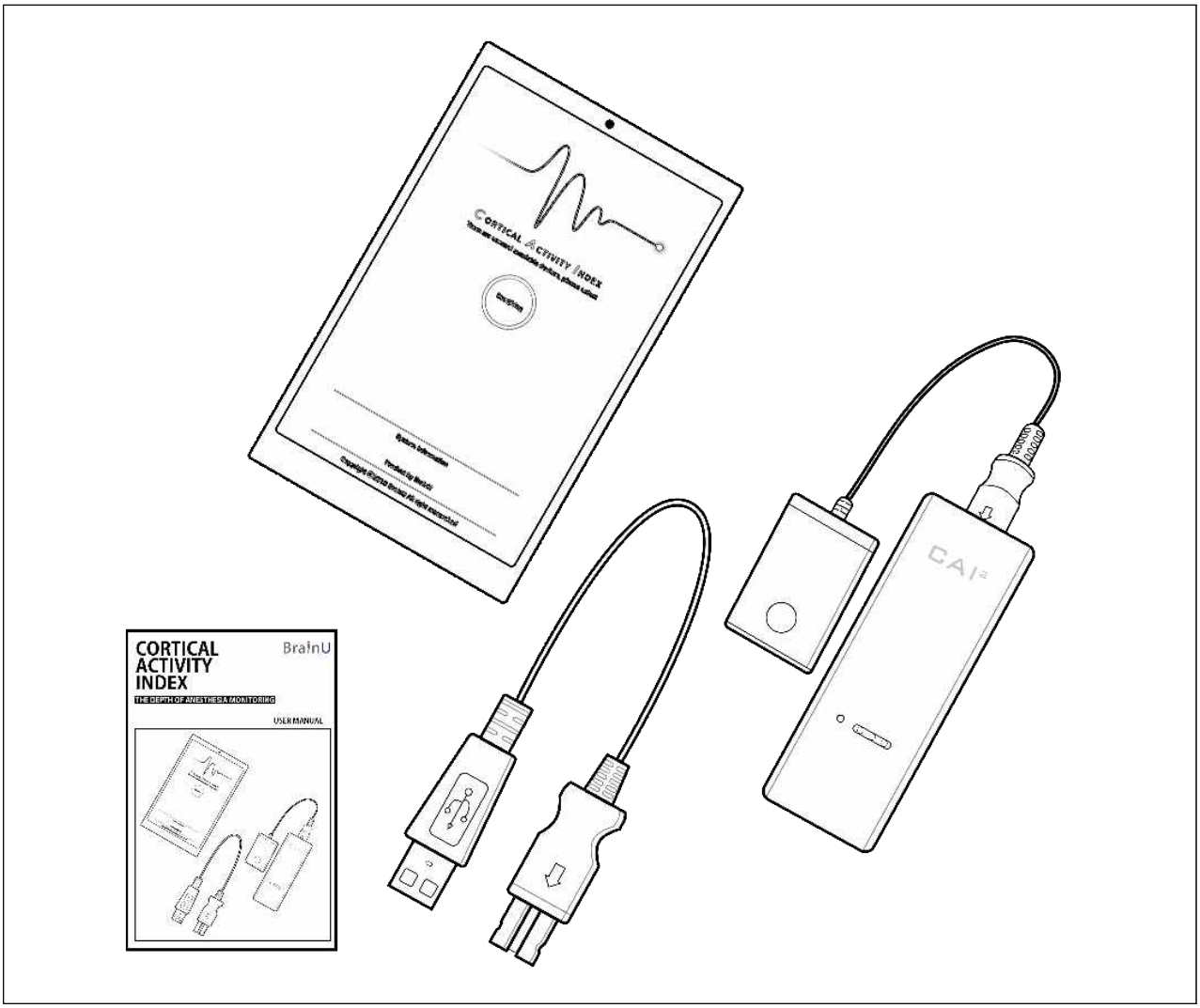
CORTICAL ACTIVITY INDEX

THE DEPTH OF ANESTHESIA MONITORING

BrainU

CAI+ *Instruction for Use*



IFU-01

Ver 1.0.0

2023.08.09

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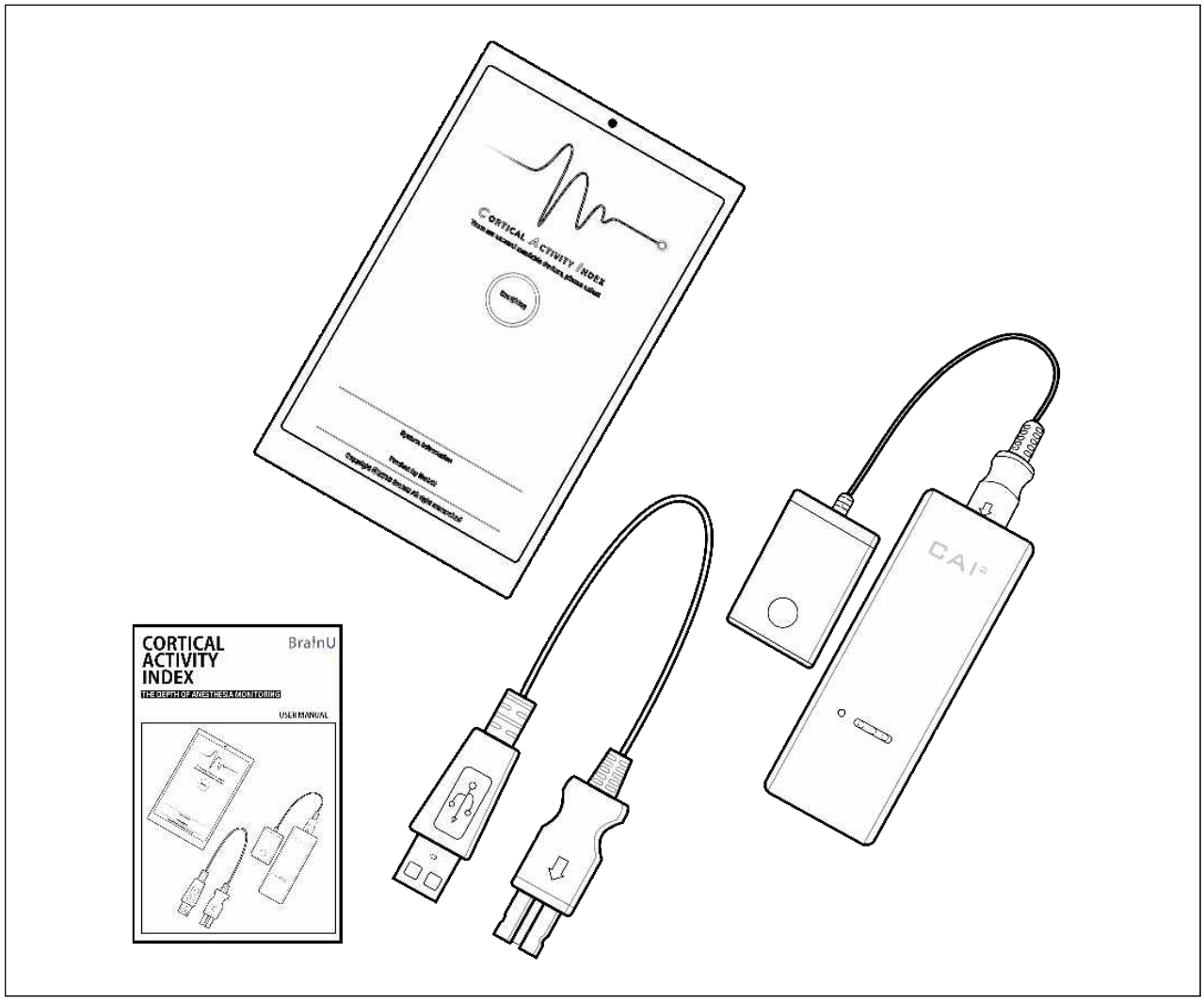


IFU-01

Ver 1.0.0

2023.08.09

Contents

I. Introduction of CAI+

A. Product description

CAI+ is a system that records electrical activity signals in the brain by attaching more than one electrode to the patient's head, and is a medical device that provides medical staff with information on the patient's level of consciousness during surgery.

1. Scope

I t e m	Depth of Anesthesia Monitoring System	**Rating**	Class 2
Model name	CAI+		
Manufacturer	BrainU Co., Ltd.		
Country of Manufacture	Republic of korea		

2. Manufacturer information

1) Manufacturer : BrainU Co., Ltd.

2) Address : 3F, 7, Yatap-ro 105beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea (13506)

3) Customer Service
   (1) TEL : 031-707-1788
   (2) e-mail : support@brainu.co.kr
   (3) Website : eng.brainu.co.kr/

3. CAI+ Monitoring System Overview

CAI+ is a system providing patient's consciousness level through their brainwave analysis during surgical procedure to medical staffs, and the system comprises with CAIs-Sensor (brainwave sensor), CAI+ Main Body (amplification module), CAI+ algorithms for calculation and analysis and Tablet.

CAI+ Monitoring System, which has capability of setting various conditions, is designed to monitor anesthetic state of brain by collecting and analyzing brainwaves.

CAI+ Monitoring System provides digitalized information through operational processing of unprocessed EEG signals. This processed information, which is called arousal index (AI) or CAI index, is closely correlated with arousal degree of a patient.
Users can change data indications and review stored data via menus on the touch screen display.

Intended propose of CAI+ Monitoring System

CAI+ Monitoring System is a device that records and analyzes the electrical signal activity of the brain by attaching two or more electrodes around the patient's forehead, indicating the degree (severity) of anesthesia to prevent medical accidents such as over-sedation and awakening during surgery.

It helps not only patient to be balanced-sedated but also hospital to use the minimum possible amount of drug. It makes it possible to monitor real-time depth of anesthesia in an operation room.

CAI+ Monitoring System provides following information.

- Present CAI Index
- Trend graph of CAI Index
- Real time unprocessed EEG waveform graph
- Various signal performance indexes (EMG, SQI)
- Burst Suppression Ratio (BSR)
- Warning index and message

※ CAI = Cortical Activity Index

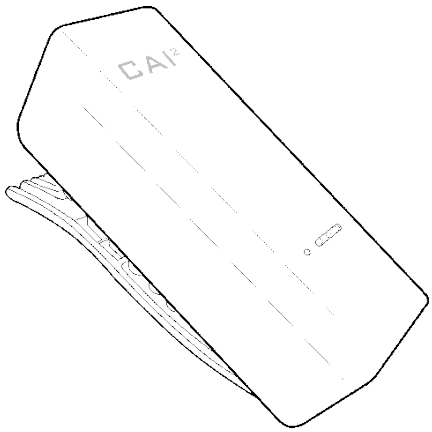
4. CAI+Monitoring System's key features are as follows:

- Miniaturized device
- wireless communication with Bluetooth
- Vital signal collection through CAIs Sensor comprising 4 electrodes
- User centric UI/UX design to facilitate accessibility
- Application control through simple touch
- Numeric indications customizable by users

B. CAI+Monitoring System's Basic Configuration

No.	Part name	Description
1	CAI+ Main Body	A device that amplifies and transmits brain waves after monitoring signals.
2	CAI+ Application	Software with Algorithm
3	Sensor Cable	Cable connection between CAIs sensor and CAI+ Main Body * Length : 1.0 m ~ 1.5 m
4	CAIs Sensor	A Sensor that collects brain waves by attaching them to a patient's forehead.
5	Snap Electrode	Consist of 2 channel EEG, GND, ref and Use with Disposable Electrode
6	Disposable Electrode	Connect to Snap Electrode for use.
7	Instruction for Use	the user manual for CAI+
8	Adapter	Power supply cable for CAI+ Main Body * Length : 1.5 m ~ 2.0 m
9	Monitor (Tablet)	A display device for CAI+ application to run

1. CAI + Main Body



< CAI+ Main Body >

CAI+ Main Body is A device that amplifies and transmits data in real time brain waves after monitoring signals.

CAI+ Main Body has a amplification module that amplifies vital signs and a communication module.

CAI+ Main Body has a 3.7 V, 2000 mAh Li-Polymer battery with terminals for sensor cabling and charging.

2. Monitor(Tablet) / CAI+ Application

< Monitor(Tablet) / CAI+ Application>

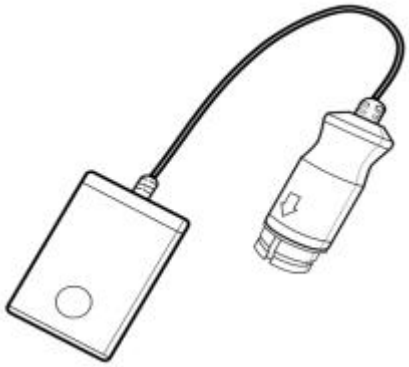
CAI+ Application that displays EEG signals processed by CAI+ Main Body on the monitor(tablet).

CAUTION	The monitor (tablet) is a dedicated CAI+ Application device. Do not use it for any other purpose. Prohibit the installation of unknown or unnecessary applications. The user is responsible for the prevention and management of malicious codes and viruses for the above.

This equipment can be affected or affected by electromagnetic interference when used in close proximity to other devices.

REFERENCE	CAI+ must be used in accordance with IEC 60601-1-2 electromagnetic compatibility requirements.

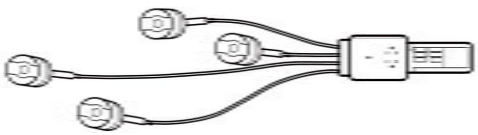
3. Sensor Cable



< Sensor Cable >

A cable that is connected to CAIs Sensor or Snap Electrode to pass data collected from CAIs Sensor (or disposable electrode) to CAI+ Main Body.

4. Snap Electrode

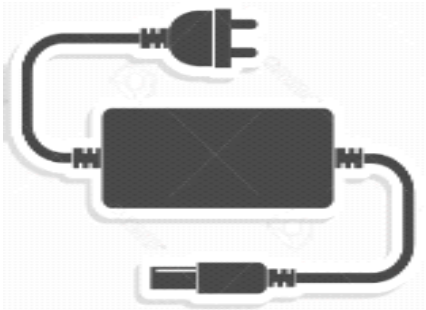


< Snap Electrode >

Snap Electrode for single-use electrodes.

CAUTION	CAIs Sensor and Snap Electrode are dedicated components of CAI+ that connect to Sensor cable. Do not connect this to products other than CAI+ Monitoring System. Do not apply excessive force to Senson cable. If excessive force is required, check the connection connector. If disconnecting the product, hold and disconnect the connector. Pulling the cable line may damage the cable.

5. Adapter / Cable (for CAI+ Main Body)



< Adapter / Cable >

< Rating of Adapter >

protection classes	class 1
Input	100 – 240 V, 50-60 Hz, 0.5 A
Output	DC 5 V, 2.0 A

WARNING: To avoid the risk of electrical shock, this device must only be connected to a supply with a protective earth

This is the power adapter/cable to power CAI+ Main Body. please Connect the power adapter/cable to the charging terminal of CAI+ body. You can check the battery level of CAI+ Main Body through the LED on CAI+ Main Body.

CAUTION

Do not connect this to products other than CAI+ Monitoring System.

Do not use impacting force to the charging terminals when connecting components. If force is required, check the condition of the charging terminal on CAI+ Main Body.

When disconnecting the product, hold the connector part and disconnect it. Pulling on the cable line may damage it.

Be careful not to place the ME device in a place where it is difficult to unplug the adapter.

6. Instruction for Use

< Instruction for Use >

User manual with instructions for how to use CAI+.

CAUTION

Users must carefully and thoroughly read the safety management information described in this instruction manual and be aware before setting and using CAI+Monitoring System.

7. CAIs Sensor

< CAIs Sensor>

CAIs Sensor is a sensor that collects brain waves by attaching them to a patient's forehead. CAIs Sensor consists of 4 electrodes. When connecting CAIs Sensor and Sensor cable connected to CAI+ Main Body, CAI+ Main Body powers on.

CAUTION	CAIs Sensor is a disposable product. After use, CAIs Sensor must be disposed of*. * Dispose of according to your hospital's waste disposal protocol. How to use CAIs Sensor is described on CAIs Sensor packaging. Please read and use it.

8. Disposable Electrode

< Disposable Electrode>

Disposable Electrode is a Sensor that is attached to the patient's forehead to collect the patient's EEG signals. Each of the 4 electrodes must be attached to Snap Electrode.

CAUTION	Disposable Electrode is a disposable product. After use, Disposable Electrode must be disposed of*. * Dispose of according to your hospital's waste disposal protocol. For instructions on how to handle and use disposable electrodes, please check the user's manual for the product you are using.

C. CAI+ Monitoring System Specification

1. CAI+ Monitoring System Specification

No.	SPECIFICATIONS	QUALITY
1	Channel number	2 Channels
2	Measurement type	Mono polar
3	Input amplifier range	± 393 μV_p
4	Input noise	2 μV_{RMS}
5	CMRR	- 105 dB
6	Bandwidth	0.5 Hz ~ 110 Hz (-3 dB)
		45 Hz ~ 65 Hz Notch (-3 dB)
7	Resolution	15 bits
8	Sampling rate	250 Hz
9	Battery Backup	Lithium Polymer Battery 3.7 V / 2000 mAh
10	Monitor OS	Android

2. Wireless (Bluetooth) Specification

Model name	CAI+
Output	6 mW
Available service of range	10 m
Frequency	2402 ~ 2480 MHz
Notice	
"This wireless device has possible electric signal interference during operation." "Due to possible electric signal interference, this wireless device cannot provide human life safety related service."	

3. Operating Frequency Range & Transmit Power

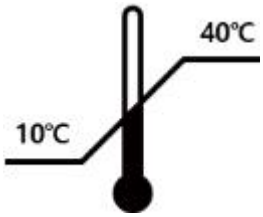
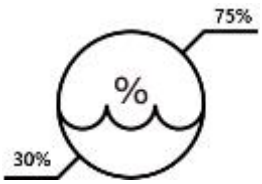
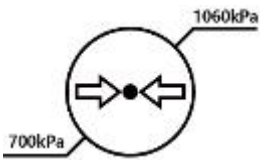
Frequency range	Output power (MAX.)
2402 MHz ~ 2480 MHz	+ 8 dBm

4. Antenna Gain

Antenna gain	0.6 dBi

D. Use Environment

1. Use Environment

Index	Temperature	Humidity	Atmospheric pressure
Condition			

CAUTION

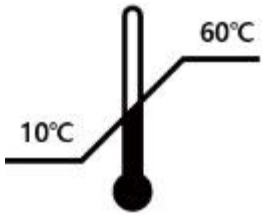
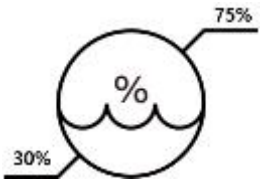
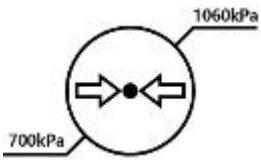
Any environment other than the above conditions may affect the reliability of the product. Pay attention to management

CAI+ is prohibited from being using in locations in places where flammable gases or vapors are present.

REFERENCE

It is recommended that CAI+ be permanently installed in anesthesia device to improve the safety and ease of use. However, if the site conditions are difficult to install permanently, you can use tongs to fix it.

2. Storage Environment of Device

Index	Temperature	Humidity	Atmospheric pressure
Condition			

CAUTION

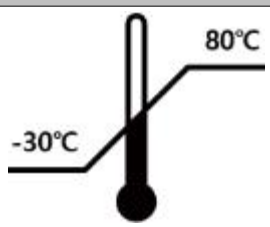
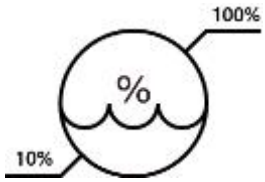
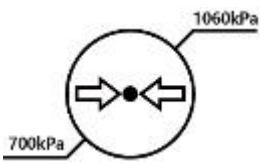
Carry out periodic battery checks for emergency use. In addition, it must be stored with the equipment powered off.

CAI+Monitoring System and CAIs-Sensor should be protected from sudden temperature changes and used after maintaining temperature and humidity similar to ordinary condition.

As adhesiveness of CAIs-Sensor may vary depending to seasonal changes, it is recommended to store them in same temperature conditions.

Do not store them in any place with metal, magnets or place affected by magnetic power.

3. Shipping Environment of Device

Index	Temperature	Humidity	Atmospheric pressure
Condition			

REFERENCE

To ensure reliable transportation, It is recommended that batteries be discharged before shipping . In addition, equipment should be transported with power off.

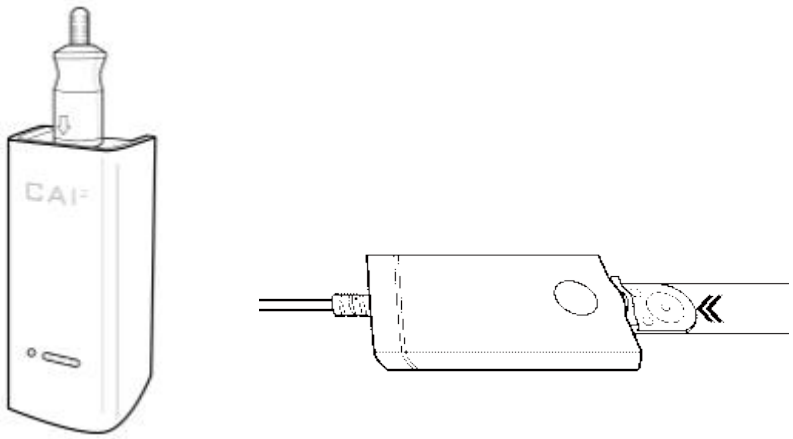
The batteries in CAI+ use certified batteries that meet the shipping conditions.

II. Operation Method of CAI+ Monitoring System

A. Preparation before use

1. Turning on CAI+

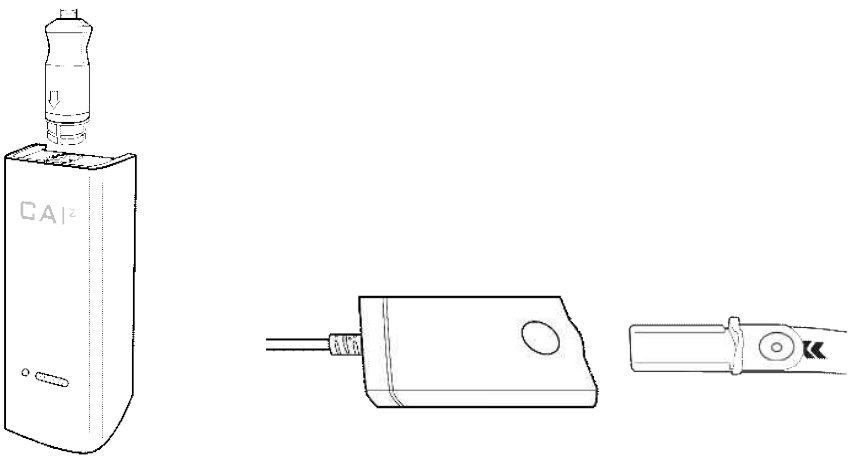
CAI+ Main Body turns on when you connect Sensor cable connected with CAIs Sensor (or Snap Electrode) to CAI+ Main Body connector.



< Turning on CAI+ Main Body >

2. Turning off CAI+

Disconnecting CAIs Sensor(or Snap Electrode) from Sensor cable connected to CAI+ Main Body will turn off the power.

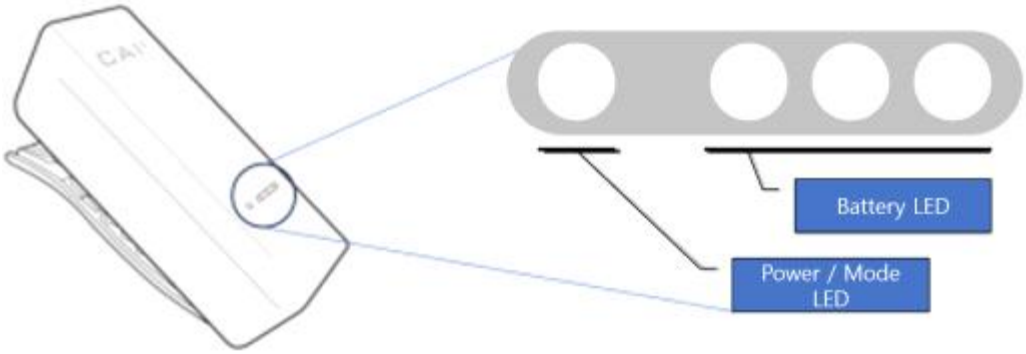


< Turning off CAI+ Main Body >

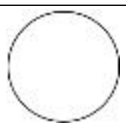
3. Power / Battery / Mode LED

1) CAI+ Status LED

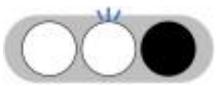
CAI+ Main Body has two LEDs for status indication. There is one power/operation status LED and three battery status LEDs, as follow.



(1) Turn On/Off / Operational Status LED

led indicator	 (-)	 (White LED)	 (Blue LED)
Turn On/Off State	Turn Off	Turn On	Turn On
Operational State	-	Standby Mode	Monitoring mode

(2) Battery Status LED

led indicator				
battery level	33% or less	34%~66%	67% ~ 100%	full battery charge

2) How to charge CAI+ Main Body

Connect the power adapter/cable to CAI+ Main Body charging port.. The status during charging can be confirmed by the number of 3 White LEDs ON. Due to the nature of the circuit, the remaining amount of LED display during charging may not match. (However, when fully charged, the LED display matches)

< CAI+ Main Body state of charge>

3) How to charge Monitor(Tablet)

Tablet, a universal display image device, can be used by connecting power cable when charged battery remain is insufficient.

When the battery level of CAI+ Main Body is below 10%, "Low Battery power (Tablet)"alarm occurs.

REFERENCE

In the top status bar of CAI+ Application, It is possible to check Serial number and battery remaining of CAI+ Main Body).

In the top status bar of CAI+ Application,It is possible to show battery remaining, charging state and current time of Tablet.

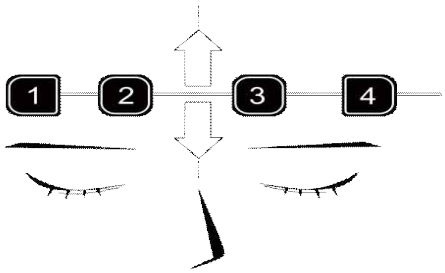
< CAI+ Application top status bar >

4. Attaching CAIs-Sensor

* How to use CAIs Sensor is described on CAIs Sensor packaging. Please read and use it.

Step 1: To obtain brainwave and electromagnetic waveform, attach 4 electrodes to human body.

Step 2: Attach channel (2) on the center of forehead and attach channel (1) and channel (3) on both side of the channel (2). And attach channel (4) on the right side of forehead, a little upper to the temple.
Attachment site of each electrode is shown in below figure.



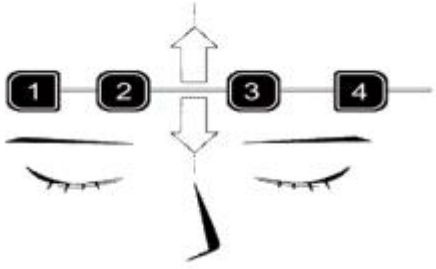
< Example of CAIs-Sensor Attachment >

5. Attaching Disposable Electrode

* For instructions on how to handle and use disposable electrodes, please check the user's manual for the product you are using.

Step 1: Attach Disposable Electrode to Snap Electrode

Step 2: Attach channel (2) on the center of forehead and attach channel (1) and channel (3) on both side of the channel (2). And attach channel (4) on the right side of forehead, a little upper to the temple.



< Example of Disposable Electrode Attachment >

B. Connecting CAI+

CAIs Sensor and Sensor cable should not be in contact with any other conductive components including conductive material and ground connection.

When using high frequency surgical device, CAIs-Sensor electrode should not be located between operation site and electrical surgical device return electrode.

When using brain stimulation device (ex: brain current evoked potential motor), CAIs-Sensorshould be located as distant as possible to reduce risk of burning and make for the sensors to be attached according to attachment locations illustrated on the sensor package.

CAIs-Sensor and Sensor cable should be located in a stable site to avoid discomfort of patients.

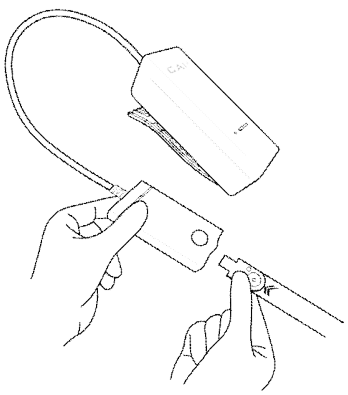
1. Connecting Sensor

* For details, please check the manual of CAIs Sensor (or disposable electrode) before use.

Step 1: After connecting CAI+ Main Body and Sensor cable, Place the front side of CAIs sensor (side with sensor drawing) upward.

Step 2: Insert CAIs-Sensor into CAIx connector until "click" is heard.

Step 3: Check the instruction indicated on the package of CAIs-Sensor and attach CAIs sensor to connection and body area (forehead) firmly as not to be detached.



< Connecting Sensor >

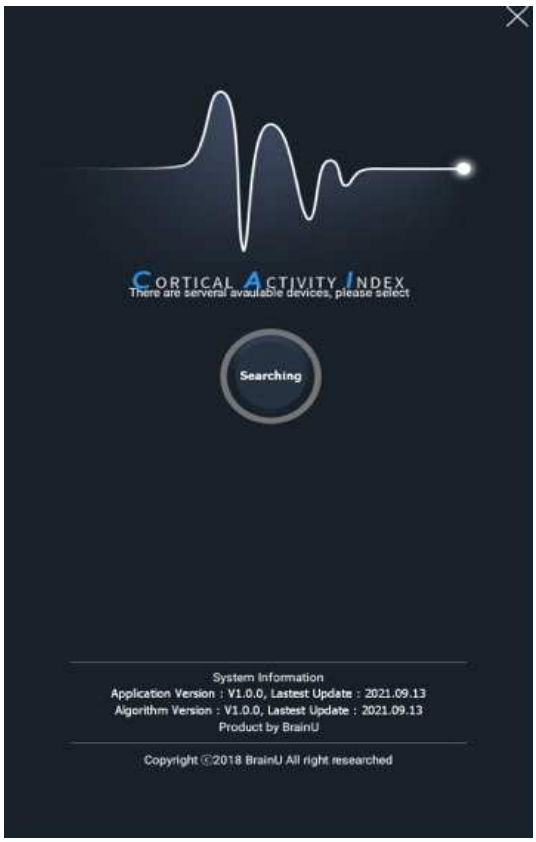
2. Booting system/connecting CAI+/checking CAIs-Sensor

When booting of CAI+Monitoring System is completed, an anesthetic depth measuring application executes automatically. When the application is executed, Bluetooth connection is to be displayed as shown in below figure.

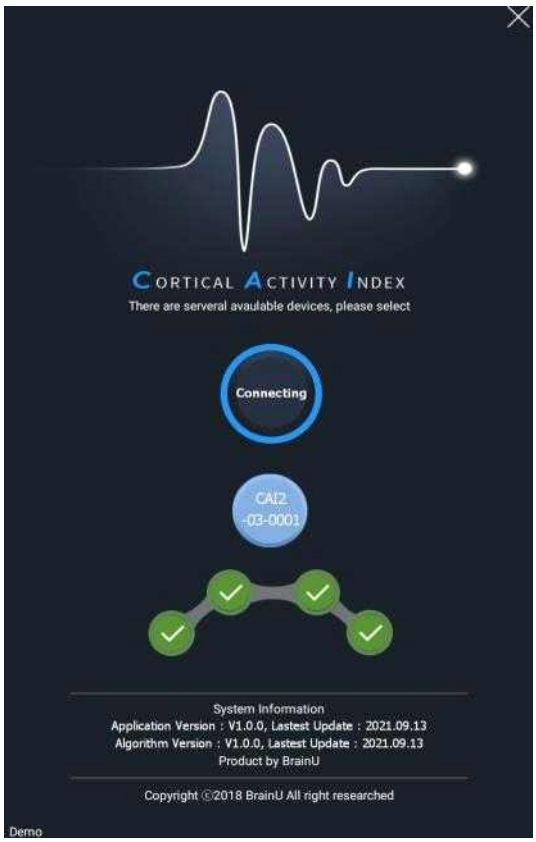
When a single amplifier is searched in device's search of Bluetooth, sensor check is started.

If more than 2 amplifiers are found, it will be displayed as shown in <Home> so that you can select an amplifier, and selecting an amplifier will start sensor check.

※ Bluetooth connection code: 1234



< Launch screen >



< Home >

3. Sensor Check

To execute CAI+ Monitoring System, check all sensors whether each CAIs sensor electrode(or Disposable Electrode) has a resistance value within reliable range. For sensor inspection, self-check is run on the system automatically or sensor check can be initiated by touching [Sensor Check] icon.

When the sensor inspection was not passed immediately or when users initiated sensor inspection manually, a sensor figure is displayed. On the sensor inspection screen, electrode number distinguished by colors representing each electrode will be displayed and status of each electrode will also be displayed

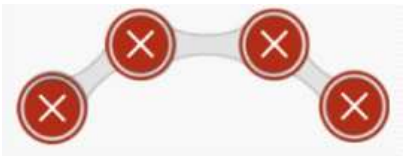
① When resistance of the electrode is within the proper range.

When all electrodes pass the inspection, monitoring will be started automatically.

② When resistance of the electrode is not within the proper range.

In this case, the user should firmly push down the adhesive pad on each electrode of CAIs Sensor attached to the patient Followed by pushing the center of each electrode down for about 3 seconds.

If the problem was not improved, detach CAIs-Sensors from forehead and reattach them to the patient after removing oily and contamination materials, or reattach new sensors according to assigned locations for attachment.



< Sensor Check Icon>

C. How to use

1. Displaying CAI index data

When the sensor inspection is completed successfully, monitoring starts automatically and relevant information is displayed on the screen.

< Main screen >

1) Calculation method

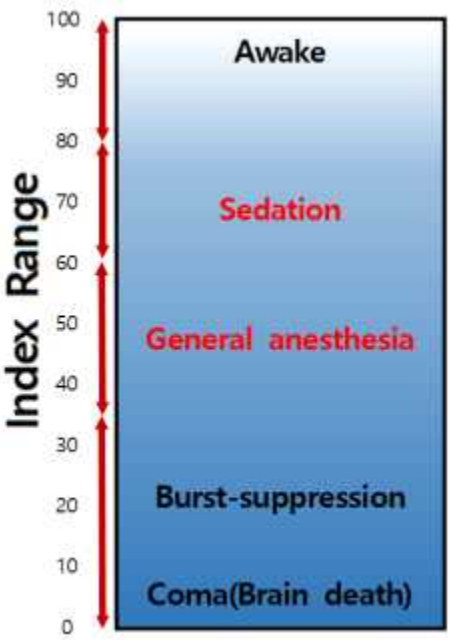
CAI+calculation method is to create index based on combination of 4 energy frequencies, offset EEG suppression ratio (BSR, Burst Suppression Ratio), and operate final CAI index.
CAI+Monitoring System calculates brain activity values within the range of 0.5 Hz ~ 110 Hz
Brain activity is calculated by measuring brainwave value above a certain level by dividing measured brainwave into certain time.
Considering the time continuity of the EEG, configure the Epoch Window and proceed with the operation. In addition, the EMG signal is calculated by separating the signal of 45 Hz ~ 65 Hz.

2) CAI index value (range: 0-100)

CAI index is obtained by processing continuous EEG parameters and it is associated with anesthesia level of patient. For example, CAI index shows relevance with gradual reduction of awakening degree and increase of anesthetic depth. CAI index is designed to trace effect variation of anesthetic medicine acting on patient brain and have relationship with its awakening degree.

CAI index should not be utilized as the only indicator to control anesthetic medicine dosage. In most individuals, awake state persists when CAI index is over "80", however in specially calm and sedate individuals, awake state may be observed even when CAI index decreases to as low as "60".

Below table shows relationship between CAI index and clinical state of patient.



< CAI Index Range >

3) Signal sensitivity index (SQI, range 0 - 100)

Signal sensitivity index is measured by signal sensitivity of EEG and calculated on the basis of resistance, intervening element and other parameters. Signal sensitivity index is indicated as a 'Bar' form and located on the upper right of the display screen

4) Electromyogram (EMG, range 0 - 100)

CAI Monitoring System contains a filter that can filter most of internally expected EMG intervening elements. EMG energy is in 80 - 130 Hz of frequency band and displayed on the Top right of screen. EMG activity may be increased in below cases during a surgical operation.

· Response to painful stimulus during operation.
· Body movement or muscle spasm

EMG window should be checked often and must check the EMG window when CAI index value is increased suddenly.

When CAI index increases simultaneously with muscular movement, it is likely that EMG will cause interference. When these phenomena occur, special attention should be taken to clinical signals of patient during operation

5) Electroencephalogram (EEG) indication

EEG activities are displayed in various scales.
Users can set them in 25 *μV*, 50 *μV*, and 100 *μV* on EEG setup window.

6) EEG suppression ratio (BSR, range 0 - 100%)

EEG suppression ratio (BSR) is a parameter induced from EEG and developed typically in deep anesthetic state. This phenomenon indicates frequency of situation when the signal is suppressed with equipotential brainwave for 16s in percentage

7) DSA (Density Spectral Array)

As a method of visualizing frequency changes over time, it is an index used to understand the distribution of frequency bands.

8) SEF (Spectral edge frequency)

SEF is the frequency with power values in the upper 90% or higher over the entire frequency range.

9) Poor signal detection

CAI+Monitoring System is designed to provide only highest reliable data and therefore. CAI+Monitoring System is designed and composed to exclude poor signals from general operation of the device.

10) Trend graph

Graph composition of trend graph shows changes of CAI index over time.
trend is indicated with bold "white" line and its scale is indicated on the left 'X' axis.

When the target range of CAI index values is set, the target range is displayed on the screen in one of 2 methods. The target range is a colored "line" format or a mode to set up the lowest and highest values.

When intending to indicate other index values, users can do it by select "BSR", "EMG", or "SQI", "SEF", DSA" on the upper left screen of trend graph.

When sensitivity of signal is unstable, the 'Artifact' message will be displayed on the message screen, especially, in cases, where the "SQI' value decreases to less than "10" correspond to this situation

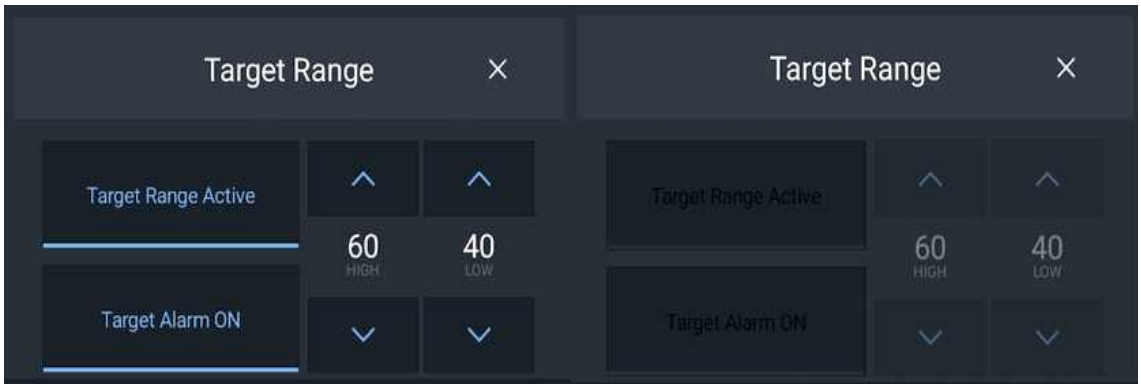
2. Main touch menu

On the screen, CAI+Monitoring System composed 4 shortcut menu at the bottom of the screen to control main functions with a single touch while monitoring patient to provide convenience to users.

< Main Screen>

1) Target Range

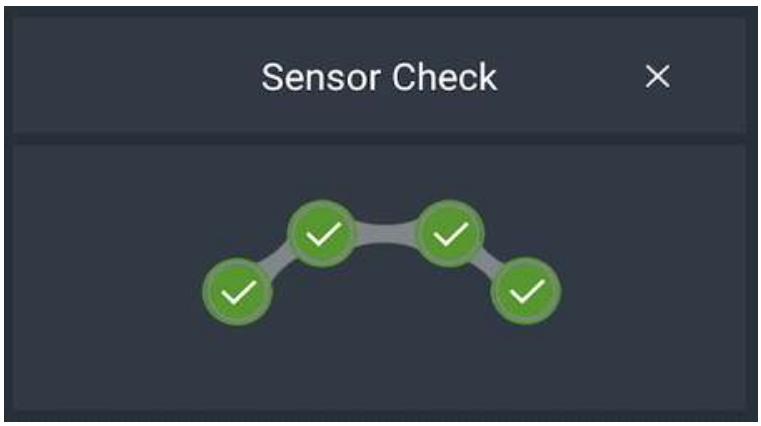
When Target Range Activate is turned on, pop-up alarm will output when values go outside of target range



< Target Range ON > **< Target Range OFF >**

2) Sensor Check

Checks current state of sensor attachment.



< Sensor Check >

3) Exit

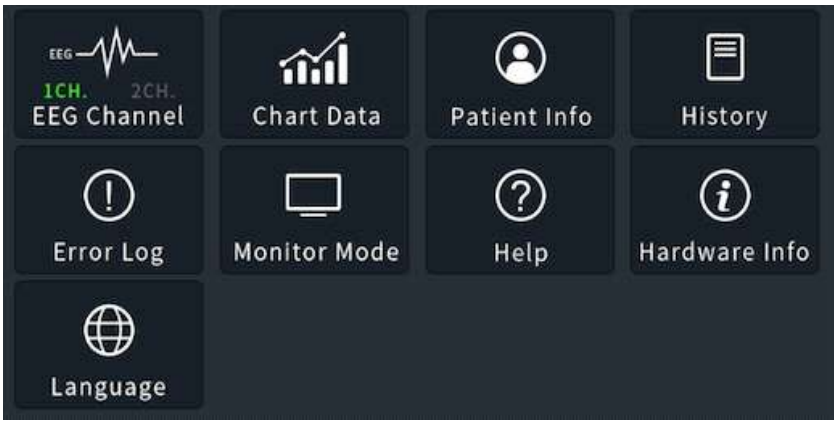
A pop-up window will be activated asking you to exit CAI+ application or save separate A/S data.

< Exit Pop-up>

Icon	Function
Standby	Disconnect from CAI+ Main Body and re-search CAI+ Main Body that can be connected. (move back to loading screen.)
Exit	Terminates CAI+Monitoring System completely.
Cancel	Close the pop-up window
A/S	Save data to AS_DATA file separately

4) Drag menu

Drag the bottom of CAI+ application up to be displayed a menu with add-ons available above. As CAI+Monitoring System has various functions, users should read this manual thoroughly prior to usage



< Drag menu >

(1) EEG Channel 1CH / 2CH

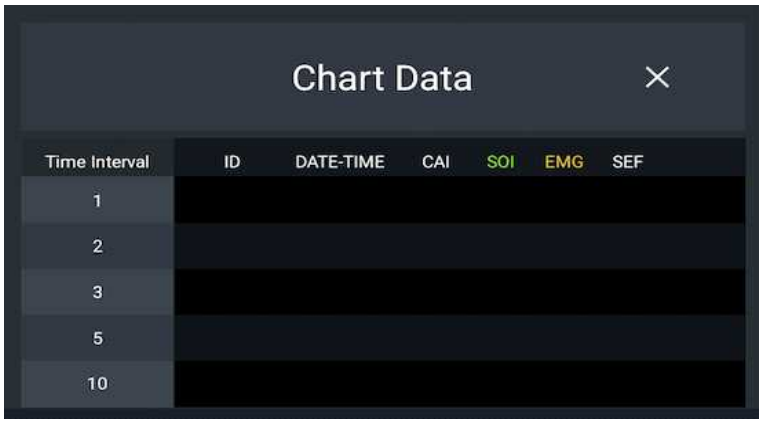
Selects either EEG channel 1 or EEG+EMG, or both of them simultaneously and displays on the main screen

< EEG Ch1 >

< EEG Ch1, Muscle movements Ch1 >

(2) Chart Data

Saves BIS, SQI, and EMG values at every interval time. Interval Time can be set as 1, 2, 3, 5, and 10 min. Initial default value is set as 3 min.



< Chart Data >

(3) Patient Info.

Inputs and saves information of patient under operation.

< Patient Info. >

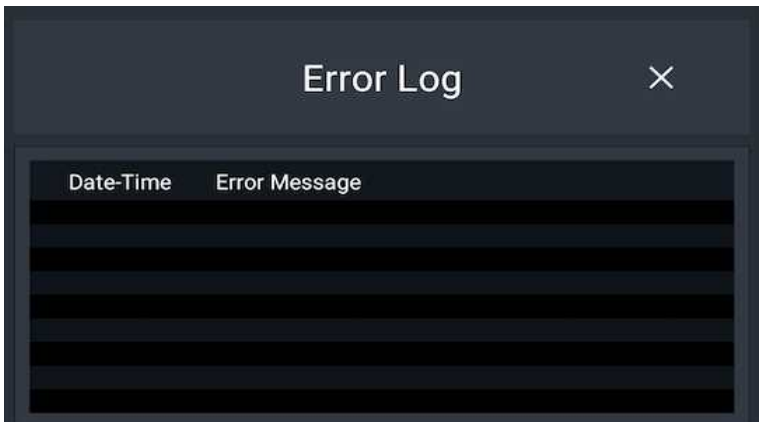
(4) History

Shows a list of files saved during past surgeries. Saved files are saved in the Export data folder.

< History >

(5) Error Log

When an error occurs on CAI+Monitoring System, the log can be checked.



< Error Log >

(6) Monitor Mode

Current setup conditions including Target Range (Min/Max) and more can be checked.

< Monitor Mode >

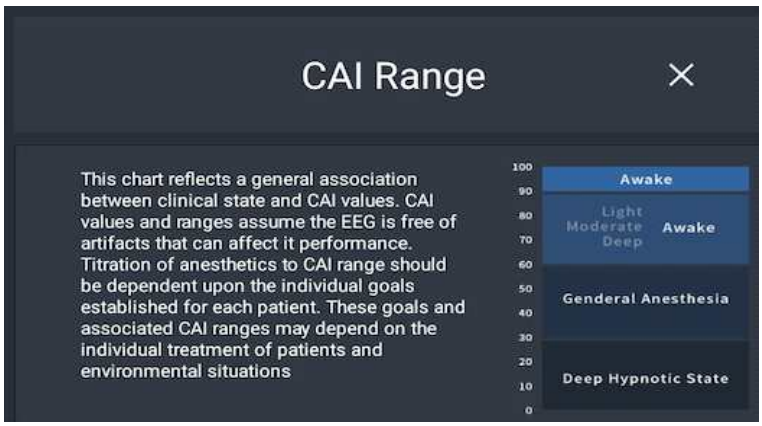
(7) Help

Necessary functions and term description of CAI+Monitoring System including CAI range, CAI display Information, Trouble shooting, Sensor testing/Trouble shooting, and Sensor Application are displayed.

< Help >

① CAI RANGE

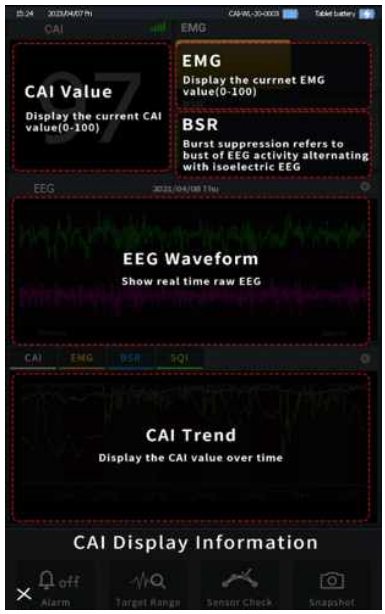
This is description of CAI index, which shows that whether the patient state is in awake or anesthesia state according to range where CAI index is located.



< Help – CAI RANGE >

② CAI DISPLAY INFORMATION

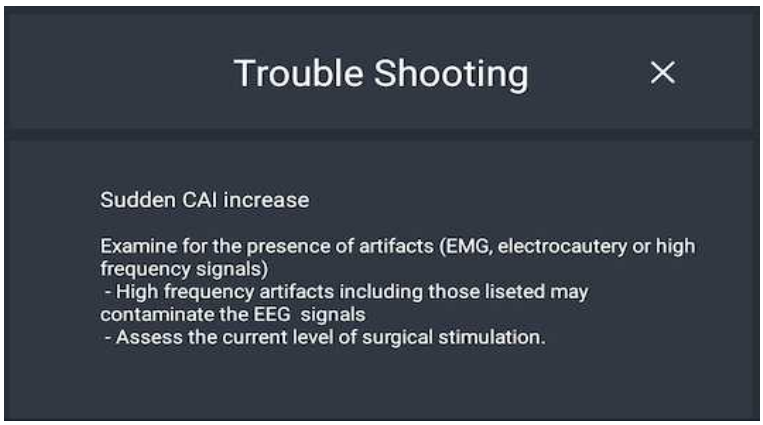
This is a screen to explain indexes and graphs located in each menu, by showing explanation of CAI index screen display in semitransparent manner.



< Help - CAI DISPLAY INFORMATION >

③ TROUBLE SHOOTING

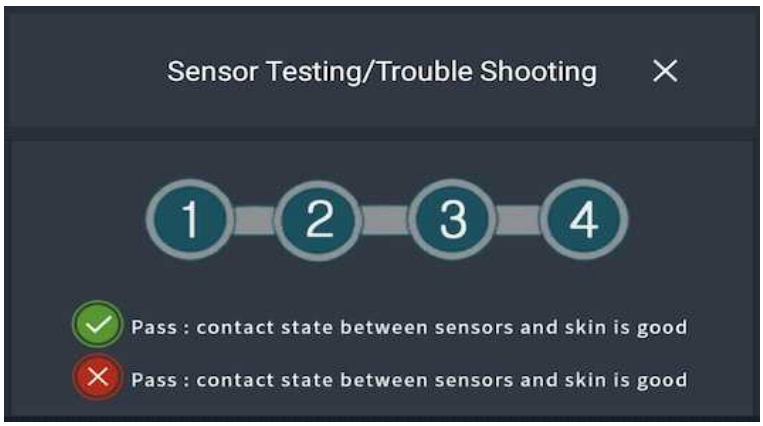
This is a screen displaying items to be inspected when EEG signal quality decreases notably or any signal with noise enters.



< TROUBLE SHOOTING >

④ SENSOR TESTING / TROUBLE SHOOTING

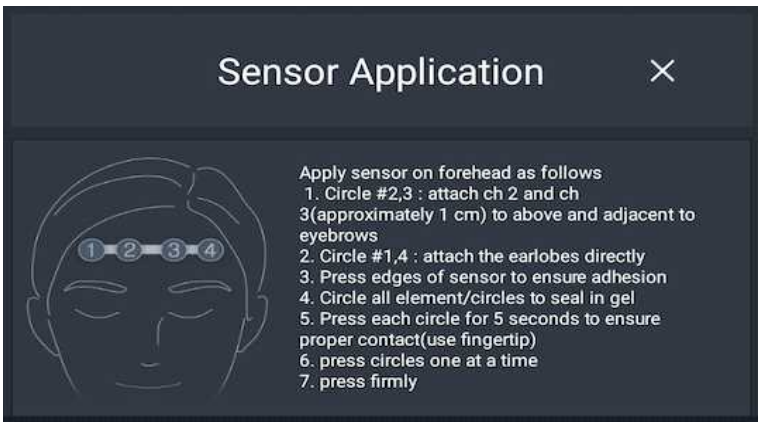
This is a screen showing explanation about sensor attachment state indicator, when Sensor Check Alarm is activated.



< SENSOR TESTING / TROUBLE SHOOTING >

⑤ SENSOR APPLICATION

This is an explanation about sensor attachment sequence.



< SENSOR APPLICATION >

(8) Hardware Info.

This is display of software information of CAI+ Main Body and Monitor(Tablet) hardware information.

< Hardware Info. >

(9) Language

CAI+ Monitoring System is displayed in English.

5) Termination of CAI+Monitoring System

When intending to terminate use of CAI+Monitoring System,

· Push CAIs-Sensor connected to CAIx connector with hand and pull it to disconnect. In order to avoid problems in power supply and signal processing for next use, do not pull the cable to disconnect it.

· Remove CAIs-Sensors from the patient.

· CAIs-Sensor is not reusable as it is produced for single use.

· Store CAIx in state that it is connected with CAI+cable to prevent loss of components.

· If CAI+use (surgery) is continuous, it can be used immediately by connecting it to a new CAIs sensor after maintaining it as Standby in CAI+ Application.

· After the last use (surgery) of the day, disconnect CAIs Sensor connected to CAI+ Main Body connector and store Senson cable and CAI+ Main Body.

· After the operation is completed, organize CAI+ and store it in a designated place for the next operation. (In case of contact/contamination with blood or other drugs after use, please wash and store in a designated place)

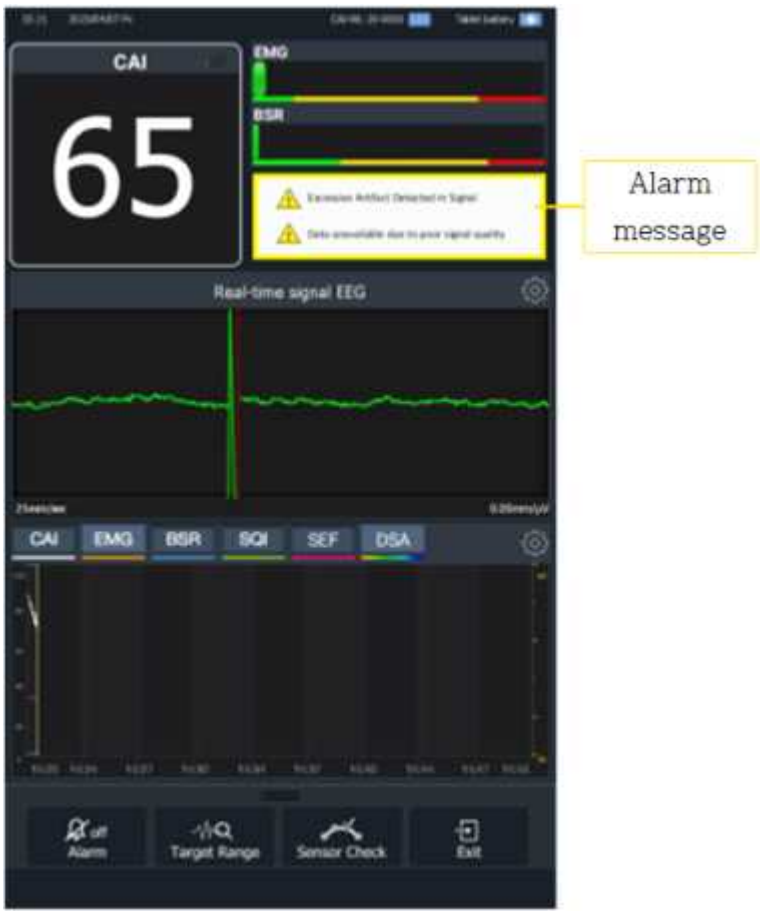
· CAI+ Main Body and monitor (tablet) should be charged for the next use.

3. Alarm

The location of the alarm window is as follows.

When Alarm

① The alarm window blinks and displays.



< Alarm Message >

Index	Error Message	Error Situations : How to display the Alarm window	How to display
CAIs Sensor	Sensor Connect Error	Occurs when CAIs sensor is not attached well	The alarm window is displayed.
Signal	Excessive Artifact Detected in Signal	Occurs when there is strong noise from the patient's movement or external environment	The alarm window blinks and displays.
CAI	Isoelectric EEG Detected	Occurs when BSR value is 100 for 63 seconds	The alarm window blinks and displays.
	CAI Out of Target Range	Occurs when it is smaller or larger than the set CAI value	The alarm window is displayed.
Battery	Low Battery Power (Monitor)	Occurs when the battery capacity of the monitor (tablet) is less than 10%	The alarm window blinks and displays.
	Low Battery Power (Amplifier)	Occurs when the capacity of CAI+ Main Body battery is less than 10%	The alarm window blinks and displays.
CAI+ Main Body	Amplifier Off	Occurs when CAI+ Main Body power is turned off	The alarm window blinks and displays.
Monitor (Tablet)	System Error	Occurs when the monitor (tablet) itself has a problem	The alarm window blinks and displays.
	Memory is full	Occurs when storage space is insufficient	The alarm window blinks and displays.

<Alarm Message>

D. After Use

1) If contaminants are adhered to, wipe off the product with a soft cloth.

2) Do not store in a place where there is metal or magnetism or where it is affected by magnetism.

3) Do not store in a place with foreign substances that affect the operation of the product, such as conductive foreign substances (liquid, dust, metal powder, etc.)

4) Protect from rapid temperature changes.

5) For the next use, check that there are no abnormalities such as operation, battery charging, damage, etc. of the product, parts, and accessories through regular inspection.

6) Do not expose the product to direct sunlight for long periods of time.

7) Store in a dry, shady place away from water or moisture.

8) Do not store together with fire, inflammables or inflammables.

9) If repair is required, contact the designated company or customer center for repair.

E. Cleaning

When blood or other potentially infectious substances or contaminated materials come into contact with this equipment or parts, it must be washed to keep it clean and to prevent malfunction of the equipment.

In addition, when using CAI+ system, if it is contacted or contaminated with liquid or blood, it is necessary to check the system to prevent future operation errors.

III. Caution / Maintenance

A. Caution / Safety Actions

1. Caution

For the safety of the product, be sure to take precautions and conduct training to comply with the items below, and use it after familiarizing yourself with the user manual.

- Use of this product for purposes other than intended use is prohibited.
- Do not replace any or all of the components provided without contacting or reporting to the manufacturer.
- Do not use if there is a defect in the sheath of the provided cable or any other problems.
- If liquids or similar substances permeate the inside of the monitor (tablet) or CAI+ main body or components during use, be sure to turn off the power of the device, disconnect the cable, and contact the manufacturer.
- Never use in the event of any form of electrical failure
- Do not use in case of any mechanical damage, different operating performance and looseness of parts assembly than the first time.
- Do not use the equipment if loss or loss of any parts inside/outside the equipment is identified.
- Do not use in an oxygen-rich environment.
- Do not use on areas with scars. Also, do not attach it to the body other than the forehead, and attach it in the correct location.
- This product can be used to monitor the degree of anesthesia, but it should not be used as the only indicator for controlling the amount of anesthetic agent used.
- This product cannot be used for brain death determination.
- If a power outage lasts longer than 30 seconds, turn CAI+ Main Body off and on. Also, rerun CAI+ Application, and check that the data stored on the monitor (tablet) is not damaged.

In all of the above situations, the user must inform the manufacturer of the situation, and in case of problems with product safety or arbitrary modification as described above, we will not be responsible for them, as they are not covered by our warranty.

1) Electricity and electric shock hazard

CAI+ Main Body, Sensor cable and CAIs Sensor must not come into contact with any conductive material or any other conductive parts including ground

EEG signal collection and analysis errors may occur if CAI+ is placed near an electric defibrillator or device that delivers electric shocks.

To prevent errors in EEG signal analysis and to ensure safety, do not use the product with an electric defibrillator or equipment with high electric shock.

· Shock Hazard: Do not attempt to connect/disconnect CAI+ Main Body and CAIs Sensor with wet hands. When connecting/disconnecting CAIs Sensor, make sure your hands are clean and dry.

· Risk of electric shock: Do not arbitrarily remove the cover of CAI+ main body while the power is connected to CAI+ main body.

· Risk of electric shock and safety prevention:
The manufacturer manufactures this equipment to comply with applicable standard safety standards for ground leakage current and patient safety current, but for electrical safety prevention, regular inspections are required at least once within a year.

Also, if blood or any other liquid is spilled on the product, immediately stop using the device, wipe it clean, and have it inspected by the manufacturer or a professional engineer.

This product contains a Li-ion battery inside. The battery has an overcharge protection function, and battery replacement must be done through the manufacturer.

CAUTION

Do not attempt to disassemble or replace the product except by the manufacturer's and distributor's engineers.

Do not charge the product with an unauthorized charger other than the USB charger provided by the manufacturer.

2) High frequency risk

CAI+ should not be used in an MRI (magnetic field) environment.

When using high-frequency surgical equipment, place it as far away from the sensor or electrode position as possible.

Considerations if You Will Be Using Electroconvulsive Therapy (ECT) Equipment

If you use electroconvulsive therapy (ECT) equipment while using CAI+, you should place the ECT electrode as far away from the sensor or electrode connected to CAI+ as possible to minimize signal interference.

Since certain ECT devices may cause malfunction of CAI+, compatibility between devices must be checked before surgery.

If there is a defect in the neutral electrode connection part of the HF surgical machine, do not use the electrode of the sensor.

3) Risk of explosion

Do not use CAI+ in a flammable environment or in a place where flammable anesthetic gas may condense.

4) User's caution

To prevent injury to the user and the patient, the monitor (tablet) should be used after ensuring that it is securely fixed in a suitable place.

To minimize the risk of strangulation of the patient, the cable connected to CAI+ Main Body must be used with caution.

Precautionary guidelines should be followed to prevent contact with blood or other infectious substances. Infectious materials must be stored in separately managed waste containers.

Avoid liquid inflow into the connection part of CAI+ main body and Senson cable. If the sensor connection of Senson cable comes into contact with fluid, it can seriously affect performance

If CAI+ is contaminated with liquid or blood, stop using it immediately and use it after inspection.

CAI+ is designed to be used with CAIs Sensor and disposable electrodes. When using disposable electrodes, be sure to use the electrode zhender provided by the manufacturer.

Do not arbitrarily disconnect the cable while using CAI+. Errors in real-time data transmission may occur.

- While using/storing CAI+, do not subject it to severe impact such as excessively bending the cable or dropping the product. (sensor cable and CAIs Sensor are designed and manufactured to be flexible, but if there is an external stimulus such as severe bending or twisting, it may affect the acquisition of EEG signals.)

- Be sure to use genuine accessories and accessories, including the charging cable, provided or approved by BrainU Co., Ltd.

- Store in a place free of dust or debris. Dust or foreign matter may cause a malfunction or cause the unit to malfunction due to fire or electric shock.

- A monitor (tablet) is a universal display device. Please use CAI+ applications only.

- Avoid downloading suspicious applications, accessing unreliable sites, and exposing unclear messages or malicious codes. (Please use only CAI+ application for the monitor (tablet), and it may cause malfunction when used for other purposes such as Wi-Fi connection.)

- If the monitor (tablet) is invaded by suspicious malicious code or virus or needs to be initialized, please contact the Brain U Customer Support Center (031-707-1788) or our Agency

- The data storage space of the monitor (tablet) is limited. It is necessary to secure sufficient storage space through periodic data backup and deletion.

5) Wash

High-pressure washing and high-pressure sterilization of CAI+ is prohibited. Most parts of CAI+ can be damaged in High-pressure washing and high-pressure sterilization environments.

6) Prevention of electromagnetic interference

CAI+ meets the electromagnetic compatibility requirements of IEC 60601-1-2, but CAI+ operation can be affected or be affected by electromagnetic interference (EMI) from other equipment.

In order to prevent the occurrence of electromagnetic interference or electromagnetic interference, be careful of the following.

- Maintain the distance between CAI+ Main Body and other equipment on the monitor(tablet)
- Keep CAI+ Main Body at least 15cm away from other equipment to minimize electromagnetic interference.
- Change the position of wires and cables of other equipment
- Limit the use of mobile communication devices as they may affect the operation of portable mobile radio frequency communication devices.
- Do not use CAI+ Main Body by placing it right next to or on top of other equipment.

 CAUTION	If it is unavoidable to use CAI+ in close proximity to other equipment, make sure that CAI+ operates in a normal environment before use. Use of accessories and parts not specifically mentioned in this user manual may increase electromagnetic wave emission of CAI+ and reduce electromagnetic wave immunity.

 REFERENCE	Maintenance, repairs, parts replacement, and software updates must be performed by medical technicians and qualified engineers authorized by the manufacturer. Our CAI+ is designed and manufactured to comply with the Food and Drug Administration's Medical Device Standard Test and to be delivered as a fit-for-purpose product.

2. Safety Actions

1) Important information for using CAI+

(1) For professional handling

CAI+ should only be used in situations where it is properly managed and supervised by a qualified medical professional or someone who has been trained in the use of the equipment. In addition, access to the system by unauthorized persons of the hospital must be prohibited.

(2) CAI+ Usage Criteria

All indicators related to this system are designed for adult patients without mental illness. The system is designed to monitor the patient's level of anesthesia by measuring brainwave (EEG) data in hospitalized patients in hospitals and institutions that manage patients on par with hospitals.

CAI index is one of several indicators displayed by this device and can be used as a reference for monitoring the effect of a specific anesthetic drug. Furthermore, by using the device together with a specific anesthetic drug, you can expect a reduction in the amount of the main anesthetic drug, as well as a reduction in emergency situations and recovery time.

CAI+ is a product that utilizes complex monitoring technology. Clinical judgment based on skilled experience must be accompanied.

Interpretation of CAI index in clinical judgment situations must be done in conjunction with other clinical signals. We do not recommend relying solely on CAI index to administer intraoperative anesthetic medication administration. Various noises or artifacts used in patient monitoring can lead to inaccurate CAI scores. Potential Artifacts can be caused by improper skin contact (high impedance) of CAIs sensor, muscle activity or muscle stiffness, head and body motion, continuous eye movement, incorrect sensor attachment position, and unusual or excessive electrical interference.

When used in combination with certain anesthetic drugs, special caution is required in interpreting CAI index. For example, if 'Ketamine' or 'Nitrous oxide/narcotics' is used as the main anesthetic induction drug, special caution is required in interpreting CAI index.

Due to limited clinical experience, special caution is required in the interpretation of CAI index in patients with known neurological diseases or taking psychiatric medications.

2) before use

User's handling or operation mistakes can lead to accidents, so be sure to familiarize yourself with the main functions of the user's manual before using the equipment in clinical practice.

Please Check the attachment location of CAIs Sensor and attach it to the patient's forehead. When the sensor is attached accurately, the correct CAI index calculation is possible and the patient's condition information to be monitored can be acquired..

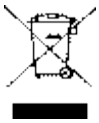
We are not responsible for device modification or parts change, reuse of consumable parts including sensors, etc., as they are not covered by our warranty. In case of equipment modification or problems, please consult with the manufacturer in advance.

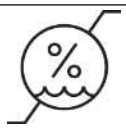
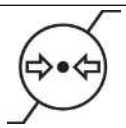
Users of this product should be aware of safety precautions and contraindications before use. Beginner users should be educated on related safety precautions

This product is a device that monitors the patient's level of consciousness, and anesthesia drug administration during surgery and clinical judgment of anesthetized patients cannot be made only with the information of this product. Interpretation of this product must be made in conjunction with other possible clinical signs..

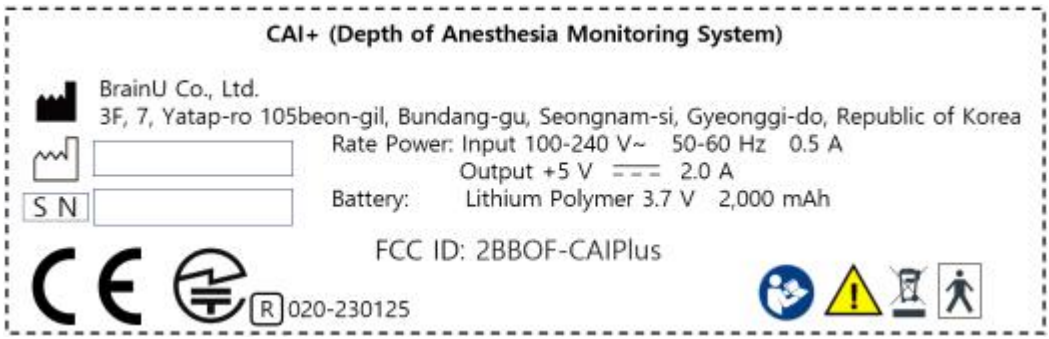
Patient monitoring information is stored on the monitor (tablet) of this product for a certain period of time.

3. label and marking information

Symbol	Reference	Explanation
	ISO 7010-W001	Caution
	-	Reference
	ISO 7000-1641	Operating instructions (Operator's Manual)
	IEC 60417-5333	TYPE BF APPLIED PART
	ISO 7000-1051	Do not re-use
	ISO 7010-M002	Refer to instruction manual/booklet
	WEEE	Waste Electrical and Electronic Equipment Directive
	ISO 7000-2498	Serial number
IPN.N.	IEC 60529	N = 0 No protection 1 Protection against solid particle more than 50 mm in diameter 2 Protection against solid particle more than 12.5 mm in diameter 3 Protection against solid particle more than 2.5 mm in diameter 4 Protection against solid particle more than 1.0mm in diameter 5 Protect against dust 6 dust tight N = 0 No protection 1 Protect against vertically falling drops 2 Protection against Dripping water when tilted at 15° 3 Protection against Spraying water

		4 Protection against Splashing of water 5 Protection against Water jets 6 Protection against Powerful water jets 7 Protection against the effects of temporary immersion in water 8 Protection against the effects of continuous immersion in water NOTE) It is not necessary to specify the number representing the characteristic. It is replaced by the letter "X". ("XX" if both digits are omitted)
	ISO 7000-0626	Keep away from rain
	ISO 7000-0621	Fragile; handle with care
	ISO 7000-0623	This way up
	ISO 7000-2606	Do not use if package is damaged
	ISO 7000-2607	Use by date
	ISO 7000-2497	Date of manufacture
	ISO 7000-3082	Manufacturer
	ISO 7000-0632	Temperature limit
	ISO 7000-2620	Humidity limitation
	ISO 7000-2621	Atmospheric pressure limitation

1) Marking information



< Width : 80 ㎜, Length : 25 ㎜ >

B. Maintenance

This equipment must be inspected by a technician authorized by the manufacturer at least once a year.

1. Equipment cleaning

When blood or other potentially infectious substances or contaminated materials come into contact with this equipment or parts, it must be washed to keep it clean and to prevent malfunction of the equipment.

In addition, when using CAI+ Monitoring system, if it is contacted or contaminated with liquid or blood, it is necessary to check the system to prevent future operation errors.

2. Washing/cleaning of CAI+ Main Body and display monitor

If blood or liquid gets on CAI+ Main Body or the monitor (tablet), remove the contaminant immediately with an absorbent, lint-free towel. (In the case of blood, it clots over time and is very difficult to remove.)

For overall cleaning, wipe with a towel dampened with detergent and lukewarm water, and finally wipe with alcohol and dry completely. (Residual moisture may affect connector contact.)

For disinfection, use a 10% bleach solution or disinfectant (Lysol(R) Professional Disinfectant Foam Cleaner Spray or PDI Disinfectant Disposable Wipes, etc.)

When cleaning the display screen of a monitor (tablet), wipe the monitor with a commercial display screen cleaner or detergent and neutral solution. (However, do not use abrasive cleaners to avoid scratching the screen.)

CAUTION

Continued use without wiping off blood or liquid may cause leakage current. Also, when disinfecting solutions are mixed and used (bleach, ammonia), harmful fumes may be generated.

Do not use high-pressure steam sterilization. It can damage components of the Product.

Avoid getting liquids into the cable connected to the patient. It may interfere with the performance of the sensor connector.

1) Maintenance

CAI+ Monitoring Systems are designed to not require periodic adjustments or calibration, but routine maintenance requires periodic checks.

Regular checks

- Check the remaining battery power of CAI+ Main Body and the monitor (tablet), and contact the manufacturer if there is a problem with the power supply of the battery. (Even if the battery has been stored in a fully charged state (at least 6 hours or more) in the past, periodic battery checks are required through the operation of the monitor (tablet).)

- After connecting CAIs Sensor (or disposable electrode) and CAI+ Main Body, check if it works properly

- Sensor cable is considered as part of consumables, and cable abrasion is expected during continuous use. Check that the cable is not contaminated, has contact problems, or is not damaged or damaged. (It is recommended to test the operation of Senson cable and connector when continuously using it for more than 6 months, and replace it if it is abnormal.)

The manufacturing year and month of the manufactured sensor cable are displayed so that you can check whether the cable is aging or not. (Cable manufacturing year and month – two digits indicate the year, alphabets A to L (A: January, B: February … L: December)

Step 1: Connect CAIs sensor (or disposable electrode) or test kit and sensor cable of CAI+ Main Body and turn on the power of CAI+ Main Body. When the power is turned on, the battery level is checked. (It is recommended to use it when the battery level is over 80%.)

Step 2: If the power does not turn on after connecting CAIs Sensor (or disposable electrode) or test kit to CAI+ Main Body, or if the sensor connection status is not confirmed in CAI+ Application, contact the BrainU customer center or agency.

- If the battery of CAI+ Main Body and the monitor (tablet) does not last more than 1 hour, you must replace it with a new device.

C. CAI+ checks

1. Leakage current check

Leakage current is a fundamental indicator of the risk of electric shock to those who come into contact with the exposed exterior surfaces of equipment.

Leakage current is carefully checked by CAI+ manufacturers to meet IEC 60601-1-1 and IEC 60601-1-1 safety standards. Leakage current should be checked regularly, at least once a year.

It should be noted that blood as well as liquids such as salt water and Ringer's solution are all conductors. Never touch any part of the system with wet hands. Always work with clean, dry hands.

The manufacturer has tested this apparatus and found that the earth leakage current and the patient safe current are less than the limits set by applicable safety standards. To remain safe, agencies must conduct periodic tests to verify applicable currents. If an event occurs, such as a blood or solution leak, testing should always be performed again before use.

CAI+ has received medical device test inspection and medical device certification, and is producing CAI+ in accordance with the management standards of the Ministry of Food and Drug Safety. Information regarding this is indicated on the product box or product label.

2. Device identification

Identification information is displayed on the product and on the packaging. This information includes device model, serial number, power rating, cautions, and manufacturer information.

3. Software information

The software version is displayed at the bottom of the Standby screen.

The application, algorithm version, and latest update information are displayed respectively.

D. Warranty information

1. Warranty coverage

BrainU Co., Ltd. guarantees the following.

- The equipment has no defects in any parts and equipment and has been assembled without any problems for professional medical personnel to use under normal circumstances, and has a 12-month warranty period from the date the product is supplied to the user.

- Other than equipment, accessories, and raw materials of all components and parts are free from defects, and there is no problem for professional medical personnel to use it under normal circumstances, and it has a 60-day warranty period from the date of supply to the user.

- If product repair is required within the warranty period, be sure to contact the designated dealer or manufacturer in your area.

- Depending on the equipment's warranty period, repair or replacement may be made.

- If you need to service the equipment, please contact the BRAINU Customer Support Center or your local agency.

- When sending the product to receive product service, please pack and send it so that parts are not lost or damaged. Damage or loss of the product during transit is not covered by the product warranty.

- The terms of this warranty apply only to the original purchaser, and resale is outside the scope of this warranty.

- For parts deemed to be within the scope of warranty, the manufacturer bears the cost of repair or replacement along with transportation. However, damage or physical damage caused by the buyer's negligence is the buyer's responsibility.

2. Warranty Exclusions

The following are not covered by the product warranty.

- Products that have been subjected to abuse, negligence, or accidents;
- Products damaged due to external reasons such as power outages or electrical failures
- Products used in violation of the precautions for this product
- Products that have been attached to non-standard accessories
- Products with removed or illegible serial numbers (or lot numbers).
- Products with evidence of security labels being removed or reapplied.
- Products that have been modified/repaired by third parties or others other than our designated technicians.
- Products disassembled, serviced, or manufactured by third parties or others other than our designated technicians

There is no obligation to repair, replace or modify the Product, in whole or in part, due to normal wear and tear.

No warranty is provided for products purchased from someone other than an authorized distributor of this product or products sold under a brand name other than Brain Co, Ltd.

3. Software license related

The computer software ("Licensed Software") that runs on the monitor (tablet) (or system) is licensed for use only under the terms of this License and is not sold separately. BrainU Co., Ltd. reserves all rights not expressly granted to you. Although you own the system, BrainU Co, Ltd retains all title, title and authority to the Licensed Software itself.

1) **License:** You are granted a non-exclusive right to use the Licensed Software in connection with the specific system on which the Licensed Software was provided

2) **Restrictions:** You may not transfer the Licensed Software from a system to another computer or system under this Agreement in any way without the prior written consent of BrainU Co, Ltd You may not distribute copies of the Licensed Software or its related documentation to others. You may not modify or translate the Licensed Software or its related documents without the prior written consent of BrainU Co, Ltd. The Licensed Software contains trade secrets, and to protect them, you may not decompile, reverse engineer, disassemble, or put the Licensed Software into a human-readable form. If you transfer the system, you have the right to transfer the Licensed Software provided that the transferee agrees to be bound by the terms of this License Agreement.

3) **Termination:** This License is effective until terminated. If you do not comply with the terms of this License, this License will automatically terminate without notice from BrainU, Co, Ltd Upon termination of this License, you may no longer use the Licensed Software.

4) **LIMITED WARRANTY:** THE LICENSED SOFTWARE IS PROVIDED "AS IS" WITHOUT ADDITIONAL WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE. BrainU, Co, Ltd does not warrant that the functions contained in the Licensed Software will meet your requirements, or that the operation of the Licensed Software will be uninterrupted or error-free, or that such errors in the Licensed Software will be corrected.

5) **LIMITATION OF REMEDY AND DAMAGES**: Regardless of the cause, the entire liability of BrainU, Co, Ltd. to you for actual damages and your sole remedy is limited to the amount paid for the system containing the Licensed Software.

4. A/S Contact

For A/S of CAI+, contact the BrainU Customer Support Center or your local agency. We support by assigning a unique ID to the service.
e-mail: support@brainu.co.kr

- Before sending for A/S of CAI+, the following items should be prepared.
- In case of an error, send all components and parts except for the sensor used to the BrainU customer support center or the corresponding local agency.
- To protect the product, pack the equipment using original packaging materials.
- Please wash the equipment before sending it to remove any infectious agent from the product. Please enclose with a detailed description of the abnormal condition of CAI+.

E. Wireless Certification Information

National	Certificate	Simbol
South Korea	KC	R-R-BrU-CAIPlus 기자재명칭(명칭): 특정소출력 무선기기 (무선데이터통신시스템용 무선기기)
USA	FCC	FCC ID: 2BBOF-CAIPLUS Contains FCC ID : 2AAQS-ISP1807
EU	CE RED	CE
JAPAN	TELEC	R 020-230125

F. Wireless Certification Information

FCC Part 15.19 Statemets:	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 Part 15.105 Statemets(Class B)	This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: - Reorient or relocate the receiving antenna. - Increase the separation between the equipment and receiver. - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. - Consult the dealer or an experienced radio/TV technician for help.
FCC Part 15.21	Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

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