



New Wave EEG Instructions for Use

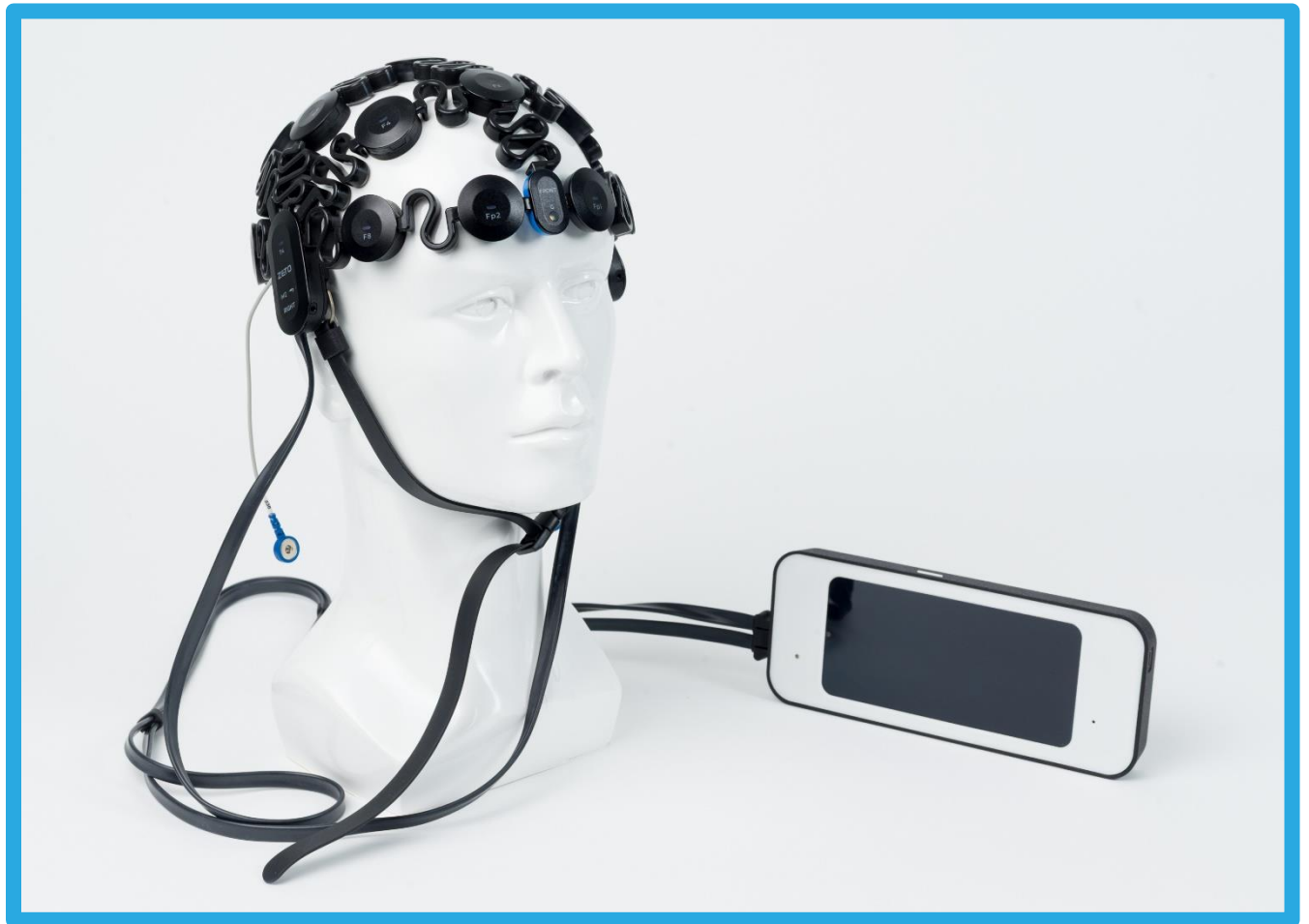


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1. About this manual

This manual is intended for the user of the New Wave wireless EEG system. It contains general operating instructions, precautionary measures, maintenance instructions and information for use of the system. Please read this manual carefully and familiarize yourself with the various controls and accessories before starting to use the product.

1.1. Company contact information

Zeto support is available via email (support@zeto-inc.com) or by phone during office hours from 8:00 a.m. – 6:00 p.m. (EST).



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Raleigh NC 27606 USA

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1.2. Warranty information

The warranty covers the following components of the system:

- New Wave Head Units (Small and Regular)
- New Wave Power Supply
- New Wave Display Unit
- New Wave Extension Unit

The New Wave Head Unit (Head Unit) is warranted against failure of materials and workmanship for 300 use cycles (a use cycle consisting of donning-setup-study-removal-cleaning) from the date of delivery.

The other covered items are warranty against failure of materials and workmanship for a period of 1 year from the date of delivery.

Repairs can only be performed by the manufacturer. The warranty is void if any of the covered items are opened by anyone other than qualified personnel authorized by Zeto.

The warranty does not cover the following:

- Customers may choose to use other cleaning agents based on their disinfection protocols. However, cleaning agents other than isopropyl alcohol 70% can cause discoloration and in rare accelerate material aging of the device. Zeto does not cover replacements under its warranty program for discoloration or accelerated aging arising from use of cleaning agents, other than isopropyl alcohol solution (up to 70%)
- Failure resulting from misuse, accident, modification, unsuitable physical or operating environment, or improper maintenance
- Failure/damage caused by a third-party product not approved by Zeto
- Any non-Zeto products

The warranty is voided by removal or alteration of identification labels on the product or its components. If you notice a significant degradation of a label, please notify Zeto about this issue as soon as possible. Warranty is also void in case of tampering or servicing by unauthorized personnel, or if seals on the enclosure are broken.

Zeto does not warrant uninterrupted or error-free operation of wired or wireless data transmission.

2. Safety information

This section contains general warnings, explanation of markings, limitations of use, safety measures, and precautionary measures that are important for the safe use of the New Wave.

2.1. Explanation of markings

This documentation and the product use the following markings.

Symbol	Meaning
IPN₁N₂	IP rating Level of protection against ingress of dust and water.
	Refer to instruction manual Not following the instructions may lead to risks.
	Mandatory action Follow the instructions to ensure safety, performance and convenience.
	Consult operating instructions Follow operating instructions.
	Type BF applied part High degree of protection against electric shock.
	Safety warning Not following the instructions will lead to risks.
	Do not push, bend, sit on, step on, push, pull or overstress flexible material Avoid exposing the device to excessive mechanical stresses.
	Contains radio transmitter. Device contains a radio transmitter, details about the radio transmission.
	Instructions about the IT network. Technical details about the required WiFi or 5G/LTE network.
	MR Unsafe This marking warns the user that the device cannot be used safely in magnetic resonance environments.
	Single Use Only This marking warns the user that the product component is disposable. Do not reuse components with this marking.



Prescription use only

The system may only be used on the order of a licensed healthcare professional.

2.2. Limitations of use



Limitations of use

The system is **not** intended for:

- Use in life support systems
- Use when alarms-based EEG classification is required
- Use in sterile environment – the Head Unit is not suitable for sterilization

The product is **not** to be:

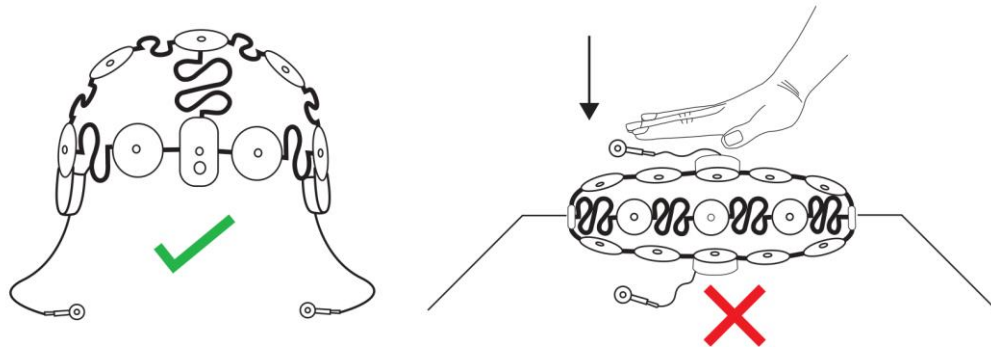
- Used near high frequency surgical equipment
- Exposed to ionizing radiation
- Used on patients undergoing electro surgery
- Used in oxygen rich environment (concentration > 25% at 1 atm)
- Used during defibrillation – defibrillation may damage the product

The product is **not**:

- Defibrillation proof
- Suitable for sterilization
- Suitable for UV disinfection
- Suitable for use in explosive atmosphere
- Suitable for use in presence of flammable anesthetics or gasses

Do not:

- Use, store or transport the system's components outside of the specified temperature conditions, this may damage the components
- Drop, sit on, step on, fold, push, pull or stretch the devices, this can damage the devices
- **Do not transport or store the head unit folded. Store it in the Zeto provided case when not in use to maintain its shape. If folded or bent out of shape the unit is likely to break.**



**ALWAYS KEEP THE HEADSET IN THE CARRY CASE
DURING TRANSPORT OR STORAGE!**

To ensure the best electrode performance, **do not**:

- Use in case the scalp and the skull of the patient is not intact, or the patient has a sensitive dermatological condition on the scalp and therefore even the very light electrode contact forces cannot be tolerated
- Use in case of open wounds or infections on the scalp to avoid cross-patient contamination

Patients with cranial anatomical alterations, including but not limited to missing skull bone flaps (craniectomy sites), intracranial pressure (ICP) drains, cerebral shunts, external ventricular drains (EVDs), cranial bolts, or other surgery- or head-injury-related structural changes, require prior assessment and written sign-off by a qualified medical professional to confirm that device placement will not result in pressure injury or other damages to neural tissue or scar tissue.

The device is **not** intended to treat patients or to be used for medical intervention. The device neither diagnoses nor suggests any diagnosis. Any medical diagnosis related to the EEG should only be derived by a certified physician. There are no known side effects from the use of this product.



Limitations of use

The product is not designed to be used near or inside magnetic resonance imaging (MRI) equipment or any other strong magnetic field. The product is MRI UNSAFE.



The product was designed to be used for prolonged times. Taking bathroom breaks during recordings is safe. However, **do not** take baths/showers with the New Wave on. Use of the product during Computer Tomography (CT) scans does not pose a safety risk for the patient, but the CT image quality, as well as the EEG recording will be significantly affected. **Do not** wear the product during CT scans for that reason.

2.3. Additional information



Additional information

- The New Wave Head Unit and its electrodes are intended for use on a healthy scalp on children, adolescents and adults having a head circumference between 45-65cm. Use outside this range has not been evaluated. The device **should not** be used on newborns with unfused fontanel.
- EEG patients may be bald or may have hair. Their hair must be parted in a way which allows direct connection of the electrodes to the scalp. To have a complete EEG test result, all electrodes must properly land on the scalp of the patients.
- The Head Unit provides real time EEG transmission to the cloud and remote controlling from the cloud when connected to a 2.4 or 5.0 GHz WiFi or a 5G/LTE network. The WiFi network works with WPA, WPA2, WPA3 or WPA2/WPA3 EAP encryption, but does not support captive portal authorization. The network must allow communication to the Internet.

- Minimum Quality of Service requirement is 2 Mbit/s upstream and 1 Mbit/s downstream bandwidth connection to the public Internet, with a latency less than 500 ms. There is no provision for the security of the network - all data communication between the New Wave and the Zeto Cloud Platform are encrypted.
- Connection to the Internet is required to utilize all features of the Zeto Cloud Platform and immediate storage of the EEG study to the cloud. However, the device may need to operate in sub-optimal network conditions such as
 - Intermittent poor or no WiFi network coverage
 - Intermittent poor or no cellular network coverage
 - Degraded network performance
 - Expired network access subscription
- In case connectivity cannot be established over WiFi, the device switches to 5G/LTE cellular connection automatically as a backup. In the event of cloud/networking/connection cannot be established, the functionality of the New Wave is provided **automatically** by the system using a built-in offline data storage until the connection is re-established. The built-in offline data storage has a storage capacity of at least 10 hours of EEG with video. The user is provided with ample notifications to take action prior to storage being full.
- The operator can start and stop an EEG study from the device, and interpret studies recorded on the device even in case of a prolonged period without a working network connection. Therefore, device functionality and safety is not dependent on the quality of the network connection.

2.4. Safety and performance warnings



Safety warnings about the product components

To keep your product safe, **do not**:

- Immerse the components of the product in any liquid except for the Head Unit and the cables directly connecting to the Head Unit during disinfection
 - Sterilize the product
 - Expose the product components to heat source of thermal radiation, moisture, vibration, mechanical shock, excessive dust or humidity
 - Open, modify or disassemble the any of the product components – as that voids warranty
 - Use the product when damaged
 - Use when wet – if any moisture penetrates the product components, have the affected devices checked by the manufacturer
 - Use caustic or abrasive cleaning agents to clean the components or electrodes – for cleaning instructions refer to Section 6
 - Bend the cables in sharp angles
 - Arrange the cables in ways that may cause tripping or strangling hazards
 - Swallow or lick electrodes
-

The electrodes contain permanent magnets. It is advised to keep a separation distance of 6 inches between the electrodes and any magnetically susceptible medical devices.



Disposable electrodes may be hazardous. **DO:**

- Store clean electrodes in their packaging until their usage
- Store the electrodes safely to prevent unauthorized access (e.g., children)
- Collect used electrodes in a separate, sealable container after use
- Dispose used electrodes by following the biohazard policies of your facility and the applicable regulations



Performance warnings

This system is designed for use in *outpatient healthcare or research facility and home* environments.

- Usage in environments such as near HF surgical equipment, magnetic resonance imaging equipment, or other equipment which produces high levels of EM disturbances will affect the performance of the system.
- In case of EM disturbances, the recorded biopotential waveforms may have environmental artifacts such as additional unexpected high frequency components superimposed.
- Some EM disturbances, such as mains frequency artifacts may be reduced by using the built-in filters of the client software.
- No harm to the patient or operator may occur when using the system in an unsupported environment.

Separation from RF communications equipment

- **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the New Wave's components, else, degradation of the performance of this equipment could occur. For further information on separation distances refer to Table 206.
- **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity and improper operation.

Use only Zeto-supplied accessories. Using non-Zeto accessories may cause a hazard of excessive heat, fire or explosion, or may result in improper operation of the Head Unit by increased emissions or decreased electromagnetic immunity.



It is recommended to check the New Wave's components and cables for mechanical damage before every study.

More comprehensive technical checks are recommended after every 20 uses.



Safety warnings about the battery

WARNING: potential for fire or burning.

- Do not disassemble or crush the battery.
- Do not heat or burn the battery.
- Do not throw the battery into fire or water.
- Do not swallow batteries.
- Do not short circuit batteries.

-
- The battery shall be replaced only by the manufacturer or by service centers approved by Zeto.
 - The customer shall refer to the handling instructions and environmental limits.



CAUTION: The battery used in the Display Unit may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 45 °C (113 °F) or incinerate.

To ensure battery safety, **DO NOT:**

- Open the Display Unit
- Charge the Display Unit below 0 °C or above 45 °C (below 32 °F or above 113 °F)
- Store the Display Unit below -20 °C or above 45 °C (below -4 °F or above 113 °F)

Follow applicable regulations and recycling instructions regarding the disposal and recycling of the product, including the internal Lithium-Ion battery. Keep away from unattended children.

Zeto ensures that the product is free from unacceptable intended use related residual risks.



First aid measures about the battery

The battery may leak or emit gasses in case of serious mishandling:

- Charging outside of the allowed temperature range
- Storing or transporting the Display Unit outside of the allowed environmental conditions
- Mechanical impacts such as crushing, perforating, disassembling

Electrolytes or other particles which leak out from the battery are harmful to the human body and the environment. Follow the instructions below to reduce risks.

- **In case of inhalation:** Seek fresh air and medical assistance immediately.
- **In case of skin contact:** Remove solid particles immediately. Flush affected areas with plenty of fresh water (at least 15 min.) Remove contaminated cloth immediately. Seek medical assistance.
- **In case of eye contact:** Flush the eye gently with fresh water (at least 15 min.) Seek medical assistance.
- **In case of ingestion:** Drink plenty of water. Avoid vomiting. Seek medical assistance. Do not attempt neutralization.



Fire and environment related accidental measures about the battery

In case of serious mishandling, the battery may catch fire:

- **Suitable extinguishing media:** Metal fire extinction powder, rock salt or dry sand shall be used. In case only water is available, it can be used in large amounts.
- **Extinguishing media with limited suitability:** Carbon dioxide (CO₂) is not suitable. Water in small quantities may have adverse effects.
- **Special protection equipment during firefighting:** Contamination cloth including breathing apparatus.
- **Special hazard:** Battery cells may explode and release metal parts. When the electrolyte contacts water traces, hydrofluoric acid may be formed. In this case avoid contact and ensure good ventilation. At contact of charged anode material with water extremely flammable hydrogen gas is generated.
- **Attention:** Do not let used extinguishing media penetrate surface water or groundwater. If necessary, thicken water or foam with suitable solids. Dispose of the residue according to applicable regulations.
- **Environment protection measures:** Bind released ingredients with powder (rock salt or sand). Dispose of it according to applicable regulations. Avoid leached substances that could penetrate the ground, canalization, or water.
- **Treatment for cleaning:** In case the battery is dismantled, small amounts of electrolytes may leak. Package the battery tightly including the components together with lime, sand, or rock salt. Then clean with water.

2.5. Security information for IT network

The New Wave streams captured EEG information to Zeto's data center in real time. To use the data center application, a computer and an internet connection provided by the user is required. Zeto has created software with ease of connection configuration in mind, while maintaining industry standard security for all data.



The network requirements of the New Wave are simple. If you have a WiFi connection with a network id, password and Internet, or 5G/LTE data service, then you can use the product on the available WiFi or 5G/LTE network seamlessly.

The purpose of the IT network connection is to control the system, and transfer data. The system uses the IT network to:

- Identify and authorize the product's connection to the data center
- Control the product from a local or remote IT device via the data center
- Transmit status indicators, such as battery and temperature to the data center
- Transmit raw captured biosignal data and video to the data center

The device connects to an IT network provided by the user, not validated by the manufacturer. The product has the following IT network requirements:



IT network requirements for connecting directly to WiFi networks

Network types:	Wi-Fi 802.11 a/b/g/n/ac 2.4+5.0 GHz
Network characteristics:	At least 2 Mbit upstream, 1 Mbit downstream bandwidth routed to the public Internet, less than 500 ms packet latency
Network configuration:	The product uses a network setup mode to enter WiFi connection credentials. Then the product obtains network settings from a DHCP enabled WiFi access point automatically. No further configuration is necessary. Note: WiFi networks using captive portals (requiring entering network credentials in a web browser) are not supported.
Technical specification:	The WiFi access point must run a DHCP service to let connecting devices automatically configure their network settings. The WiFi access point and the underlying IT network must be configured to allow outgoing HTTPS traffic on port 443 and route data towards the public Internet. Although cybersecurity measures of the product are independent of the IT network, it is advised using WEP/WPA2/WPA3/WPA2 Enterprise/WPA3 Enterprise WiFi authentication to protect the access point from unauthorized access. There is no requirement for opening ports on firewalls or setting up any port forwarding rules.



Warning about IT network used by multiple medical devices

Connection of the New Wave to an IT-NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties.

The user's RESPONSIBLE ORGANIZATION shall identify, analyze, evaluate and control these RISKS.

Subsequent changes to the IT-NETWORK/DATA COUPLING could introduce new RISKS. The following considerations and changes regarding the IT-NETWORK/DATA COUPLING may be necessary:

- changes in the IT-network/DATA COUPLING configuration
- connection of additional items to the IT-NETWORK/DATA COUPLING
- disconnecting items from the IT-NETWORK/DATA COUPLING
- update of equipment connected to the IT-NETWORK/DATA COUPLING
- upgrade of equipment connected to the IT-NETWORK/DATA COUPLING



List of utilized network ports

For improved cybersecurity, the user's RESPONSIBLE ORGANIZATION should keep only the used ports open and close all ports that are not utilized. The New Wave communicates on the following network ports:

- TCP 443
- UDP 443
- UDP 49152-65535

2.5.1. Vulnerability Disclosure

No unacceptable residual risks have been identified and no hazardous situations may result from loss of WiFi or 5G/LTE connectivity or the cybersecurity of the device getting compromised. Zeto guarantees that its products are shipped malware-free. Cybersecurity risks that stem from poor security practices of the user could not be mitigated. To prevent any harm resulting from malpractices, please follow your facility's cybersecurity policies.

2.6. Precautions

Precautions of use



Avoid cross-patient contamination. Always clean the Head Unit and replace electrodes after use according to the cleaning instructions to avoid cross-patient contamination. (For cleaning instructions refer to Section 6).



For sedated, unconscious, or otherwise immobile patients, appropriate repositioning and pressure-injury prevention protocols shall be followed. These may include, but are not limited to:

- Regular repositioning of the patient, including head position in bed or chair
- Use of pressure-relieving mattresses or cushions, as clinically indicated
- Daily inspection of the skin for signs of irritation or erythema, particularly over bony prominences

If signs of skin irritation or pressure injury are observed, adjust, twist, or reposition the electrodes as necessary to relieve pressure. Please consult with the hospital Wound Care Nurse to ensure you follow your local hospital's policy & procedures.



The New Wave Head Unit is built from flexible materials. This allows the Head Unit to align to different head shapes and sizes. Using flexible materials limits mechanical stability. **Avoid doing the following to the flexible materials:**

- Bending
- Sitting on
- Stepping on
- Pushing
- Pulling
- Overstressing

Failure to follow the above recommendations may damage the Head Unit.



To meet RF exposure guidelines during body-worn operation, the Display Unit should be positioned at least 1.5 cm away from the body.

To ensure the best performance, avoid recording with the New Wave in the proximity of electromagnetic emitters, e.g.:

- RF controlled devices like drones or RC cars and their remote controllers
- Security systems, such as metal detectors or EAS
- Diathermic devices, electrocautery devices, electrosurgical units, etc.

Keep at least 6.5 feet distance between RFID readers and New Wave and its components during recording.

3. System overview

3.1. What is the New Wave system?

The New Wave system is a wireless, full montage electroencephalograph (EEG) system implementing:

- The New Wave Head Units (Small and Regular)
- Electrode sets
- The New Wave Display Unit (DU) that ensures communication between the Head Unit and a personal computer. The DU provides power to the Head Unit and displays information.
- The Zeto Cloud Platform, which receives, stores, retrieves and visualizes EEG study waveforms
- The New Wave Extension Unit (EU) for additional patient lead wires
- Additional patient lead wires for ECG, EOG, custom EEG reference, EMG, and additional auxiliary signals.

The product provides an integrated approach for wireless acquisition and recording of electroencephalographic (EEG) biopotential signals. Wireless WiFi or 5G/LTE technology allows the patient to move around the clinic or in the field, while real time data is collected, displayed, and analyzed.

The product uses soft electrode technology to obtain high quality EEG without the need for scalp preparation. Setting up the studies takes only a few minutes. A stretchable mechanism and a range of replaceable electrodes allow aligning the Head Unit to different head shapes and sizes, while keeping electrode positions aligned to the 10-20 EEG system.

The New Wave system has two Head Unit variants, Small and Regular. The Small Head Unit is designed for patients with head circumferences between 45 cm and 55cm, while the Regular Head Unit is designed for patients with head circumferences between 55cm and 65cm. These ranges might vary slightly depending on the head shape, hair style, etc. Outside the dimensions, the two Head Units are equivalent in functionality, therefore the rest of this document will use only the term "Head Unit".

The New Wave records a 19-channel full montage EEG, with optional mastoid references (A1/A2) and additionally up to 8 auxiliary channels. Auxiliary channels use any combinations of the provided 11 electrode lead wires for EOG, ECG, EMG, external reference and two auxiliary EEG channels. Electrode lead wires are compatible with off-the-shelf sticky pad electrodes using industry standard snap-on connectors.

EEG capture is referential, using a set of pre-configured internal references and external references. The captured data can be analyzed in various montages digitally, such as bipolar longitudinal, bipolar transversal and circumferential.

Electrode contact quality is continuously monitored by the system. Data segments causing non-biophysical signals due to inadequate contact quality or heavy external interference are marked automatically.

The Display Unit contains WiFi and 5G/LTE radio transmitters. All EEG channels have a sampling rate of up to 500 Hz; and the signals are precisely converted to digital data at 24 bits of resolution.

The New Wave is fully compatible with the Zeto Cloud Platform (K172735). Captured data is streamed to the Zeto Cloud Platform in real-time. The Zeto Cloud Platform can process low-pass, high-pass, and notch

filtering, perform montage transformations while recording or when interpreting a previous recording. Recordings are stored on the cloud server and are available for interpretation by a local or a remote physician.

The operator of the product can use a tablet, a desktop computer, to configure and control the New Wave using the client software. The client software visualizes recordings in real-time and allows browsing of previous recordings for interpretation. The operator may also use the display unit of the New Wave to start/stop recordings, visualize recordings in real time and browse previous recordings on the device even in case of limited or no WiFi or 5G/LTE network connection.

With the Zeto Cloud Platform it is possible for the physician or a technician to remotely connect to a real-time recording and verify the signal quality and/or derive a diagnosis in real-time.

3.2. Intended use / Indications for use

The New Wave system is intended for prescription use in an outpatient healthcare facility, research, or home use to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The New Wave system acquires, transmits, displays and stores electroencephalogram (EEG), and optionally electrocardiogram (ECG), electrooculogram (EOG), electromyogram (EMG), orientation sensor data, photic sensor data, external trigger signals, and video. The system is only intended to be used for short-term recordings up to 2.5 hours.

The New Wave System is not intended for use in the following situations:

- Not intended for use in newborns
- Not intended for use in inpatient or hospital
- Not intended for recordings longer than 2.5 hours
- Not intended as a replacement for comprehensive neurological evaluation or diagnosis



The New Wave is for prescription use only.

4. Initial setup

There are a few initial steps necessary to start using the system.

4.1. Before you start, package contents

During unboxing, carefully unpack your New Wave. The package contains the following parts:

New Wave package contents

New Wave Head Unit



New Wave Display Unit



New Wave Power Supply



New Wave DU Bracket



ECG and additional electrode lead wires

Cables to connect snap-on ECG electrodes, external reference, EOG, EMG and auxiliary EEG electrodes. (Colors may vary).



New Wave Extension Unit

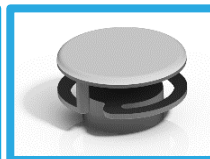
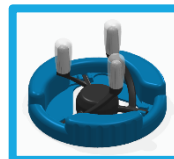


Carry Case



Electrodes

The New Wave comes with single use disposable electrodes **available and reorderable in specific packages**. For the available types refer to the images on the right:



Long Term Flex Electrode and Front Electrode



Short Term Flex electrode

Electrode sets

The various sets are delivered in sealed, protective pouches, which hold the electrodes in trays.

Short Term Electrode Set (yellow)

Special electrode set designed for quick recordings, no longer than 2.5 hours.

Contents: 17 × Short Term Flex Electrodes
 3 × Front Electrodes
 4 × Snap-on Electrodes

Long Term Electrode Set (blue)

Electrode set designed for comprehensive, longer recordings on the most common electrode layout.

Contents: 17 × Long Term Flex Electrodes
 3 × Front Electrodes
 4 × Snap-on Electrodes



First, carefully unpack the New Wave. Put the components on a table, where you can perform the initial setup. The New Wave Head Unit is fragile, please handle with care. **Do not** push, pull, stretch, step on it, sit on it.

4.2. Charging the battery



Use only original Zeto parts for charging the Display Unit. Using 3rd party devices in the charging port may lead to damage and/or injury.

Your New Wave might have had a long nap on a shelf. To bring it to its best shape, first charge the battery.

- Plug in the charger to an AC outlet
- Connect the USB C cable between the charger and the charging port on the Display Unit.

As soon as the charger is connected a charging indicator will show up on the DU's screen.

Fully charging the battery may take up to 2-3 hours. Fully charging the DU prior to its first use promotes prolonged battery life.

Please charge the DU every two weeks to maintain battery life even if the New Wave is not in use.

Please note, that when a powered off device is connected to the charger, it charges only with low power to maintain the battery state. To initiate a normal charging, disconnect the charger as shown on the display, and connect it to the DU again.

4.3. Turning on the Display Unit

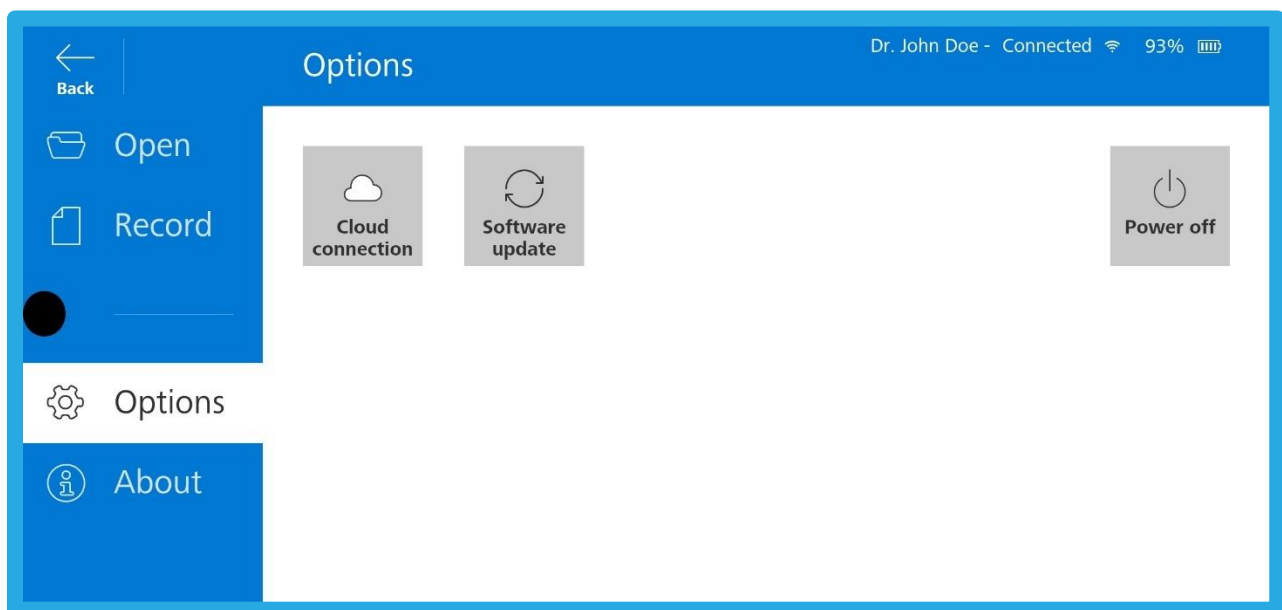
The DU has a single physical button on the side. You can turn on the device by pressing the button.

4.4. Setup of the Display Unit

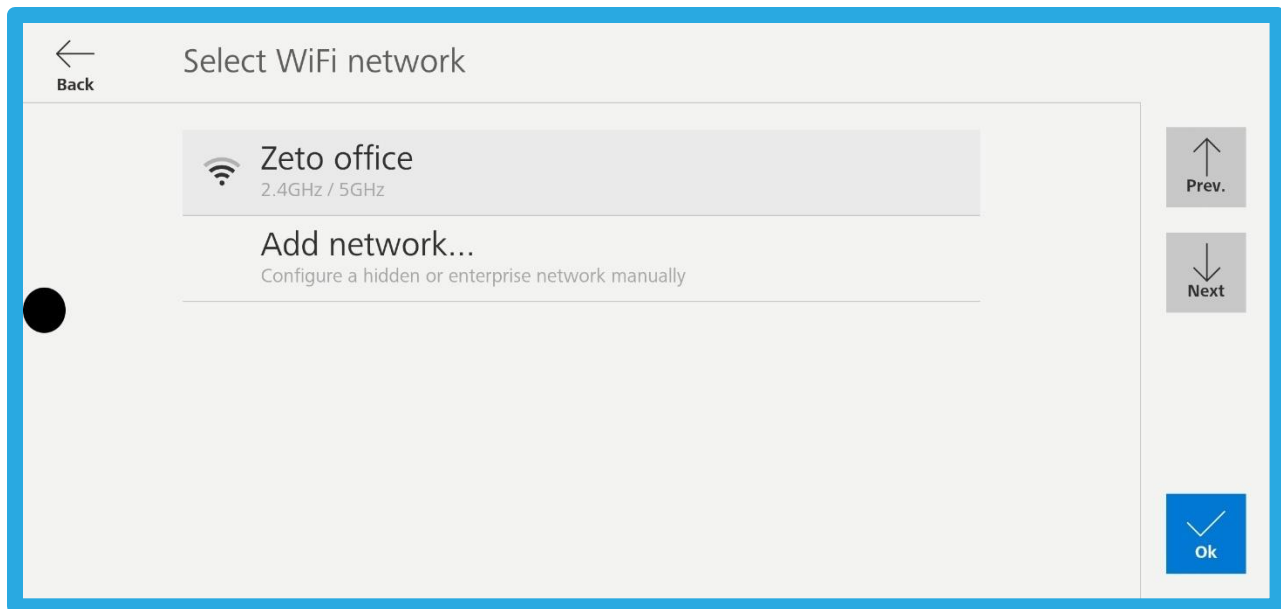
Initially, your DU will not be connected to any network. The screen will prompt you to connect to your facility's network.



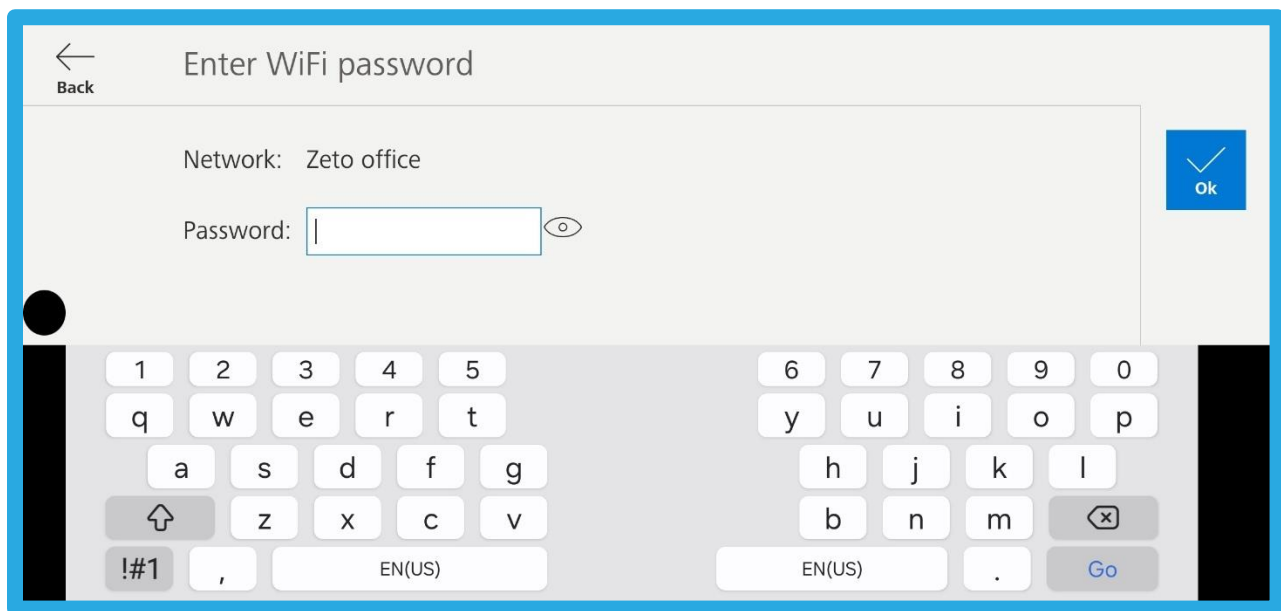
The user interface of the Display Unit and the Zeto Cloud Platform may be subject to change. The screenshots visible in this user manual may slightly differ from the latest UI design.



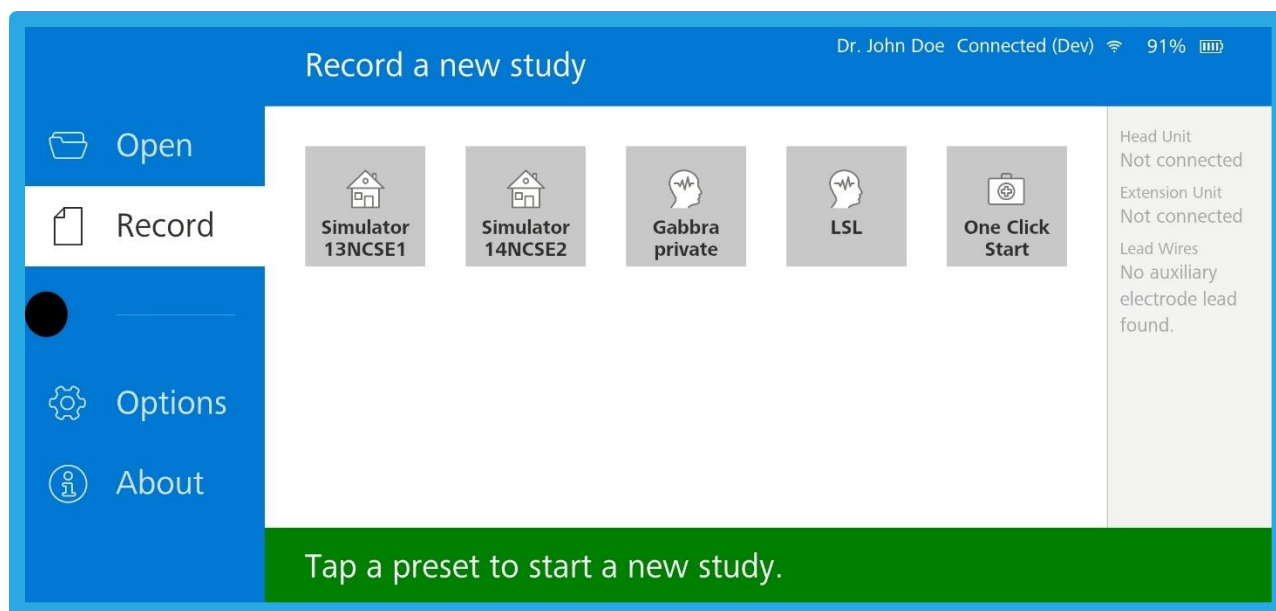
To set up your WiFi connection, tap “Options” and select “Cloud connection”. You will see the network selection screen, like below:



Once the list of available WiFi networks has been scanned, choose the network you wish to connect to and press the **Ok** button at the bottom right of the list. In case of authenticated networks, you will be prompted to type the WiFi password:



Type the password and tap **Connect** at the top right corner. Now, your DU should be ready. Once connected, the New Wave will remember your network settings. Returning to the home screen, the device will greet you with a **Ready** status.



For the setup of the Zeto Cloud Platform refer to the next Section.

4.5. Logging in to the Zeto Cloud Platform

Navigate to <https://zetoserver.com> and log in with your user credentials (provided by ZETO). Use a HTML5 compliant browser such as Chrome or Edge on Windows or a Mac platform.



For further information about the Zeto Cloud Platform and its everyday usage, press F1 to open online help, and access the Zeto Cloud Platform user's manual.

4.6. Cleaning



To avoid cross-patient contamination, always follow the cleaning instructions to clean the Head Unit after every use. Disposable electrodes must be collected and disposed according to the biohazard policy of your facility.

You may already have a cleaning policy in effect in your hospital or clinic. Please, follow the cleaning instructions in Section 6, and clean the Head Unit.

5. Daily use

Once set up, using New Wave is very simple. Have the patient sitting, put on the Head Unit (ensure that the electrodes land correctly), strap on the DU and any accessory you may need for your studies, and you are ready to go.

5.1. Using the Display Unit

First, press the power button to turn on the system. Press the button again if you want to turn off the system. When turning off, the New Wave enters a low-power standby state to conserve power. In case you don't plan to use the device for a prolonged time, or you need to turn off the device for flight transport, press the **Options** button on the DU screen, and press the **Power off** button in the **Options** menu to fully shut down the device. You may need to connect the device to the charger to turn it on again when the device is fully discharged.

5.2. Indicator LEDs



DU Indicator	Status
Both the status LED and the screen are off	Off
Green status LED	On
Red status LED	On — battery charge is below 10%
Blinking green status LED	Monitoring/Recording
Blinking red status LED	Monitoring/Recording — battery charge is below 10%

The electrode indicators work when the system is in ready status, and during monitoring mode and contact quality mode.

When the system is in ready status, the indicators will show whether the electrode channels are active or not:



Electrode Indicators	Status
Off	The electrode channel is inactive
Blue	The electrode channel is active

When the system is in monitoring mode and contact quality mode, the indicators will operate as per the following:



Electrode indicators	Status
Off	The electrode channel is inactive
Green	Good contact quality
Yellow	Weak contact quality
Orange	Poor contact quality
Red	Contact issue

5.3. Electrode setup



Zeto offers various electrode sets. For the list of available sets, please refer to Section 4.1. The electrode sets contain a combination of disposable Flex and Front electrodes.



For most head shapes and sizes, landing on a hairy scalp, we suggest using Flex electrodes. Front electrodes are recommended for positions landing directly on skin, such as Fp1, Fp2 and Fpz.

Choose the electrode set best fitting your study. Remove the electrodes from their packaging only before the beginning of the study. Sealed packaging protects the electrodes and ensures prolonged shelf-life. Once you open the sealed package, use up the full electrode pack in the same study.

To ensure that the Head Unit is ready for operation, snap on the electrodes to the Head Unit. Snap the magnetic electrodes to the electrode sockets. During the electrode setup you may change the electrodes at any time by just pulling off an electrode from its socket and snapping on another one.

If electrode changing is necessary while the Head Unit is on a patient, gently grasp the corresponding electrode pod and lift it until the electrode is no longer in contact with the scalp or hair. While holding the pod in this position, remove the electrode by pulling it off from its socket, then snap on a new one. Once the new electrode is securely attached, release the pod so that the electrode contacts the patient's head again. If necessary, adjust the electrode position by rotating it.

When handling the electrodes, avoid contacting the gel-coated tips. For Flex electrodes, hold and rotate them by the outer ring, which is specifically designed to allow easy handling. For Front electrodes, which do not have such a ring, gently grasp the base of the electrode to ensure that your fingers remain away from the gel-coated tip.





Used disposable electrodes must be collected and disposed according to the biohazard policy of your facility.

Do not use expired electrodes.

5.4. Donning

The New Wave Head Unit helps all electrodes land at their desired position per the International 10-20 EEG system. Putting on the New Wave Head Unit is as easy as putting on a beanie cap. Please follow the steps below to ensure the New Wave Head Unit sits correctly on the head. Please note that the units may vary slightly from the ones shown on the images.

1. Put the DU (and the EU if necessary) into the New Wave DU Bracket and on a stand (as necessary). In case of the stand, fix it near the place of the recording.
2. Connect the cable of the Head Unit to the DU. If you face issues with this step, consider doing it first instead of step 1.



3. If you plan to record auxiliary signals, connect the cable of the EU to the DU. If you face issues with this step, consider doing it first instead of step 1.



4. Put the Head Unit on with the correct orientation (the flat pill-shaped electrode pod with an LED should land on the center of the forehead, the other pill-shaped electrode without the LED should land on the center of the back of the head). Start either from the forehead or the inion, and carefully work your way to the opposite side of the patient's head by gently stretching the Head Unit.

5. The pods have indicator LEDs, which show the contact quality of each electrode once the study setup has been started. Refer to Section 5.2 for the color-coding. Alternatively, the Contact Quality tab on the Display Screen provides the same information (for further information refer to the Zeto Cloud Platform online user guide).
6. Consider adjusting the difficult-to-land pods with circular motion. Alternatively, rotating the electrodes of the difficult areas may help too.
7. Once all the indicator LEDs are green, fasten the chin strap. Ensure that the strap is comfortable. This step can be done earlier too if you expect the fastening to misadjust the Head Unit.

5.5. Recording an EEG

Once all electrodes land well, and you have a well readable EEG on the screen, initiate the recording via the Zeto Cloud Platform or the Display Unit. This will start a recording session. All data is recorded in the cloud, so there is no need to worry about free storage space for the data. A blinking red dot denotes the recording.



The New Wave allows the recording of an EEG while the patient is sitting, lying, or moving (not too intensely, within network range).



If the study involves patient movement, prepare enough movement space, and please maintain a clear cable management to prevent tripping and product damage.



Ensure that the study site is separated from excessive mechanical vibrations and electromagnetic fields. The patient should keep at least 20 cm distance from plugged in power cables.



Strangulation hazard. Before commencing the session, ensure that the cables are arranged in a way that prevents the cables from winding around the patient's neck. Failing to arrange the cables in a safe way may lead to risk of strangulation.



Conductive parts of the New Wave (e.g. electrodes, neutral electrodes and connectors) should not contact other conductive parts of the New Wave, or with any conductive material connected to Protective Earth (grounding).

A routine EEG session usually takes 20 – 40 minutes. You may record an EEG session for up to 2.5 hours depending on the battery state, the sampling rate and study configuration. The DU also shows the recording state.

To stop recording, click the **Stop** button in the Zeto Cloud Platform or the. Alternatively, you can also tap **Stop** on the DU's screen.

Note that you have a good set of filtering, montage transformation and other tools at your disposal during the setup and recording session. The changes in filters, montage, and so on will not affect the actual recording. The record can be interpreted with any settings at any time later.

5.6. Recording with additional sensors

The New Wave contains built-in sensors for photic triggering and head position. With the help of a camera connected to the recording computer and the built-in camera, New Wave can record up to 4 video streams. New Wave provides two additional ports on the New Wave Head Unit and six additional ports on the EU for connecting up to 8 electrode lead wires with snap-on electrode connectors for recording:

- ECG
- EOG
- EMG
- additional 2 auxiliary EEG channels

or to use an external wired reference, such as a nose reference.

Please follow the steps below to configure using an electrode lead wire at the recording setup:

1. Pick a lead wire or pair of lead wires. Each lead wire is color coded and labeled by function.
2. Snap on the lead wire connector to a disposable sticky patch electrode.
3. Stick the electrode to the proper position. Follow standard positions for EOG electrodes. The two ECG electrodes can go on the collar bones.
4. Connect the electrode lead wire to the two extension ports of the New Wave Head Unit at the left-right ear, or to any EU ports.
5. The Zeto Cloud Platform automatically recognizes the connection, and the new channel appears on the recording setup page.



Warning: Please connect both electrode lead wires and apply both electrodes for differential channel pairs such as ECG (RA, LA), EOG (HEOG+, HEOG- and VEOG+, VEOG-)

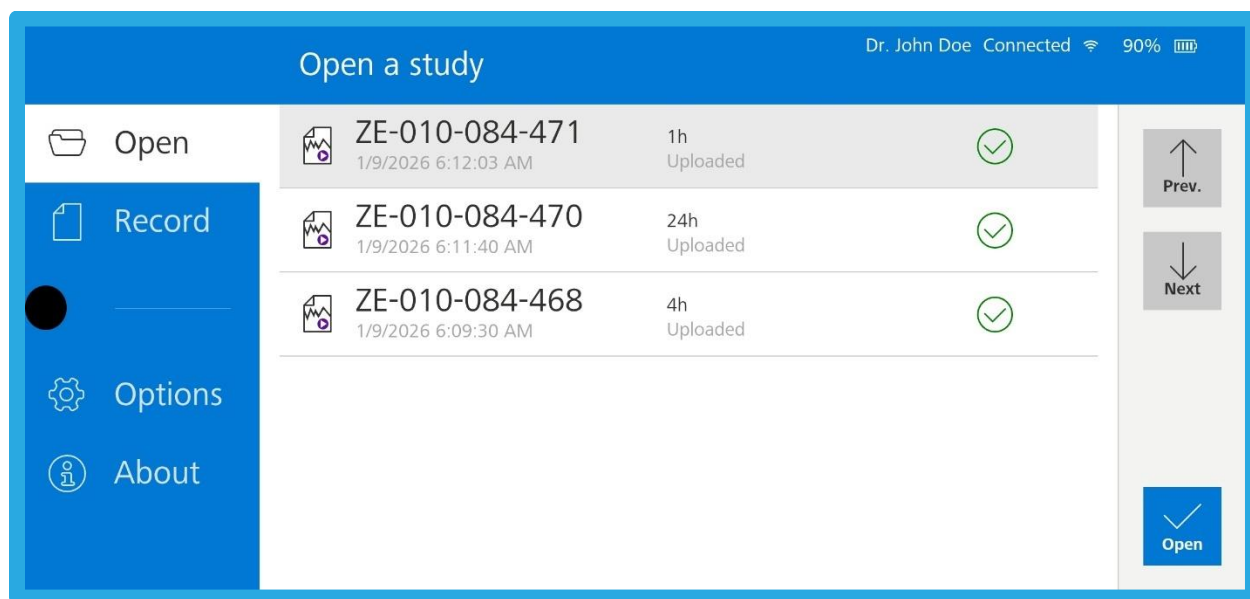
To record photic signal pulses, the front band of the Head Unit must face the photic stimulator device at a distance shorter than 30 cm and a viewing angle below 30 degrees. Photic unit must be started by the operator per its applicable instructions and protocol.



Do not remove or disconnect electrode lead wires during recording. In case a lead wire gets unexpectedly unplugged, simply plug it back.

5.7. Open EEGs for interpretation

To open EEG Studies on the DU, select the “Open” page. A list of the last recorded studies will appear in chronological order. Select one and tap “Open”.



The EEG is shown on the DU for navigation and interpretation.

6. Cleaning and maintenance

6.1.1. Why to clean?

The New Wave is a reusable medical device (with the exception of the electrodes) which is initially supplied clean to the operator and requires the operator to reprocess (i.e., clean and disinfect) its components prior to subsequent patient use.

The New Wave's components are not sterile and are not intended to be sterilized.

If your facility does not have a cleaning and disinfection policy, please follow the detailed cleaning instruction below.

6.1.2. What to clean?

The inside surface of the Head Unit comes in contact with skin or hair. Therefore, it needs to be cleaned and disinfected. The outside surfaces, i.e., surfaces facing away from the head when worn by the patient can be cleaned and if desired may be disinfected as well.

The other components (the DU, EU, cables, etc.) may be cleaned semi-regularly. Disinfect these components as necessary.



Customers may choose to use other cleaning agents based on their disinfection protocols. However, cleaning agents other than listed in section 6.1.4 can cause discoloration and in rare cases accelerate material aging of the device. Zeto does not cover replacements under its warranty program for discoloration or accelerated aging arising from use of cleaning agents other than listed in the aforementioned section.



Always follow the precautionary steps provided by the manufacturer for the disinfecting liquid and your facility (toxicity and fire hazards may apply). Zeto cannot be held responsible for any harm due to not following prescribed procedures.



Do not clean the electrodes. The electrodes are designed for single use, and should be disposed according to the biohazard policy of your facility.

6.1.3. Cleaning preparation

Before cleaning:

- Ensure that all the electronics are turned off.
- Inspect the New Wave Head Unit for any damage before cleaning.
- Remove all the electrodes from the Head Unit. (Dispose of used electrodes by following the biohazard policies of your facility and the applicable regulations).

6.1.4. Cleaning steps - Head Unit

Before the disinfection step, remove any major contaminants/debris from the device that can be practically removed by hand.

Disconnect the Head Unit and place it on a clean surface.

Use a cleaning agent in accordance with your facility's sanitization or infection-control protocol. Commonly used surface wipes or alcohol-based sprays may be used (such as Envirocide®, Metrocide®, Lysol® wipes and cleaning solutions, Purple wipes, Sani-Cloth® wipes, Isopropyl alcohol (IPA) up to 70% concentration), provided they are non-corrosive and compatible with plastics.

Wiping the device with isopropyl alcohol (IPA) up to 70% concentration has been confirmed not to adversely affect the device housing or markings.

Other non-corrosive cleaning or disinfecting agents may also be used, based on your facility's procedures.

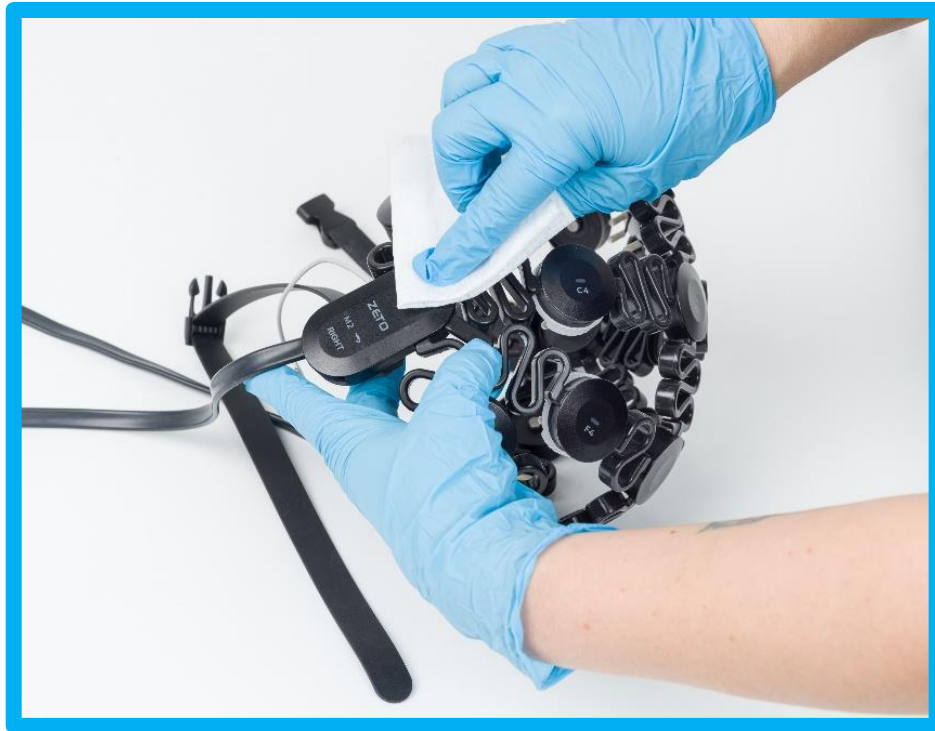
Do not use chlorine-based or bleach solutions, abrasive cleaners, or strong solvents (e.g., acetone, methyl ethyl ketone (MEK)), as these may damage the device.

In case of spray, apply the isopropyl alcohol thoroughly all over the Head Unit. Ensure that the disinfectant reaches every nook and cranny at any angle. Let the isopropyl alcohol exert its antimicrobial effect for at least 30 seconds, but for no more than 2 minutes. Alternatively, wipe the Head Unit directly with the germicidal disposable wipes.



Warning: Skin contact of the disinfectant may be irritative. Ensure using protective wear such as nitrile gloves.

Dry the Head Unit using a lint-free, clean wipe or soft cloth. Pay special attention to the cleaning of the patient-contacting parts. Hard-to-reach, tiny areas may be cleaned using Q-tips.



6.1.5. Cleaning of the other components

You may disinfect all the other components of the New Wave, like the Display Unit, the Extension Unit and the cabling by wiping it with isopropyl alcohol wet wipes. Please note that the units may vary slightly from the ones shown on the images.



Notes



Use a cotton swab dipped in isopropyl alcohol to clean any gaps and areas that cannot be accessed otherwise. Smaller gaps can also be dried with a cotton swab.

Store the New Wave in a dry place at room temperature. Avoid storing the device exposed to direct UV light (like sunshine) for extended periods (i.e., days or weeks), to prevent the degradation of the polymer parts.

Only use pH-neutral disinfectant for cleaning.

Only use non-abrasive disinfectant for cleaning.

The New Wave is not designed for cleaning with heat or UV rays.

Do not disinfect with bleach (for example hydrogen peroxide or sodium hypochlorite) or with other organic solvents - as these may damage the plastic surfaces.

Adhere to disinfectants with the correct concentration (Zeto suggests 70% isopropyl alcohol for cleaning).

Zeto has evaluated the effects of multiple cleanings/disinfections as indicated above and found that during the expected service life of the New Wave their parts and accessories do not suffer any unacceptable risks caused by the cleaning. These processes do not result in the loss of basic safety or essential performance.

6.1.6. Inspection



As the final step of the reprocessing, please follow the steps below to ensure that the New Wave has been cleaned thoroughly:

1. Visually inspect all the patient-touching components, look for residue, debris, stains.
2. If the components are free of any residue, debris, stain or damage, then the product is ready for the next use.
3. Please repeat the cleaning process described in Sections 6.1.3, 6.1.4 and 6.1.5 if there are contaminants left on the New Wave.

6.2. Battery instructions

If you are not using the New Wave for a long period, store it in a dry place at room temperature. To ensure prolonged battery life, fully charge the Display Unit monthly.



To avoid reducing battery life, do not store the Display Unit completely discharged for prolonged periods.

6.3. Disposal instructions

To protect the environment, return the to-be-disposed devices to Zeto. Zeto follows the applicable regulations of disposal of electronics and batteries.

If returning the devices containing batteries is not feasible, follow the applicable regulations regarding the disposal.

USA: Lithium-ion batteries contain valuable recyclable materials and are accepted for recycling by Call2Recycle, Inc. Visit their website at www.call2recycle.org for additional information.

EU: In the European Union, manufacturing, handling and disposal of batteries is regulated based on the DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC. Customers find detailed information on disposal in their specific countries using the website of the European Portable Batteries Association (http://www.epbaeurope.net/legislation_national.html).

7. Troubleshooting



Issue	Recommended action
The Display Unit's screen works only in landscape mode.	The Display Unit is designed to work in landscape mode.
The Zeto Cloud Platform warns that the Head Unit is not connected.	Check the Head Unit's connection on the DU's port.
I cannot change the sampling rate.	The device is likely recording. If you need to change the sampling rate, stop the recording.
I cannot change reference.	The device is likely recording. If you need to change the reference, stop the recording.
The Head Unit indicator LEDs do not work.	Please configure the Contact Indicator LEDs to be ON in the Device Setup Workspace configuration of the Zeto Cloud Platform. LEDs show contact quality in monitoring (setup). During recording the LEDs are intentionally turned off.
The Zeto Cloud Platform displays the warning message: Poor network connection, trying to reconnect.	The patient may have left the range of the WiFi network. Ask the patient to move back in range. If the warning is displayed despite the patient being in range, check the WiFi router or contact your internet service provider. Once the connection is reestablished, the device will automatically return to its previous state.
In a shared session the measurement mode suddenly changed.	Turning on impedance measurement mode switches all viewers' screens to impedance measurement mode too. EEG display resumes once the impedance mode is turned off.
I have been logged out.	The system logs out its users automatically after a few minutes of inactivity. Log back in the usual way.
Low Signal-to-Noise Ratio, noisy signals despite correct landing.	The patient may unintentionally touch electronically conducting surfaces. Remove conducting objects from the vicinity if possible.

I am unable to start a new study. A red LED blinks rapidly next to the DU button.	The New Wave prevents the initiation of new studies if the battery charge level drops to 7%. Recharge the Display Unit.
The recording stopped automatically. A red LED blinks rapidly next to the DU button.	Ongoing studies are terminated if the battery charge level drops to 1%. Recharge the Display Unit.
The DU does not wake up when pressing the button.	The DU's charge level may be low. Charge up the DU's battery.
The DU does not start to charge when connected to the charger.	Initiating the charging takes a few seconds in case the device battery is fully depleted. The device will turn on as soon as reaching to a minimum charge level.
The DU starts to charge very slowly when connected to the charger in powered off state	When a powered off device is connected to the charger, it charges only with low power to maintain the battery state. To initiate a normal charging, disconnect the charger as shown on the display, and connect it to the DU again.
The system does not detect the auxiliary channels when the Extension Unit is connected during the study.	Please connect the Extension unit and all the required auxiliary lead wires prior to starting the study.

8. Technical specifications

8.1. New Wave technical specifications



Specifications

Number of the fixed EEG electrode channels on the New Wave Head Unit:	19 as per the 10-20 EEG system
Number of measuring references:	3 (Cz, A1/A2, internal), software-based rereferencing is available
Number of semi-fixed EEG electrodes on the New Wave Head Unit:	2 (A1 and A2 in the mastoid area)
Number of fixed DRL electrodes on the New Wave Head Unit:	1 in the Fpz position
Electrode lead wire ports:	2 on the New Wave Head Unit, 6 on the Extension Unit
Lead wire types:	EEG, ECG, EOG, EMG, External Reference, 2 auxiliary EEG
EEG/DRL electrode types:	Conductive silver layer, conductive plastic, conductive soft-tip
Semi-fixed/external electrode types:	Conventional off-the-shelf ECG/EEG patch electrodes with snap-on connectors
EEG electrode input impedance:	>1 TΩ
EEG, EOG, EMG, ECG signal range:	±375 mV
Sampling rate:	Variable, max. 500 Hz
Sampling resolution:	24 bits
EEG, EOG, EMG, ECG sensitivity (smallest potential change captured):	44.7 nV
Leakage current:	<5 pA (room temperature)
Noise:	1 μV RMS
Common mode rejection at power line frequencies:	>120 dB (with DRL loop working)
Wireless communication:	Wi-Fi 802.11 a/b/g/n/ac 2.4 and 5.0 GHz 5G/LTE (with SIM-card, depends on available cell phone service)
Wireless frequency:	2.4 and 5.0 GHz band, LTE
Wireless bandwidth:	up to 54 Mbit/s
Number of photic trigger sensors:	1

Head movement indicator channels:	Pitch and roll
Power supply:	3.85 V DC, 5000 mAh Lithium-Ion battery within the Display Unit
Operating time:	up to 2.5 hours long EEG study, generally up to 6 hours without video, up to 4 hours with video
Battery charger:	External, dedicated IEC 62368-1 compliant USB C AC/DC adaptor Samsung EP-T1510 Input: 100-240 V AC, 50/60 Hz, 0.5 A Output: 9 V DC, 1.66 A max, 15 W max.
User control:	Display Unit touchscreen, Display unit button, application on the recording computer
Dimensions:	Head Unit: a hemisphere with an approximate radius of 8 cm (3.1 in) Display Unit: 22 cm × 9 cm × 2.2 cm (8.8 in × 3.5 in × 0.86 in)
Weight:	Head Unit: approx. 406 grams (14.3 ounces) Display Unit: approx. 380 grams (13.4 ounces)
The New Wave does not contain components which can be repaired by SERVICE PERSONNEL.	

8.2. Accessories and parts



Specifications

Electrode set:	Short term and long term sets with various amount of Flex and Front electrodes
Extension Unit:	6 × 2.5 mm jack ports
Supported lead wires:	Supplied by Zeto, automatically detected by the system. ECG input type: RA, LA EEG input type: REF and other auxiliary EEG EOG input type: HEOG+, HEOG-, VEOG+, VEOG- EMG input type: EMG1+, EMG1-

8.3. Environmental conditions



Condition	Operation	Transportation	Storage
Temperature:	5 °C to 40 °C 41 °F to 104 °F	-20 °C to 45 °C -4 °F to 113 °F	0 °C to 45 °C 32 °F to 113 °F
Relative humidity:	65 ± 20%RH, noncondensing	65 ± 20%RH	65 ± 20%RH
Altitude:	-390 m to 2000 m	-390 m to 15000 m	-390 m to 3012 m
Atmospheric pressure:	70 kPa to 106 kPa	12 kPa to 106 kPa	70 kPa to 106 kPa

8.4. Operational characteristics of the New Wave



Manufacturer and product

Manufacturer:	Zeto, Inc.
Product type:	Electroencephalograph
Model:	New Wave
Product description:	Wireless EEG System

Equipment and environment

Kind:	ME equipment
Mode of operation:	Continuous operation
Environment:	Outpatient Healthcare or Research facility Home

Safety

Supply mains isolation:	Mains plug
Protection class while charging:	Class II
Protection class during use:	Class II or INTERNALLY POWERED
CISPR11 emission class:	Class B
Ingress protection:	IPXX
PEMS class:	Class A

Communication

Contains radio transmitter:	WiFi, 2.4 and 5.0 GHz WiFi bands, 5G /LTE
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IPN₁N₂





Applied parts

Applied part:	Type BF
Applied parts, EEG channel:	19 channels + 1 channel DRL electrodes

Power port

Charging:	USB-C port
Charge voltage:	9 V DC
Charge current:	Up to 1.66 A
Charger mains connection:	100-240 V AC, 50/60 Hz, 0.5 A

8.5. System Requirements

Minimum (interpreting)	Minimum (recording)	Recommended (interpreting)	Recommended (recording)
no strict hardware requirements	16 GB RAM	16 GB RAM Latest Intel Core i5 or i7 CPU	32 GB RAM Latest Intel Core i5 or i7 CPU

In all cases the recommended operating systems are Windows or Mac OS.

Browser: HTML5 compliant such as Google Chrome or Edge

9. Compliance

9.1. Electromagnetic compatibility of the New Wave

The New Wave is designed for use in *outpatient healthcare or research facility and home environments*, and tested according to the following limits:

TABLE 201

Emission test	Compliance	Electromagnetic environment - guidance
RF radiated emissions CISPR 11	Group 1, Class B	The New Wave uses RF energy only for its internal function. Therefore, RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF conducted emissions CISPR 11	Group 1, Class B	The New Wave can be used in all establishments, including domestic establishments.
Voltage Fluctuations and Flicker	IEC 61000-3-3	The New Wave 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.
Harmonic Distortion	IEC 61000-3-2 Class A	The New Wave 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.

TABLE 202

Immunity test	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 60601-4-2	±15 kV air ±8 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Electrodes are sensitive to ESD events. In case of an ESD event, the system will automatically recover. In the unlikely event of unexpected malfunction, turn off the devices and on again.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user may need to take mitigation measures, such as relocating or re-orienting the equipment.

TABLE 204

Immunity test	Levels	Guidance
Proximity fields from RF wireless communications equipment	Test frequencies were: 385 MHz, 450 MHz, 710 MHz, 745 MHz, 780 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz, 5240 MHz, 5500 MHz, 5785 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the New Wave, including cables, than the recommended separation distance (refer to Table 206).
Conducted disturbances introduced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in amateur and ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the New Wave, including cables, than the recommended separation distance (refer to Table 206).
RF immunity IEC 60601-4-3	Test level: 10V/m with 80 % AM at 1 kHz modulation, 1 GHz – 2.7 GHz Compliance level: 10V/m 80 MHz – 1 GHz Compliance level: 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of the New Wave, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. In the case of 80 MHz – 1 GHz frequency band higher than 4 µV peak-to-valley noise can occur which automatically disappears provided the external RF source declines. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ where 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 meters (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 radiation symbol next to this paragraph.
Surge IEC 61000-4-5	±0.5 kV lines to earth ±1 kV lines to earth	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Electrodes are sensitive to ESD events. In case of an ESD event, the system will automatically recover. In the unlikely event of unexpected malfunction, turn off the devices and on again.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial, home or hospital environment.
Voltage dips, and interruptions IEC 61000-4-11	0% U _T ^c (100% dip in U _T) for 5 seconds 70% U _T (30% dip in U _T) for 0.5 second 0% U _T (100% dip in U _T) for 0.5 period at phase angles: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°.	Mains power quality should be that of a typical commercial, home or hospital environment.

Immunity test	Levels	Guidance
Proximity fields from RF wireless communications equipment	Test frequencies were: 385 MHz, 450 MHz, 710 MHz, 745 MHz, 780 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz, 5240 MHz, 5500 MHz, 5785 MHz	

NOTE 1 At 80 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 strength 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 New Wave is used exceeds the applicable RF compliance level above, the New Wave should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the New Wave components.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

^c U_T denotes the a. c. mains voltage prior to application of the test level.

TABLE 206

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

The New Wave is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the New Wave can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the New Wave; recommended distances are listed 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 (m)		
	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 $d = 2.3\sqrt{P}$
0.01 W	0.12 m	0.12 m	0.23 m
0.1 W	0.38 m	0.38 m	0.73 m
1 W	1.2 m	1.2 m	2.3 m
10 W	3.8 m	3.8 m	7.3 m
100 W	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

9.2. Radio Communication



Radio communication

Wireless technology in use:

WiFi, 2.4 and 5.0 GHz band, LTE
2.4 GHz ISM radio for emitting time synchronization data

Modulation:

802.11 a/b/g/n/ac

Operating Frequencies of the Display Unit	Emission power
663-698 MHz	68 mW
663-698 MHz	93 mW
663-698 MHz	79 mW
663-698 MHz	56 mW
663-698 MHz	68 mW
663-698 MHz	93 mW
663-698 MHz	79 mW
663-698 MHz	56 mW
699-716 MHz	104 mW
699-716 MHz	86 mW
699-716 MHz	104 mW
699-716 MHz	86 mW
777-787 MHz	66 mW
777-787 MHz	55 mW
777-787 MHz	66 mW
777-787 MHz	55 mW
788-798 MHz	178 mW
788-798 MHz	142 mW
788-798 MHz	178 mW
788-798 MHz	142 mW
814-824 MHz	353 mW
814-824 MHz	284 mW
814-824 MHz	353 mW
814-824 MHz	284 mW
821.5 MHz	114 mW
821.5 MHz	94 mW
821.5 MHz	114 mW
821.5 MHz	94 mW
824-849 MHz	143 mW
824-849 MHz	112 mW
824-849 MHz	90 mW

	824-849 MHz	68 mW
	824-849 MHz	143 mW
	824-849 MHz	112 mW
	824-849 MHz	90 mW
	824-849 MHz	68 mW
	1.695-1.71 GHz	211 mW
	1.695-1.71 GHz	155 mW
	1.695-1.71 GHz	211 mW
	1.695-1.71 GHz	155 mW
	1.71-1.78 GHz	176 mW
	1.71-1.78 GHz	301 mW
	1.71-1.78 GHz	249 mW
	1.71-1.78 GHz	133 mW
	1.71-1.78 GHz	176 mW
	1.71-1.78 GHz	301 mW
	1.71-1.78 GHz	249 mW
	1.71-1.78 GHz	133 mW
	1.85-1.915 GHz	275 mW
	1.85-1.915 GHz	229 mW
	1.85-1.915 GHz	221 mW
	1.85-1.915 GHz	166 mW
	1.85-1.915 GHz	275 mW
	1.85-1.915 GHz	229 mW
	1.85-1.915 GHz	221 mW
	1.85-1.915 GHz	166 mW
	1.8502-1.9098 GHz	956 mW
	1.8502-1.9098 GHz	373 mW
	1.8502-1.9098 GHz	956 mW
	1.8502-1.9098 GHz	373 mW
	1.8524-1.9076 GHz	146 mW
	1.8524-1.9076 GHz	146 mW
	2.305-2.315 GHz	101 mW
	2.305-2.315 GHz	79 mW
	2.305-2.315 GHz	101 mW
	2.305-2.315 GHz	79 mW
	2.402-2.48 GHz Bluetooth	11 mW
	2.402-2.48 GHz Bluetooth	3 mW
	2.412-2.472 GHz 2.4 GHz WiFi	122 mW
	2.496-2.69 GHz	443 mW

	2.496-2.69 GHz	405 mW
	2.496-2.69 GHz	311 mW
	2.496-2.69 GHz	408 mW
	2.496-2.69 GHz	443 mW
	2.496-2.69 GHz	405 mW
	2.496-2.69 GHz	311 mW
	2.496-2.69 GHz	408 mW
	2.5-2.57 GHz	191 mW
	2.5-2.57 GHz	161 mW
	2.5-2.57 GHz	191 mW
	2.5-2.57 GHz	161 mW
	3.45-3.55 GHz	359 mW
	3.45-3.55 GHz	331 mW
	3.45-3.55 GHz	359 mW
	3.45-3.55 GHz	331 mW
	3.55-3.7 GHz	97 mW
	3.55-3.7 GHz	124 mW
	3.55-3.7 GHz	109 mW
	3.55-3.7 GHz	92 mW
	3.55-3.7 GHz	120 mW
	3.55-3.7 GHz	97 mW
	3.55-3.7 GHz	112 mW

USA – FCC compliance of the radio communication

New Wave	Contains FCC ID:	A3LSMA156U
	Name of grantee:	Samsung Electronics Co. Ltd.
	Equipment class:	NII - Unlicensed National Information Infrastructure TX
	Device type:	Mobile phone
	Modular type:	Does not apply

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

To meet RF exposure guidelines during body-worn operation, the Display Unit should be positioned at least 1.5cm away from the body.

The equipment has been tested and found to comply with the limits for a class B digital devices, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The 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 the 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 equipment and other modules/products.
- Increase the separation between the equipment and module/product.
- Consult the dealer or an experienced radio/TV technician for help.

Changes and modifications made to the equipment without the approval of the manufacturer may void the FCC authorization to operate this equipment.
