



## Zeto ONE Instructions for Use



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## 1. About this manual

This manual is intended for the user of the Zeto ONE Head Unit 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).



**Zeto, Inc.**  
**4917 Waters Edge Dr, Suite # 221**  
**Raleigh, NC 27606 USA**

**+1 (833) 938 – 6334**  
**+1 (833) ZETO EEG**  
<https://zeto-inc.com/>

## 1.2. Warranty information

The warranty covers the following components of the system:

- Zeto ONE Head Unit (Head Unit)
- Zeto ONE Power Supply
- Zeto ONE Display Unit
- Zeto ONE Extension Unit

The Zeto ONE Head Unit (Head Unit) is warrantied 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 warrantied 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 isopropanol 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 Zeto ONE.

### 2.1. Explanation of markings

This documentation and the product use the following markings.

| Symbol                                                                              | Meaning                                                                                                                                       |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IPN<sub>1</sub>N<sub>2</sub></b>                                                 | IP rating<br>Level of protection against ingress of dust and water.                                                                           |
|    | Refer to instruction manual<br>Not following the instructions may lead to risks.                                                              |
|    | Mandatory action<br>Follow the instructions to ensure safety, performance and convenience.                                                    |
|    | Consult operating instructions<br>Follow operating instructions.                                                                              |
|  | Type BF applied part<br>High degree of protection against electric shock.                                                                     |
|  | Safety warning<br>Not following the instructions will lead to risks.                                                                          |
|  | Do not push, bend, sit on, step on, push, pull or overstress flexible material<br>Avoid exposing the device to excessive mechanical stresses. |
|  | Contains radio transmitter.<br>Device contains a radio transmitter, details about the radio transmission.                                     |
|  | Instructions about the IT network.<br>Technical details about the required WiFi or 4G/LTE network.                                            |
|  | MR Unsafe<br>This marking warns the user that the device cannot be used safely in magnetic resonance environments.                            |
|  | Single Use Only<br>This marking warns the user that the product component is disposable. Do not reuse components with this marking.           |

## 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:

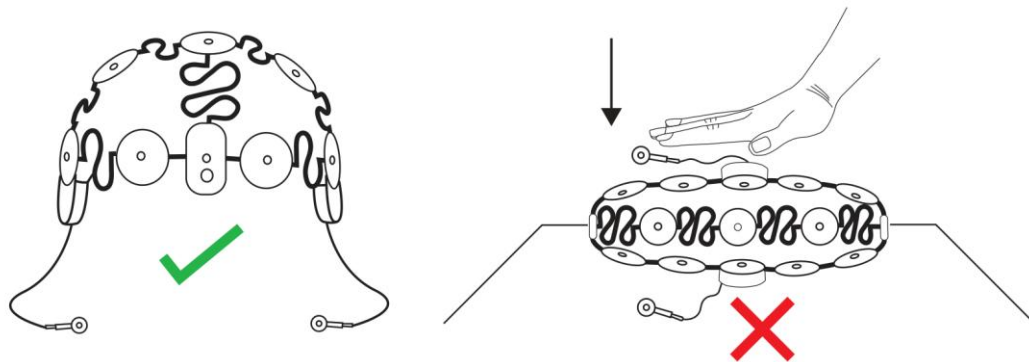
- Used near high frequency surgical equipment
- Exposed to ionizing radiation
- Used on patients undergoing electro surgery
- Used in oxygen rich environment (concentration > 25% at 1 atm)
- Used during defibrillation – defibrillation may damage the product

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

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 Zeto ONE 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 Zeto ONE 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. 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 4G/LTE network. The WiFi network works with WPA, WPA2 or WPA 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 Zeto ONE 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 4G/LTE cellular connection automatically as a backup. In the event of cloud/networking/connection cannot be established, the functionality of the Zeto ONE 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 (e.g. in transport). 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
- Do not 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 *healthcare or research facility, home, and transport* environments (ground, water and air).

- Use of the Zeto ONE as a Transmitting Portable Electronic Device in an air transport environment is subject to permit of the aircraft operator, as per section 7.1 of FAA Advisory Circular AC No: 91.21-1D. The Zeto ONE has been evaluated to RTCA DO-160 Category G.
- 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 Zeto ONE'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 Zeto ONE'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 may 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 Head 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 Head Unit below 0 °C or above 45 °C (below 32 °F or above 113 °F)
- Store the Head 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 Head 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 (CO<sub>2</sub>) 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 Zeto ONE 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 Zeto ONE are simple. If you have a WiFi connection with a network id, password and Internet, or 4G/LTE data service, then you can use the product on the available WiFi or 4G/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:   | <p>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.</p> <p>Note: WiFi networks using captive portals (requiring entering network credentials in a web browser) are not supported.</p>                                                                                                                                                                                                                                                                      |
| Technical specification: | <p>The WiFi access point must run a DHCP service to let connecting devices automatically configure their network settings.</p> <p>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.</p> <p>Although cybersecurity measures of the product are independent of the IT network, it is advised using WEP/WPA2/WPA2 Enterprise WiFi authentication to protect the access point from unauthorized access.</p> <p>There is no requirement for opening ports on firewalls or setting up any port forwarding rules.</p> |



#### Warning about IT network used by multiple medical devices

Connection of the Zeto ONE 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 Zeto ONE 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 4G/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 clean or replace electrodes after use according to the cleaning instructions to avoid cross-patient contamination. (For cleaning instructions refer to Section 6).



The Zeto ONE 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 Zeto ONE 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 Zeto ONE and its components during recording.

## 3. System overview

### 3.1. What is the Zeto ONE?

The Zeto ONE is a wireless, full montage electroencephalograph (EEG) system implementing:

- The Zeto ONE Head Unit
- The Zeto ONE 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.
- Multiple types of electrodes and electrode sets.
- The Zeto Cloud Platform, which receives, stores, retrieves and visualizes EEG study waveforms
- The Zeto ONE 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 4G/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 Zeto ONE 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 4G/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 Zeto ONE 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 Zeto ONE 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 Zeto ONE 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 4G/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 Zeto ONE is intended for prescription use in a healthcare facility, home, and specific transport environments to acquire, transmit, display and store EEG and auxiliary signals for adults and children, not including newborns. The Zeto ONE 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 Zeto ONE is for prescription use only.

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## 4. Initial setup

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

### 4.1. Before you start, package contents

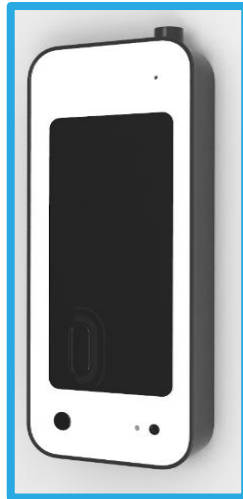
During unboxing, carefully unpack your Zeto ONE. The package contains the following parts:

#### Zeto ONE package contents

Zeto ONE Head Unit:  
Unit:



Zeto ONE Display

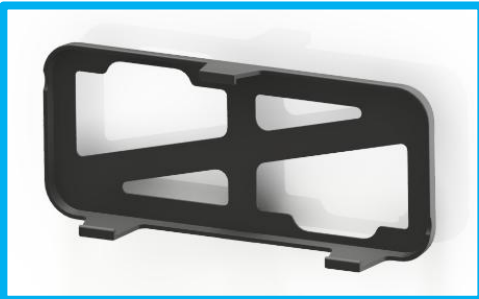


Zeto ONE Power Supply:

An adapter for charging the Display Unit (colors may vary).



Zeto ONE 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).



Zeto ONE Extension Unit:

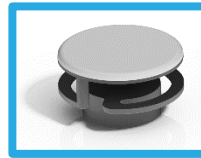


Carry Case



## Electrodes:

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



Flat electrode



Flex Electrode



Short Term Flex electrode

## Electrode sets

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

### Electrode Set Short Term:

Special electrode set designed for quick recordings, no longer than 90 minutes.

Contents: 17 × Short Term Flex Electrodes  
3 × Front Electrodes  
4 × ECG Electrodes

### Electrode Set — Basic

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

Contents: 17 × Flex Electrodes  
3 × Front Electrodes  
4 × ECG Electrodes



First, carefully unpack the Zeto ONE. Put the components on a table, where you can perform the initial setup. The Zeto ONE 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 the quick charging. Using 3<sup>rd</sup> party devices in the quick charging port may lead to damage and/or injury.

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

- Plug in the quick charger to an AC outlet
- Connect the other end of the charging cable to the charging port on the Display Unit (round protruding port).

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 Zeto ONE is not in use.



The device currently does not support simultaneous recording and charging. If you plug the device in the charger, any recordings will stop immediately.

### 4.3. Turning on the Display Unit

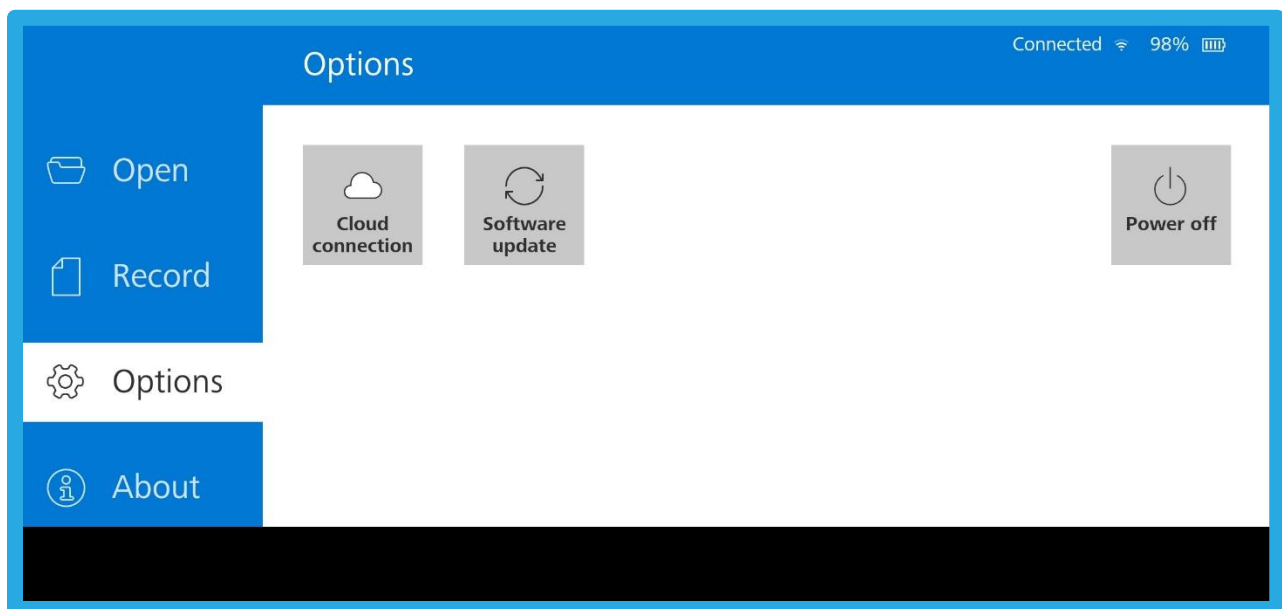
The DU has a single physical button next to the touch screen. You can turn on the device by connecting it to the power network via the Power Supply and pressing the button.

### 4.4. Setup of the Display Unit

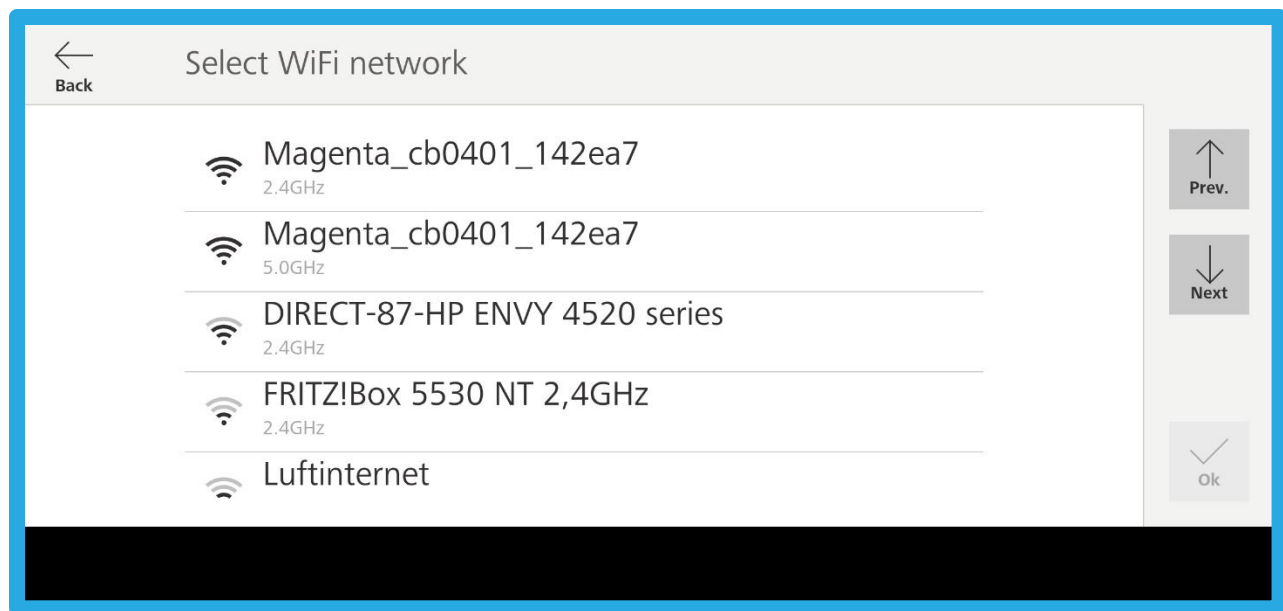
Initially, your DU will not be connected to any network. The screen will prompt you to connect to your facility's network.



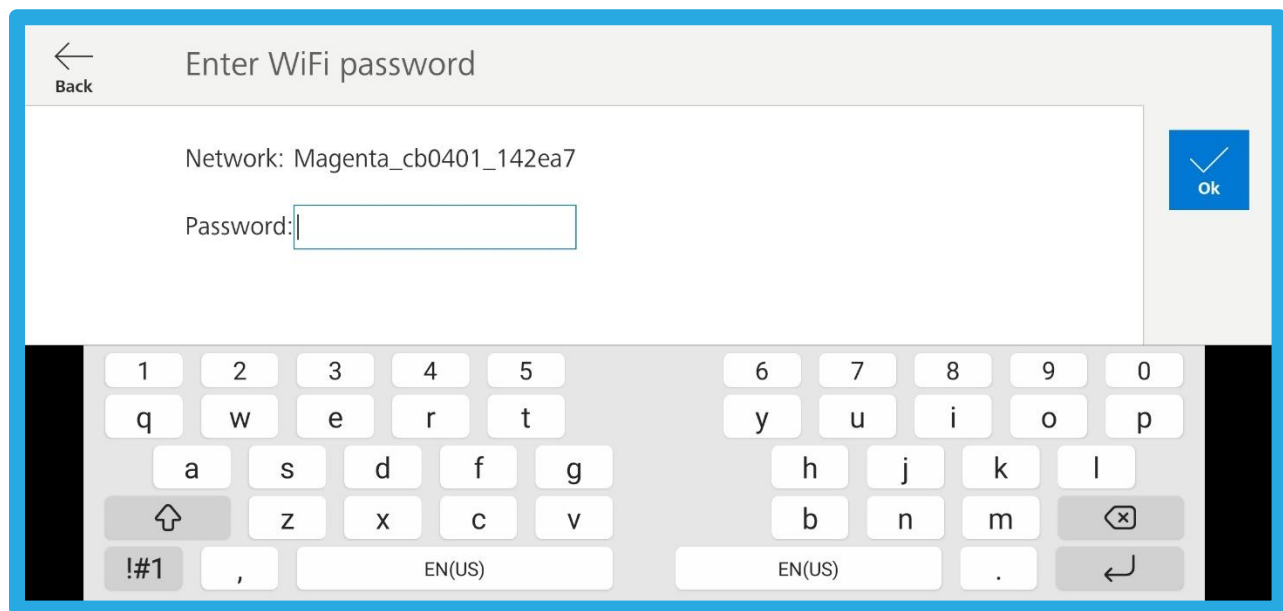
The user interface of the Display Unit and the Zeto Cloud Platform may be subject to change. The screenshots visible in this user manual may slightly differ from the latest UI design.



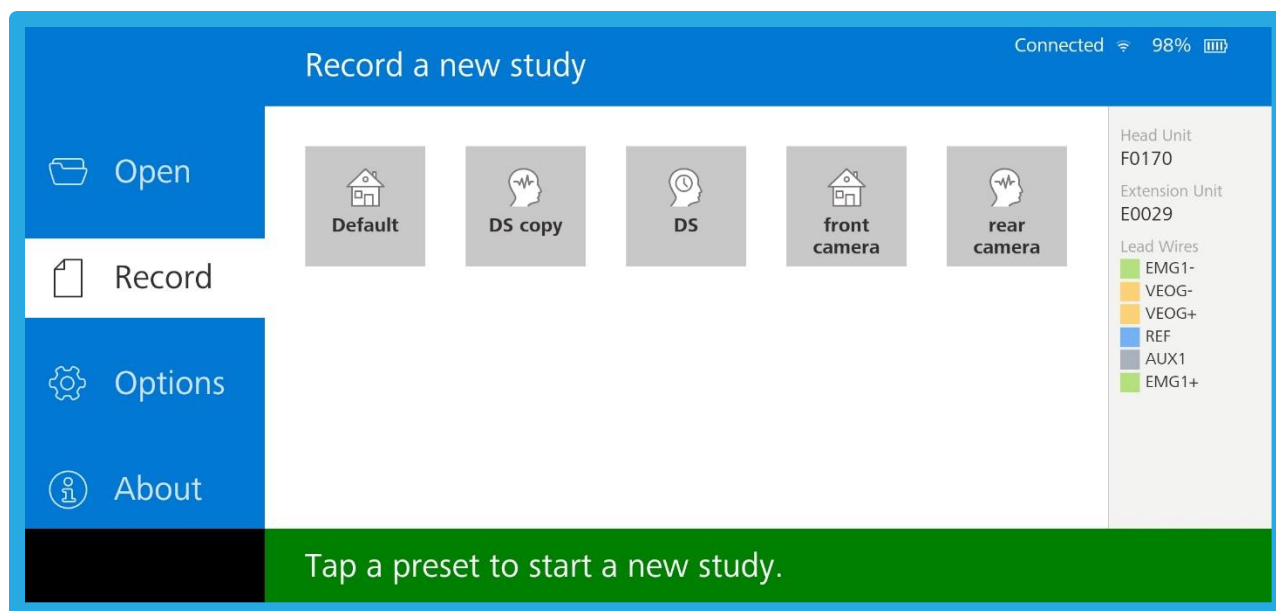
To set up your WiFi connection, tap “Options” and select “Cloud connection”. You will see the network selection screen, like below:



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 Zeto ONE 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 Guidance document.

#### 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 the Zeto ONE 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 and hold the power button for 1 second to turn on the system. Press the button again if you want to turn off the system. When turning off, the Zeto ONE 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 **Settings** button on the DU screen, and press the **Power off** button in the **Settings** menu to fully shut down the device. You need to connect the device to the charger to turn it on again when the device is fully shut down or 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             |

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:



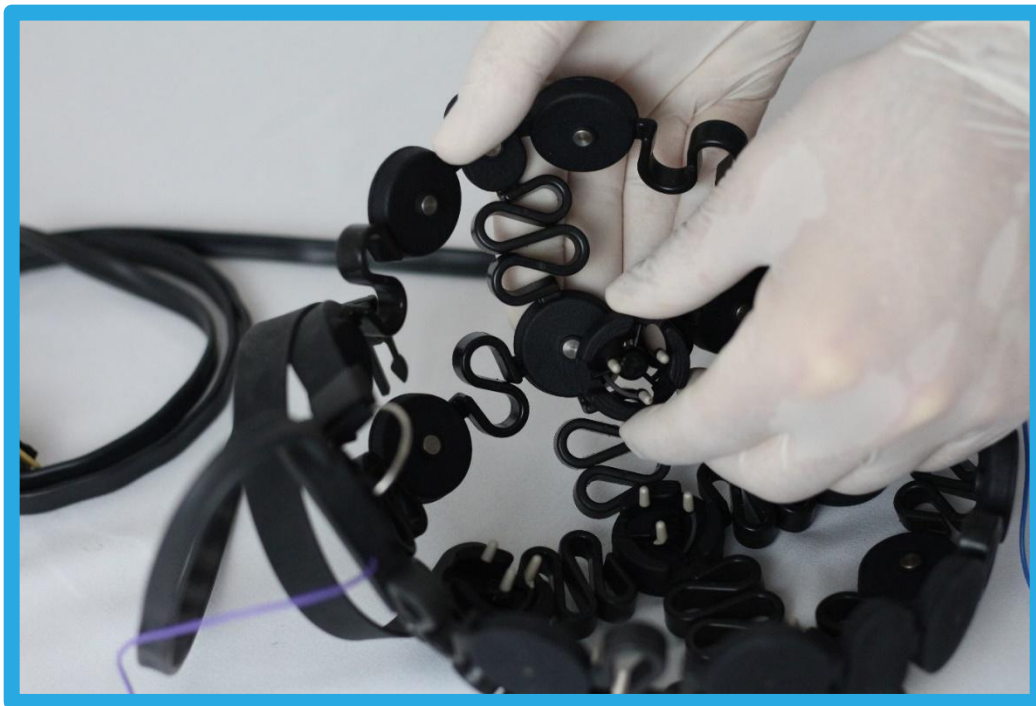
| Electrode indicators | Status                            |
|----------------------|-----------------------------------|
| Off                  | The electrode channel is inactive |
| Green                | Good contact quality              |
| Yellow               | Weak contact quality           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

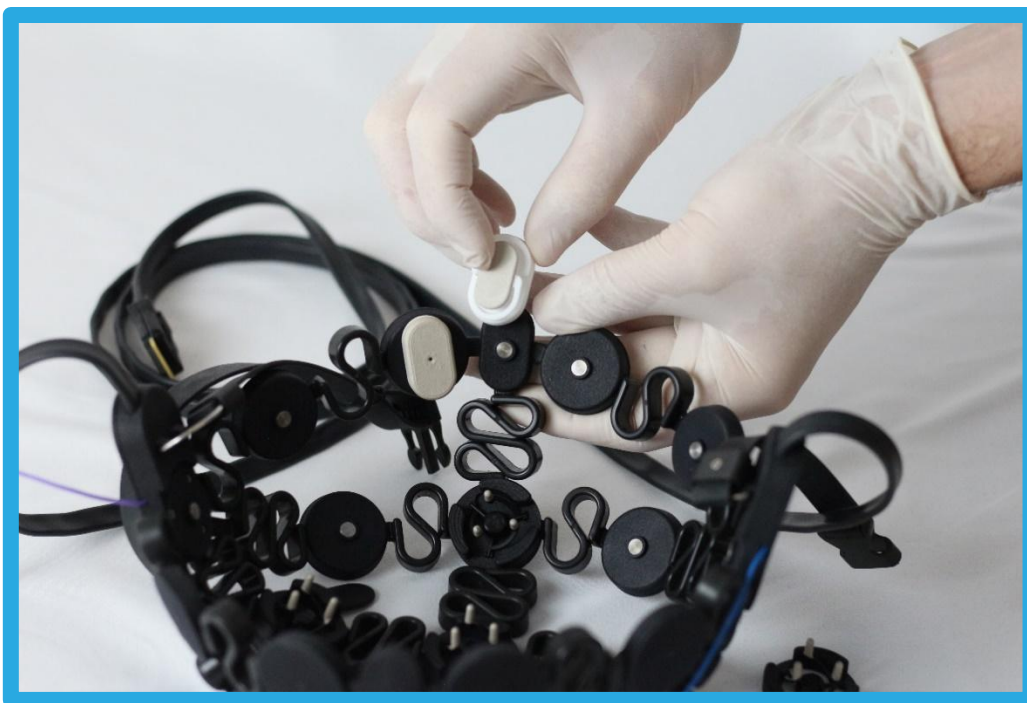
### 5.3. Electrode setup



Zeto offers various electrode sets. For the list of available sets, please refer to Section 4.1. The electrode sets come with various combinations of flex and flat electrodes, Ag/AgCl electrodes with optional gel tip. For most head shapes and sizes, landing on a hairy scalp, we suggest using flex electrodes. Flat electrodes are recommended for positions landing on skin such as Fp1 and Fp2.

Choose the electrode set best fitting your study. Remove the electrodes from their packaging only before the beginning of the study. Try to use the entire electrode pack. 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. Note that you may change the electrodes at any time by just pulling off an electrode from its socket and snapping on another electrode.





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 Zeto ONE Head Unit helps all electrodes land at their desired position per the International 10-20 EEG system. Putting on the Zeto ONE Head Unit is as easy as putting on a beanie cap. Please follow the steps below to ensure the Zeto ONE Head Unit sits correctly on the head:

1. Put the DU (and the EU if necessary) into the Zeto ONE 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.



Note: The Head Unit and the Extension Unit are not plug-and-play devices. Please ensure that the Display Unit is on standby (its green LED is off) when you connect the Head Unit and/or the Extension Unit to it.

---

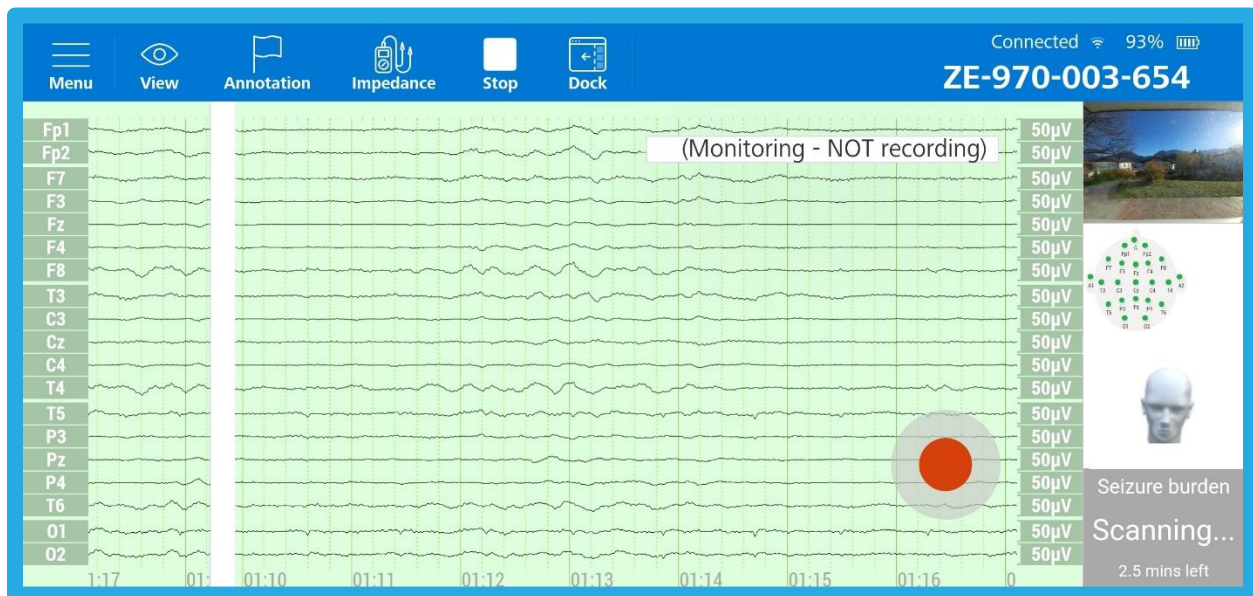
4. Put the Head Unit on with the correct orientation (the flat pill-shaped electrode pod with an LED should land on the center of the forehead, the other pill-shaped electrode without the LED should land on the

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 Zeto ONE 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 Zeto ONE (e.g. electrodes, neutral electrodes and connectors) should not contact other conductive parts of the Zeto ONE, 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 approximately 4 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 Zeto ONE 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 IP-camera, Zeto ONE can record up to 4 video streams. Zeto ONE provides two additional ports on the Zeto ONE 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 Zeto ONE 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-)

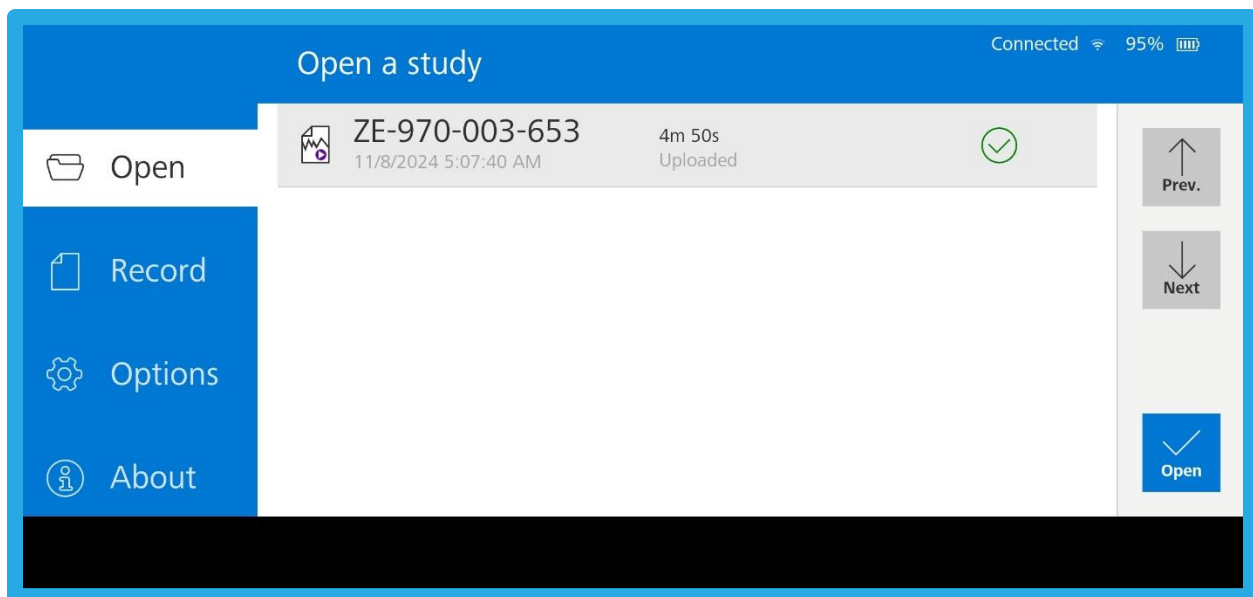
To record photic signal pulses, the front band of the Head Unit must face the photic stimulator device at a distance shorter than 30 cm and a viewing angle below 30 degrees. Photic unit must be started by the operator per its applicable instructions and protocol.



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 Zeto ONE is a reusable medical device 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 Zeto ONE'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 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 isopropanol solution (up to 70%).



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.

### 6.1.3. Cleaning preparation

Before cleaning:

- Ensure that all the electronics are turned off.
- Inspect the Zeto ONE 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

**IPN<sub>1</sub>N<sub>2</sub>** The Zeto ONE is **IP22**-rated.

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

To begin the disinfection, disconnect the Head Unit and place it on a clean surface.

Prepare isopropyl alcohol 70% as a spray or of-the-shelf germicidal disposable wipes (e.g. SaniWipes).



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 Zeto ONE, like the Display Unit, the Extension Unit and the cabling by wiping it with isopropyl alcohol wet wipes.



## 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 Zeto ONE 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 Zeto ONE 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% isopropanol for cleaning).

Zeto has evaluated the effects of multiple cleanings/disinfections as indicated above and found that during the expected service life of the Zeto ONE 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 Zeto ONE 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 Zeto ONE.

### 6.2. Battery instructions

If you are not using the Zeto ONE 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](http://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](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 LED to be ON in the <b>Options</b> menu 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: <b>Poor Head Unit connection, trying to reconnect.</b> | <p>The patient may have left the range of the WiFi network. Ask the patient to move back in range.</p> <p>If the warning is displayed despite the patient being in range, check the WiFi router or contact your internet service provider.</p> <p>Once the connection is reestablished, the device will automatically return to its previous state.</p> |
| 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 Zeto ONE 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 5%. 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.                                           | Ensure that the display is off by pressing the button on the DU. The charging should initiate within seconds.                                                                                                                                                                                                                                                                                                        |
| The photic detection is inconsistent.                                                                    | Please apply photic signals whose frequency are higher than 10 Hz.                                                                                                                                                                                                                                                                                                                                                   |
| The system does not detect the auxiliary channels when the Extension Unit is connected during the study. | The Extension Unit and the Head Unit are not plug-and-play components. The system either does not detect the auxiliary channels or operates incorrectly when the Head Unit or Extension Unit is connected during the study. If you need to use the aforementioned components, please stop the current study, then connect the EU/HU while the DU is on standby (green LED off on the DU) and then restart the study. |

## 8. Technical specifications

### 8.1. Zeto ONE technical specifications



#### Specifications

|                                                                       |                                                                                                            |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Number of the fixed EEG electrode channels on the Zeto ONE 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 Zeto ONE Head Unit:        | 2 (A1 and A2 in the mastoid area)                                                                          |
| Number of fixed DRL electrodes on the Zeto ONE Head Unit:             | 1 in the Fpz position                                                                                      |
| Electrode lead wire ports:                                            | 2 on the Zeto ONE 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 T $\Omega$                                                                                              |
| EEG, EOG, EMG, ECG signal range:                                      | $\pm 375$ 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 $\mu$ V 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<br>4G/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 channels:                                                              | indicator 3 acceleration, 3 angular velocity                                                                                                                    |
| Power supply:                                                                        | 3.85 V, 3950 mAh Lithium-Ion battery within the Display Unit                                                                                                    |
| Operating time:                                                                      | 4 hours                                                                                                                                                         |
| Battery charger:                                                                     | External, dedicated AC/DC medical adaptor<br>Mean Well GSM18E09<br>Input: 100-240V 50/60 Hz 0.5-0.25 A<br>Output: 9V 2A 18W max.<br>Medical protection class II |
| User control:                                                                        | Display Unit touchscreen, Display unit button(s), application on the recording computer                                                                         |
| Dimensions:                                                                          | Head Unit: a hemisphere with an approximate radius of 8 cm (3.1 in)<br>Display Unit: 22 cm × 9 cm × 2.4 cm (8.8 in × 3.5 in × 0.9 in)                           |
| Weight:                                                                              | Head Unit: approx. 406 grams (14.3 ounces)<br>Display Unit: 437 grams (15.4 ounces)                                                                             |
| The Zeto ONE does not contain components which can be repaired by SERVICE PERSONNEL. |                                                                                                                                                                 |

## 8.2. Accessories and parts



| Specifications        |                                                                                                                                                                                                                |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrode set:        | Zeto soft electrodes with optional gel tip                                                                                                                                                                     |
| Extension Unit:       | 6 × 2.5 mm jack ports                                                                                                                                                                                          |
| Supported lead wires: | Supplied by Zeto, automatically detected by the system.<br>ECG input type: RA, LA<br>EEG input type: REF and other auxiliary EEG<br>EOG input type: HEOG+, HEOG-, VEOG+, VEOG-<br>EMG input type: EMG1+, EMG1- |
| Medical Cart:         | Tryten Nova Connect, 22.4" × 20.4" × 71.8"<br>ISO9001:2015 Certified, Tip Resistant with IEC 60601                                                                                                             |
| Medical Monitor:      | Manufacturer, CybernetPCAP Multi-Touch 24" Display, UL/cUL/IEC60601-1 Certified,                                                                                                                               |

### 8.3. Environmental conditions



| Condition             | Operation                        | Transportation                     | Storage                          |
|-----------------------|----------------------------------|------------------------------------|----------------------------------|
| Temperature:          | 5 °C to 40 °C<br>41 °F to 104 °F | -20 °C to 45 °C<br>-4 °F to 113 °F | 0 °C to 45 °C<br>32 °F to 113 °F |
| Relative humidity:    | 65 ± 20%RH,<br>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 Zeto ONE



#### Manufacturer and product

|                      |                       |
|----------------------|-----------------------|
| Manufacturer:        | Zeto, Inc.            |
| Product type:        | Electroencephalograph |
| Model:               | Zeto ONE              |
| Product description: | Wireless EEG System   |

#### Equipment and environment

|                    |                                                                       |
|--------------------|-----------------------------------------------------------------------|
| Kind:              | ME equipment                                                          |
| Mode of operation: | Continuous operation                                                  |
| Environment:       | Healthcare or Research facility<br>Home<br>Transport (ground and air) |



IPN<sub>1</sub>N<sub>2</sub>



#### Safety

|                                  |            |
|----------------------------------|------------|
| Supply mains isolation:          | Mains plug |
| Protection class while charging: | Class II   |
| Protection class during use:     | Class II   |
| CISPR11 emission class:          | Class B    |
| Ingress protection:              | IP22       |
| PEMS class:                      | Class A    |

#### Communication

|                             |                                           |
|-----------------------------|-------------------------------------------|
| Contains radio transmitter: | WiFi, 2.4 and 5.0 GHz WiFi bands, 4G /LTE |
|-----------------------------|-------------------------------------------|

2.4 GHz ISM radio for emitting time synchronization data. **(Available only in Display Units with serial numbers G0465 and lower):**

| Applied parts               |                                        |
|-----------------------------|----------------------------------------|
| Applied part:               | Type BF                                |
| Applied parts, EEG channel: | 19 channels + 1 channel DRL electrodes |
| Power port                  |                                        |
| Charging:                   | Zeto Quick Charge Port                 |
| Charge voltage:             | 9 V DC                                 |
| Charge current:             | Up to 1.6 A                            |
| Charger mains connection:   | 100-240 V AC<br>50/60 Hz 0.5-0.25 A    |

## 8.5. System Requirements

| Minimum<br>(interpreting)                                             | Minimum<br>(recording) | Recommended<br>(interpreting)                  | Recommended<br>(recording)                     |
|-----------------------------------------------------------------------|------------------------|------------------------------------------------|------------------------------------------------|
| no strict hardware requirements                                       | 16 GB RAM              | 16 GB RAM<br>Latest Intel Core i5 or i7<br>CPU | 32 GB RAM<br>Latest Intel Core i5 or i7<br>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 Zeto ONE

The Zeto ONE is designed for use in a *healthcare or research facility, home or transport (ground and air) environment*, and tested according to the following limits:

TABLE 201

| Emission test                      | Compliance            | Electromagnetic environment - guidance                                                                                                                                                                                    |
|------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF radiated emissions<br>CISPR 11  | Group 1, Class B      | The Zeto ONE 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<br>CISPR 11 | Group 1, Class B      | The Zeto ONE can be used in all establishments, including domestic establishments.                                                                                                                                        |
| Voltage Fluctuations and Flicker   | IEC 61000-3-3         | The Zeto ONE 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 Zeto ONE 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)<br>IEC 60601-4-2 | ±15 kV air<br>±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 %.<br><br>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 Zeto ONE, 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<br>6 Vrms in amateur and ISM bands                                                                                                                                                                                                                     | Portable and mobile RF communications equipment should be used no closer to any part of the Zeto ONE, 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,<br>1 GHz – 2.7 GHz<br>Compliance level: 10V/m<br>80 MHz – 1 GHz<br>Compliance level: 10V/m                                                                                                                                  | Portable and mobile RF communications equipment should be used no closer to any part of the Zeto ONE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>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.<br><br><b>Recommended separation distance</b><br>$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ 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). |
| <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the radiation symbol next to this paragraph.</p> </div> </div> |                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Surge IEC 61000-4-5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ±0.5 kV lines to earth<br>±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 %.<br>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 <sub>T</sub> <sup>c</sup> (100% dip in U <sub>T</sub> ) for 5 seconds<br>70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 0.5 second<br>0% U <sub>T</sub> (100% dip in U <sub>T</sub> ) 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.

<sup>a</sup> 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 Zeto ONE is used exceeds the applicable RF compliance level above, the Zeto ONE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Zeto ONE components.

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

<sup>c</sup>  $U_T$  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 Zeto ONE System components

The Zeto ONE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zeto ONE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zeto ONE; 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<br>$d = 1.2\sqrt{P}$                        | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 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 |
|-------------------------------------------|----------------|
| 699.7-715.3 MHz                           | 95 mW          |
| 700.5-714.5 MHz                           | 74 mW          |
| 704-711 MHz                               | 92 mW          |
| 704-711 MHz                               | 69 mW          |
| 782 MHz                                   | 160 mW         |
| 782 MHz                                   | 120 mW         |
| 793 MHz                                   | 103 mW         |
| 793 MHz                                   | 78 mW          |
| 829-844 MHz                               | 99 mW          |
| 829-844 MHz                               | 77 mW          |
| 1.7107-1.7543 GHz                         | 204 mW         |
| 1.7107-1.7543 GHz                         | 159 mW         |
| 1.7124-1.7526 GHz                         | 201 mW         |
| 1.7125-1.7775 GHz                         | 231 mW         |
| 1.7125-1.7775 GHz                         | 180 mW         |
| 1.72-1.77 GHz                             | 206 mW         |
| 1.72-1.7325 GHz                           | 195 mW         |
| 1.72-1.7325 GHz                           | 149 mW         |
| 1.72-1.77 GHz                             | 169 mW         |
| 1.8502-1.9098 GHz                         | 416 mW         |
| 1.8507-1.9093 GHz                         | 326 mW         |
| 1.8524-1.9076 GHz                         | 309 mW         |
| 1.8525-1.9075 GHz                         | 242 mW         |
| 1.86-1.9 GHz                              | 308 mW         |
| 1.86-1.9 GHz                              | 236 mW         |
| 2.3075-2.3125 GHz                         | 13 mW          |
| 2.3075-2.3125 GHz                         | 13 mW          |
| 2.355 GHz                                 | 10 mW          |
| 2.355 GHz                                 | 10 mW          |
| 2.402-2.48 GHz (Bluetooth)                | 3.2 mW         |
| 2.402-2.48 GHz (Bluetooth)                | 9 mW           |

|  |                        |        |
|--|------------------------|--------|
|  | 2.412-2.472 GHz (WiFi) | 429 mW |
|  | 2.5025-2.5675 GHz      | 149 mW |
|  | 2.5025-2.5675 GHz      | 116 mW |
|  | 2.5035-2.6825 GHz      | 175 mW |
|  | 2.5035-2.6825 GHz      | 138 mW |
|  | 2.506-2.68 GHz         | 166 mW |
|  | 2.506-2.68 GHz         | 128 mW |
|  | 2.51-2.56 GHz          | 129 mW |
|  | 2.51-2.56 GHz          | 100 mW |
|  | 2.58-2.61 GHz          | 125 mW |
|  | 3.5575-3.6925 GHz      | 155mW  |
|  | 3.56-3.69 GHz          | 154 mW |
|  | 3.56-3.69 GHz          | 116 mW |
|  | 5.18-5.24 GHz (WiFi)   | 65 mW  |
|  | 5.26-5.32 GHz (WiFi)   | 63 mW  |
|  | 5.5-5.72 GHz (WiFi)    | 65 mW  |
|  | 5.745-5.825 GHz (WiFi) | 60 mW  |

#### USA – FCC compliance of the radio communication

|          |                                                                 |                                                          |
|----------|-----------------------------------------------------------------|----------------------------------------------------------|
| Zeto ONE | Contains FCC ID:                                                | A3LSMG715U1                                              |
|          | Name of grantee:                                                | Samsung Electronics Co. Ltd.                             |
|          | Equipment class:                                                | NII - Unlicensed National Information Infrastructure TX  |
|          | Device type:                                                    | Mobile phone                                             |
|          | Modular type:                                                   | Does not apply                                           |
|          |                                                                 |                                                          |
|          | Contains transmitter module FCC ID                              | R7TAMB2524                                               |
|          | <b>(For Display Units with serial numbers G0465 and lower):</b> |                                                          |
|          | Name of grantee:                                                | Wuerth Elektronik eiSos GmbH & Co KG                     |
|          | Equipment class:                                                | DXX - Part 15 Low Power Communication Device Transmitter |
|          | Device type:                                                    | ISM radio module                                         |
|          | Modular type:                                                   | Single modular                                           |

The Zeto ONE 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

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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.

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