Compact EEG2 Mobile

User Manual

Product Release Version 1.5

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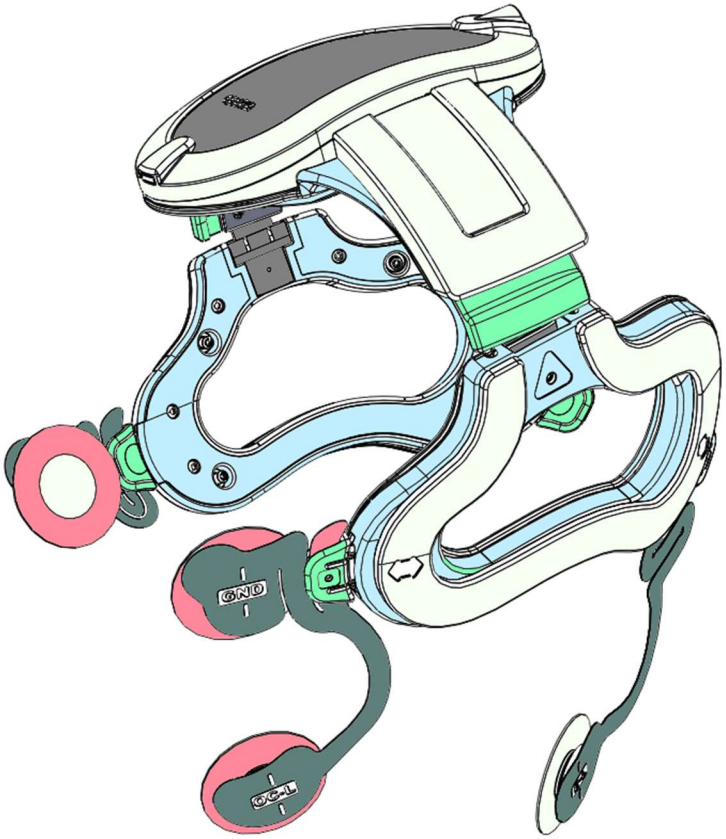

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Contents

1. Introduction

This user manual is a reference for using the NEBA® Compact EEG (CEEG2) mobile system. The manual covers preparation and use of the NEBA® CEEG2 and includes important safety information concerning the device. It does not provide training in clinical practices or EEG. If additional information is needed, please call the NEBA® Support Center at 1-888-539-4267.

Please carefully read the information in this manual in its entirety and review the information periodically to ensure that you will be able to use the NEBA® Compact EEG2 mobile system confidently and as intended.

The EEG recording and associated patient preparation are restricted to healthcare practitioners and personnel under direct supervision of a healthcare practitioner in a professional healthcare facility.

CEEG2 users must be trained and certified by NEBA Health, LLC prior to operation of the CEEG2 mobile system.

2. NEBA® Compact EEG2 Indications for Use

The NEBA® Compact EEG2 (CEEG2) Mobile Headset is an EEG recording system intended for use in NEBA® -based EEG assessment. The CEEG2 Headset is an EEG electrode positioning system used to quickly, accurately, and reliably place electrodes on the head and transmit electrophysiological signals from the electrodes to a recording or monitoring device. The headset electrode placement system includes a headset-mounted wireless EEG amplifier module. The system supports six electrode locations (CZ, left ocular, right ocular, left ear, right ear, and ground) on four flat flexible leads and one plastic tab (the latter to support the CZ electrode).

3. Product Safety Information

Safety Information, Warnings, and Cautions
Safety and Regulatory Compliance Notices

Type of protection against electric shock:
Class I, Internally Powered

Degree of protection against electric shock:

Type BF Applied Parts

Degree of protection against ingress of water:
IPX0 (not protected against ingress of water and other liquids)

Warnings, Cautions, and Notes

In order to reduce safety hazards and protect the system from damage, users of the NEBA® Compact EEG2 Mobile System should familiarize themselves with all warnings and cautions in this manual. Users include clinicians and support staff who interpret results, operate the system, or prepare or assist the patient.

Certain context-related warnings and cautions are not listed in the summaries below. It is recommended that you read all context-related safety information (in addition to all summary safety information) before using the system.

Warnings

A warning statement in this manual indicates a condition or act, which if not corrected or discontinued immediately, may result in illness, injury, or death. Warning statements are preceded by the word "warning" in bold and capitalized type.

WARNING To ensure safety, as well as optimal performance of the NEBA® Compact EEG2 mobile system, follow all instructions for use. Read the user manual in its entirety before using the device in a clinical setting, and use the device only as directed.

WARNING CONDUCTIVE AND CONNECTION HAZARDS

The conductive parts of electrodes and connectors should not contact unintended conductive parts of the device or any other conductive elements, including earth ground. Do not insert items into any opening of device or its power supply. This could short internal components, which could cause fire or electrical shock**.**

Disconnect power cords, interconnect cables, and lead wires, by grasping on the connector, not by pulling on the cable or wire. As you pull out the connector, keep it evenly aligned to avoid bending any connector pins.

WARNING ELECTRICAL SAFETY

To avoid the risk of electrical shock and fire hazard, inspect the system power adapter's AC and DC cords and plugs on a regular basis. Ensure they are not damaged. To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protective earth ground.

Use only the power supply unit, plug adapters, and AC power cord that came with your device or that you received from an authorized NEBA Health retailer.

WARNING SERVICE HAZARDS

The device has no user serviceable parts. Do not disassemble the system components for any reason as improper servicing may compromise the safety or performance of the system. Refer all service to authorized personnel only.

WARNING CONTAMINATION, CLEANING, AND DISINFECTING HAZARDS

Improper cleaning or disinfecting of any part of the device can result in device damage or a safety hazard. Clean and disinfect the device and device components using the approved methods provided in this manual. Verify compatibility of your institution's safe practice cleaning requirements with the device's approved methods. In the event of any discrepancies, consult with both NEBA® and your institution to ensure joint compatibility of cleaning and disinfecting practices.

Contamination Hazard: Electrode and patient pads/wipes and disposable electrodes are intended for single use only. To prevent contamination and other hazards, do not reuse these supplies.

To reduce the potential for infection or irritation, electrodes should be applied only to normal, intact, clean, healthy skin. Do not apply electrodes to irritated, damaged, broken, or otherwise compromised skin.

WARNING STACKING AND LOCATION HAZARDS

The instrument should not be close to or stacked with other equipment. If it must to be close or stacked, it should be observed and verified to be able to operate normally under any stacked configuration.

Cautions

A caution statement in this manual indicates a condition or act, which if not corrected or discontinued immediately, may result in equipment damage, equipment failure, invalidation of a procedure, or data loss. A caution statement is reserved for conditions where injury is unlikely. Caution statements are preceded by the word "caution" in bold and capitalized type.

CAUTION INTERFERENCE AND ELECTROMAGNETIC COMPATIBILITY

The NEBA® Compact EEG2 mobile system complies with required standards for electromagnetic compatibility. While the system is designed to greatly minimize noise induced from external sources, EEG recorders are sensitive devices. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- Increase separation between devices. Ensure that there is no electrical equipment powered on within ten feet of the patient, amplifier, and monitor. Additionally, verify that any power supplies and power strips within three feet of the patient and EEG system are removed from the area or unplugged prior to recording. If you are having trouble complying with this requirement, contact NEBA® Customer Support for assistance.
- Re-orient device cabling
- Plug other devices into separate outlet circuit branches

The NEBA® Compact EEG2 mobile system is not intended to be used near equipment that may emit strong magnetic fields (for example, radio equipment, MRI machines, third party computers and display monitors, motors, refrigerators, air conditioning and heating units, and interference prone florescent lighting).

The device is not MRI compatible. Do not use the device in the vicinity of MRI or other magnetic medical equipment.

The device should not be used while the patient is connected to other equipment, including any other medical or electrical equipment.

The CEEG2 headset continuously monitors human electrophysiological signals and has both real time monitoring functionality on the recording device and algorithmic controls to warn operators if the device has experienced degradation to performance. If the device experiences any electromagnetic disturbances, it will be visible on the recording device and the software will report a warning that the reading was not acceptable.

While this device has been evaluated for RF immunity, future Portable RF equipment may affect this medical electrical equipment. Portable RF equipment shall be used at distance greater than 30 cm (12 inches) around this medical equipment, cabling, or accessories.

CAUTION OVERHEATING AND GENERAL ENVIRONMENTAL CONDITIONS FOR USE

To reduce occurrence of EEG interference, do not expose the system to excessive moisture or temperature, or to direct sunlight or direct energy sources such as heat lamps. Do not operate the system near water (or liquid) sources or containers. Allow the unit sufficient time to adjust from large temperature or humidity changes. Environmental conditions for use and storage are listed in the product specifications section (section 5) of this manual. Do not operate or store the equipment outside the ranges specified in Section 5.

This device is a patient connected device that does not have a defibrillator approved applied part. To reduce the risk of damage to the device, do not connect the patient to the NEBA® Compact EEG2 mobile system, or otherwise use the device, in conjunction with the use of an external defibrillator, implantable defibrillator, or cardiac pacemaker.

CAUTION STATIC DISCHARGE

Static shock is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to damage the device or cause temporary discomfort to the user or patient. Use of anti-static spray on carpets, chairs, and static-prone flooring, and the use of anti-static mats can reduce the risk of static shock and static damage to the system.

To avoid explosion or fire, do not use the device in the presence of a flammable anesthetic mixture or under combustible atmospheric conditions.

The device is not intended for use in an operating room or intensive care environment.

CAUTION DAMAGE, SERVICE, REPAIR, REPLACEMENT, AND DISPOSAL

Do not Power On the unit if there is any visible damage.

Take care not to drop or subject the NEBA® Compact EEG2 mobile system and its components to excessive mechanical shock or pressure.

The NEBA® Compact EEG2 mobile system has been designed to operate effectively with NEBA® electrodes. Contact NEBA® for replacements or suitable substitutes.

Do not use electrodes or patient applied pads/wipes from previously opened pouches or packets. Electrode pouches and patient pad/wipe packets should be opened only at the time of the patient procedure and should be immediately discarded, along with any unused contents, after the procedure.

CAUTION Always wear protective disposable FDA cleared medical examination gloves when using PDI Sani-Cloth AF3 equipment cleaning wipes.

CAUTION USA ONLY: Federal law restricts this device to sale by or on the order of a licensed physician/health professional.

CAUTION Simultaneously touching the patient (through direct body contact or through the conductive part of the patient electrodes) and non-medical equipment or the CEEG2 Computer (including computer accessories, keyboard, or monitor) may degrade patient isolation and contribute to increased EEG artifact.

To reduce the risk of introducing EEG artifact, do not operate the device during an electrical storm, and ensure the patient is not connected to the device during an electrical storm.

Notes

A note provides specific information regarding a device function, design feature, process, or procedure. Note statements are preceded by the word "**Note**" in bold type.

Other Conventions Used in This Manual

Numeric steps indicate references for parts identification or procedural instructions which must be performed in a specific order.

Bulleted lists indicate information provided in list format, but they do not indicate a sequence of events.

4. Device Symbols Reference and Abbreviations

	Power Stand-by
	Protective earth terminal (ground)
	Disposable (single use only)
	Alternating current (A/C)
	Direct current (D/C)
	Operating Instructions
	Recyclable
	Manufacturing location
	Marking indicating component classified as UL 60601-1 compliant by Underwriters Laboratories, Inc. with respect to fire, mechanical, and electric shock hazards.
	Universal Serial Bus (USB) connection
	Type BF equipment (per UL 60601-1 and IEC 60601-1)
	Includes RF transmitter IEC 60417-5140 (2003-04) for non-ionizing radiation

	Hinge (caution)
	Caution: Impedance out of range
	Sound on
	Sound off
	Notch on
	Notch off
	CZ lead channel as defined in the International 10-20 System for Electrode Placement
	Ocular leads channel (see electrode placement information in this manual)
	Pause the EEG recording
	Stop, erase, and restart the EEG recording
	Alternate/switch the display mode
	This device complies with Part 15 of the FCC Rules. See notes in section 5.

Abbreviations

- A1 (or A2) – Active 1 (or active 2) EEG amplifier connection
- A/C (or AC) – Alternating Current
- BF – An IEC applied part classification indicating the degree of protection against electric shock
- C – An impedance designation for the CZ electrode location
- CEEG – Compact EEG (NEBA EEG recording system)
- CZ – An electrode placement location of the International 10-20 system
- D/C (or DC) – Direct Current
- E – An impedance designation for the linked ears electrode locations
- EOG – Electrooculogram
- EC REP – European Community Authorized Representative
- EN – "European Norm" used to indicate specifications or directives drafted and approved by the European Committee for Standardization
- EEG – Electroencephalograph
- GND - Ground
- hPa – Hectopascal
- ID – identification or identifier
- IEC – International Electrotechnical Commission
- I/O – Input/Output
- L – An impedance designation for the left (patient) ocular electrode location
- LCD – Liquid crystal display
- LED – Light emitting diode
- NEBA® – A system consisting of EEG recording, analysis, and reporting components and indicated for use as an assessment aid for Attention Deficit/Hyperactivity Disorder
- OC – Ocular
- O/S – Operating System
- P/N – Part number
- PTID – Patient ID (assigned by the clinician)
- R – An impedance designation for the right (patient) ocular electrode location
- R1 (or R2) – Reference 1 (or reference 2) EEG amplifier connection
- SRID – Serial recording ID (serially incremented for each recording)
- UL – Underwriters Laboratories Inc.
- USB – Universal Serial Bus (a device connection and communication standard)
- Wi-Fi – Wireless connection to the Internet

5. NEBA® CEEG2 Mobile Specifications

Operating Conditions:
Operating Temperature: 10°C and 40°C
Relative Humidity: 30% to 70%
Pressure: 700 hPa – 1060 hPa

Storage Conditions:
Storage Temperature: -40°C and 70°C **
Relative Humidity: 10% to 100%
Pressure: 500 hPa – 1060 hPa

NEBA® CEEG2 Computer:
Microsoft Surface Pro Model: 1807
Weight: 1.79 lbs (812 g)
Operating Temperature: 10°C and 35°C
Display
- Screen: 12.3" PixelSense™ Display
- Touch: 10 point multi-touch

Network: 4G LTE Cat 9 modem up to 450Mbps
Battery Life: Up to 12.5 hours
Exterior: Computer Keyboard
Electrical
- AC Power Adapter Input: 100-240 volts A/C, 50/60 Hz
- AC power Adapter Output(s): 15 volts D/C, 2.58 Amps
- AC power Adapter Microsoft Model: 1800 44W

FCC ID: C3K1807

NEBA® CEEG2 Headset Wireless Charger:
NEBA Health Model: P9038-R-EVK
AC Power Adapter GlobTek Model: GTM46101-1005-USB
AC Power Adapter Input: 100-240V, 50/60Hz, 0.3A
AC Power Adapter Output: 5.2V, 2.5A, 13W
USB Cable: 5-Pin Type-A male to micro-B Male, 6 ft length w/ ferrite bead
Charging Output: 5 watt, Qi-compliant Transmitter
FCC ID: 2A2SM-P9038REVK

NEBA® CEEG2 Wireless Dongle:
NEBA Health Model: CEEG2-WIRELESS-DONGLE
USB Type A male connector
Power required: 5V, 0.5 A
Radio operating Frequency: 2.4 GHz transmitter
Contains FCC ID: UYI25

NEBA® CEEG2 Headset:
NEBA Health Model: CEEG2
Radio operating Frequency: 2.4 GHz transmitter
Contains FCC ID: UYI25

Supplied EEG Electrodes:
NEBA Health Model: CEEG2-ELECTRODES
Disposable Electrodes are Type BF Applied Parts

Note: In the event of headset damage or inoperability (for instance, due to damaging drop or other mishap) contact NEBA Health for replacement options.

Note: The useful life of the CEEG2 Recording System is three years from date of first use. After three years of use, contact NEBA Health to discuss refurbishment or use beyond the three year useful life.

Note: This device is compliant with IEC 60601-1-2 Electromagnetic Disturbances – Requirements and Tests.

Note: This product utilizes the R25 Transceiver Module (FCC ID: UYI25), which operates in a frequency band from 2400MHz to 2483MHz, in 1 MHz channels, utilizes Bluetooth 4.0, and uses GFSK modulation.

FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

– Reorient or relocate the receiving antenna.

– Increase the separation between the equipment and receiver.

– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

– Consult the dealer or an experienced radio/TV technician for help.

This equipment has been tested and meets applicable limits for radio frequency (RF) exposure. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

RF Exposure Statement

This equipment complies with the FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20cm between the radiator and any part of your body.

6. System Setup and Overview

Package Contents

The Compact EEG2 mobile system package includes a headset module, a computer, a keyboard and an accessory kit used for connecting patients to the EEG system. The following is a complete list of the package contents (quantities are noted to the left of the item description) shipped with the CEEG2 Recording System.

Table 6-1: Consumable and Reusable Items

Assembly Description: CEEG2 Recording System

Qty	Description	Manufacturer	Model
1	**CEEG2 Computer Assembly**		
	Surface Pro	Microsoft	1807
	Keyboard / Mouse Pad Combo	Microsoft	FMM-00001
	Power Cord	Microsoft	1800
	LTE SIM Card	Twilio	Nano-Programmable
1	**CEEG2 Headset Assembly**		
	CEEG2 Wireless Headset	NEBA Health	CEEG2
	Electrode Assembly	NEBA Health	71010
	Wireless Dongle	NEBA Health	70100
1	**CEEG2 Charging Assembly**		
	Charging Base	NEBA Health	P9038-R-EVK
	A/C Adapter	GlobTek	GTM46101-1005-USB
	USB Cable	Tripp-Lite	UR050-003-WH
10	**CEEG2 Accessory Kit Assembly**	NEBA Health	70012

Please take the time to verify you have received all items listed above and notify NEBA® in the event there is any discrepancy.

WARNING In addition to the cables sold by the instrument manufacturer as spare parts for internal components, the use of other accessories and cables may result in increased emission or reduced immunity

Test Procedure

The CEEG2 device does not have any user required test procedure. The device does self test when it is turned on and connected to the CEEG2 Recorder software.

System Setup

The CEEG2 computer requires a wireless transmit/receiver dongle to communicate with the headset. The computer has a USB Type-A female connector port on the side, see figure 6-1. The dongle must be inserted into the USB port before starting the system or powering on the headset.

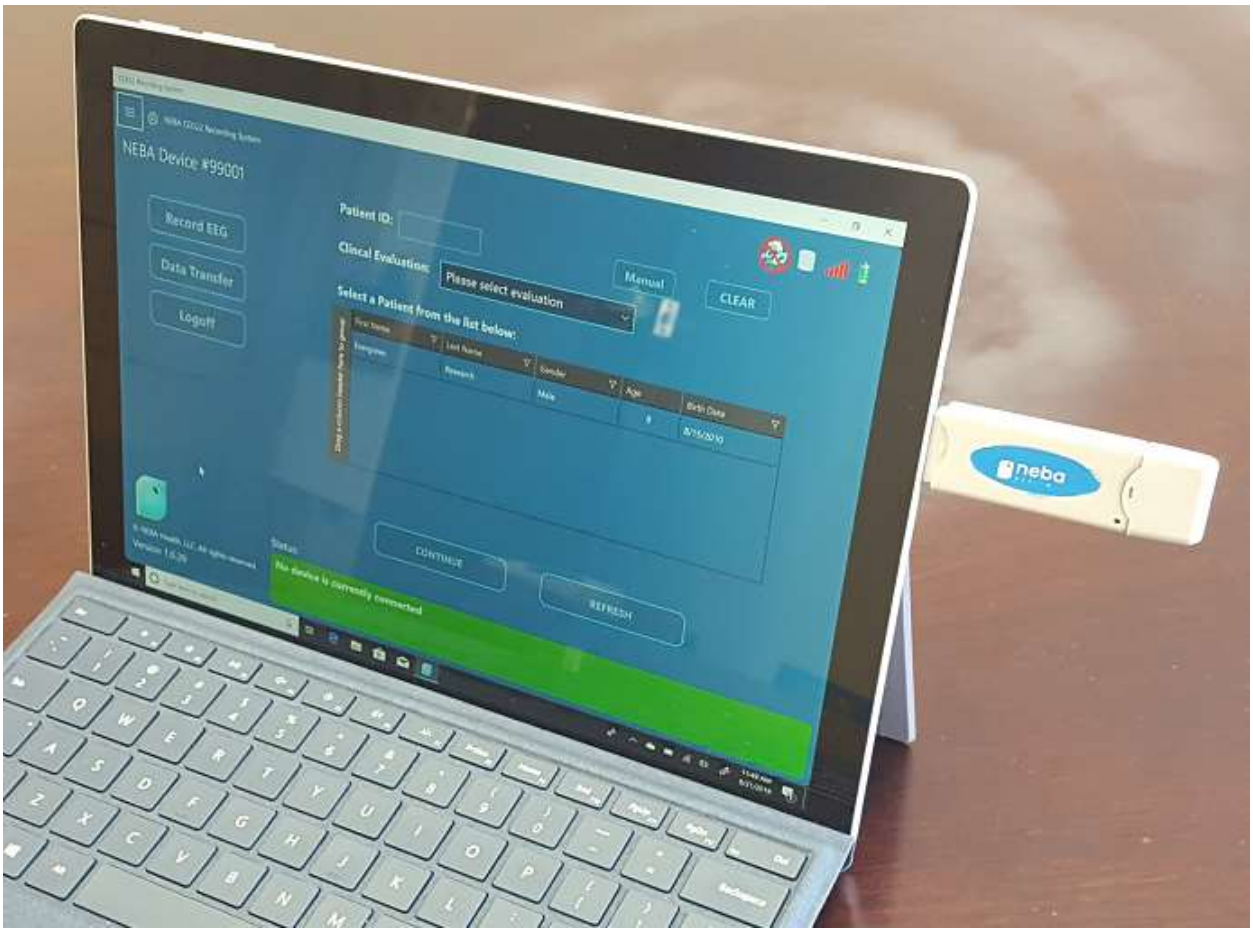
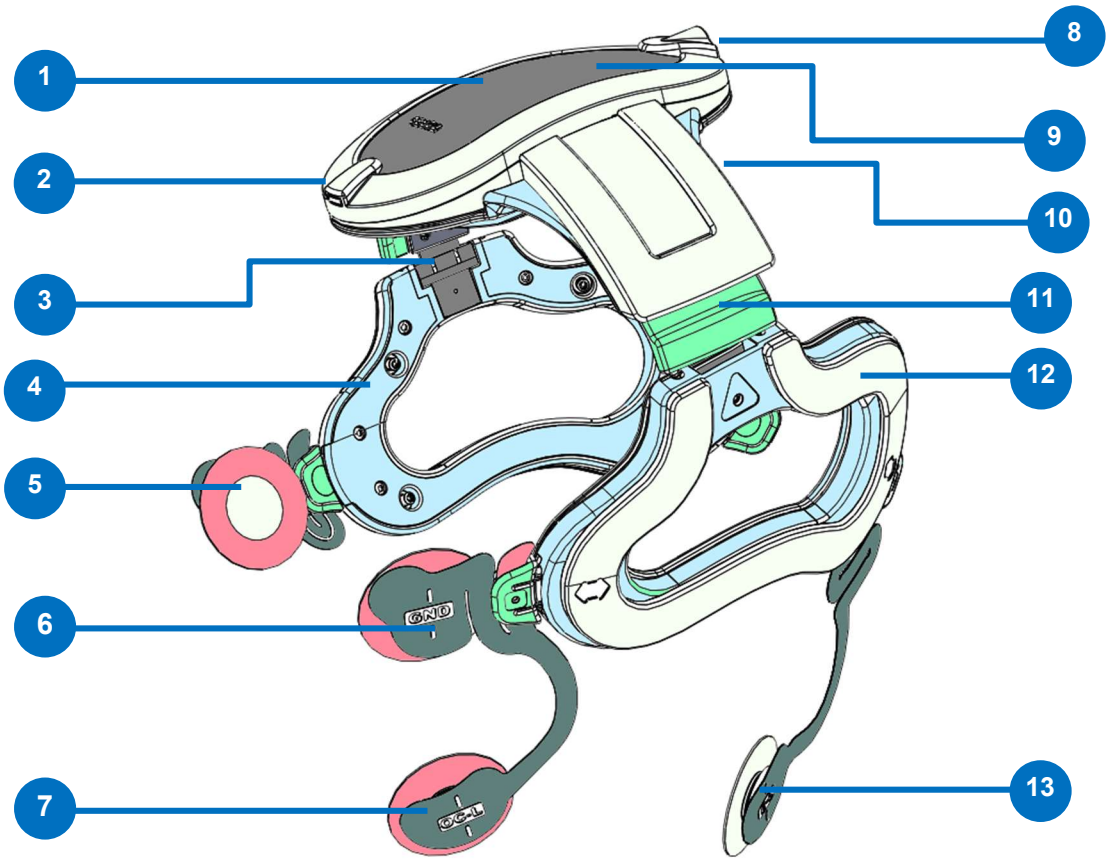


Figure 6-1: CEEG System Setup

System Overview

The Compact EEG (CEEG2) System is an electroencephalograph (EEG) recorder designed for two-channel EEG recording in support of the NEBA® Assessment Aid and its associated report. The CEEG2 System consists of two primary components: (1) the **CEEG2 Headset/Amplifier Module**, which receives and amplifies the patient's brain electrical activity (EEG signals); (2) the **CEEG2 Computer/Dongle** used to monitor the recording, store the recorded data, and submit the recorded data for subsequent analysis. The headset its constituent and interconnecting parts are depicted in the CEEG2 Headset diagram (see Figure 6-2).

The CEEG2 System display consists of a top level menu (figure 8-3) for EEG recording, EEG data transfer (by internet transmission), and system log off. The EEG recording screen is activated by pressing the top level menu "Record" button. The recording screen, along with descriptions of its interface components, is shown in figure 6-3.



1 CEEG2 Computer Amplifier Top
2 Power LED
3 Hinge (caution)
4 Support Assembly (Right)
5 OC-R (Right Ocular)
6 GND (Ground)
7 OC-L (Left Ocular)
8 Charging LED
9 Power button (Push Button)
10 CZ (Located under headset)
11 Adjustment Band
12 Support Assembly (Left)
13 Ear Electrode (Left, Right not Shown)

Figure 6-2: CEEG System Diagram

1 Sound on/off (default on)
2 Alarm, impedance out-of-range (CZ)
3 CZ trace label
4 Impedance (CZ)
5 Notch filter, 50 Hz (Europe) or 60 Hz (USA)
6 Alarm, impedance out-of-range (ocular)
7 Ocular trace label
8 Impedance (OC)
9 Pause recording (toggle)
10 Restart recording (and save current)
11 Patient entry button
12 Record mode button
13 Patient and recording information line
14 Amplitude scale (microvolts)
15 CZ trace
16 Ocular (OC) trace
17 Time scale (seconds)
18 Elapsed recording time (hours:minutes:seconds)
19 Save current recording and exit recording screen

Figure 6-3: CEEG2 Recording Screen

7. Patient Preparation

Instructions to the Patient at Time of Scheduling

Patients should be consulted the evening prior to their recording session and reminded to comply with the following guidelines:

- Have clean hair, but do not shampoo within one hour before the session.
- If hair can be parted, part hair along the middle/midline.
- Refrain from using any makeup or hair-styling products.
- Limit intake of caffeine or candy the day of the scheduled appointment.
- Be well rested and alert for the data collection procedure.
- Avoid wearing contact lenses if possible; bring eyeglasses if they are generally worn.
- Remove hairstyles such as weaves or braids.

Patient Hookup using the CEEG2 Headset

The electrode connection to the patient consists of six electrodes that combine to form two recording and monitoring channels. One channel is used to assess the brain electrical potentials at the top of head and is designated the "CZ" channel. The other channel is designated "OC" (ocular) or "EOG" (electrooculograph) and is used to assess eye blinks and gross eye movements. Each recording channel requires an active electrode, a single or dual reference electrode, and a ground electrode. For the CZ channel, two electrodes are connected to the ears and combined to serve as the reference.

Step-by-Step Electrode Patient Hookup Instructions

The CEEG2 headset is a durable electrode headset that helps to improve the precision of electrode placement. Once the headset is fitted, the electrodes themselves will properly fall into their correct positions. No measurements or markers are needed.

WARNING To prevent transmission of infectious agents, wear protective gloves (FDA cleared medical examination) while placing the template and electrodes, and while otherwise contacting the patient.

CAUTION The headset is designed for patient contact using biocompatible materials. To reduce the possibility of allergic reaction to headset materials, the headset use should be limited to <30 minutes of contact with patient per day.

WARNING To prevent transmission of communicable disease, it is recommended that only disposable electrodes be used. In such patients that have such a disease, any non-disposable component that contacts the

patient and may transmit disease should be discarded after the recording. Precautions complying with universal standard of care should be employed to prevent contact with blood or other potential infectious substances. Dispose of contaminated materials in accordance with institutional, local, and federal guidelines and laws.

WARNING To prevent device damage or patient or operator injury, keep EEG headset and computer away from liquids, and situated to minimize the likelihood of being inadvertently knocked or tripped over.

Fitting the CEEG2 headset:

1. Remove hats, caps, hair bands, and earrings, if worn.
2. Where possible (and if not already parted), part the patient's hair or have the patient part their own hair along the middle/midline. This improves access to the skin at the C/CZ location at the top of the head.
3. Seat the patient in a straight-back chair and ensure that the patient remains seated during the electrode hookup and EEG recording. If you desire to have the patient more comfortable, use a chair that reclines. Ensure the patient does not fall asleep.
4. The CEEG2 headset will fit any size head with a circumference of 42cm to 62cm.
5. Identify the front of the CEEG2 headset by finding the "neba" logo on the top of the headset (see figure 7-1).

Figure 7-1: Compact EEG2 mobile system – Device Orientation

6. The power button is located at the back of the top of the headset. Simply press the power button and the light in the front of the headset will turn blue (see Figure 7-2).

Figure 7-2: Compact EEG2 mobile system – Power Button

WARNING To reduce the potential for infection or irritation, electrodes should be applied only to normal, intact, clean, healthy skin. Do not apply electrodes to irritated, damaged, broken, or otherwise compromised skin.

Two types of disposable electrodes are supplied for use with the CEEG System. Specialized pre-gelled, non-adhesive electrodes are provided in a two-pack pouch and are designed for the CZ (black aperture) electrode site. The adhesive-backed Disposable Electrode Set, supplied in a seven-pack pouch, is for use at the five other electrode sites (left and right ocular, left and right ear, and ground). An adhesive-backed electrode may also be used for the CZ location in the event the headset pressure is insufficient at that location. Note that both types of disposable electrode pouches contain spare electrodes that should be discarded if not used during the patient visit.

7. Position yourself behind the patient's head, clean the CZ (1) area of the patient's head with an electrode prep pad. Make sure to scrub that area well (see Figure 7-3).

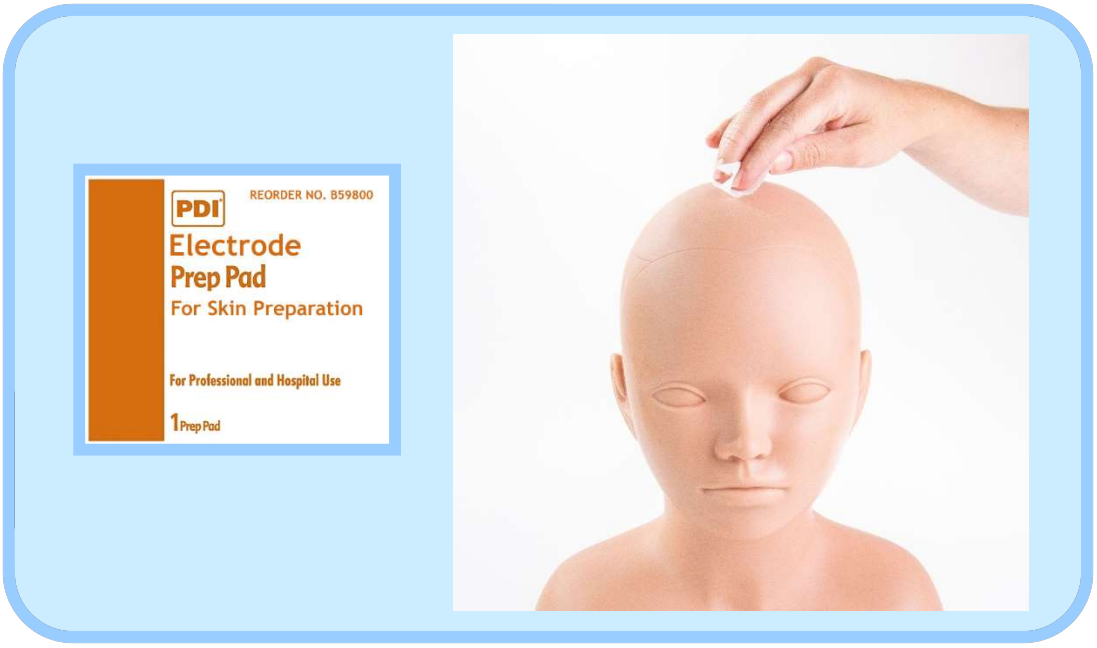


Figure 7-3: CZ area cleaning

8. Gently place a disposable electrode or the CZ to the snap located under the headset (see Figure 7-4).

Figure 7-4: CZ Electrode Placement

9. Place CEEG2 headset over the patient's head, placing the power notification light in the front and centered on the midline part made for the CZ placement. Slide down the left and right supports of the headset to fit the patient comfortably (see Figure 7-5). The supports of the headset are adjustable.

Figure 7-5: CEEG2 Headset Placement

10. The side supports should rest above each ear comfortably. The supports have pads that are used for a more comfortable fit (see Figure 7-6).

Figure 7-6: CEEG2 Headset Support Placement

11. Insert the flex leads into the headset. Match number to number making sure they snap in completely. The numbers are located on the headset ports and flex lead connector ends (see Figure 7-7). The connections are color coded to help in selecting the correct flex lead and port for connection.

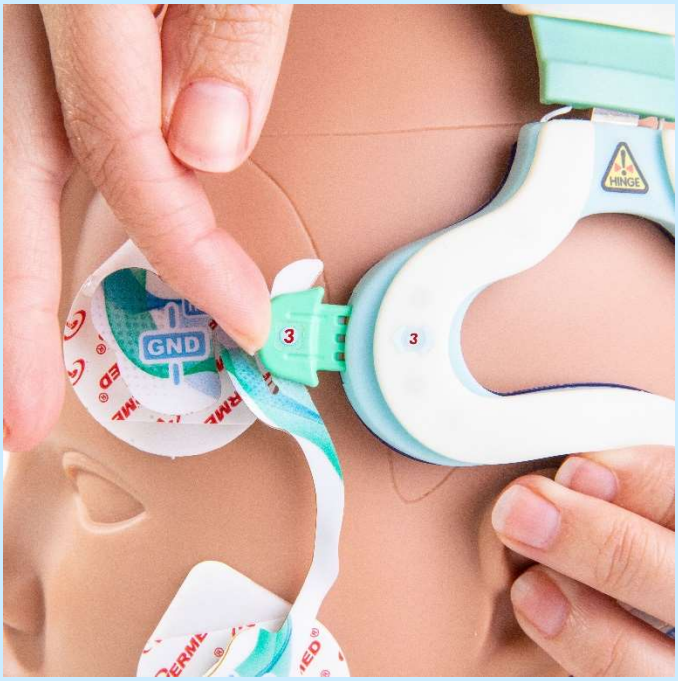


Figure 7-7: Flex Lead Connection to Headset Port

12. Clean each remaining area with an Electrode pad. Once each area is clean, apply disposable electrodes to each remaining area. Electrode will snap easily to each insert.

    1) CZ (located under the main part of the headset)
    2) OC-R (Right Ocular)
    3) GND (Ground), OC-L (Left Ocular)
    4) E-R (Right Ear)
    5) E-L (Left Ear)

Figure 7-8: Electrode Pad Installation

Instructions to the Patient Prior to Recording

After connecting the patient and prior to recording data, prepare the patient by following the steps below (alternatively, these steps may be carried out while electrode impedances are being verified):

1. Instruct the patient to get into a comfortable position. Check the position of the patient, create a neck roll from a towel if necessary, or make other adjustments to ensure comfort. It is advisable to have the subject in a position where the EEG recording cannot be seen. This will deter the subject from attempting to affect the signals on the display.
2. Before acquiring data, run the patient through a series of commands in order to help the patient relax, reduce tension, etc. Ask the patient to:
    a. Say aloud words beginning with the letter "L."
    b. Repeatedly clench and release different muscle groups.
    c. Relax jaw, roll shoulders, or make other movements to fully relax and expend all unnecessary movement/tension.

Always check with the patient before initiating the recording to ensure the patient is relaxed and ready for testing.

8. EEG Recording

NOTE: Prior to recording, unplug the computer AC power adapter. Use only the battery while recording an EEG session. This will reduce the noise associated with the power system and reduce the risk of a tripping hazard from the power cord. In case of cord entaglement the power adapter cord is attached using magnets for easy disconnection of the computer.

Starting the Recording Session

Ensure that the Wireless Dongle is connected to the USB port on the right of the computer tablet.

1. Turn on the computer by pressing the button on the top left of the tablet.
2. Log into the system by typing the username and password at the Login screen and click the Login button. See section 10, 'Securing the System', for details.

Patients assigned to the device are listed in the 'Patient Selection List', Figure 8-1. If this page does not appear, click the "Record EEG" button in the menu. These patients have been assigned to the device through the MyNeba application by the patient's caregiver. During registration on MyNeba, the caregiver enters a key code which identifies the CEEG2 Recording System.

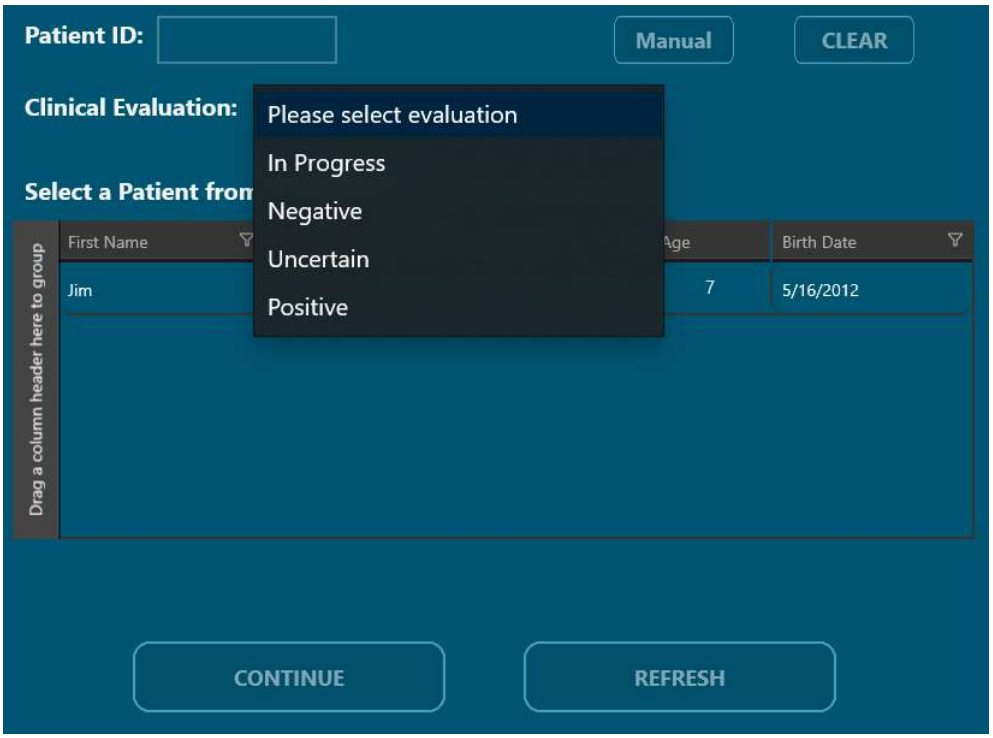


Figure 8-1: Patient Selection Screen

CAUTION The list contains the patient's first name, last name, gender, age, and birthdate. It is important to verify these items and ensure the correct patient is identified. If the patient's age is outside the NEBA required age, the background of the age field will turn orange (in this case, placing the mouse over the age will show 'Age out of Range').

To start a recording session without a patient selected, click the Manual button at the top of screen. This will display the patient information manual entry screen. See the 'Patient Information Manual Entry' instructions on page 32 to proceed.

Patient Selection

If a patient has registered since the list was opened, click the refresh button to re-populate the list and retrieve the patient's information.

The following items are required before recording can be initiated.

1. **Enter the patient ID** (enter the patient ID consisting of a maximum of 9 alpha-numeric characters).
2. **Select clinical evaluation** (click the dropdown arrow to select the appropriate value from the list – *In Progress, Negative, Uncertain, or Positive*).

Verify the information in the list is correct for the patient selected.

3. **Choose the correct patient** (click the row to select a patient from the list).
4. **Click the CONTINUE button** to enter the recording mode.

Note: If you receive the following error, "One or more errors occurred. (There was no endpoint listening at Https://...", on initial login, click the  . Next click the "Close App" button in the upper right corner of the screen. This will restart the Recording system and remove the errors.

Headset Communication Troubleshooting

If the device is properly connected, the software will display the CEEG2 Device Connected icon:

If the software is unable to connect to the CEEG2 device the icon will appear with a red crossed out circle. Do not proceed until the device is properly connected:

If the software reports that it cannot detect the EEG device, check the USB Dongle connection, press the "Power" button on the top of the CEEG2 Headset Module for 1 second to turn the device off. Then press the "Power" button again to turn the CEEG2 Headset back on. If after these steps the CEEG2 device is still not detected, contact NEBA Health for assistance.

The wireless headset uses Radio Frequency Technology transmitting at 2.4GHz. The radios in the headset and dongle are low powered so not to interfere with other wireless technology used in the surrounding environment. During EEG data collection the headset may loose connection with the dongle. You will notice the EEG traces have stopped drawing to the screen. Ensure that the headset is within 15 feet of the computer and dongle. The dongle and headset should be within line of sight and no walls or equipment between them.

Patient Information Manual Entry

Skip this section and proceed to 'Patient List' if the patient has already been selected from the patient list, as described above. If no patient has been selected, the following patient information fields need to be entered in the Patient Information box prior to EEG recording.

1. **Enter the patient ID** (enter the patient ID consisting of a maximum of 9 alpha-numeric characters)
2. **Select clinical evaluation** (click the dropdown arrow to select the appropriate value from the list – *In Progress, Negative, Uncertain, or Positive*).
3. **Enter the date of birth** (specified using a four digit year)
4. **Enter the patient gender.** (Click the radio button next to the correct gender)
5. Click "CONTINUE" button when you are ready to start the EEG recording.

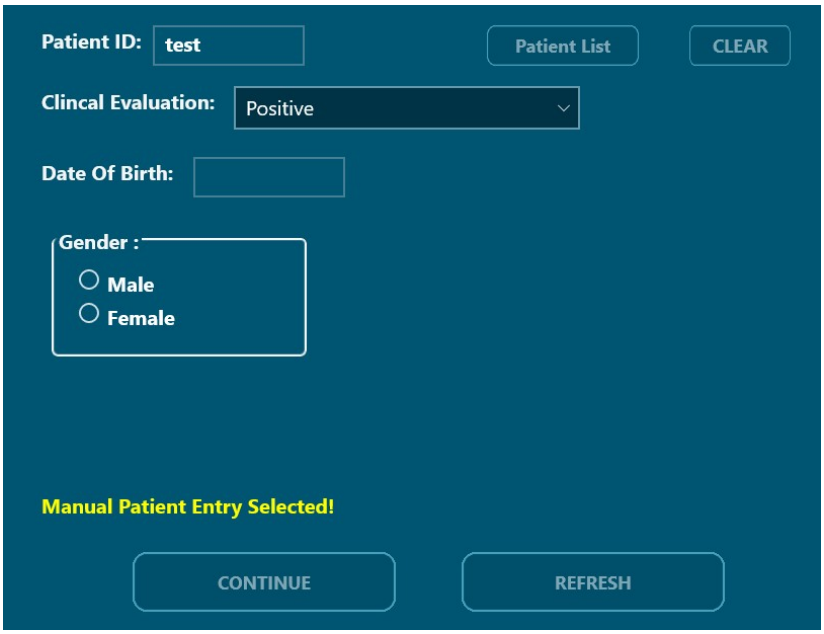


Figure 8-2: Patient Information Entry Dialog

Recording the EEG

The patient EEG data collection consists of a 10-minute "eyes open" recording.

1. Instruct the patient to relax and sit quietly while looking at a location on a wall (or at some object) for the entire recording (see ***Appendix B*** for more detailed information concerning eye movements and other artifacts).

2. Once the EEG recording screen has been entered ensure the patient information is correct at the top of the screen. **Click the "RECORD" button** to begin EEG recording.
3. The CEEG2 will enter "Impedance" mode where electrode impedances are displayed for verification. After 10 seconds the device returns to EEG streaming mode. **Ensure that all impedances are below 10.0k (ohms) (figure 8-4)**.

Impedance values are located on the left side of the display. The letters CZ and OC are channel labels for reporting each of the impedance values as follows: **CZ** – CZ or Ears and **OC** – Left or Right ocular. Good impedance values (≤ 5 K ohms) are indicated in green text. Marginal (but acceptable) impedance values are indicated in tan text (marginal values are > 5 K ohms and ≤ 10 K ohms). If the impedance of any channel exceeds 10 K ohms, indicating the impedance is out of range, the channel's impedance value text will change color to orange, an alarm will sound, and an alarm symbol will appear on the display.

Note: If any impedance is higher than 10 K ohms (orange indicator), inspect the corresponding electrode connection. If required, remove the problem electrode, clean and re-prep the site, and/or rearrange hair as necessary to improve the impedance.

4. To check impedances at any time during EEG recording, click the slider button labeled "Impedance" as shown in Figure 8-4.
5. If you wish to pause the recording after it starts, simply click  (clicking  will resume the recording). To abort before the 10 minute session completion and save the recording, click the "SAVE/EXIT" button.

Figure 8-3: Main Menu

If you need to restart the recording, you can click the "Restart" Button,  . Follow the instructions in the dialog menu that appears.

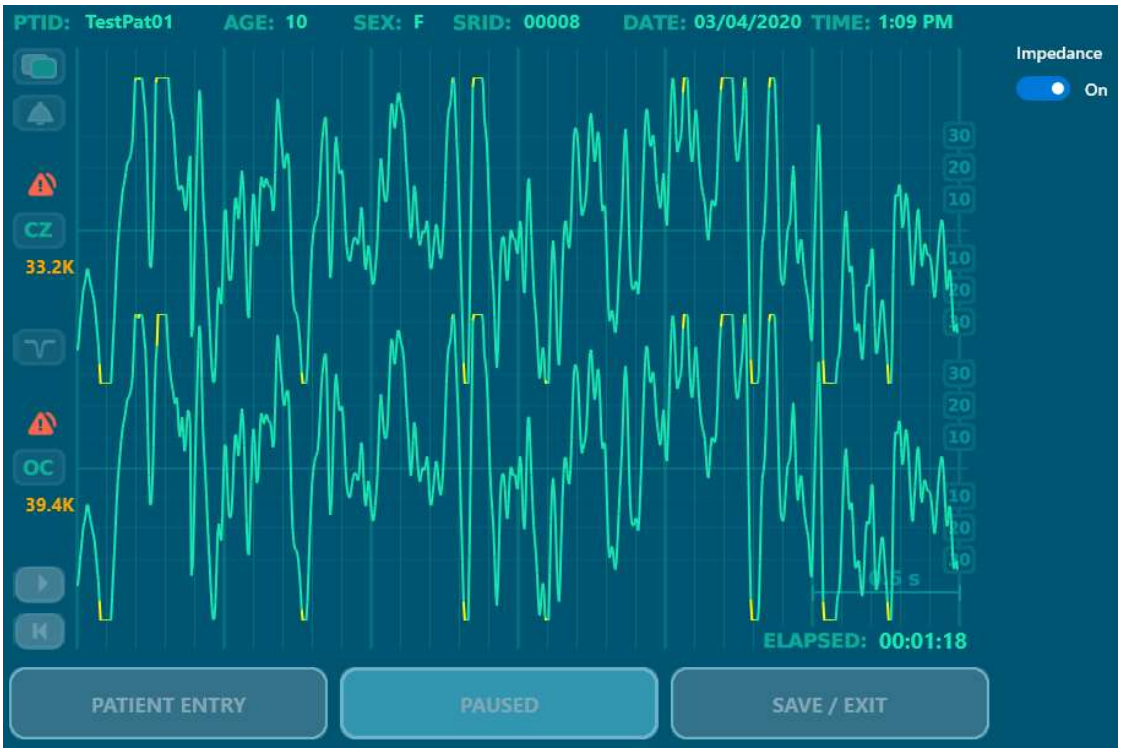


Figure 8-4: CEEG Display

There are a number of commands that the user can invoke while the EEG is being monitored and recorded:

- Pause/Continue command (- toggle)
- Notch On/Off command (- toggle)
- Sound On/Off command (- toggle)
- Restart command (- which deletes the current EEG data and records a new session under the same patient information)

When a user pauses the recording, the EEG data is temporarily suspended from being written to disk.

Monitoring the Patient and the Recording

The following general monitoring guidelines are recommended (for detailed information regarding patient and recording monitoring, please refer to Appendix B, "Artifacts and Minimizing Their Occurance").

1. Observe the patient during the recording, and try to ensure that the patient remains still, yet relaxed, and minimizes any type of tension and body or facial movements that may contribute to artifacts.

CAUTION To ensure recording quality, observe the patient to verify the patient is not drowsy, sleepy, or lethargic during the recording.

2. Monitor the EEG traces during the recording and watch for signs that may indicate excessive artifacts, or loose or low quality connections.

Note: If the EEG traces stop updating on the display the headset may have lost connection with the wireless dongle. Ensure that the headset is within 15 feet of the computer and dongle. The dongle and headset should be within line of sight and no walls or equipment between them.

3. Monitor the EEG traces for extraneous interference signals. Note that an optional notch filter is used to minimize the presence of power line noise from the waveforms displayed on the screen. By default, the notch filter is on (depicted by the top icon at left) at the start of the recording but can be toggled off (or back on) by clicking the icon.

   Note that whenever you exit the recording, the software will first measure electrode impedances for a period of few seconds, save the EEG session, then proceed to the Data Transfer scenario.

4. You may gauge the quality of the recorded data with respect to the elapsed recording time displayed on the bottom right corner of the screen. If the EEG recording is of consistently poor quality, you may wish to exit the recording, address the problem, and then re-record the EEG.
5. The recording will automatically stop after the required 10 minute recording period ("00:10:00" will be displayed next to the "ELAPSED" label at the bottom right of the screen).

Ending the Recording

When data collection is complete, the system will proceed to the Data Transfer scenario. To exit recording before the 10 minute automatic time, click the "SAVE/EXIT" button.

You must exit the recording prior to connecting another patient or re-recording the existing patient.

The recorded data will be saved and analyzed for sufficient acceptable data. The following message will appear displaying information about the acceptability of the recorded data.

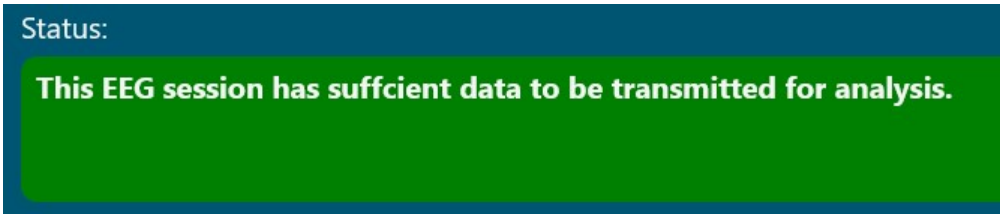


Figure 8-5: Sufficient Data Display

If data quality is insufficient the following dialog (figure 8-6) will be displayed. This data will be saved in the archived data folder.

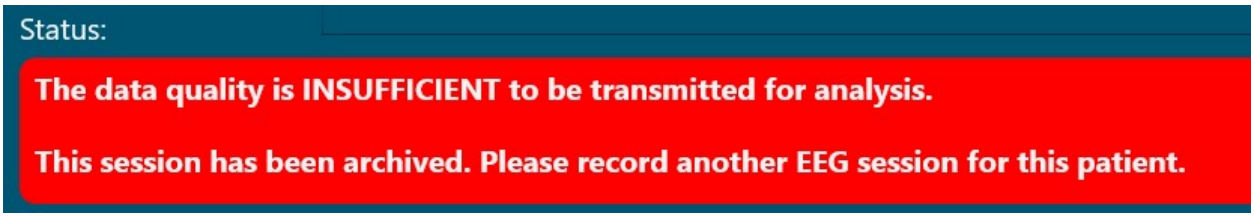


Figure 8-6: Insufficient Data Display

CAUTION To reduce the risk of electrode pulling or abrading the skin, do not remove the headset prior to removing electrode pads using the flowing procedure.

Disconnecting and Cleanup

When the recording is complete, follow the steps below for electrode and headset removal, patient cleanup, and headset cleaning:

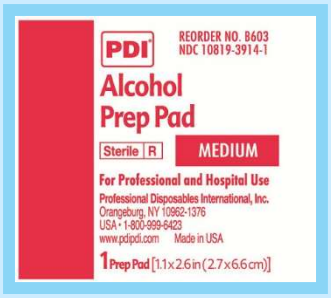
1. Power down the headset by pressing the power button for 2 seconds until the blue power indicator goes out, see figure 7-2.
2. Electrode removal for adhesive-backed electrodes:

   NOTE: For electrode pads located over hair regions, hair pulling and adhesion may be minimized by wetting the pad with a small amount of water or rubbing the pad's exterior surface and interface with an alcohol wipe (PDI Alcohol Prep Pad). Where possible, peel direction should be in the direction of hair growth. It is sometimes helpful to wet or wipe the skin and hair areas as they become exposed during pad removal.

   a. Gently lift up one side of the electrode pad to gain access to the undersurface of the pad.

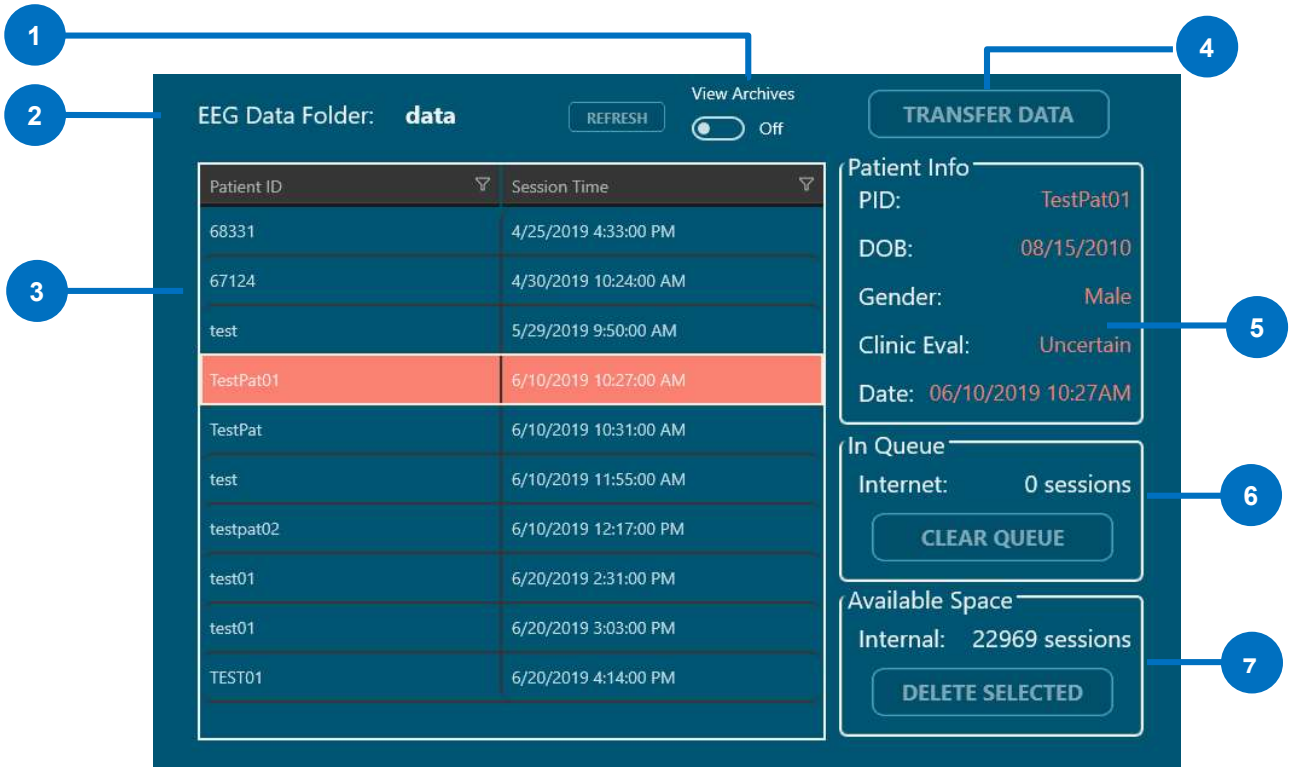
   b. Gently and slowly peel back the electrode pad over itself, trying to maintain a peel direction as close to 180° as possible. While peeling, skin or hair pulling can sometimes be minimized by supporting the skin or hair areas as they become exposed during pad removal.
3. Discard disposable electrodes and pouches in accordance with local or institutional policy. Do not reuse disposable electrodes and do not retain electrodes from opened pouches (electrodes will be compromised soon after the pouch's factory seal is broken).
4. After all facial electrode pads have been removed, lift the headset from the patient's head taking care not to snag the patients hair on catch points of the headset. Also take care not to pull the patients hair with the adhesive from the CZ electrode.

5. Remove residual gel/paste from the patient by wiping the electrode site with PDI Alcohol Prep Pads, or by providing wipes for the patient or their guardian to use for cleanup.
6. Clean the headset, snap leads, and lab area after the session. Follow the guidelines for proper cleanup and care (see *"Appendix A: Cleaning and Maintenance Instructions"*). Note that cleaning should ideally be completed immediately after the session to prevent any gel from drying and becoming more difficult to remove.



9. EEG Data Submission and NEBA® Processing

To order a NEBA® report, EEG recordings must be transferred to a data processor for artifacting and analysis. EEG data is transferred by Internet upload. This is accomplished by using the Data Transfer scenario (figure 9-1) of the CEEG2 recording system.



1 View Archives Checkbox
2 Current Displayed Folder
3 Recording Session List
4 Transfer Button
5 Selected Patient Info
6 Session Transfer Queue
7 System Space Availability

Figure 9-1: CEEG2 Data Transfer Tool

Once the EEG recording is complete the data transfer scenario will be displayed. If transferring data at a later time or if the scenario is not displayed, click the "Transfer Data" button on the main menu (figure 9-2).

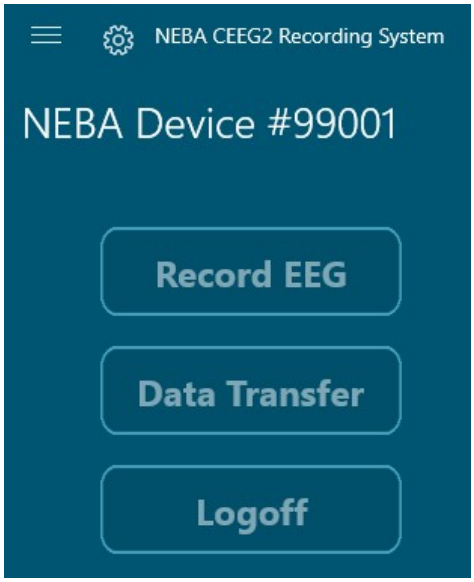


Figure 9-2: CEEG Recording System Main Menu

Internet Delivery

The CEEG2 Recording computer comes preconfigured to use Cellular LTE data services for Internet transfer.

Note: Wireless security is provided through SSL certificates across the LTE data network to NEBA servers.

To ensure that your computer is communicating with the LTE network and NEBA Health servers, check that the connection icons are indicating connection, see figure 9-3.

Figure 9-3: Status Icons

Table 9-1: Status Icons

Icon	Status	Description
LTE Network	Connected 	The white bars indicate signal strength of LTE network
	Not Connected 	No bars or red bars indicate that the LTE network is not connected
Battery	Charging 	The battery is charging
	Discharging 	The battery is discharging and AC power adapter is not connected
Database	Connected 	Connected to NEBA Database Server
	Not Connected 	Unable to Connect or Find NEBA Database server
CEEG2 Headset	Connected 	CEEG2 Headset connection properly established
	Not Connected 	CEEG2 Headset connection not established with software

Transfer EEG Data to Processor over Secure Internet

To transfer EEG data to the processor over the internet, follow these steps:

1. From the main CEEG Recording System menu (figure 9-2), click the "Data Transfer" button.
2. Select the data recordings to be transferred by selecting the row from the list to the desired Patient ID(s).
3. Click the "Transfer Data" button, figure 9-1(4). You will be prompted to confirm the transfer.

See Appendix C for message descriptions.

EEG Data Transfer Tool Information

The Data Transfer Tool has several areas which display system information, see figure 9-1. These areas can be used to determine the status of the data transfer system.

1) The view archive toggle, when ON, displays the contents of the archive folder on the system. When data is transferred it is archived and removed from the EEG Data Folder. This helps you to know what data has yet to be transferred for processing by keeping the "EEG Data Folder" at a manageable size.

2) Item 2 in figure 9-1 displays the current folder, "data" or "archived". Use this label to ensure you are looking at the correct sessions to transfer.
3) The recording session list displays the EEG recordings in either the "EEG Data Folder" or the "Archive Folder". The list has 2 columns for each row. The row is selected for the recording session to transfer. The "Patient ID" column shows the patient ID entered at recording setup. The "Session Time" column displays the date and time the recording session began.
4) The "Transfer Data" button is used to initiate the internet transfer of the selected EEG data.
5) The "Patient Info" area provides a quick look at the patient's information entered during recording session setup. By selecting a row in the session list, you can view the patient ID (PID), the date of birth (DOB), the gender (Male or Female), and the EEG collection or session date (Date). This information should be checked against the patient records before transmitting data for processing. Any discrepancy between the stored patient information and the patient record can delay processing of submitted data.
6) The "In Queue" area displays the number of recording session data either queued for internet transmission. Note that if the number of sessions in the internet queue is greater than zero, internet transmissions are not complete. For internet transmissions to complete, the CEEG2 Recording System must be turned on.
7) The "Available Space" area provides a view of available storage capacity on the CEEG2 Recording System internal storage.

Manage Available Space

To recover needed space on the recording system:

1. To remove items from the archive folder, toggle the "View Archives" to ON position.
2. Select sessions in the recording session list using the shift or ctrl keys and selecting the row desired.
3. Click "Delete Selected" button. You will be prompted to confirm the action.
4. To delete sessions from the EEG data folder, toggle the "View Archives" to OFF position and perform steps 2 and 3 above.

See Appendix C for message descriptions.

There may be instances that require a re-submittal of EEG recording sessions. Since the data is stored in the archive folder, it can be re-transmitted when required.

Note: Do not retransmit data unless asked to do so by the EEG processor. This may create duplicate orders for reports.

Moving Data for Retransmission

To retransmit data, use the archive folder:

1. Toggle the "View Archives" slider to the ON position.
2. Select sessions in the recording session list.
3. Click the "Move Data" button. You will be prompted to confirm the transfer.

See Appendix C for message descriptions.

10. Securing the System

Login

Pressing the power button on the top right side of the CEEG2 Computer will turn the system on. Once the system has initialized a login screen will appear, figure 10-1. Using the keyboard and mouse pad combo, you can enter the assigned username and password for your MyNeba.com account to start the CEEG2 system software.

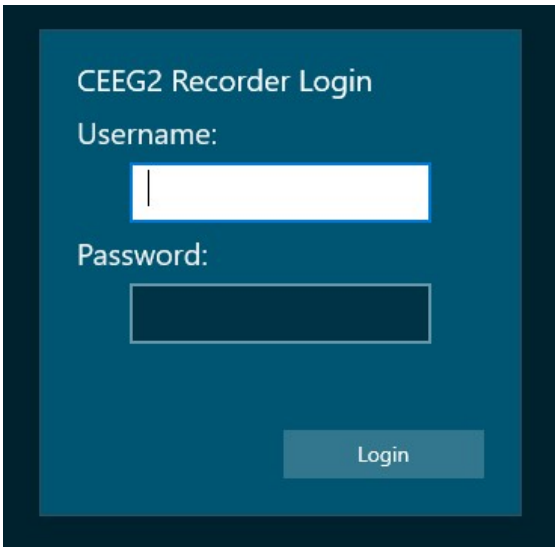


Figure 10-1: Login Screen

Logoff

When you have finished all recording and will be away from the system for a length of time, the system should be secured to reduce the chance of un-authorized access. To secure the system, click the "Logoff" button from the main menu (figure 9-2).

Restart

If the system is not functioning as previously specified, restarting may restore it to normal. The system can be restarted by pressing CTRL+ALT+DEL on the keyboard then clicking the power icon at the bottom right of the screen, figure 10-2.

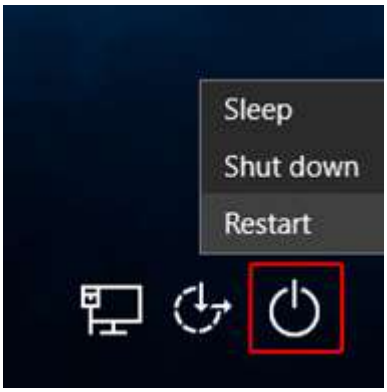


Figure 10-2: Shutdown - Restart

Shutdown

The system should be shut down when not in use. This will ensure a longer life of system components and secure the system from un-authorized access. To shut down the system, press CTRL+ALT+DEL then click the "Shutdown" menu item (figure 10-2).

If your computer stops responding, or hangs, use the following methods to force a shutdown, and then restart.

Be aware, though, that whenever possible, you should shut down your Surface in the normal manner:

- Press and hold the power button until the Slide to shut down your PC screen appears (about 4 seconds), and then slide down.

Or

- Press and hold the power button until the screen turns off (about 10 seconds), then release the power button.
- Press and release the power button to turn your computer back on. You should see the Microsoft logo.
- If that doesn't work, here's how to make sure your computer turns off completely:
    - Press and hold down the power button until your computer restarts and you see the Windows logo screen (this takes about 20 seconds), then release the power button.

11. Computer Operation

Diagram of Computer

Figure 11-1: Computer features

1. USB 3.0
2. Charging Port
3. Kickstand
4. Power button

Clean and care of your CEEG2 computer

To keep your computer looking and working great, clean the touchscreen and keyboard frequently, and keep your computer covered when you're not using it.

CAUTION To reduce likely damage to the system, completely power down and disconnect the system when cleaning the CEEG2 Computer. Turn the system power off at the power switch on the CEEG2 Computer, remove the keyboard, then disconnect the AC adapter from the electrical outlet and computer. Do not allow the power adapter and cables to become wet or damp and do not connect or disconnect the system components when any component is wet or damp.

General cleaning recommendations

To keep your computer looking and working great, use a soft lint-free cloth (microfiber cloths work great) dampened with a little bit of mild soap and water, or screen wipes. Clean every 3-6 months or whenever needed.

Note - Don't apply liquids directly to your computer.

Battery health

All rechargeable batteries wear out eventually. Here's how to get the longest life from your battery:

- Once a month, let your battery drain below half way before charging it.
- Avoid having your computer plugged in 24/7.
- Store your computer in a cool, dry room when you're not using it.

If you plan to store your computer for an extended period of time, charge it to 50% every six months to help make sure it stays chargeable.

Touchscreen care

Scratches, finger grease, dust, chemicals, and ultraviolet light can affect the performance of your touchscreen. Here are a few things you can do to help protect the screen:

- **Clean frequently.** The computer touchscreen is coated to make it easier to clean. You don't need to rub hard to remove fingerprints or oily spots. Use a soft, lint-free cloth (either dry or dampened with water or eyeglass cleaner—never glass or other chemical cleaners) or a screen cleaning wipe to gently wipe the screen.
- **Keep it out of the sun.** Don't leave your computer in direct sunlight for a long time. Ultraviolet light and excessive heat can damage the display.
- **Keep it covered.** Close the cover when you're taking your computer with you, or if you're not using it.

Cover and keyboard care

There's not much you need to do to keep the Touch Cover or the Type Cover working its best. To clean it, wipe with a lint-free cloth dampened in mild soap and water. Don't apply liquids directly to your computer or to the cover. Do this often to keep your Touch Cover or Type Cover looking great. See Appendix A for sanitizing methods.

If the spine or magnetic connections of your cover get dirty or stained, apply a small amount of isopropyl alcohol (also called rubbing alcohol) to a soft, lint-free cloth to clean.

Alcantara® material care

Figure 11-2: Keyboard Care

Some computer devices and accessories feature spill and absorption-resistant Alcantara® material.

Regular care

To keep the Alcantara looking good, wipe it with a lint-free white cloth dampened with a mild soap and water solution or a screen cleaning wipe whenever needed.

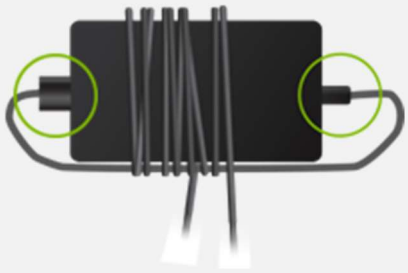
Stain removal

If you spill something on the Alcantara material, try to clean it within 30 minutes to help prevent any stains from setting. Use swirling motions, gently clean with a white line-free cloth dampened with soap and water. A simple solution of two parts water to one-part mild soap (like hand soap) will do. Wipe dry using a clean light-colored cloth.

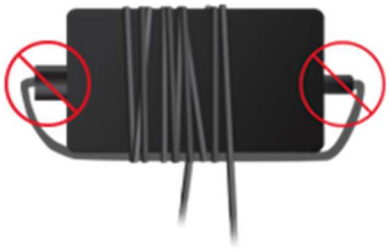
Power cord care

Power cords, like any other metal wire or cable, can be weakened or damaged if repeatedly twisted or bent in the same spot. Here are a few things you can do to keep your power cord from being damaged:

- **Avoid twisting or pinching your power cord**.
- Don't wrap your power cord too tightly, especially around the power brick. Instead, wrap it using loose coils rather than tight angles.



Correct: Cord wrapped loosely



Incorrect: Cord wrapped too tightly

Figure 11-3: Cord Storage

- **Inspect your power cord regularly, especially where it joins the power brick.**
- Avoid pulling on the power cord when unplugging your computer. Gently removing the connector from the charging connector can help prevent damage to your power cord.

Correct: Unplugging gently

Incorrect: Tugging on cord to unplug

Figure 11-4: Unplugging Cord

- If you find any damage on any part of your computer chargers' cords, stop using the cord and NEBA Health for support options.

How to charge computer

Connect your charger

To begin charging your computer, connect the power supply to the computer, and to a power source such as a wall outlet, power strip, or surge protector.

WARNING To avoid electrical shock, do not attempt to connect or disconnect the A/C or D/C power cords with wet or gel soiled hands. Make certain that your hands are dry and clean before connection or disconnection.

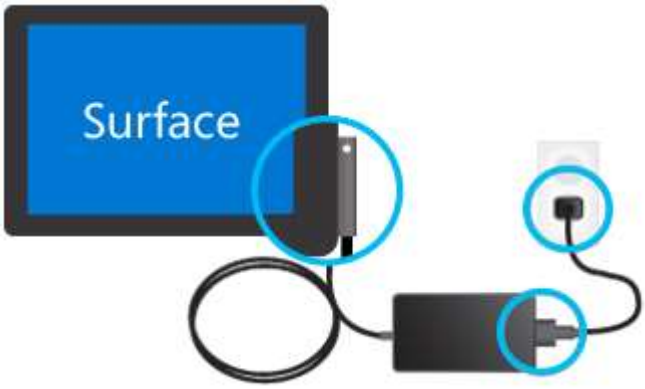


Figure 11-5: Cord Connection

You can plug the charging connector into the charging port on your computer in either direction, see figure 11-1 (2) and Figure 11-5.

When the power supply is connected to your computer, connected to a power source, and your computer is receiving power, the LED on the tip of the power supply will light.

If your LED light is not lit, you may have an issue with your power supply. Contact NEBA Health for service support.

How to charge headset

Connect your charger to cradle

To begin charging your headset, connect the USB power supply to the charging cradle using provided USB Type A connector to Type micro-B cable, and to a power source such as a wall outlet, power strip, or surge protector, figure 11-6.

WARNING To avoid electrical shock, do not attempt to connect or disconnect the A/C or D/C power cords with wet or gel soiled hands. Make certain that your hands are dry and clean before connection or disconnection.

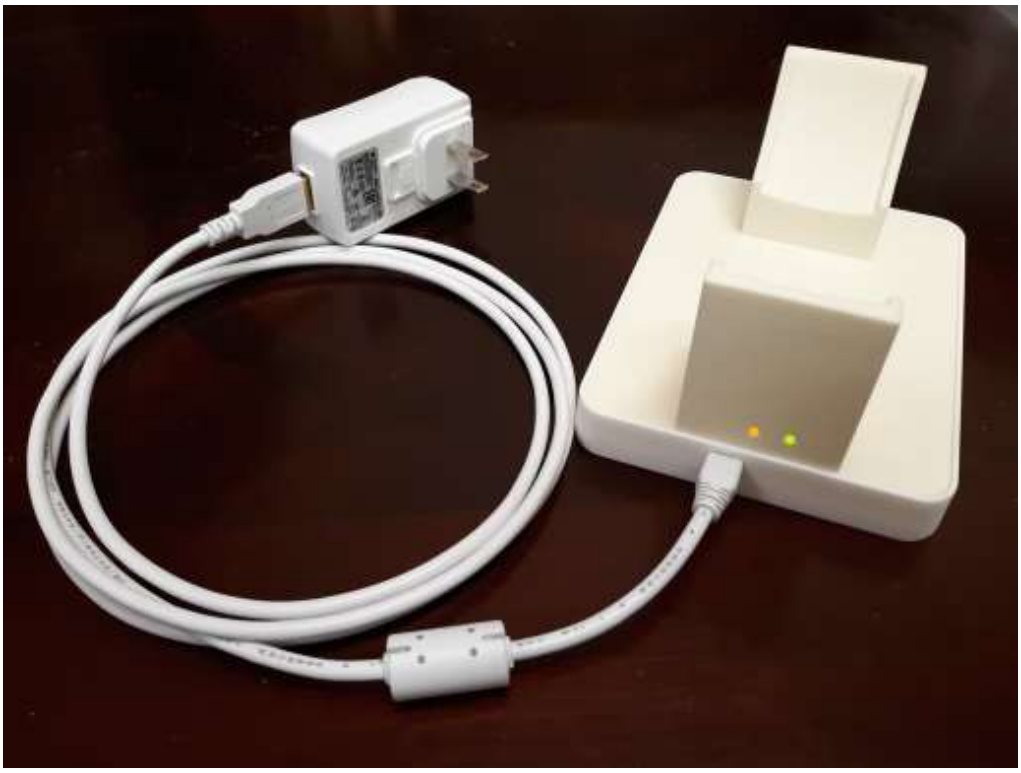


Figure 11-6: Power Cord Connection to Charging Cradle

Two LEDs (orange/green) on the charger cradle indicate the various functional states of the charging system including possible fault conditions. Table 11-1 shows the various indications for each status.

The Action column in table 11-1 provides actions to perform when experiencing the given LED status while the charger is powered on. Follow the instructions in the table for using the charging cradle.

NOTE When experiencing the "Fault" status the charger removes power to the transmitting coil. This will also provide the "No Light" indication of table 11-2, if the headset is on the cradle. This function provides safety assurance that the battery in the headset is not damaged by the fault or foreign object.

Table 11-1 – Charger LED Status

	Green LED	Orange LED	Status	Action
Standby	On	On	Waiting for headset to charge.	Install headset onto cradle.
Transfer	Blink 1Hz	Off	Providing power to headset receiver.	Allow headset to charge.
Low-Power	Blink 2Hz	Off	Insufficient power to charge headset. headset receiver too far from transmitter.	Ensure headset is correctly positioned in charger cradle.
Fault	Off	Blink 4Hz	Charger has detected a fault or foreign object and has terminated power transfer to headset. Foreign objects can produce over-heating of the charger. Power supply fluctuations can cause fault conditions also.	Remove any foreign object from charger. Ensure proper power supply for wall charger. Remove headset from charger base until charger is in standby status. Replace headset to begin charging.

When the headset is sitting in the charging cradle which is connected to a power source, the LED on the back of the headset will light, figure 11-7.

> **If your headset LED light is not lit,** you may have an issue with your power supply or charger. Follow the instructions in table 11-1. Contact NEBA Health for service support, if unable to resolve using the actions provided.

The headset charging LED has three colors to indicate the charging mode.

Table 11-2: Headset LED Status

LED	Status		Description
Yellow	Charging		The yellow LED indicates the headset battery is charging.
Red	Faulting		The red LED indicates an issue with the charging system and the battery is not charging.
Magenta	Charge Complete		The magenta LED indicates that the headset battery has finished charging.
No Light	Not Charging		No Light indication shows that the headset battery is not charging.

Figure 11-7: Headset Charging LED

NOTE

In the event of a repetitive fast transient event, the wireless charger will stop charging the headset as a security feature. Once the fast transient event has passed, the wireless charger will reset and continue charging the headset.

Appendix A

Cleaning the Headset and Electrode Leads

Electrode snap leads may be cleaned using PDI Sani-Cloth AF3 wipes. Gently wipe patient-side snap connectors and lead wires.

WARNING PDI Sani-Cloth AF3 wipes are intended for equipment cleaning only and are not intended for patient or skin contact due to possible skin irritation. To reduce risk of accidental patient contact, separate AF3 wipes from those supplies intended specifically for patient use.

CAUTION To reduce possible skin irritation, always wear protective disposable FDA cleared medical examination gloves when using PDI Sani-Cloth AF3 equipment cleaning wipes.

WARNING To reduce the chance of electrical stock, never connect wet or damp electrode leads to a patient.

Compact EEG2 Mobile System Cleaning

WARNING **Electrical Shock Hazard:** Allow sufficient time after cleaning or disinfecting for the system to dry completely before powering the system back on.

CAUTION To reduce the chance of damaging the system, do not use any solution that is corrosive or abrasive to clean or disinfect the CEEG2 system. If you are concerned whether a cleaner or disinfectant will harm the system, contact NEBA® customer service.

Follow these steps to power the system down prior to cleaning or disinfecting:

1) Turn the CEEG2 Computer off.
2) Disconnect the system power supply from the A/C power outlet.

For general periodic cleaning, wipe the system (CEEG2 Computer and keyboard) with PDI Sani-Cloth AF3 wipes (follow instructions for use; refer to usage warnings above). Disinfection of the system may also be carried out using compatible methods, in accordance with your local and institutional polices for surface and equipment disinfection. It is recommended that you use an EPA-approved low-level disinfectant for general disinfection. For visibly soiled areas, you may clean, then disinfect; or use a detergent disinfectant instead. See Table A-1 for approved cleaning and disinfecting solutions.

TABLE A-1	
Disinfectants/ Cleaning Solutions	**Brand**
Sani-Cloth AF3 wipes Isopropyl Alcohol 70% CaviCide 	PDI

Appendix B

Artifacts and Minimizing Their Occurrence

This appendix lists the major sources of EEG artifacts, along with methods that may help minimize their occurrence. It is advisable that a clinician be present during the recording to monitor artifacts and make any necessary artifact-reducing changes.

Eye Artifact

Eye fluttering or blinking will lead to low frequency waves in the EEG. It is desirable that the subject have a "natural" blink rate during the recording. The subject should not try to avoid blinking, nor should they blink excessively. Excessive eye movements can be minimized by having something for the subject to look at or concentrate on (a simple object or point on the wall, etc). If necessary, pause the recording and let the subject shut their eyes for a moment.

Muscle Artifact

Electromyographic (EMG) activity, which is commonly called muscle artifact, is generated by tense muscles. The subject may appear calm and relaxed, yet some electrode derivations may be more or less obscured by continuous EMG with a voltage higher than the EEG. This artifact occurs most commonly in the frontal and temporal areas, although it may occur at any other electrode location.

Elimination of muscle or EMG artifact may be difficult. First, every effort should be made to make the subject more comfortable. Sometimes having the subject open his/her mouth slightly will decrease the amount of muscle artifact. Sometimes tension may be reduced with *brief* hyperventilation. The tech can pause the recording and have the subject hyperventilate for *1-2* seconds; and then resume recording. In addition, a towel used as a neck roll can be placed at the base of the subject's neck to eliminate EMG. Finally, if EMG persists, it is often best to do nothing, as constantly reminding the subject to relax can increase tension. With the passage of time over the recording period, anxiety and tension sometimes tends to decrease.

Electrocardiographic Artifact

Another common physiological artifact is the electrical activity of the heart (EKG or ECG). Usually the EKG voltage at the scalp is relatively small (1 to 2 μV), which is masked by the EEG activity (usually 20-100 μV).

There is individual variability in the amount and persistence of EKG artifact. Its presence is related to the field of the heart potentials over the surface of the scalp, which is influenced by the body's conduction pathways. In general, a short and stout person with a short and wide neck may present the largest EKG artifacts in their EEGs. EKG artifact usually is recognizable by its rhythmicity. If EKG components are mixed with EEG activity, they may sometimes resemble sharp waves.

To help minimize EKG artifact, you may try the following: Place the subject in a reclining chair; tilt the head back slightly leaving the subject in a comfortable position; and make sure the subject's chin is not resting on his/her chest. You may try further modifying the subject's head position to help reduce the EKG artifact.

Pulse Artifact

The slow waves of pulse artifacts can occur when an EEG electrode is placed over a pulsating vessel. The mechanical movement caused by pulsation of an artery can cause a slow wave that sometimes simulates EEG activity. There is a direct relationship between the EKG and the pulse waves.

Pulse artifact can occur in any lead. If the subject is lying on the involved electrode, the artifact sometimes may be eliminated by moving the head slightly. Slightly shifting the electrode position may also eliminate the artifact.

Glossokinetic Potentials

The tongue is electrically charged. The tip of the tongue is more positive than the root. These charges act like a battery. Movement of one pole relative to the other will change the electrical field around the mouth and jaws. This field can sometimes spread to the upper part of the face. These changes are called glossokinetic potentials and are a rather commonly overlooked form of noise or artifact in the EEG.

Movement of the tongue can cause single or rhythmic slow waves that are seen predominantly in the temporal regions, but also may be seen in other areas. These slow waves may be reproduced by asking the subject to say words such as 'lilt', 'long' or 'large'.

Chewing and sucking movements can cause a variety of artifacts, including EMG potentials and slow activity, likely related to tongue movement. These artifacts are commonly seen in very young subjects. They can also occur in demented or other uncooperative subjects. Elimination of the artifact is sometimes difficult. Therefore, its definite identification is essential.

Respiration

Respiration may cause two types of artifact. One type may be fairly rhythmic, slow activity that is synchronous with the body movement related to respiration. The movement causes mechanically induced impedances to change in an electrode. Respiration artifact may also appear as a slow or sharp wave occurring synchronously with inhalation and/or exhalation, involving only some electrodes, usually those on which the subject is lying. These artifacts sometimes are eliminated by repositioning the subject's head.

Skin Potentials

Skin potentials may cause low frequency artifact. An area of the skin with many sweat glands is electrically negative relative to an area less well supplied with sweat glands. The voltage difference may be as much as 50 mV (or up to 100 times the voltage of the EEG). The sweat glands generate electrical potentials when active. Secondarily, the production of sweat changes the concentration of electrolyte between the electrode and the skin, causing a battery effect which acts as a further source of slow artifact.

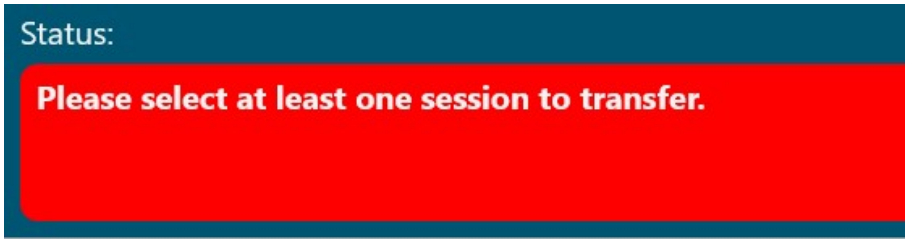
The only method of reducing artifact associated with sweat gland activity is to reduce the cause of sweating. Cooling the head, wiping the area with alcohol, and providing air conditioning to control the recording environment have been the time–honored procedures. *Mildly* abrading the area (with a blunt object, such as the back of a cotton swab applicator) under the electrode can sometimes help reduce the local skin potential, which in turn can improve the recording quality in the presence of undesirable skin potentials.

Appendix C

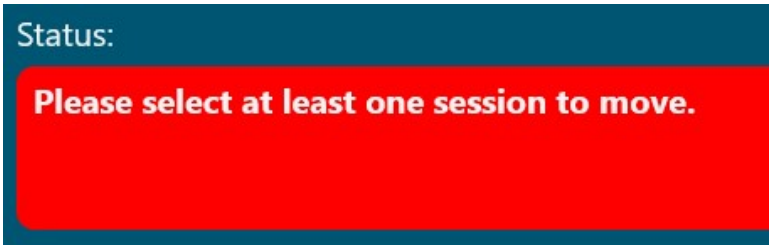
Data Transfer Message Box Descriptions

There are several data transfer message boxes which give information, require confirmation or give warning about data transfer events.

When transferring data from the system you must select a data session from the Recording Session list. If no session is selected when clicking the transfer button, message 1 or 2 will appear warning you to select sessions for transfer.



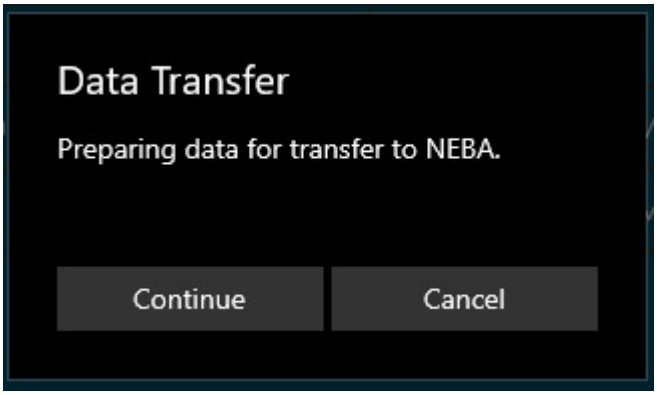
Message Box 1: No Selection Warning



Message Box 2: Archive Folder No Selection Warning

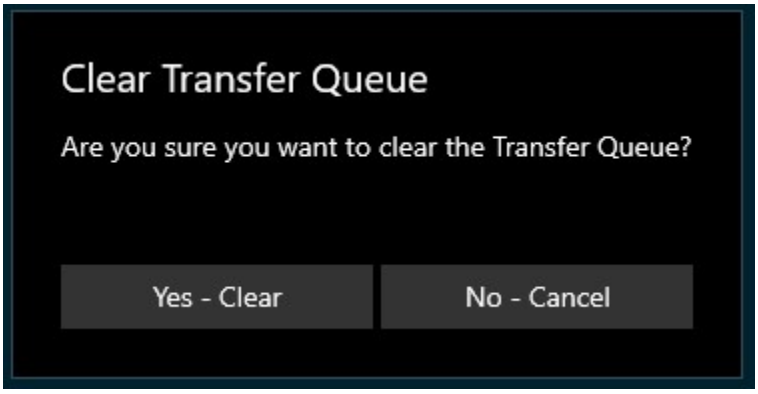
Once you have selected data for transfer and clicked the "Transfer" button, you will be asked to confirm that the transfer action is what you intended. Clicking "Continue" in message box 3 will move the data to a transfer queue for upload to NEBA Health servers. Clicking "Cancel" will cancel the data transfer leaving the data selected in the list. There are two areas that you can transfer data from, the EEG data folder and archive folder. Message box 3 ask you to confirm transfer from these folders.

Message box 3 ask you to confirm the transfer across the internet is what you intended.



Message Box 3: Internet Transfer Confirmation

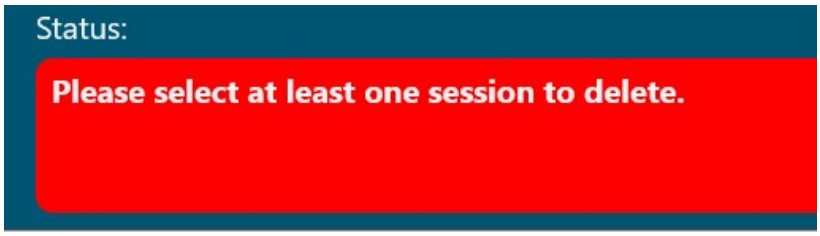
In the event that the data transfer is unsuccessful and NEBA Health customer service asks you to re-submit data, the transfer queue can be cleared using the "Clear Queue" button in the "In Queue" area. When this button is clicked message box 4 is displayed asking you to confirm that clearing the "Internet Queue" is what you intended. Clicking the "Yes" button will clear the queue and clicking "No" will cancel the clearing action.



Message Box 4: Clearing Transfer Queue Confirmation

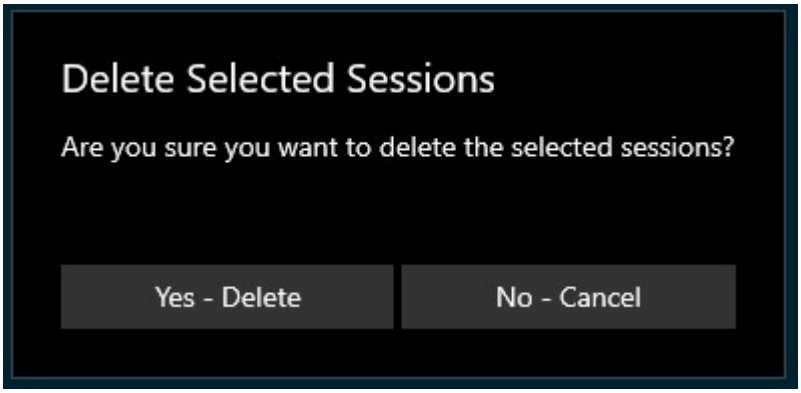
In the event the computer drive gets full the "Available Space" area be used to remove sessions. To clear space select sessions from the archive or data folders.

Click the "Delete Selected" button in the available space area to clear the sessions. When no sessions are selected in the recording session list, message 5 is displayed warning you to select data for deletion.



Message Box 5: No Selection for Deletion

With sessions selected for deletion message box 6 will appear. Clicking "Yes" in the message boxes will delete the selected data. Clicking "No" will cancel the delete action.



Message Box 6: Data Deletion Confirmation

Appendix D

Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1, Class B	The System uses RF energy only for its internal function. There, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

IMMUNITY TEST	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Dips: 0% UT for 0.5 cycle at 0°, 45°,90°,135°,180°,225°,270 and 315° 0% UT for 1 cycle at 0° 70% UT for 25 cycles (50Hz) & 30 cycles (60Hz) at 0° Interruptions: 0% UT for 250 cycles (50Hz) & 300 cycles (60Hz)	Dips: 0% UT for 0.5 cycle at 0°, 45°,90°,135°,180°,225°,270 and 315° 0% UT for 1 cycle at 0° 70% UT for 25 cycles (50Hz) & 30 cycles (60Hz) at 0° Interruptions: 0% UT for 250 cycles (50Hz) & 300 cycles (60Hz)	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

IMMUNITY TEST	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	Outside ISM Bands: 3 Vrms 150 kHz to 80 MHz Inside ISM Bands: 6 Vrms 6.765MHz-6.795 MHz, 13.553 MHz-13.567 MHz, 26.957 MHz-27.283 MHz, 40.66 MHz-40.70 MHz	Outside ISM Bands: 3 Vrms 150 kHz to 80 MHz Inside ISM Bands: 6 Vrms 6.765MHz-6.795 MHz, 13.553 MHz-13.567 MHz, 26.957 MHz-27.283 MHz, 40.66 MHz-40.70 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	**Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – Radiated, radio-frequency, electromagnetic field immunity, frequency range and levels

Frequency Range and Level: RF wireless communication equipment			
Test Frequency (MHz)	**Modulation**	**Minimum immunity Level (V/m)**	**Immunity Level Applied (V/m)**
385	Pulse Modulation: 18 Hz	27	27
450	FM ± 5 Hz deviation: 1 kHz sine	28	28
710 745 780	Pulse Modulation: 217 Hz	9	9
810 870 930	Pulse Modulation: 18 Hz	28	28
1720 1845 1970	Pulse Modulation: 217 Hz	28	28
2450	Pulse Modulation: 217 Hz	28	28
5240 5500 5785	Pulse Modulation: 217 Hz	9	9

NOTES:

- If it is necessary to achieve the immunity test levels, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m (as permitted by IEC 61000-4-3)
- For some services, only the uplink frequencies are included
- The carrier shall be modulated using a 50% duty cycle square wave signal
- As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used; while this may not represent the actual modulation, it would represent the absolute worst theoretical case

Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 1.2\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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