

NeuroBuds™

Instructions for use

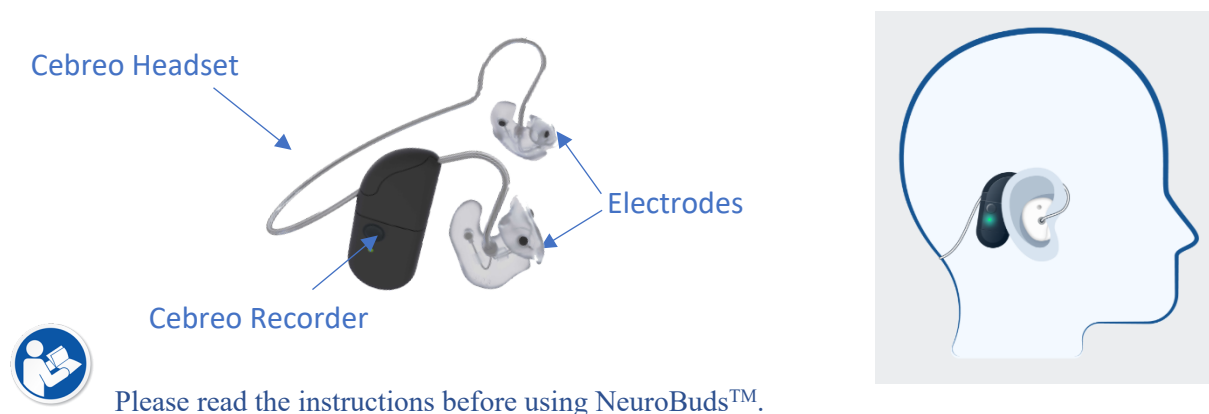


Table of contents

1. Intro	3
2. Scope of Delivery	3
3. Intended use	4
4. Indications for Use	5
5. Intended Use environment	5
6. Intended operators	5
7. Contraindications	5
8. Warnings and Precautions	5
9. Potential side effects	7
10. Operating Instructions	7
11. Troubleshooting and Error Handling	13
12. Technical specifications	13
13. Electromagnetic compatibility	15
14. Symbols	17
15. Contact Information	18

1. Intro

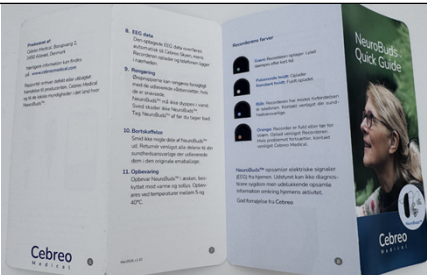
These Instructions for Use inform the use and care of Cebreo Medicals NeuroBuds™. NeuroBuds™ consists of the Cebreo Headset and the Cebreo Recorder. NeuroBuds™ is non-sterile and non-invasive.



2. Scope of Delivery

The following components are included with NeuroBuds™ upon delivery:

SKU	Description	Image
202000001	Main Unit	
202000003	Charger Adaptor	
202000002	Earpiece	
602000003	Power Adaptor	

		
N/A	Phone	
602000006	Travel case	
601000010	Daycase	
602000009	Quick Guide	

3. Intended use

The intended use of the Recorder is to acquire, record, and transmit electrical brain activity (EEG) of patients of all ages.

The Headset is a single patient, multiple use cutaneous electrode array that is applied directly to a patient to record physiological signals (e.g., the electroencephalogram) using the Recorder on patients of 6 years and older.

4. Indications for Use

The Recorder is intended to be used to acquire and record electrophysiological signals, primarily the electroencephalogram and optionally auxiliary data, and transmitting such recorded signals, to support purposes such as diagnosis, cure, monitoring, prevention, prediction, prognosis, mitigation, treatment or alleviation of any disease, disorder or condition that alter the electroencephalogram (EEG).

5. Intended Use environment

The intended use environments include home use and professional healthcare facility but not ER (emergency room), ICU (intensive care unit), and OR (operating room), there are no special requirements to the use environments. NeuroBuds™ is not approved for use during flights.

6. Intended operators

The Healthcare professional is the operator responsible for prescribing the device, training, factory resetting and cleaning the Recorder between patients, and supporting the patient with troubleshooting.

NeuroBuds™ is intended to also be operated by the patient (lay user) after being trained by a Health Care Provider. The patient (lay user), who operates the device during normal use at home, including turning it on, inserting the earpieces, charging, and daily handling.

7. Contraindications

- Users with poor hand dexterity may need assistance inserting the Earpieces
- People with physical limitations determined during the imprint procedure (e.g., size of ear canal, drainage, excessive cerumen, lack of an outer ear)
- Users that are known to be prone to ear infection.

8. Warnings and Precautions

Warnings and Precautions
Read the Instructions for use

NeuroBuds™ must be protected from water.
IP22
CHOKING HAZARD

Warnings and Precautions

Small parts not for children under 3 years or any individuals who tend to place inedible objects in their mouths.

STRANGULATION HAZARD keep the charging cable outside reach of children in order to prevent strangulations.

NeuroBuds™ cannot be used simultaneously with in-the-ear hearing aids or ear plugs

If the Recorder is not used for a long period, please fully charge the battery once every 3 months.

The Recorder must not be used together with high frequency surgical equipment.

The Recorder is not defibrillator proof.

NeuroBuds™ electrodes should not contact other conductive parts including earth.

The use of this device next to other devices or with other devices in a stacked form should be avoided, as this could result in incorrect operation. If use in the manner described above is necessary, this device and the other devices should be observed to ensure that they are working properly.

The EEG signal is expected to be influenced if a phone or other Radio Frequency devices are used within approximately 0,3 m of the Recorder.

Portable RF communications equipment, including but not limited to phones and hearing aid, (including peripheral devices such as antenna cables and external antennas) should be used no closer than 30 cm to any part of NeuroBuds™, including cables specified by the manufacturer. Otherwise, the performance of this device may be negatively impacted.

The electromagnetic compatibility was tested in accordance with the information in IEC 60601-1-2 with the test setup according to IEC 80601-2-26. No special precautions are necessary for compliance with the technical specifications and safety over the expected service life.

Risk of fire, burns, or device damage due to battery overheating.

Lithium-ion batteries can overheat if physically damaged, short circuited, over charged, or exposed to high ambient temperatures.

Risk of chemical injury and device damage due to battery electrolyte leakage.

A damaged battery may leak and shall not get in contact with the skin. The electrolyte is corrosive and poisonous. It may cause harm to the body. If contact with skin wash thoroughly. If ingested contact a doctor immediately.

The provided power adaptor shall always be used for charging and charging shall be performed indoors in a dry environment.

Do under no circumstances open the device.

Only use accessories manufactured provided by Cebreo Medical.

Children using NeuroBuds™ must be supervised by an adult.

No known sensitising substances have been used in NeuroBuds. However, should any allergic reactions occur, please stop using the device and consult your Health Care Professional.

If there is any indication that the performance of the device is impaired contact your Health Care Professional or Cebreo Medical for support.

Excessive contact with sweat or cleaning agents may impair the device's functionality. In case of doubt, please contact Cebreo Medical for support.

Only charge the device using the Cebreo Charger from main supply.

Do not charge from cars or similar vehicles.

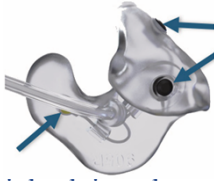
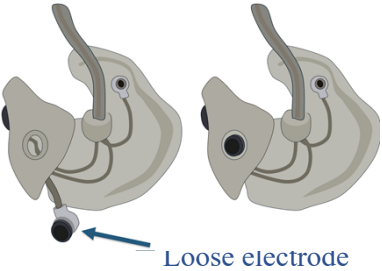
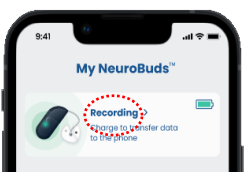
Report any serious incident occurring while using NeuroBuds™ to the manufacturer and the relevant authority in the country where NeuroBuds™ was used.

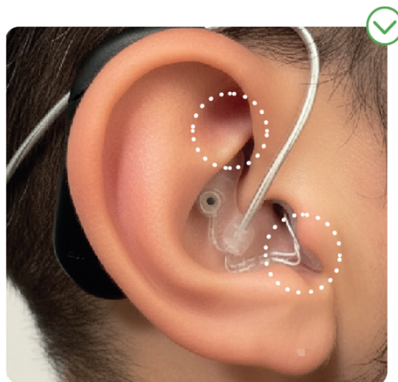
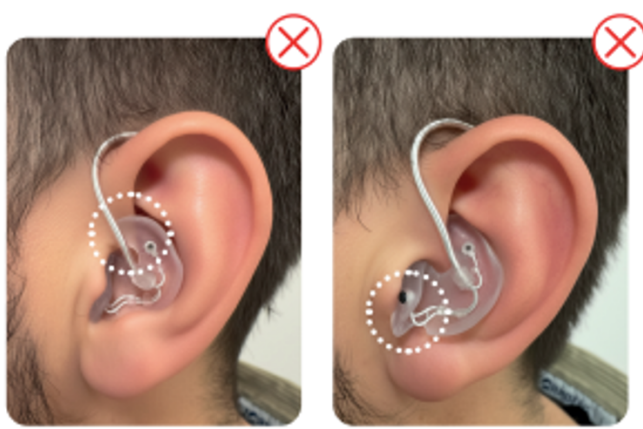
9. Potential side effects

Soreness in the ear, swelling of the outer ear, skin irritation.

10. Operating Instructions

#	How to:	Detailed instruction
1	Turn on the phone	Press the lower button on the right side for 2-3 seconds.
2	Assemble Headset and Recorder	
3	Before each recording	1) Clean your ears well with a water based wet wipe intended for cleaning the skin. Dirt impairs the electrodes' contact with the skin and results in a poorer recording. 

#	How to:	Detailed instruction
		2) Wipe the 3 electrodes in each Earpiece carefully.  If an electrode has fallen out, you can gently push it back into the earpiece. 
4	Start recording	Turn on NeuroBuds™ by pressing the Recorder button until the light flashes green. The light will shift to constant green and dim after a while. The phone confirms "Recording".  

#	How to:	Detailed instruction
5	Insert the earpieces	Place the Recorder behind your right ear. Carefully insert the Earpieces. Use your finger to check that the Earpieces are well inserted in both the upper and the lower part of the ear. You can use a mirror or take a photo of the ear to better be able to see if the Earpiece is inserted correctly – as seen in the picture below. 
6	Pay attention to	The electrodes need good skin contact to record the brain activity (EEG). Check that no electrodes are visible.  Incorrect: the Earpiece top is sticking out Incorrect: a Sensor is visible.
7	During use	In case your ear gets sore while lying on the Earpiece, try to reduce pressure on the Earpiece by placing your ear between two pillows. You can also try to remove the Earpiece and reinsert it, to ensure it has been placed correctly. If you experience any problems, please contact your health care provider.

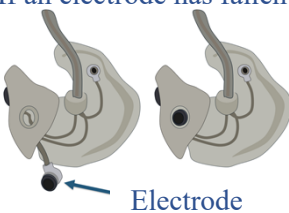
#	How to:	Detailed instruction
8	EEG data	The recorded EEG data is automatically transferred to the Cebreo Cloud when the Recorder is connected to the Charger and placed next to the Phone.
9	Charging	Charge the Recorder by connecting it to the provided Cable and the Adaptor. The Recorder Light turns white and the Phone confirms "Charging". To charge the Phone, remove the charge Adaptor and insert the provided Cable. Note: Keep small parts and the charging cable out of reach of children. 
10	Calendar	A green dot on the calendar indicates the date a recording was started and confirms the data has been transferred to the cloud. A yellow dot means that the data is stored on the phone and will be transferred to the cloud later.
11	Maintenance and Cleaning	NeuroBuds™ can be cleaned gently with a wet wipe. Make sure the electrodes are attached to the Earpieces after the cleaning. For clinicians and Health Care Provider (HCP): If the Recorder is changed in between patients, please follow the instructions in the "HCP guide_ Clean and reset NeuroBuds."

#	How to:	Detailed instruction	
12	Storage and Handling	To protect the device from dust and lint ingress, store NeuroBuds™ in the case protected from heat and direct sunlight. NeuroBuds™ is intended to be used at temperatures between +5 and +40 °C (41-104 °F), at a relative humidity range between 15 % and 90 % (non-condensing), and at pressures between 700 and 1060 hPa. NeuroBuds™ can be and stored at temperatures between +5 and +35°C (41-104 °F), at a relative humidity range between 15 % and 90 % (non-condensing), and at pressures between 700 and 1060 hPa. NeuroBuds™ can be transported at temperatures between -10 and +55 °C (14-131 °F), at a relative humidity range between 15 % and 90 % (non-condensing), and at pressures between 300 and 1060 hPa.	
13	Expected service life	The Headset has in-use lifetime of 3 months. The Recorder has in-use lifetime of 6 months.	
14	Disposal Instructions	Do not discard any parts of Headset., Recorder or its accessories. Please return all components to the manufacturer using the original packaging.	
15	Recorder signals		
		Colour	Status
		Green, pulsating/slow blinks	Starting up
		Green, constant	Recording is ongoing. The light will fade to low intensity after a short while. The phone displays "Recording"
		White slow blinks	The Recorder is charging. The phone displays "Charging"
		White, constant	Fully charged battery
		White, fast blinks	Ready for factory reset (Health Care Provider only)

#	How to:	Detailed instruction	
	  	Blue, constant	Pairing mode. The Recorder is ready for pairing with the phone.
		Orange, fast blinking for 30 seconds – then shuts down	Recorder memory is full or battery is empty. Please charge the Recorder. If the problem persists, please contact Cebreo Medical.
16	Mark an event	If relevant, the Health Care Professional can ask the patient to register an event (e.g. time of going to sleep or registration of a seizure) by making a short button press (less than 1 second) on the Recorder button. The button shall be pressed while a Recording is ongoing. The event is logged with the data, accessible to the Health Care Professional, once the data has been transferred from the Recorder to the Phone and the Cebreo Cloud.	

Note: Bluetooth connection affects the intensity of the light. When there is an active link, the light is brighter when there is no connection the light is dimmer. Except for when the light has faded to low in the recording.

11. Troubleshooting and Error Handling

#	What	To do
	If the Recorder has been reset by accident and the light on the Recorder is blue 	Select "Settings" and "Factory Reset" on the phone. Follow the instructions on the phone and scan your personal QR-code that is placed on the Quick guide.
	If an electrode has fallen out of the Earpiece 	Gently press the electrode back into the silicone. If in doubt, please contact your Health Care Professional.
	If the light on the Recorder blinks orange 	The Recorder is full or battery is low. Please charge the Recorder. If the light is still orange, there may be a technical error. Please contact your Health Care Professional or Cebreo Medical for support.

12. Technical specifications

What	Specification
Product name	NeuroBuds™
Electrodes	4 measurement electrodes, 2 reference electrodes/DRL (Driven Right Leg)
Sampling frequency	4 channels EEG @ 250 Hz, 3 axis-accelerometer @ 125 Hz
EEG data resolution	EEG signals are digitized at 16-bit resolution with a bit weight of 115 nV/bit.
Dynamic range	72 dB
Common Mode Rejection Ratio	Min. 86 dB
Input inferred noise	Min. 0.8 µVRMS from 0.5 Hz to 100 Hz
Battery life when recording	Min. 20 hrs
Recorder memory size	Min. 20 hrs of recording
Dimension	Recorder: 36 x 20 x 7 mm Recorder incl. Headset connector: 49 x 20 x 7 mm
Weight	Headset: ca. 6 g Recorder: 4,3 g Charge adaptor: 2,3 g

What	Specification
Battery	Rechargeable lithium coin-cell
Charging time	Max. 6 hrs from 10-80%
Time to transfer EEG-data when the Recorder is full	Max. 20 hrs – typically 3 hrs
Connectivity	Data is transferred from the Recorder to the Phone via Bluetooth.
Bluetooth	The Bluetooth module is an NRF5340 module. It supports Low Energy (LE) with a frequency range of 2400 MHz to 2483,5 MHz. Frequency hopping is used across 40 channels, each 2 MHz wide. Effective Isotropic Radiated Power (EIRP): -14 dBm
Charger	Medical Power Supply Class 2/Household Power Supply Model GTM96180-0807-2.0 Input: 100-240 V 50-60 Hz, 0.19A @ 100V, 0.12A @ 240V Output: 5,0 V 1,5 A, 7,5 W The Power Supply Unit is part of the Medical Electrical Equipment. USB charger 5 V certified 60601-1, 2 MOOP
Applied Part specification	When connected for use, the Recorder and Headset together form the applied part (Type BF) according to IEC 60601-1

13. Electromagnetic compatibility

This instruction guides you on electromagnetic compatibility (EMC) related matters for NeuroBuds™. NeuroBuds™ and has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices. The essential performance is accurate recording of electroencephalogram (EEG) signals

Electromagnetic Emissions:

Manufacturer's declaration – electromagnetic emission	
Emissions Test	Compliance
Conducted radio frequency emissions, EN 55011	Group 1, Class B
Radiated radio frequency emissions, EN 55011	Group 1, Class B
Voltage fluctuations and flicker, EN 61000-3-3	For use without additional conditions

Electromagnetic Immunity

Manufacturer's declaration – electromagnetic immunity		
Immunity test	Test level – Safety	Test level – Performance
Electrostatic discharge EN 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air
Radiated radio frequency electromagnetic field EN 61000-4-3	80-2700 MHz: 10 V/m	80-6000 MHz: 3 V/m

Manufacturer's declaration – electromagnetic immunity		
Immunity test	Test level – Safety	Test level – Performance
Proximity fields from radio frequency wireless communication equipment EN 61000-4-3	385 MHz, 27 V/m	385 MHz, 6 V/m
	450 MHz, 28 V/m	450 MHz, 9 V/m
	710 MHz, 9 V/m	710 MHz, 3 V/m
	745 MHz, 9 V/m	745 MHz, 3 V/m
	780 MHz, 9 V/m	780 MHz, 3 V/m
	810 MHz, 28 V/m	810 MHz, 18 V/m
	870 MHz, 28 V/m	870 MHz, 18 V/m
	930 MHz, 28 V/m	930 MHz, 18 V/m
	1720 MHz, 28 V/m	1720 MHz, 18 V/m
	1845 MHz, 28 V/m	1845 MHz, 18 V/m
	1970 MHz, 28 V/m	1970 MHz, 18 V/m
	2450 MHz, 28 V/m	2450 MHz, 9 V/m
	2750 MHz, 20 V/m	2750 MHz, 7 V/m
	3250 MHz, 20 V/m	3250 MHz, 7 V/m
	3750 MHz, 20 V/m	3750 MHz, 7 V/m
	5240 MHz, 9 V/m,	5240 MHz, 6 V/m
	5500 MHz, 9 V/m	5500 MHz, 6 V/m
	5785 MHz, 9 V/m	5785 MHz, 6 V/m
	5925 MHz, 5 V/m	5925 MHz, 5 V/m
	6525 MHz, 5 V/m	6525 MHz, 5 V/m
	7125 MHz, 5 V/m	7125 MHz, 5 V/m
	24750 MHz, 9 V/m	24750 MHz, 9 V/m
	25000 MHz, 9 V/m	25000 MHz, 9 V/m
	27500 MHz, 9 V/m	27500 MHz, 9 V/m
	29000 MHz, 9 V/m	29000 MHz, 9 V/m
Electric fast transient/burst EN 61000-4-4	±2 kV (AC power port)	±1 kV (AC power port)
Surge EN 61000-4-5	± 0,5 kV, 1 kV L-L	± 0,5 kV, 1 kV L-L, ± 0,5 kV, 1 kV L-L (AC power port)
Conducted disturbances induced by radio frequency fields EN 61000-4-6	0.15-80 MHz: 3 V 6 V in ISM bands 6 V in ISM and amateur radio bands	0,15-80 MHz: 3 V
Power frequency magnetic field EN 61000-4-8	30 A/m	3 A/m
Proximity magnetic fields EN 61000-4-39	30 kHz, 8 A/m	N/A
	134,2 kHz, 65 A/m	
	13,56 MHz, 7.5 A/m	

Manufacturer's declaration – electromagnetic immunity		
Immunity test	Test level – Safety	Test level – Performance
Voltage dips, short interruptions and voltage variations EN 61000-4-11	0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles	0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles

Note: 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.

14. Symbols

Symbol	Description
	CE mark
	Serial number
	Ingress protection class: IP22, protected against solid objects (like fingers) up to 12mm and dripping water when tilted up to 15 degrees
	Read the Instructions for Use
	Do not dispose in trash
	Protected against electric shock applied part BF (not defibrillation proof)
	Medical Device
	Manufacturer
 eIFU Indicator	eIFU (this document)

	Temperature range in Celcius and Fahrenheit
	Humidity range
	Pressure range
	FCC ID
	Protect from heat and sunlight
	Keep away from rain

15. Contact Information



Cebreo Medical A/S
Borupvang 2
3450 Allerød, Denmark

support@cebreomedical.com