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Instructions for Use

iSyncWave (ISW-MUS101)

iMediSync Inc.

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Seoul, 06247, Republic of Korea

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Rx ONLY

CAUTION: Federal(USA) law restricts this device to sale by or on the order of a physician.

Document Number: IMS-W02-IFU

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1. Introduction

This user manual is intended for reference by iSyncWave users. The manual includes information about components, instructions for use and safety precautions of iSyncWave. Please read the user manual before using iSyncWave. We recommend storing the manual in a safe place near the device.

1.1 Company Information

Company Name: iMediSync Inc.

Phone Number: +82-2-747-7422

Address: 3F, TIPS TOWN 3, 175 Yeoksam-ro, Gangnam-gu

Factory Address: Factory-1, 20, Centum seo-ro, Haeundae-gu, Busan, Republic of Korea

1.2 Device Information

Product Name	Electroencephalograph (iSyncWave)
Model Name	ISW-MUS101(US),
Intended Use	Acquire electroencephalogram(EEG) and wirelessly transfer data to tablet
How to Use	Refer to manual
Type of protection against electric shock	Internally powered ME Equipment
Degree of protection against electric shock	BF applied part
Degree of harmful ingress of water	IPX0
Degree of safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide	Not suitable for use
Weight	1.59kg

1.3. Device Specification

Number of Electrodes	19
Reference Electrode	A1
Channel Position	International 10-20 system
Battery	Rechargeable Li-ion
Rated Input Voltage	3.6 V⎓, 2 950 mAh (Li-ion Polymer Battery)
Sampling Rate	250Hz

Digital Signal Resolution	24 Bit
Wireless Connection	Bluetooth Low Energy (BLE) v5.0
Accuracy of signal reproduction	Within 10%
Input dynamic range	+/- 1 mV
maximum offset voltage	+/- 300 mV
Noise	4 μV peak to peak
Frequency range and bandwidth	0.5 ~50 Hz
Common mode rejection	89 dB
Description of all functions	Impedance check, Signal check, EEG recording and review
Description of waveform displays	Tablet Application (Real time display)

1.4 Recommended Tablet Specifications

Processor	CPU Speed	2.3 GHz, 1.7 GHz(Octa-Core)
Display	Resolution(Main)	2000 x 1200(WUXGA+)
Memory	RAM Size(GB)	4
	ROM Size(GB)	128
Wi-Fi	802.11 a/b/g/n/ac 2.4G+5 GHz, VHT80 MIMO	
Bluetooth	Bluetooth v5.0 (LE up to 2 Mbps)	
System	Android 8 (Oreo)	

* It is recommended to use the tablet PC and charger approved by safety test as an electronic device.

2. Device Overview

2.1 How the Device Works

iSyncWave is a wireless EEG measurement device that applies dry EEG measurement technology to an international 10-20 system compliant size-adjustable headset.

iSyncWave measures 19 channel EEG and PPG in real time and transfer the data through BLE wireless connection to the iSyncWave App. The data is displayed and recorded via the iSyncWave App.

iSyncWave uses dry electrode technology, which doesn't require a preparation process(e.g., applying conductive gel), to obtain high quality EEG signal. This device measures overall EEG data using 19 EEG electrodes, 1 reference electrode and 1 ground electrode.

With iSyncWave, you can measure both EEG and synchronized PPG data.
EEG is measured from 19 channels using the reference electrode. The measured data can be digitally converted to common average, longitudinal and transverse montage.

Before measuring the EEG, you can check the impedance of each electrode under the impedance check screen in the iSyncWave app. EEG amplifier, analog-to-digital converter and Bluetooth are built in the device. All EEG and PPG signal is sampled at 250Hz and then converted to digital data at 24-bit resolution.

The user can organize and control iSyncWave during the measurement process with iSyncWave app. The measured data is automatically saved and can be seen on iSyncWave app.

iSyncWave can be only used by professional and/or medical personnel with product training and experience in EEG measurement. The professional and/or medical personnel can check the signal quality in real time and refer to the measured data in clinical practice.

2.2 Intended Use

iSyncWave is intended to be used to acquire EEG, the electrical activity signals of the brain, from normal individuals and patients(children to adults) with a head circumference between 50cm to 62cm.

2.3 Indication of Use

iSyncWave is to be used to measure electroencephalogram from the scalp of children and adults. It is not suitable for electro-cerebral inactivity (ECI) determination.

2.4 Patient-Contacting Components

19 EEG electrodes, 1 reference electrode, 1 base electrode and 1 PPG sensor

2.5 Intended Environment of Use

iSyncWave is intended for use in clinical environment.

2.6 Intended user profile and environment in usability test

2.6.1 Intended user environment

1) Conventional environment in hospital

2.6.2 Intended user profile

At least two individuals (a guide and an evaluator) performed a usability validation evaluation with a given scenario. A participant should be qualified for User Profile.

1) The users who participate in the validation evaluation shall have a qualification equal to or higher than the requirement for the user profile.

2) The qualification requirement for the user profile includes:

a) Education:

-. Persons who have completed appropriate training in the product.

-. Healthcare practitioners including doctors.

b) Knowledge:

–. Persons who understand the physical principle of EEG and have received relevant training.

-. Persons who understand and have been trained in hygiene related to EEG measurement.

c) Language skill:

–. Persons who understand the content of Instruction for Use written in English.

d) Experience:

–. Persons who have completed appropriate training in iSyncWave.

-. Persons who have completed appropriate training in the EEG analysis software.

3. Safety Requirements

3.1 Warnings

1. The amplifier shall meet the safety requirements of EN 60601-1, safety class II, and applied part BF.
2. The manager of the device shall provide a safe environment for a typical EEG system compliant to EN 60601-1-1 requirements.
3. iSyncWave shall be only operated by an individual who has been designated and has received safety training.
4. Before handing the electrodes, please carefully read the operation manual provided by the manufacturer and only use the provided electrodes.
5. Please refer to the user manual for the information of the recommended tablet specifications, operating system, and the requirements of those settings.
6. Safety precautions for the user and subject to avoid the risk of electrical shock hazard caused by mechanical shock:
   The EEG system shall not be operated if the device is mechanically damaged. The damaged

device and/or components shall not be used and be requested for repair service. If the amplifier is damaged, please contact the manufacturer or the service center.

7. Safety precautions to avoid hazards in the event of inadequate hygiene or if the subject contacts the device contaminated with toxic substance:
   If the device's hygiene is inadequate, clean the device with alcohol. If the device is contaminated by toxic substance, stop using the device and contact the manufacturer or the service center.
8. Inadequate EEG recordings or inaccurate interpretation of EEG can be caused by the following: user's inadequate ability to operate the device , inaccurate placement of electrodes, electromagnetic interference, problem with computer device, use of alternative software and/or operating system not provided by the manufacturer. The User operating the iSyncWave device shall have adequate knowledge and experience in EEG measurement and the device.
9. Before wearing the device, please turn on the device for the safety of the patient/subject.
10. Before taking off the device, please turn off the device for the safety of the patient/subject.
11. Do not modify this equipment without authorization of the manufacturer.
12. Do not use the device with HF surgical equipment to protect the patient against burns.
13. Do not use the device with defibrillator.
14. The conductive parts of electrode should not contact other conductive parts including earth.

3.2 Precautions

1. Read all instructions and labels including this manual before starting to use the device system.
2. Do not attach or detach any device components while the device is on to prevent any damage to the system or components. Turn off the device when attaching or detaching any components to the device.
3. Do not use acetone or any other cleaning solvents to clean the device.
4. The battery life of the device may be shortened if the device is used frequently and/or for a prolonged period of time.
5. The battery life of the device is affected by how often you charge and discharge the battery.
6. The battery life and capacity may decrease when the device is stored in a high-temperature environment.
7. The battery may self-discharge when the device is in storage.
8. Keep the battery charged. If the battery is discharged, it may take a longer time to fully charge.
9. Do not immerse the device into any liquid.
10. Do not expose the device to direct sunlight, heat source of thermal radiation, moisture, vibration, mechanical shock, excessive dust, or humidity.
11. The warranty will be void if the device is opened, disassembled, or altered by any unauthorized personnel.
12. Do not use when the device is damaged.
13. Do not use when the device is wet. If any moisture penetrates the device, have the device

checked by the manufacturer.

14. Do not use caustic or abrasive cleaning agents to clean the device or electrodes.
15. Do not charge when the patient/subject is wearing the device.
16. Always clean the electrodes after each measurement according to the cleaning instructions.
17. For electrode channels that have persistent problems with signal quality, check the wear of the electrode coating.
18. The battery used in this device may present a fire or chemical burn hazard if mistreated.
    To ensure battery safety,
    a. Do not detach or disassemble the battery from the device
    b. Replace the battery at the service center designated by the manufacturer
19. Do not excessively pull or overstress the device as it may break the device.
20. Do not sit or place a heavy object on the device.
21. Do not use the device under the environment with strong electromagnetic Interference.

3.3 IT Network

The iSyncWave device is connected to the tablet via Bluetooth. Through the tablet the following can be done:

a. Control and operate the device
b. Check real time and saved EEG data through iSyncWave app
c. Retrieve and review the EEG data in iSyncWave app

3.4 Explanation of Markings

Symbol	Meaning
	Follow instructions for use
	Stand-by
	Follow manual or operating instructions
	Keep dry
	Keep away from sunlight

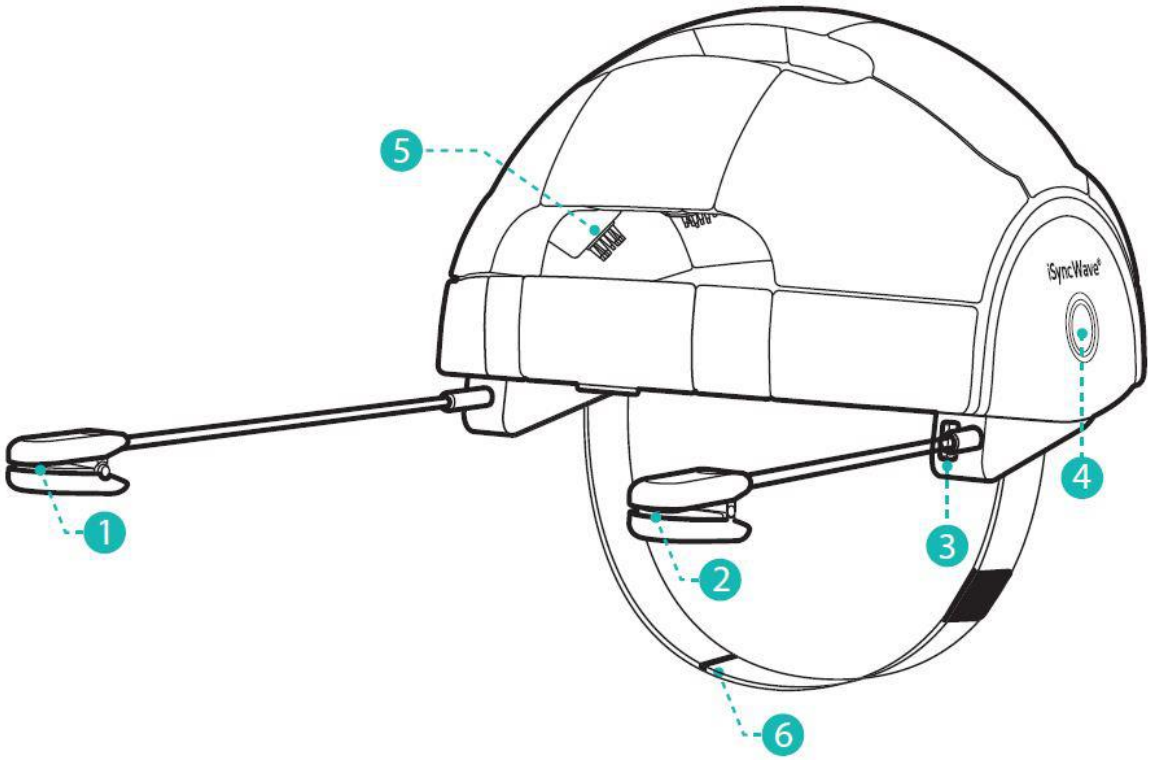
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Separate collection for waste of electrical and electronic equipment.
MD	Medical device
Rx ONLY	CAUTION: Federal(USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of manufacture
#	Model number
SN	Serial number
UDI	Unique Device Identifier
CE	CE mark

EC REP	Authorized Representative in the European Community
	Type BF Applied Part

4. Device Components

4.1 Bottom

The reference electrode connector is at the bottom left side of the device. The PPG sensor and USB-C connector is at the bottom right side of the device. You can connect the reference electrode and PPG sensor through the connector. The device can be charged through the USB-C connector.



	Name	Model Name	Description
1	Reference electrode	REF-W01	Ear clip sensor serving as reference point for EEG measurement

2	PPG sensor	PPG-W01	Ear clip sensor measuring PPG
3	USB-C charging port	-	Charge lithium-ion battery
4	Power button	-	Turn the device power on and off
5	Electrode	-	Electrodes for EEG measurement
6	Chin strap	-	Secure the device on patient/subject when using the device

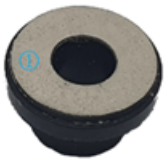
4.2 Right

The power button is at the right side of the device. When the device is turned on or charging, the LED light on the power button will indicate the status of the device.

<Power Button LED Status>

Status	Color	Description
When turned on	Green	Battery level above 30%
	Magenta	Battery level below 30%
When charging	Green	Battery level above 95%
	Magenta	Battery level below 95%
When measuring	None	

4.3 Types of Electrodes



No.	Name	Description
1	Brush electrode	Ag/AgCl coated conductive polymer (Used except on forehead)
2	Flat electrode	Ag/AgCl coated conductive polymer (Used on the forehead)

5. How to Use the Device

After unpacking from the box, check if the package contains all components; iSyncWave device, accessories, and user manual.

- Carefully read the user manual and share the documentation if necessary.

- Check the accessories.
- The products listed in the components are compatible products.

5.1 Charging the Battery

Before using iSyncWave for the first time, fully charge the battery. Fully charging the battery may take up to three hours. This will help extend the battery life of the device.

- Connect the USB-C charging cable to the charger.
- Plug in the charger to a power outlet.
- Connect the end of the USB-C charging cable to the USB-C charging port of iSyncWave, which can be found on the bottom right side of the device.
- Place the device on a sturdy flat surface and make sure the bottom side of the device is facing down.
- If the device is fully charged, the LED status indicator on the power button will be green.

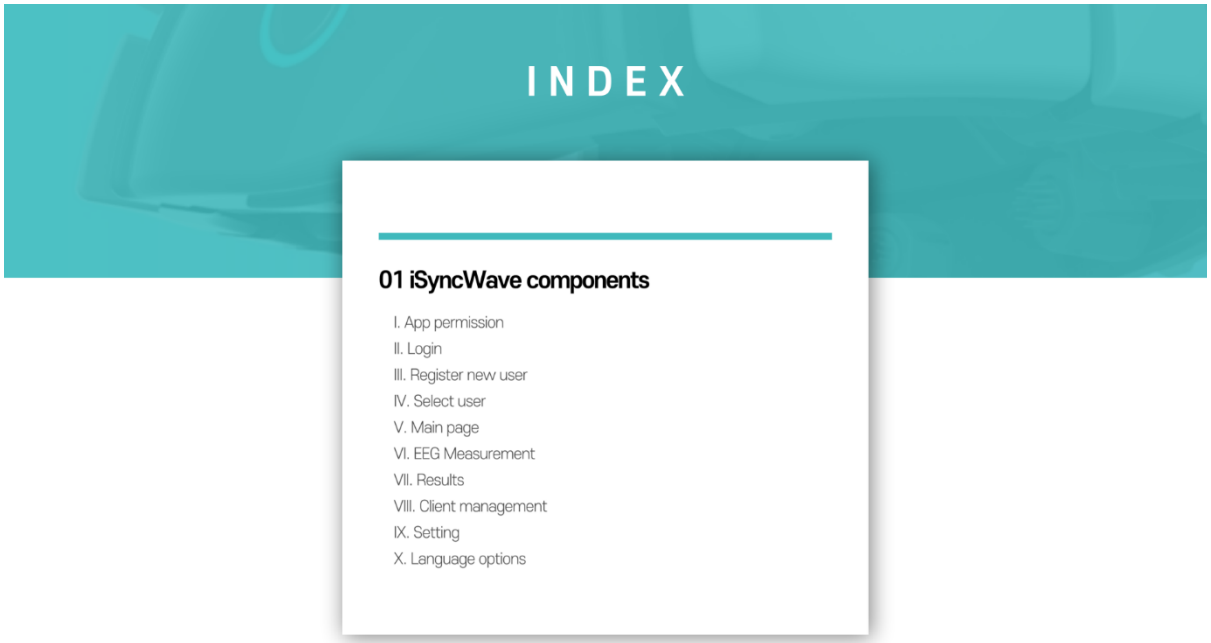
The LED status indicator on the power button will indicate the battery status as follows:

Color	Description
Green	Battery level above 95%
Magenta	Battery level below 95%

5.2 Connecting iSyncWave and iSyncWave app

1. Press the power button and hold for more than 2 seconds to turn on the device
2. Run the iSyncWave app on the tablet
3. Connect your tablet to a Wi-Fi network through the settings panels of your tablet PC
4. Register the patient/subject under the iSyncWave app
5. Connect the iSyncWave device to the tablet via Bluetooth

5.3 Using iSyncWave app



I. Allow iSyncWave for access

1. **App permission**

   Review the App Permission Information Guide then proceed to 'Confirm'

II. Login

1. **Enter ID (Email) & Password**
   - Enter your email at the [Email]
   - Enter your password at the [Password]
   - Click [LOG IN]

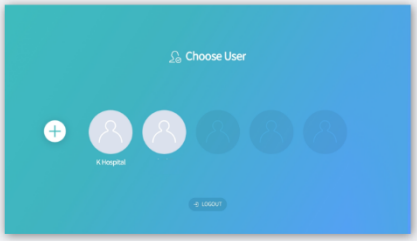
2. **Automatic login**
   - Check the automatic login option at below to stay logged in with your current account.

3. **Find password**
   - Reset your password in case the current password is lost/forgotten.

III. New user registration

Step 01

Select/add new user



① To add new user, press the [+] located at the left side.

Step 02

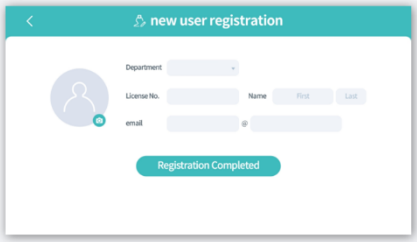
Enter PIN code

① Enter 4 digit PIN code provided from the iMediSync.
② Press 'Confirm' to complete.

III. New user registration

Step 03

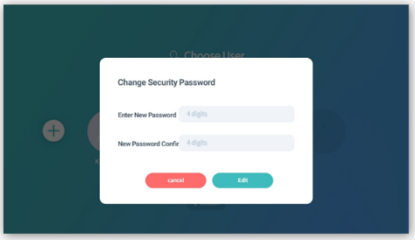
Register new user



① Under [Department] section, select [Neurology] / [Brainwave Analysis]
② Enter your Doctor license number
③ Enter your full name
④ Enter your email
⑤ Press [Registration Completed] after completing the above steps

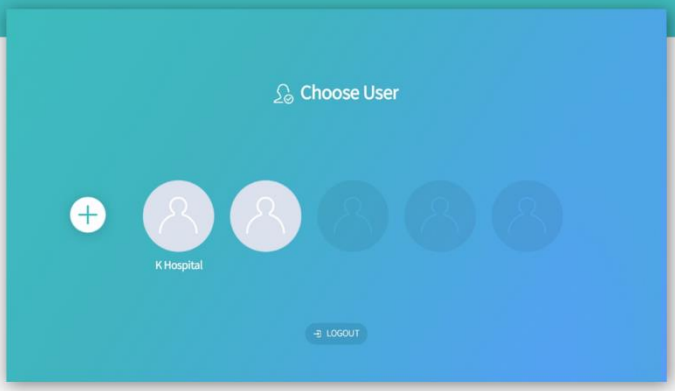
Step 04

Create new password



① Select your newly created user account at the [Choose user] page
② At the [Change security password] pop-up, enter your 4 digit security PIN code
③ At the new password confirmation, enter your new PIN code
④ Press [Edit] after completing the above steps

IV. Select user

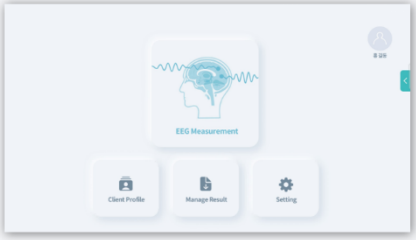


1. **Select user**
   - Select your registered user profile.

V. Main page

Step 01

Main page



① The following overview is the main page of application

② Main page is organized with [EEG Measurement], [LED Therapy], [Client Profile], [Manage result] and [Setting]

③ Press the icon to switch users

Step 02

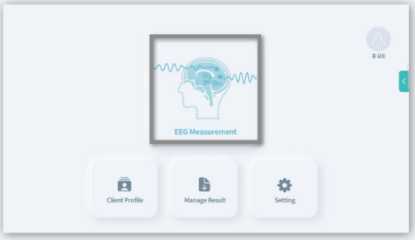
Main page

① Utilize the [Quick menu] on the right side for convenience

VI. EEG Measurement

Step 01

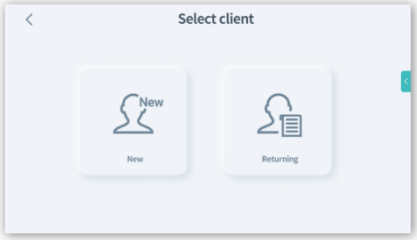
Main page



① Prepare iSyncwave heltmet device and run the application
② Press [EEG Measurement] after completing the preparation

Step 02

Select client

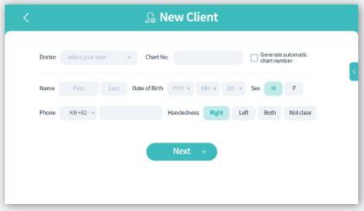


① Press [New] to add new client. * Step3
② Press [Returning] to perform measurement on previous client. *Step4

VI. EEG Measurement

Step 03-1

Register new client



① Select supervisor to perform the measurement on the client
② Enter the chart number or press [Generate automatic chart number]
③ Enter required information of the client
④ Select options in [Handedness]
⑤ Press [Next] after completing the steps above

Step 03-2

Consent to Use of personal information agreement

① Review the terms of 'Use of personal information agreemen t', proceed to consent at the bottom of the term [I agree to the collection and use of personal information abo ve (required)].

Step 03-3

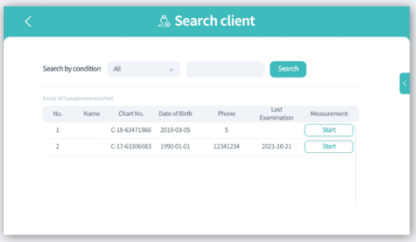
Submit your signature

① Click [Completed] after submitting your signature
② Activate the iSyncWave helmet device

VI. EEG Measurement

Step 04-1

Existing client



① Following is the page when you select [Existing client]
② Select opion when using [Search by condition] to select your existing client
③ After selecting your client, press [Start] under [Measurement] section.
④ Activate the iSyncWave helmet device for the [EEG Measurement].

Step 04-2

Existing client

① Watch the test measurement guide video through the [Start] icon.
② After watching the video to the end, press [Measurment].
③ If you click the [Measurment] icon, the device connection screen appears.

VI. EEG Measurement

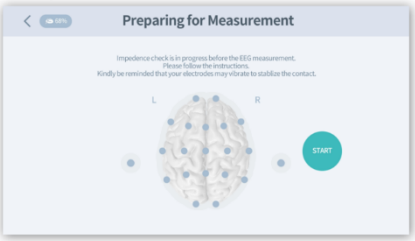
Step 05

Device connection

① Press [Connect] to activate the bluethooth
② iTurn on the iSyncWave heltmet device by pressing the power button
③ Check if the application and the helmet device connection is in sync

Step 06

Preparing for measurement



① Equip the helmet according to the instruction
② Press [Start] for the impedance check

VI. EEG Measurement

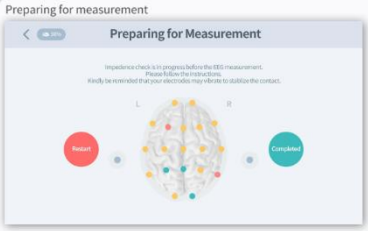
Step 06-1

Preparing for measurement

① Check the impedance status by the colored dots of electrodes
② Press [Vibration] to adjust the fitting of electrodes automatically.

Step 06-2

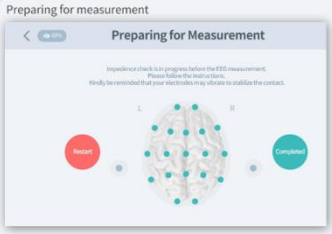
Preparing for measurement



① If the impedance is unstable, press [Try again] after adjusting the fitting of electrodes to the head.

Step 06-3

Preparing for measurement

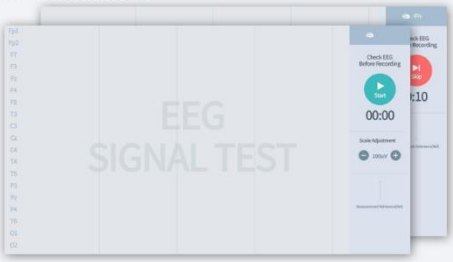


① Please perform the impedance testing until all signals turn to [Green]
② Press [Completed] to proceed to the next step

VI. EEG Measurement

Step 07-1

Check EEG before recording



① Check the signal quality at the [EEG SIGNAL TEST] page
② Press [Start] to perform the test
③ Click [Skip] if the signal test is not neccessary
④ By utilizing the [Scale Adjustment] function, you can control the mi crovolts (mV) to control the scale in EEG measurement.

Step 07-2

Check PPG before recording

① Check the PPG signal quality at the [PPG SIGNAL TEST] page which will be integrated to the HRV Summary report after the measurement.

VI. EEG Measurement

Step 07-3

Complete signal test before recording

① Click [Complete] after confirming both signal test.
② If neccessary, press [Retry] after completing both signal test for re-confirmation.

Step 07-2

Complete signal test before recording

① Press [Back] button to activate the EEG measurement [Notice]
② If you wish to finish the EEG measurement, click [Yes]
③ If you wish to proceed with the EEG measurement, click [No]

VI. EEG Measurement

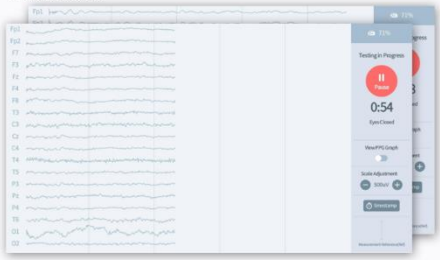
Step 08-1

Testing in progress

① Press [Start] to run the EEG Measurement
② Adjust the scale (mV) at the right bottom side if neccesary

Step 08-2

Testing in progress

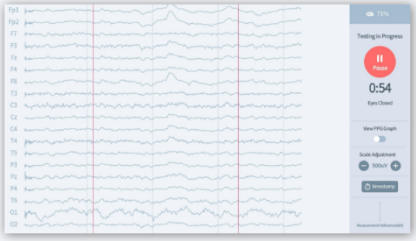


① Perform the EEG measurement with [Eyes open/closed] under the instruction of supervisor
② You can pause/restart the EEG measurement if neccesary.
③ You can switch screen to PPG measurement by pressing [View PPG Graph] in the center

VI. EEG Measurement

Step 08-3

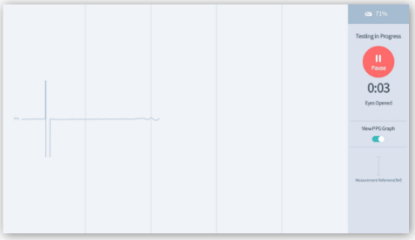
Testing in progress



① [Time stamp] allows you to mark a specific location.

Step 08-4

Testing in progress



① Check the PPG measurement if neccesary

VI. EEG Measurement

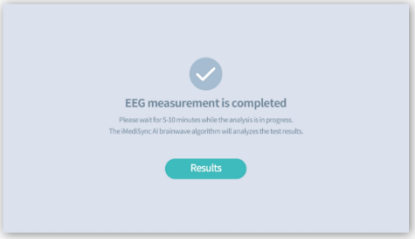
Step 09

Measurement data upload

① The measured EEG data will be uploaded to our server for analysis and rep ort upon completion of the measurement.

Step 10

EEG Measurement completed



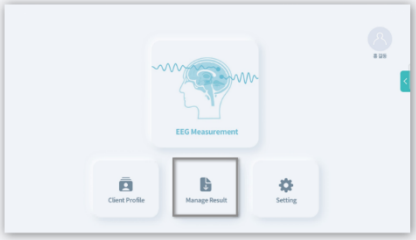
① Following is the page after completing EEG measurement.

② Click [Results] to check the current analysis status of your measu rement

VII. Results

Step 01

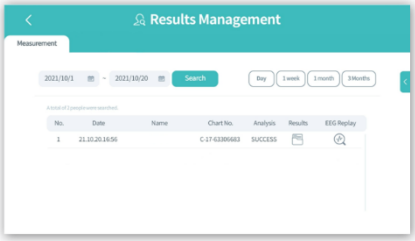
Main page



① Click [Manage result] at the main page

Step 02

Manage result

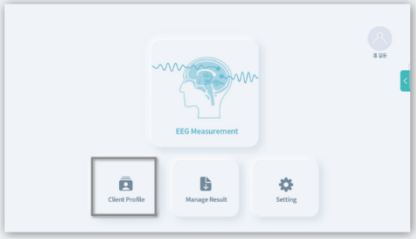


① Above is the [Results Management] page.
② You can manually search for individual result by selecting start/end date.
③ The result will be displayed as the success/fail if the measured clean data is under 30 seconds or longer.
④ Press the [Results] icon to check the summary report
⑤ Press the [EEG Replay] icon to rewatch the EEG measurement

VIII. Client management

Step 01

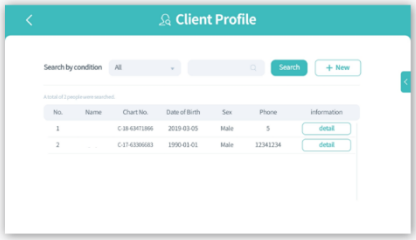
Main page



① Click [Client Profile] at the main page

Step 02

Client management

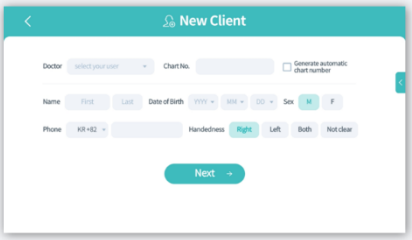


① Above is the page displayed at [Client Profile]
② Search and select your client using the [Search by condition]
③ Register new client by pressing [+ New]
④ Check the currently registered clients in this page
⑤ Press [Detail] under the Client information section for more detailed information.

VIII. Client Management

Step 03-1 동일

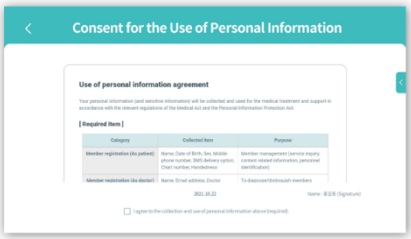
New client



① Select supervisor to perform the measurement on the client
② Enter the chart number or press [Generate automatic chart number]
③ Enter required information of the client
④ Select options in [Handedness]
⑤ Press [Next] after completing the steps above

Step 03-2

Consent for the Use of Personal information



① Review the terms of 'Use of personal information agreement', proceed to consent at the bottom of the term
[I agree to the collection and use of personal information above (required)].

VIII. Client Management

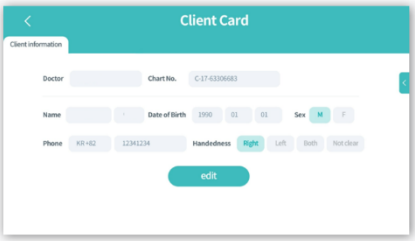
Step 03-3 동일

Submit your signature

① Click [Completed] after submitting your signature
② Activate the iSyncWave helmet device

Step 04

Client Card

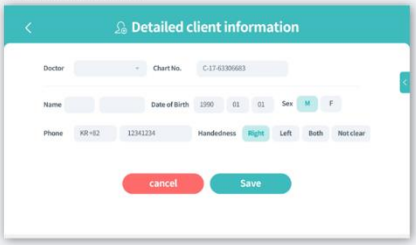


① Above is the [Client Card] page after pressing the [Detail]
② Confirm client information at the following page
③ Press [Edit] to make adjustment on client information

VIII. Client Management

Step 04-1

Detailed client information

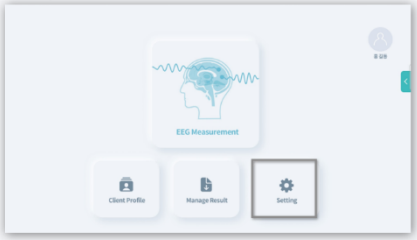


① Above is the [Detailed client information] after pressing [Edit] at the [Client Card] page
② Edit client information if neccesary
③ Press [Save] after the editing is completed.

IX. Setting

Step 01

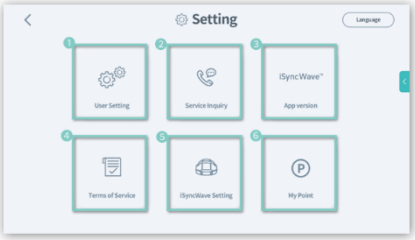
Main page



① Press [Setting] at the main page

Step 02

Setting

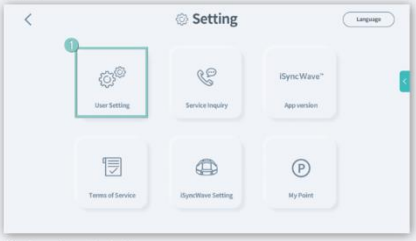


① Press [User Setting] to manage the registered user/supervisor of the account
② Press [Service Inquiry] to send general inquiries to our client support center.
③ Press [App version] to perform update and check current version of the application.
④ Press [Terms of Service] to review the service terms and condition of the iSy ncWave
⑤ Press [iSyncWave Setting] to customize settings for iSyncWave helmet device an d the application
⑥ Press [My Point] to check your currently points purchased/received

IX. Setting

Step 03

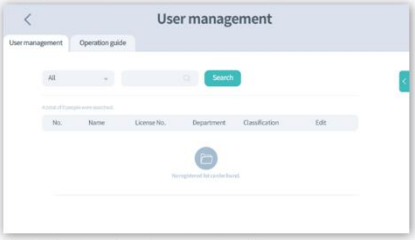
Setting



① Press [User Setting]

Step 03-1

User management

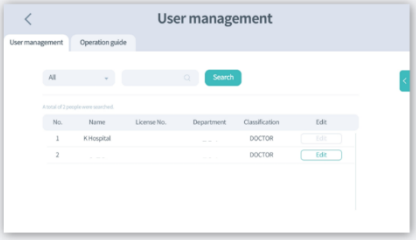


① Seach registered users by pressing [Search]
② The list of registered users will not show up until the [Search] function is activated

IX. Setting

Step 3-1

User management



① Above is the list of registered users using [Search]
② Press [Edit] to make adjustment on registered user if necessary

Step 03-1

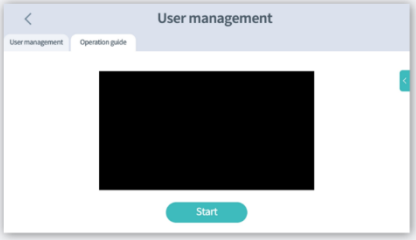
User Modification

① Above is the [User Modification] page after pressing [Edit]
② Edit [Department] if necessary
③ Edit [License No.] if necessary
④ Edit [Name] if necessary
⑤ Edit [email] if necessary
⑥ Delete a contact via the [Delete Contact] icon.
⑦ Press [Completed] after the adjustment is completed

IX. Setting

Step 03-2

User management



① Above is our [Operation guide] video for iSyncWave
② Press [Start] to watch the video

Step 03-2

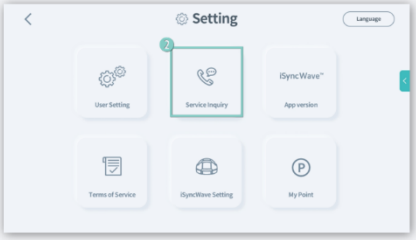
User management

① Watch iSyncWave operation guide video

IX. Setting

Step 04

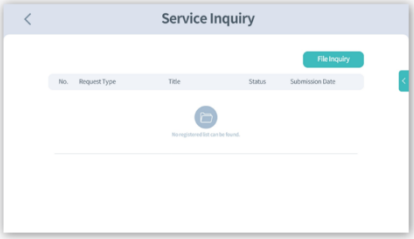
Setting



① Press [Service Inquiry] at the main page

Step 04-1

Service inquiry



① Above is the [Service Inquiry] page
② Press [File Inquiry] to submit your inquiries and concerns for review

IX. Settings

Step 04-1

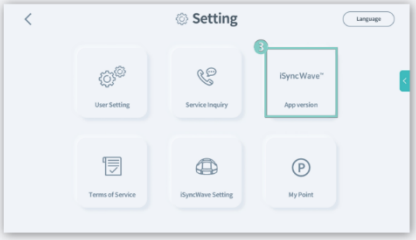
Service Inquiry

① Press [Please select] to choose category of your inquiry
② Enter the title of your inquiry at [Please enter the title.]
③ Enter the contect of your inquiry at [Content]
④ Press [Cancel] to stop writing your inquiry
⑤ Press [Submit Inquiry] to save and upload your inquiry

IX. Setting

Step 05

Setting



① Press [App version] at the main page

Step 05-1

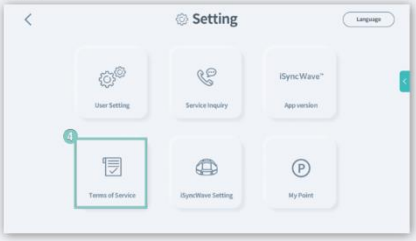
Application version information

① Above is the [App version information] page
② [Press [Update] to update the application to the current version

IX. Setting

Step 06

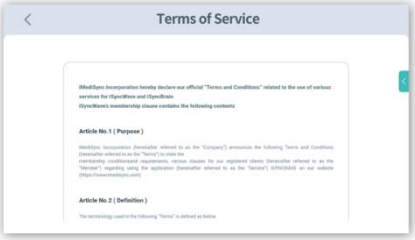
Setting



① Press [Terms of Service] at the main page

Step 06-1

Term of Service

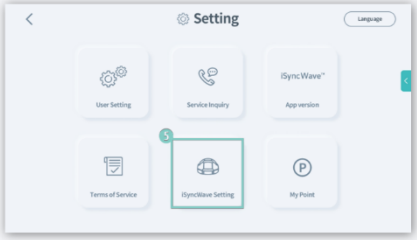


① Above is the [Terms of Service] page
② Scroll down and review the terns and conditions for iMediSync.

IX. Setting

Step 07

Setting



① Press [iSyncWave Setting] at the main page

Step 07-1

iSyncWave setting

① Above is the [Measurement time] adjustment page in the [iSyncWave Setting] main page
② Adjust the measurement length for [Eyes Closed]
③ Adjust the measurement length for [Eyes Open]
④ Adjust the measurement cycle for [Number of Cycles]
⑤ Press [Save] after all the adjustment is completed

IX. Setting

Step 07-2

iSyncWave setting

① Above is the [Register device] page
② Press [QR SCAN] to activate the QR scanning function
③ The serial number will be automatically generated after the QR SCAN
④ Click [Register] to register your device to our directory.

Step 07-2

iSyncWave setting

① Above is the QR SCAN page
② Automatically scan your device at the following page then proceed to device registr ation

IX. Setting

Step 07-3

iSyncWave setting

① Above is the [iSyncWave update] page
② Press [iSyncWave Connect] to sync your helmet device and application

Step 07-3

iSyncWave 설정

① Above is [Device connection for bluetooth] page
② Search your device by pressing the icon
③ Connect your device to the application after the search is completed
④ Press [EXIT] to go back to the main page

IX. Setting

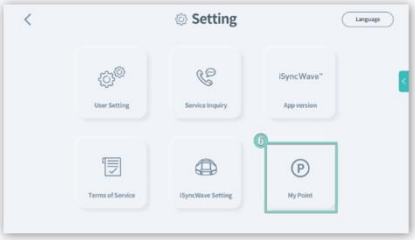
Step 07-4

iSyncWave 설정

① Above is the [Noise filter setting]
② An automatic noise filtering will be activated according to your country of residency
③ Press [Save] after adjusting your frequency (50/60Hz)

Step 08

iSyncWave 설정

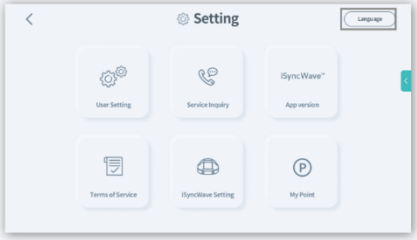


① Press [My Point] at the main page
② The following feature will be updated in our future maintenance

X. Language setting

Step 01

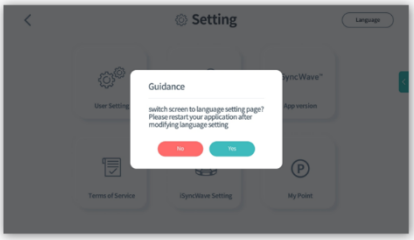
Setting



① Above is the [Setting] page.
② Press [Language] at the top right corner

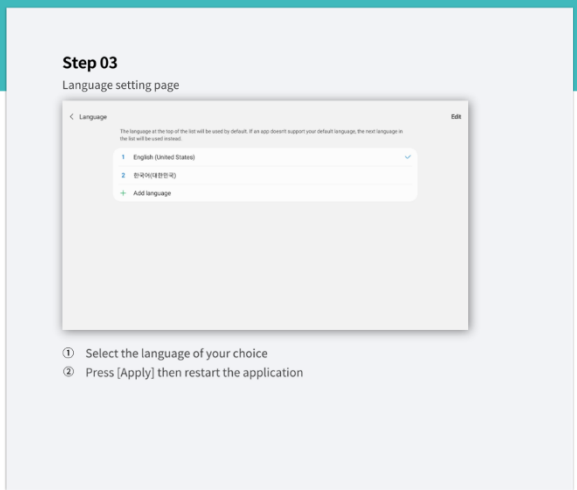
Step 02

Setting



① A [Guidance] message will pop-up before switching to language setting page
② Press [Yes] if you wish to proceed
③ Press [No] if you want to discontinue

X. Language setting



5.4 Putting on iSyncWave and Measuring EEG

1) Find a comfortable environment and position to measure EEG.
2) Go to the Settings page and set the measurement time.
3) Put on the iSyncWave device on patient/subject's head so that the electrodes are in good contact with the scalp. Put on the chin strap to secure the device.
4) Check for the electrode impedance on the iSyncWave app.
5) After checking the electrode impedance, start measuring EEG.

5.5 Shutting down iSyncWave

Press the power button and hold for more than 2 seconds to shut down the device.

5.6 Software Display

Horizontal Scale: (EEG scale test: 4seconds, EEG record: 5seconds)

* Horizontal Scale can't be adjusted

Vertical Scale: 20,30, 50, 70, 100, 150, 200, 300, 500, 700 μV

* Vertical Scale can be adjusted and selected

Montage: Ear reference, Common average reference, Longitudinal, Transverse

5.7 System message list

No	Popup Message	Causes of Popup	Required Action
1	The remaining battery is low. Please restart after recharging the device.	When the battery charging of iSyncWave(HardWare) is less than 10%	A user is recommended to charge the iSyncWave hardware before use of the device
2	The connection with iSyncWave has been lost. Do you wish to reconnect?	When bluetooth connection of iSyncWave(HardWare) with a tablet is lost	A user is recommended to bluetooth connect iSyncWave hardware with a tablet on the iSyncWave app
3	You have failed to upload. Please try again after checking your WI-FI connection	When upload of the Measured Data failed after a recording	A user is recommended to Wi-Fi connect with a tablet on the iSyncWave app
4	Update is required. Switch screen to update page?	When update version of iSyncWave application is released	A user is recommended to update iSyncWave app on Google app store.
5	The countries that are in reach of our automatic noise filtering service could enable the following function by turning on the GPS. Therefore, it doesn't require any additional adjustment.	When iSyncWave app try to find an appropriate line noise filter	The line noise filter is automatically set using GPS information. No action required.

5.8 Installing and Using the Battery

1. The battery life depends on how often the device is used, charge/discharge cycle, storage condition and operating temperature.
2. After being fully discharged, it takes up to 3 hours in room temperature to fully charge. The battery run time depends on how much battery is consumed. Given that the battery is fully charged, you can measure EEG for 6~7 hours. The battery is designed to last 250 charge/discharge cycles. If a slowdown in battery performance is observed, replace the battery by contacting the manufacturer or service center.
3. The battery is charged when you connect the USB-C charging cable with the device. When the device is in use, the battery will not charge. The LED indicator on the power button will be green when the device is charged more than 95% and magenta when charged less than 95%.

4. Disposal instructions

   To protect the environment, always follow the local law, rules, and policies of disposal instruction of electronics and batteries.

   USA: Lithium-ion batteries are classified by the federal government as non-hazardous waste and are safe for disposal in the normal municipal waste stream. These batteries, however, do contain recyclable materials and are accepted for recycling by Call2Recycle, Inc. Please go to their website at www.call2recycle.org for additional information.

   EU: In the European Union, manufacturing, handling, and disposal of batteries is regulated on the basis of 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 web site of the European Portable Batteries Association (http://www.epbaeurope.net/legislation_national.html).

6. Cleaning and Maintenance

The device shall be cleaned and disinfected as the electrodes and inner surfaces of iSyncWave come in contact the skin and hair.

Before cleaning, make sure the power of the device is turned off. If the power is on, hold the power button for 2 seconds to turn off the device.

CAUTION: Do not use ammonia or acetone to clean the device.

6.1 Outside Surface

1. Place the device facing down on a flat surface. Make sure the chin straps are released and out of the device.
2. Apply Isopropyl Alcohol on a soft towel and gently wipe the outside surface of the device. You can use a wet wipe instead of a soft towel.
3. Wipe down both sides of the chin strap with Isopropyl Alcohol.

6.2 Cleaning the Electrodes

CAUTION: Do not bend the bristles of the brush electrodes while cleaning.

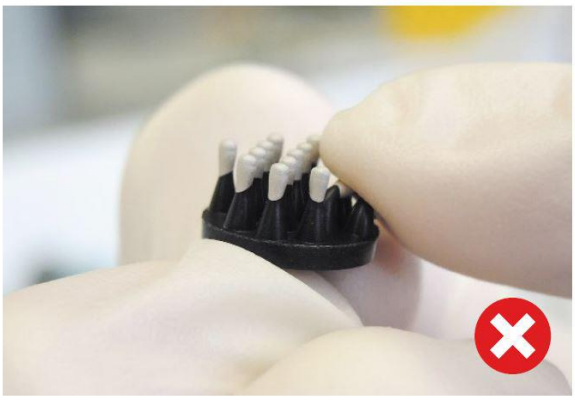
1. For brush electrodes: Gently brush the electrode using a soft brush(e.g., toothbrush or facial cleansing brush) slightly dipped in Isopropyl Alcohol.
2. For flat electrodes: Apply a small amount of Isopropyl Alcohol on a cloth or gauze and gently

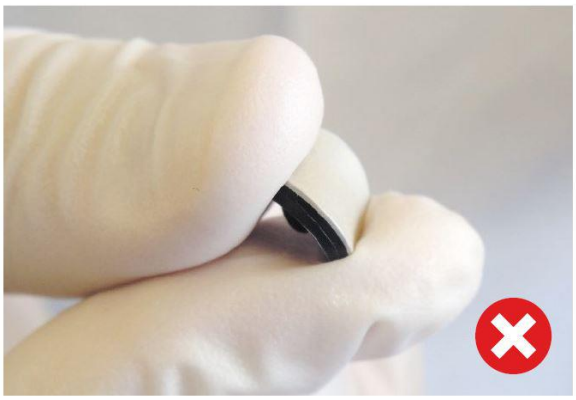
wipe the surface of the electrode.

3. Always clean and dry the electrodes after each measurement for the subsequent user.

6.3 Maintaining the Electrodes

1. If there is a channel with persistent signal quality problem, check the wear of the electrode.
2. Avoid excessively bending or applying force to the electrode bristles as it may cause wear, shortening the electrode lifetime.





6.4 Replacing the Electrodes

Replace the electrodes if the signal quality degrades, normally the electrodes can be used for about 200 tests. We recommend replacing the electrodes following the instructions below.

6.4.1 Removing the Electrodes

1. Put a flat-head screwdriver between the electrode and the metal holder and push upwards.	2. Push the screwdriver until the electrode is lifted.
3. Slightly pull the electrode with your hands.	

6.4.2 Installing the Electrodes

1. Place the electrode on the metal holder.	2. Push the electrode down using the provided pusher.

6.5 Essential Performance

Test Name	Test Method	Test Criteria	Test Period
Accuracy of signal reproduction	Measurement of the degree of reproduction after inputting a signal in the range of ±0.5 mV that changes at a speed up to 12 mV/s.	Reproduced within 20% error or +/- 10uV as a larger value.	Once a year
Dynamic input range and differential offset	When a DC offset voltage within the ±300 mV range and a differential input signal voltage of ±0.5 mV that changes at a speed of up to 12 mV/s are applied, measure whether the time variability output signal amplitude meets the test criteria throughout the range of the DC offset.	Less than 10 %	Once a year
Frequency response	The output from 0.5 Hz to 50 Hz is 71% to 110% of the output for the 5 Hz sinusoidal input signal.	0.5 Hz ~ 50 Hz	Once a year
Noise level	Connect all input channel with reference and measure the internal noise level for each channel.	Less than 4.0 μV	Once a year
Common mode rejection	Measure the output signal for each channel using power frequency signal of 1V 50/60 Hz as a input	More than 89 dB	Once a year

6.6 Maintaining and Storing the Device

1. Get the device inspected at least once a year by an authorized technician.
2. Store the device away from moisture, dust, and humidity.
3. Store the device in an isolated space safe from inclines, shocks, and vibrations.
4. Do not drop the device when storing.
4. Turn off, clean, and dry the device after every use.
5. Keep the device and the electrodes away from direct sunlight.
6. Keep the device out of reach of children.
7. Before using the device after a long time, check whether the device operates normally.
8. Do not store the device in an environment with extreme temperature changes, high temperature

and high humidity.

- Storage/Transport Temperature: -50 ℃ ~ 50℃
- Storage/Transport Humidity: 25% ~ 95% (Noncondensing)
- Storage/Transport Atmospheric pressure: 700hPa ~ 1060hPa
- Operating Temperature: 10 ℃ ~ 40℃
- Operating Humidity: 30% ~ 85% (Noncondensing)
- Operating Atmospheric pressure: 700hPa ~ 1060hPa

6.7 Transporting the Device

1. Turn off the device when transporting the device.
2. When transporting the device long distance, make sure to pack the device in a shock proof packing.

7. Compliance

7.1 Electromagnetic Compatibility-Guidance and manufacturer's declaration

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The ISW-MKR101 is intended for use in the electromagnetic environment specified below.
The customer or the user of the ISW-MKR101 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The ISW-MKR101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The ISW-MKR101 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The XD2000 PX is intended for use in the electromagnetic environment specified below. The customer or the user of the XD2000 PX should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5 cycles 70 %UT (30 %dip in UT) for 25 cycles <5%UT (>95%dip in UT) for 5 s	<5%UT (>95%dip in UT) for 0,5 cycle 40 %UT (60 %dip in UT) for 5,6 cycles 70 %UT (30 %dip in UT) for 25,30 cycles <5%UT (>95%dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ISW-MKR101 requires continued operation during power mains interruptions, it is recommended that the ISW-MKR101 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ISW-MKR101 is intended for use in the electromagnetic environment specified below. The customer or the user of the ISW-MKR101 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the iSyncWave, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ISW-MKR101 is used exceeds the applicable RF compliance level above, the ISW-MKR101 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ISW-MKR101. [b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the XD2000 PX			
The ISW-MKR101 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ISW-MKR101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ISW-MKR101 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	V1= 3 Vrms	E_1= 3 V/m	E1= 3 V/m
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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.

8. Product Warranty

8.1 Troubleshooting

Issue	Solution
App login error	Check Wi-Fi Settings
Bluetooth connection error	Restart the device and try again. If the error persists, contact the service center.
EEG measurement error	Restart the device and try again. If the error persists, contact the service center.
PPG measurement error	Reconnect the PPG sensor to the connector. If the error persists, contact the service center.
Wear of electrode Ag/AgCl coating	Replace the electrode(s).
Increased charging time of battery	Inspect and/or replace the battery through the service center.
Decreased device run time	

8.2 Warranty Claim

Contact the service center if you are unable to resolve the issue after reviewing the user manual.

8.2.1 Warranty Coverage

1. The warranty provides at no extra cost to the user.
2. The device is warranted for a period of 1 year.
3. The device is warranted for the functional or performance defects arising when used for normal purposes in accordance with the user manual. (The wear of Ag/AgCl coating of electrodes is not covered under the warranty.)
4. If an identical defect of the same product occurs within 6 months after being repaired by authorized personnel and has been used normally, the repair will not be charged.

8.2.2 Warranty Exclusion

The warranty is not applicable in any of the following cases and is subject to charged repair:

1. Expiry of warranty period and/or inability to check warranty period
2. Failure or damage caused by user's negligent use, neglect, or careless operation of device
3. Failure caused by use of device not in accordance with the user manual
4. Failure or damage caused by using electricity of unauthorized voltage
5. Failure caused using parts, accessories or consumables that are not approved by the manufacturer
6. Product or its parts has been arbitrarily removed, altered, modified, damaged
7. Product has been serviced and/or repaired by unauthorized personnel that is not designated

by the manufacturer

8. Service fee may apply for services irrelevant to product defects(e.g., product training, irregular inspection, Bluetooth or Wi-Fi connection problem due to external environment, cleaning the insides of the device, defect due to using third-party products and/or software) regardless of the warranty period.

※ Repair and service may be denied in any of the following cases

1. Unable to perform repair or provide service due to the user's intention and negligence
2. Unable to replace or repair due to discontinuation of parts after the warranty period
3. Damage resulting from a force majeure event such as fire, explosion, storm, flood, earthquake, or other natural disasters
4. Removal, obliteration, or alteration of identification labels(model number, serial number etc.) of the product

8.3 Warranty Period

1. Warranty period refers to the period which the manufacturer or authorized seller is obliged to repair the quality, performance, functional defects from normal use for free.
2. The warranty become effective at the date of purchase. Please retain the product warranty card or the proof of purchase. If you do not have your warranty card or proof of purchase, your warranty will start 90 days after the date of manufacture, according to the manufacturer's records.
3. The warranty is confined to the first purchaser of the product at an authorized dealer.
4. The warranty is not applicable to second-hand products or products purchased from a unauthorized dealer. The manufacturer will not be responsible for the compensation of damage for the repair and service of those products.
5. The warranty for products delivered under a separate contract with the manufacturer follows the contents of the contract.

8.4 Warranty Card

Warranty Card
Product Name: **Model Number:** **Serial Number:** **Date of Purchase:** **Place of Purchase:** **Warranty Period: 1 year from date of purchase** **Client Name:** **Organization:** **Phone Number:** This is to certify that this device has passed the strict quality control and comprehensive inspection.

FCC Compliance Statement

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

FCC Interference Statement

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from which the receiver is connected. • Consult the dealer or an experienced radio/TV technician for help.

FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 5 mm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

IEEE 802.11b or 802.11g operation of this product in the USA is firmware-limited to channels 1 through 11