UNEEG™ MYCONNECT

USER MANUAL – USER

UNEEG™ medical

TABLE OF CONTENTS

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 transfer data from UNEEG™ MyConnect to the healthcare professional.
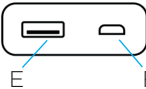- A UNEEG recorder and an inserted UNEEG implant must be available.
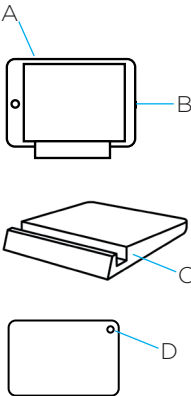
2.2 UNEEG™ MYCONNECT DEVICE DESCRIPTION
The figure shows the assembled UNEEG™ MyConnect with a UNEEG recorder and power supply.
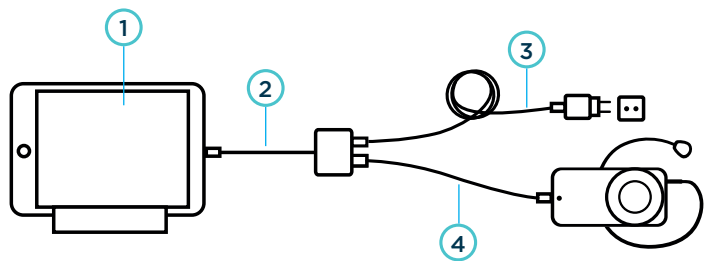
The components included in UNEEG™ MyConnect are described in the table below.

NO.		ITEM NUMBER	NAME	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.
			Camera (D)	For scanning the QR code when setting up a patient.
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™ Cloud	Transfers data from UNEEG™ MyConnect to the health-care professional.

3. SYMBOLS AND LABELLING

Key to symbols on equipment and packaging:

SYMBOL	EXPLANATION
	Manufacturer
	Date of manufacture
LOT	Batch code
REF	Catalogue number
SN	Serial number
	Temperature limit
	Consult instructions for use
	Not for general waste
CE	CE marking
MD	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
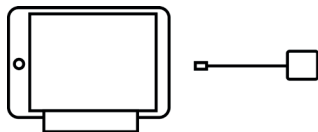
3. Connect the power supply to the USB hub.
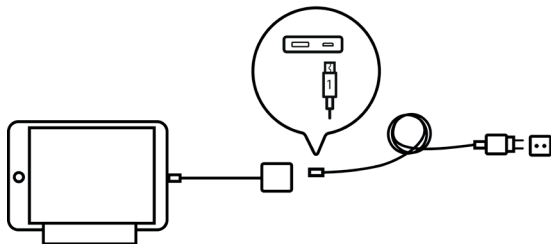
4. Connect the connector cable (20 cm) to the USB hub.
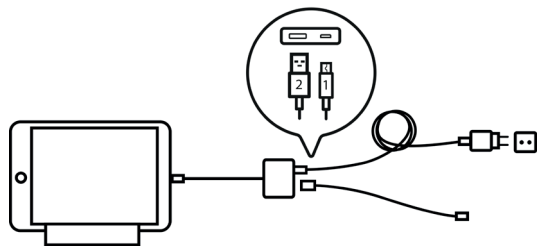
5. Turn on the tablet and follow the on-screen instructions. The tablet is ready to be connected with the recorder.
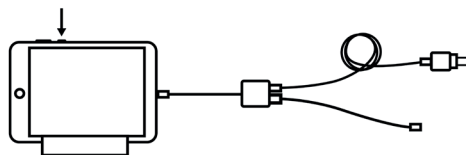
4.2 DAILY USE

4.2.1 HOME PAGE
The tablet starts up on the home page. The home page shows:
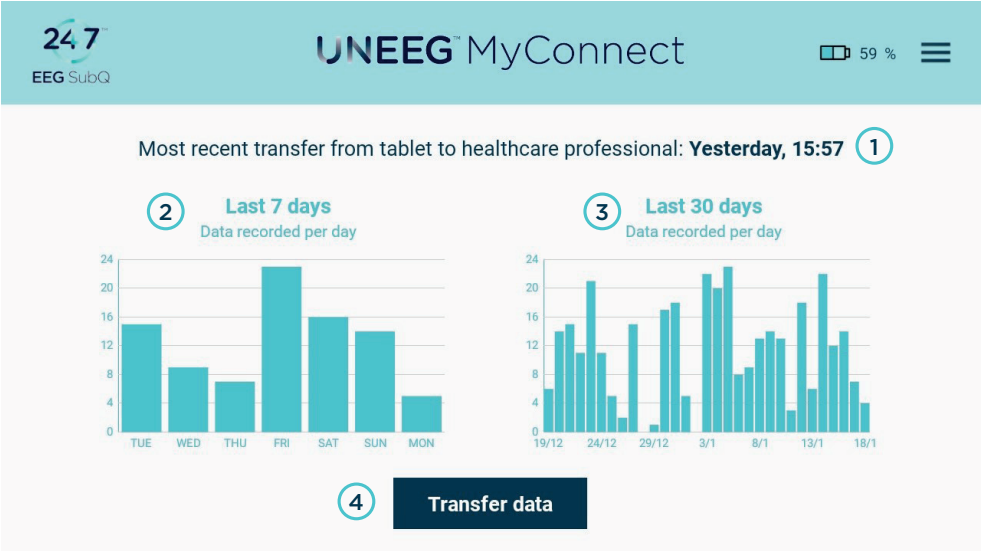
The time for the latest data transfer from the tablet to your healthcare professional, at the hospital's local time zone.

An overview of recorded data for the past 7 days.

An overview of recorded data for the past 30 days.

Button to begin the transfer of data from recorder to tablet.

4.2.2 MENU
The menu in the top right provides the following options:
• Instruction for use
• Select language
• Select Wi-Fi
• About the app

4.2.3 SELECTION OF WI-FI

To transfer recorded data to your healthcare professional, the tablet must be connected to Wi-Fi. To select Wi-Fi use the menu on the top right. Tab the Wi-Fi you want to connect to. Once connected a Wi-Fi icon will appear next to the menu.

If there is no Wi-Fi connection available, data will be transferred to the tablet when the recorder is connected. The stored data is transferred to the healthcare professional once the tablet is connected to Wi-Fi and new data is transferred to the tablet.

4.2.4 TRANSFER EEG DATA

To transfer the data, you can do one of the following:

- Tap 'Transfer data' on the home page and follow the instructions for connecting the recorder to the tablet. Once the recorder has been connected correctly, transfer will begin automatically.
- Alternatively, connect the recorder to the tablet, and the data transfer will begin automatically.
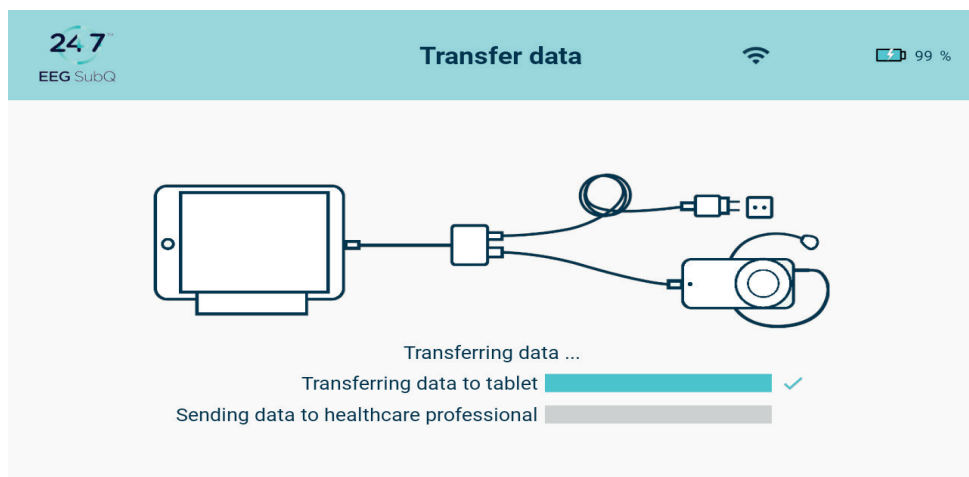
Two pop-up windows may appear the first time you connect the recorder to the tablet. Tick the checkbox to avoid these pop-ups in the future. Tap 'OK' to continue. If you tab 'Cancel' data will not transfer.

You will receive a notification if the tablet is not connected to Wi-Fi. You must then select whether you wish to continue data transfer to the tablet or connect to Wi-Fi in order to transfer data to the healthcare professional.

4.2.5 CHARGING THE RECORDER

The recorder charges when it is connected to the tablet. Leave the recorder connected to the tablet after data transfer has been completed to finish charging.

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 user device and must be returned to your healthcare professional, 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 your healthcare professional. Do not attempt to repair the equipment. The equipment does not need servicing during its lifetime.

6. TROUBLESHOOTING

This table provides information on how to react in various situations. If you would like further assistance on the use of UNEEG™ MyConnect, or in the event of incidents, please contact your healthcare professional.

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 of inactivity.	Turn on the tablet, see section 2.
	No power to the tablet.	Connect the tablet to a power outlet, see section 2.
The tablet informs you that data was not transferred.	The tablet's storage capacity is full.	Contact your healthcare professional.
	The recorder is disconnected.	Connect the recorder to the tablet. Make sure the recorder is connected to the tablet during the transfer of data.
	Wi-Fi connection is lost.	Reconnect the recorder to Wi-Fi and restart the data transferring.
	Connection to UNEEG™ Cloud could not be established.	Try again later.
	The tablet has not been used for 90 days and has therefore been rendered inactive.	Contact your healthcare professional.
	No data was found on the recorder.	Record data on your recorder before attempting to transfer data again.

PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
	The recorder contains data from an unknown implant.	If you want to retrieve the data, tap 'Cancel' and contact your healthcare professional.
		If you want to delete the data on the recorder, tap 'Delete data'. All data will be deleted from the recorder and the recorder will then be available for use.
	The recorder has encountered an error.	Contact your healthcare professional.
	Other error.	Try again later.
The tablet informs you that the tablet cannot connect to Wi-Fi.	The tablet is not connected to Wi-Fi.	Connect to Wi-Fi
		Continue the transfer without Wi-Fi. Your data will be transferred to the healthcare professional as soon as the tablet is connected to a Wi-Fi network.
	The password you entered for the Wi-Fi is incorrect.	Enter the correct password.
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 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 your healthcare professional.

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 extreme 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 your healthcare professional.

If any breach related to data security is detected, your healthcare professional will inform you of how to act to ensure that data protection is maintained.

CE