers data from UNEEG™ MyConnect to the healthcare professional.

3. SYMBOLS AND LABELLING

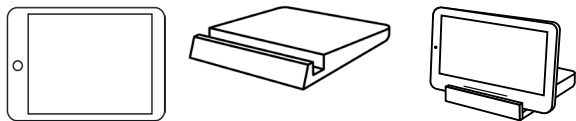
Key to symbols on equipment and packaging:

SYMBOL	EXPLANATION
	Manufacturer
	Date of manufacture
	Batch code
	Catalogue number
	Serial number
	Temperature limit
	Consult instructions for use
	Not for general waste
	CE marking
	Medical device
	Wi-Fi
	Battery power level

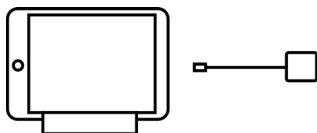
4. USING THE SYSTEM

4.1 HOW TO ASSEMBLE YOUR EQUIPMENT

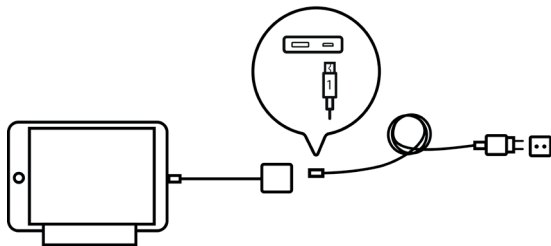
1. Place the tablet in the holder (optional).



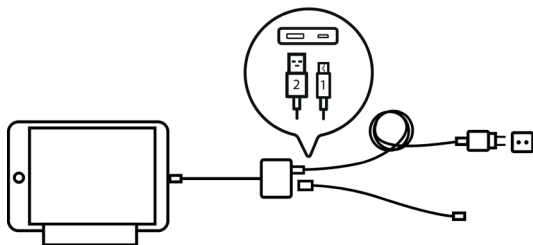
2. Connect the USB hub to the tablet.



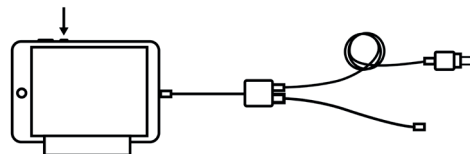
3. Connect the power supply to the USB hub.



4. Connect the connector cable (20 cm) to the USB hub.



5. Turn on the tablet and follow the on-screen instructions. The tablet is ready to be connected with the recorder.



4.2 SETTING UP THE SYSTEM FOR A PATIENT

The purpose of setting up the system for a patient is to create a wireless connection for transfer of recorded data between UNEEG™ MyConnect and the healthcare professional. The setup ensures that the app only recognises recorded data from the specific patient.

If recorders have already been used by the patient at home, data shall be offloaded prior to setup.

4.2.1 BEFORE STARTING SETUP

On the tablet:

- 1. Select language.
- 2. Select Wi-Fi. A Wi-Fi connection is necessary in order to complete the setup. UNEEG™ MyConnect does not support captive web portal for Wi-Fi access. If the Wi-Fi connection is interrupted, you need to restart the setup process.
- 3. A welcome screen is shown with the required prerequisites.

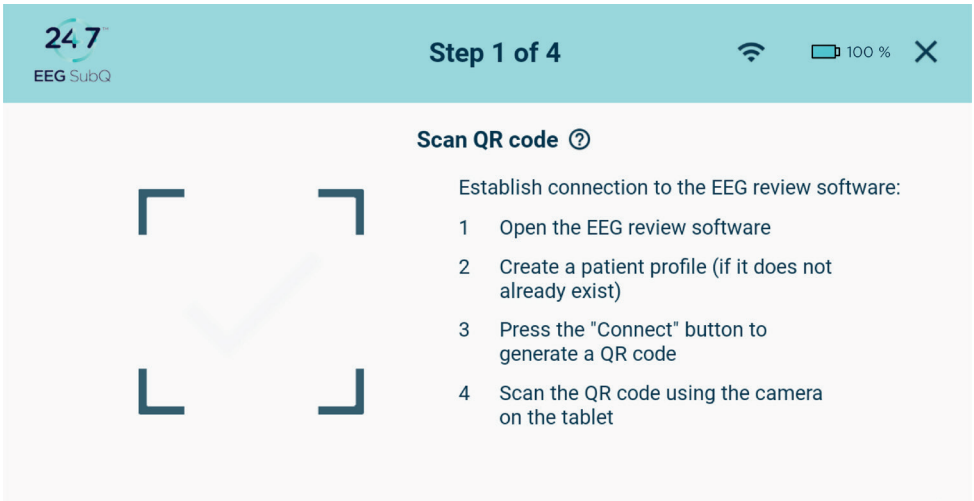
4.2.2 SETTING UP DATA TRANSFER

Setting up data transfer will require 4 Steps, which are explained below.

Step 1 of 4: Scan QR code


- Open and create a patient profile in the EEG review software if one is not already available (1+2).
- Select 'Connect' in the EEG review software and a QR code is generated and displayed on the computer screen (3).
- Scan the QR code by holding the camera on the tablet in front of the computer screen so that the QR code is displayed in the app's camera field, see the figure below (4).

Once the QR code has been scanned, tap 'OK' to continue.






Step 2 of 4: Record test data

In order to set up a connection between the patient and the EEG review software, there must be a minimum of one minute of EEG data from the patient on the recorder. If no EEG data exists from the patient on the recorder, record one minute of data as described in the app, see the figure below.




Step 2 of 4




Record 1 minute of EEG data


If the patient already has recorded EEG data, continue to next step



Press the button for 3 seconds to turn on the recorder





Attach the recorder and record for 1 minute



Take off the recorder and press the button for 3 seconds to turn off the recorder

Start timer



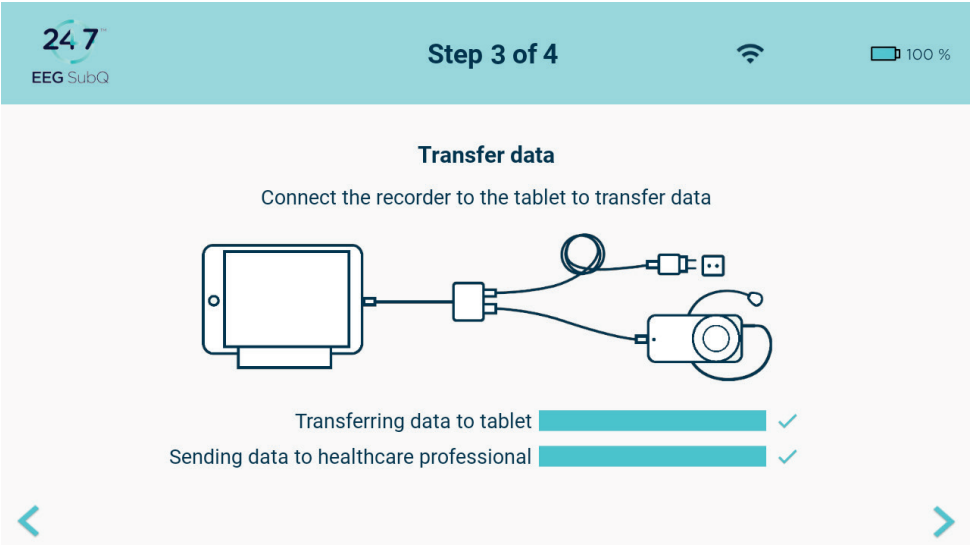
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Step 3 of 4: Transfer test data

Connect the recorder to the tablet as shown in the figure.

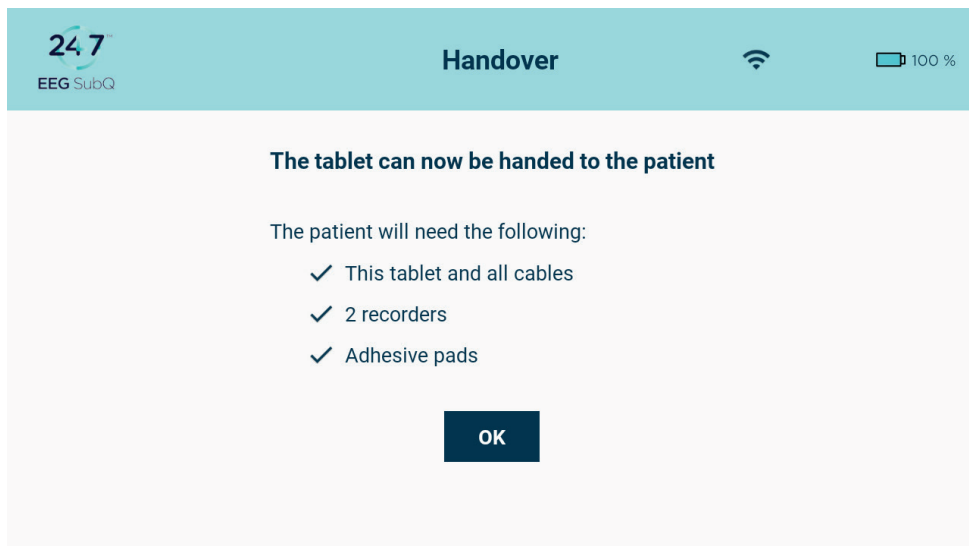
Once the recorder is connected, transfer will begin automatically. The app will indicate when the transfer is complete.

Two pop-up windows appear the first time you connect the recorder to the tablet. Tick the checkbox to avoid these pop-ups in the future. Tap 'OK' to continue. If you tab 'Cancel' data will not transfer.



Step 4 of 4: Complete setup

Setup of tablet and data transfer is now complete. Tap 'OK' to proceed to hand over UNEEG™ MyConnect to the patient.



4.2.3 HANDOVER OF EQUIPMENT TO THE PATIENT

The setup is now complete. Hand the items listed on the screen to the patient. Tap 'OK' to continue to the home page for patient use.

The patient's daily use of UNEEG™ MyConnect is described in the user manual for user.

4.3 CHARGING THE TABLET

Charge the tablet by connecting the power supply to a power outlet. The equipment may only be charged using the power supply provided with UNEEG™ MyConnect.

4.4 SERIOUS INCIDENT REPORTING

Per European Regulations: Report any serious incident that has occurred in relation to this device to the manufacturer and the competent authority of the EU Member State where the device was used.

5. MAINTENANCE AND DISPOSAL OF EQUIPMENT

5.1 HANDLING

Handle UNEEG™ MyConnect with care.

See environmental conditions under 7. TECHNICAL SPECIFICATIONS.

5.2 CLEANING

For information concerning the tablet, see the instructions from the manufacturer of the tablet.

5.3 RETURN OF THE EQUIPMENT

The equipment is a single patient device and must be returned to UNEEG medical when no longer in use.

5.4 REPAIRS

Modifying the equipment or using it for any purpose other than those described in this user manual is not permitted.

If the equipment is broken or components are defective, contact UNEEG medical. Do not attempt to repair the equipment. The system does not need servicing during its lifetime.

6. TROUBLESHOOTING

This table provides information on how to react in various situations. Please note the error message number together with the version number of the app and email it to UNEEG medical at uneeg@uneeg.com. Troubleshooting during daily use is described in the user manual for users.

PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
The tablet shows a black screen.	The tablet is turned off.	Turn on the tablet, see section 2.
	The screen on the tablet has turned off. The screen turns off automatically after 2 minutes if the tablet has not been used.	Turn on the tablet, see section 2.
	No power to the tablet.	Connect the tablet to a power outlet, see section 2.
QR code cannot scan.	There is too much backlight on the screen where the QR code is displayed.	Avoid the backlight and try again.
	The cursor on the screen is placed over the QR code.	Move the cursor away from the QR code and try again.
	Other error.	Contact UNEEG medical.
The tablet informs you that the tablet cannot connect to Wi-Fi.	The password you entered for the Wi-Fi is incorrect.	Enter the correct password
	UNEEG™ MyConnect does not support captive web portal for Wi-Fi access.	Use a Wi-Fi without captive web portal or a hot-spot for Wi-Fi access.
The tablet informs you that the recorder is connected to the tablet.	The recorder can only be connected when the tablet asks you to connect it. This only applies during the set-up process.	Disconnect the recorder until you are asked to connect it in step 3 of 4.

PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
The tablet informs you that data was not transferred.	The recorder is disconnected.	Connect the recorder to the tablet. Make sure the recorder is connected to the tablet during the transfer of data.
	No data was found on the recorder.	Go back to step 2 of 4 in the setup and repeat the process .
	Wi-Fi connection is lost.	Reconnect the recorder to Wi-Fi and repeat the process.
	Connection to UNEEG™ Cloud could not be established.	Try again later.
	The recorder contains data from more than one implant.	Use an empty recorder and repeat the setup.
	The recorder has encountered an error.	Contact UNEEG medical.
	Other error.	Try again later.
The tablet informs you that the battery level of the tablet is below 25%.	Data transfer requires a battery level of at least 25%.	Connect the tablet to a power outlet.
The tablet informs you that the data upload was not confirmed in the EEG review software.	Data was received in the EEG review software but no confirmation could be sent to the tablet.	Verify manually that data has been received in the EEG review software. If data has been received in the EEG review software, tap 'Data is received'.
	Data has not been received in the EEG review software.	Verify manually that data has been received in the EEG review software. If data has not been received in UNEEG™ EpiSight, contact UNEEG medical.

PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
The tablet informs you that something went wrong.	An error has occurred in the app.	Try again later. If the error persists, please restart the tablet.
The data transfer does not start.	The two pop-up notifications were cancelled.	Disconnect the recorder, connect again and press 'OK' to the two pop-up notifications.

If suspicious activity occurs on the tablet, other than already described in the table, please shut down the tablet by long pressing the power button and contact UNEEG medical.

7. TECHNICAL SPECIFICATIONS

UNEEG™ MYCONNECT	
Tablet	For information concerning the tablet, see the instructions from the manufacturer of the tablet.
Power supply	For information concerning the power supply, see the instructions from the manufacturer of the power supply.
Connector cable	Length: 200 mm Junction 1: USB A port Junction 2: Micro USB port (8 mm)

7.1 ENVIRONMENTAL CONDITIONS

Avoid subjecting the equipment to temperatures of below 5 °C or above 35 °C.

7.2 DATA PROTECTION


All data saved on UNEEG™ MyConnect is protected in a safe format.

To ensure there is no misuse of data on the tablet, the tablet will become inactive if it is not used as intended for a period of 90 days. If this situation occurs, please contact UNEEG medical.

If any breach related to data security is detected, UNEEG medical will inform you of how to act to ensure that data protection is restored.

7.3 CYBERSECURITY BILL OF MATERIAL

The main off-the-shelf software components that are used in UNEEG™ MyConnect can be found on the UNEEG website.



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