CORTICAL ACTIVITY INDEX

THE DEPTH OF ANESTHESIA MONITORING

MANUAL

THE BEST TECHNOLOGY AND NEW VISION, THE CONTACT MOMENT ALL POSSIBILITY MEET, CREATING A NEW STANDARDIZATION BASED ON THE HARMONY BETWEEN HUMAN AND TECHNOLOGY.

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Introduction of Cortical Activity Index (CAI) System

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

CAI 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 (brainwave sensor), CAIx (amplification module), CAI monitor and algorithms for calculation and analysis.

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

CAI 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.

CAI 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 can determine whether the impedance of patients is within normal range, using assembly compatible software algorithm technology as well as highly advanced components with cable to connect CAIs and CAIx for patient interface.
In addition, CAI has convenient functions for user settings, which enable users to easily display information and review stored data.

CAI also includes information which customers need for utilizing and operating CAI, as well as for the maintenance and troubleshooting.

CAI's key features are as follows:

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

About this user manual

- CAI was manufactured with care for users' safety.
- Conduct instruction for users about safety precautions and contraindications prior to device installation and operation.
- Read this manual carefully before operating, as users' mistake in handling and mishap may lead to accidents.
- This user manual contains all information on setting and operation of Charm Engineering's CAI.
- Keep this manual with CAI for users to access and use it freely.
- This user manual was prepared to be used as a service information manual for service engineers and biomedical engineers who provide maintenance and inspections of the device as well as for general users.
- Users must read the safety management information described in this manual fully and thoroughly before using CAI System.

Chapter 1 Safety Precautions

Important information for using CAI

CAI should be used only in conditions where managed and supervised by qualified medical professionals and persons who completed training to use medical devices.

All indicators related to this system were designed to be used for adult and child patients. Also, this system was designed to monitor brain state of patients by obtaining brainwave data (EEG) from patients hospitalized in a hospital or an equivalent institute which can provide patient management equivalent to the hospital.

CAI index is one of indicators in this CAI device, which can be used as a reference to monitor effectiveness of certain anesthetic agent. Furthermore, as certain anesthetic drug is used along with CAI device, reduction of main anesthetic drug amount can be expected as well as reduction of emergency situations and recovery time.

For adult patients, administration of anesthetic drug assisted by CAI index can decrease occurrence of arousal during general anesthesia or restoration from sedation.

CAI, which is a device utilizing complex monitoring technologies, must be used with clinical judgment based on skilled experiences.

In the situation of clinical judgment, interpretation of CAI must be performed along with other possible clinical indications. It is not recommended to manage administration of anesthetic agent during surgery on the basis of CAI information only. Poor signal or artifacts of various indexes used in the CAI monitoring may induce inaccurate CAI values. Potential artifact may be developed by improper skin contact (high impedance), muscular activation or stiffness, head and body movement, continued ocular movement, inaccurate sensor attachment site, and unusual or excessive electrical interferences.

CAI values should be interpreted with special care in combined use of certain anesthetic drugs. For example when Ketamine or Nitrous oxide/narcotics were used as main anesthetic drugs, special care is required for interpretation of CAI values.

For patients with any known neurological disorder or taking psychiatric drugs, special care should be taken for CAI values interpretation due to limited clinical experiences on the above application.

1.1 Safety Actions

This section describes contents that users must know for safe and proper device usage. Please, read below contents carefully.

Introduction

Warning and precaution: Before using this device in clinical environment, users must read this instruction manual thoroughly and be aware of contents.

Prior to usage

- Read this manual carefully before usage, as user's mistake in handling and operation of device may lead to accidents.
- For sensor attachment locations, attach it on the patient's forehead after confirming instruction of sensor attachment location. Once the sensor is attached accurately on the specified location, users can obtain correct interpretation of CAI value and status information of patient will be monitored. (Accurate attachment of sensor can prevent errors in interpretation of brainwave signal).
- As remodeling of device, modification of components, or reuse of disposable components by users are not part of the warranty scope, and Charm Engineering is not responsible and liable for any reliabilities arose due these actions. When there is any issue with device modification or potential problems, please discuss with Charm Engineering in advance.
- All users of this device should read cautions and contraindications thoroughly for safety prior to the usage and instruction of preventions for safety should be provided to new users.
- This device, which is a monitoring device for anesthetic state of patient, should not be used to administer anesthetic drug and make any clinical decision of patient under anesthetic based on only the information from this device. Interpretation of findings from this device must be made along with application of other available clinical signals.
- The monitoring information is recorded/saved in this device system for certain duration of time.

Caution & Notice: In this manual, Caution and Notice has following respective meanings.

■ Caution & Notice

"Caution and Notice" sign is used to inform any harm from device damage, inaccurate data, and/or improper procedure to users, although no activity or situation makes them be injured.

1.2 Precautions and Safety Measures

For the operation of this device, please consider below precautions and safety measures.

Checking Power Supply

Must use the battery power supply provided by the manufacturer.

CAI is operated with the internal battery. Must check battery remains before usage.

In addition, even though the battery has been stored after fully charged (charged for at least 6 hours), it is necessary to inspect the battery remains regularly through operation of CAIx and CAI monitor.

Charge state of CAIx

Mode	Details	LED ON/OFF State	
Charging	During charging	Charge status by number of white LED 1~4 lighting	
	Charging completed	4 White LEDs On	○○○○
Check battery remains	75~100%	4 White LEDs On	○○○○
	50~75%	3 White LEDs On	○○○◯
	25~50%	2 White LEDs On	○○◯◯
	15~25%	1 White LED ON	○◯◯◯
	1~15%	1 Orange LED ON	●◯◯◯

When remaining battery is under normal (2 White LEDs On), recharge and use the battery to maintain sufficient power supply.
Check charged power in CAIx and CAI monitor and then use them with sufficient electrical power.
→ When the battery level of CAIx is below 10%, "Low Battery power (Amplifier)"alarm occurs.

*** Checking charge status of CAI monitor**

CAI monitor is a universal display imaging device, of which battery charge status can be checked by anyone who uses it. When remaining battery is insufficient, the device can be used connecting power cable to the power supply.

When remaining battery of CAI monitor is insufficient, the system can be used after connecting power cable to the power supply.

→ When the battery level of CAI monitor is below 10%, "Low Battery power (Monitor)"alarm occurs.

The charge status of CAIx can also be checked on CAI monitor.
When the device is used after storing it for long period of time, device's remaining battery must be checked prior to the usage. If the CAIx or CAI monitor do not operate stably for at least 1 hour after full recharge, it is necessary to replace the battery as battery life has expired.

When storing the device, do not store it at excessively high or low temperatures. Storing at excessively high or low temperatures, the device may face malfunction or shortening of the battery life.

Be careful for micro USB charging terminal for power supply, which should not be in contact with metal material.
When the charging terminal is in contact with metal, the terminal may cause permanent battery failure. (Do not use any failed device or battery)

※ For replacement or new purchase of CAIx or CAI monitor, contact customer service or local representatives of Charm Engineering Co., Ltd.

Electrical hazard and electric shock risk

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

CAI has a potential to develop an error in vital signals to be obtained when the device is located around heart electric defibrillator or a device giving electric shock.

To prevent vital signal error of this device and ensure operation stability, do not use the device together with heart electric defibrillator or a device to giving high electric shock.

Shock risk: Do not attempt to connect or disconnect CAIs and CAIx with wet hand. When connecting CAIs, check that the user's hands are clean and dry prior to use.

Risk of electric shock: Do not remove CAIx cover when the CAI monitor is being operated or plugged in to the power outlet.

Electrical Shock Risk and Safety Prevention: Although this device was manufactured with ground leakage current and patient safety current adequate to applicable standard safety specification, the device should receive regular inspection at least once a year for electrical safety prevention.

When blood or any other liquid is spilled on this device, do not continue to use it and must conduct ground leakage current test immediately.

Power supply is equipped with an internal fuse and when replacement of power supply is required, it should be replaced with new power supply comprising CAI device of the manufacturer.

This device is a power supply embedded device, which has rechargeable battery in the device. The battery has overcharge prevention and its replacement should be made through the manufacturer.
Caution: Do not disassemble or replace manually except by qualified personnel from the manufacturer.

This device is a power supply embedded product, which includes no equipotential access.

Caution: This device is a power supply embedded product, so do not connect and use several instruments simultaneously due to risks that might be brought by summing of leakage current.

High Frequency Risk

CAI is not designed to be used in MRI (magnetic field) conditions.

When using a high frequency operational device, place it as far as possible from the electrode of CAI and make the electrode attached to the location marked on the CAIs package.

* Considerations in using electroconvulsive therapy (ECT) device

When it is required to use an ECT device during application of CAI, the ECT electrode should be placed as far as possible from this CAIs sensor to minimize signal interference. As certain ECT device may interfere normal monitoring function of CAI system, it is required to check compatibility between devices during patient preparation.

When any defect occurs in the neutral electrode connection part of HF surgical device, do not use the electrode of the sensor.

Danger of Explosion

Do not use CAI in any ignitable environment or possibly ignitable anesthetic gas deposited place.

Precautions of Users

In order to prevent injury of users or patients, it is required to ensure that the CAI monitor is secured firmly in proper location prior to its usage.

Any cable connected with CAIs must be located carefully to minimize risk of patients being strangled.

Prevention guidelines should be followed to prevent contact with blood or any other infectious materials. Infectious materials should be stored in waste containers under separate management.

As dangerous and harmful gas may be generated, do not mix disinfectant solutions. (e.g.: bleach or ammonia)

- Avoid liquid ingress to connection cable of patient. When the sensor connection part of patient connecting cable is in contact with any liquid, interference may be caused to the performance of patient connecting cable.
- ※ When any liquid or blood contaminated the CAI system, system inspection must be conducted along with cleaning after use.
- (For system inspection, refer to Chapter 4 Maintenance Inspection and Cleaning.)
- CAI was designed to be used together with CAIs. Use of any electrodes other than CAIs and use of incompatible sensor with CAI devices may be misconceived due to inaccurate data and restrict warranty of the device.
- Do not disconnect the cable arbitrarily during use of CAI. Real time data transmission and power problem would possibly occur.
- Do not apply shock to components of CAI system by bending excessively or dropping them. (The CAI cable was designed and manufactured to have flexibility, and external stimulations such as excessive bending may affect gathering of accurate vital signal.)
- Use only accessories and components including the power charge cable provided and approved by Charm Engineering.
- Store it in place without dust or foreign matters. Failure from dust or foreign matters, or malfunction from fire or electric shock may occur.
- CAI monitor is a universal display device and should be used only for operation of CAI system (operation of CAI software).
- Do not download any suspicious application or visit unreliable site. In addition, avoid exposure to unclear message or malignant code. (The monitor should be used only as CAI monitor and other uses such as Wi-Fi connection may cause possible malfunction.

- Bluetooth function should be turned on only when using CAI.
- When any suspicious malignant code or virus was invaded into CAI monitor or the initialization of device is required, inquire to customer service or local representative of Charm Engineering.
- When storage space of device is not enough, stored data should be backed up to external or other storage space for future use.

Cleaning

When cleaning and sterilizing CAI, do not autoclave it. Autoclaving can damage most of CAI components.

Prevention of Electromagnetic Interference

Although CAI satisfies electromagnetic compatibility requirements of IEC 60601-1-2, operation of CAI may give or receive effects due to electromagnetic interference (EMI) of other device.

To prevent electromagnetic interference (EMI),

- Increase distance between devices.
- Change location of power line and cable of the device.
- CAI monitor should maintain at least 15 cm of distance from other device to minimize EMI.
- As CAI device may be affected by operation of portable mobile radio frequency communication device, it is not recommended to use mobile communication device.

CAI should not be placed beside or on top of other device during usage.
When it is unavoidable to use it near to other devices, ensure to check whether CAI operates as in normal conditions prior to usage.

※ Use of any accessary or component not mentioned specifically in this user manual, can increase electromagnetic discharge of CAI and decrease electromagnetic immunity.

※ Maintenance, repair, component replacement, and S/W update should be completed by the qualified medical engineers.

※ CAI product of Charm Engineering was designed and manufactured to comply with medical device standard test of the Food and Drug Administration and provided as suitable device.

1.3 Alarm display

Alarm window is displayed in red box location on the screen.
Alarm sound can be turned off or turned on with ON/OFF of bell shaped icon on the left bottom of screen.

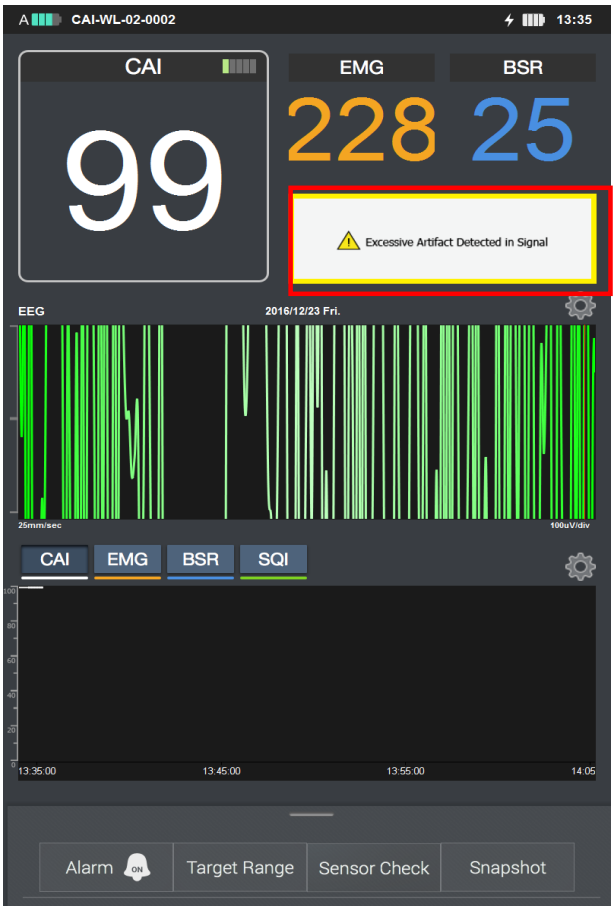


Figure 1.1 Alarm display

※ Display method of alarm

① Alarm sounds, with flash of alarm window.
② Alarm sounds, with display of alarm window.

Contents of Alarm

Classification	Error state – Alarm window display method	Error Message	Display method
CAIs	When CAIs are not attached firmly	Sensor Connect Error	②
Signal	When strong noise develops from patient movement or external conditions	Excessive Artifact Detected in Signal	①
CAI	When the BSR value is 100 for 63s	Isoelectric EEG Detected	①
	When the value is smaller or greater than set CAI value	CAI Out of Target Range	②
Battery	When battery capacity of CAI monitor is below 10%.	Low Battery Power (Monitor)	①
	When battery capacity of CAIx monitor is below 10%.	Low Battery Power (Amplifier)	①
CAIx	When CAIx is turned off	Amplifier Off	①
CAI monitor	When CAI Monitor has its own issues developed	System Error	①
	When there is not enough DB storage space.	Memory is full	①

Chapter 2 Product description

This section describes operational features, specification and explanation of CAI device and its installation and operation.

2.1 Board operation features

Examine and record amplitude accuracy, frequency response characteristics, Common Mode Voltage Removal Ratio(CMRR), input referred noise, current consumption, and power size per band.

2.1.1 Device to be used

Waveform generator: Agilent 33120A
60dB attenuator: Agilent 8491A, 51691(accurate attenuation is 0.00106)
DC Power Supply

2.1.2 Amplitude accuracy

Input signal condition

- Amplitude: 200mVpp (Setting waveform generator as 100mVpp)
- Frequency: 10Hz(EEG), 100Hz(EMG)
- Waveform: Sine wave

Measurement method
Connect lines according to below connection diagram and obtain input signal amplitude with the viewer program.

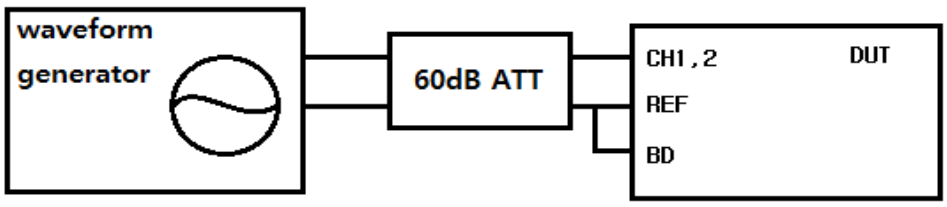


Figure 2.1 Connection diagram of waveform generator, 60dB attenuator, and test board.

Measurement results

- Measurement value: 102.4uVp, 102.5uVp (EEG); 98uVp (EMG)
- Theoretical estimate value: 106.0uVp
- Error (EEG): 5% (mass production error)
- Error (EEG): 10% (mass production error)

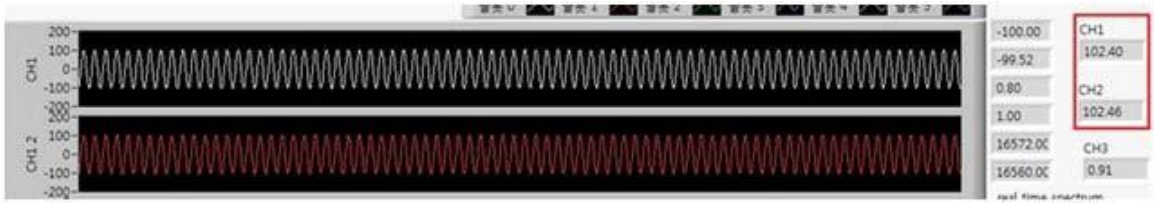


Figure 2.2 Result of amplitude accuracy measurement for brainwave signal channel. The measurement values were 102.4uVp and 102.5uV, respectively.

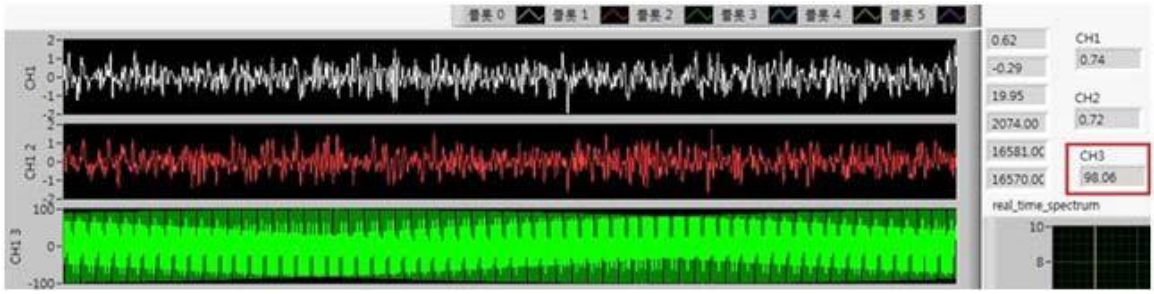


Figure 2.3 Result of amplitude accuracy measurement for electromyogram signal channel. The measurement value was 98.1uVp.

2.1.3 Frequency Response

Input signal condition

- Amplitude: 200mVpp (Setting waveform generator as 100mVpp)
- Frequency: 2/10/30/40/50(2~48)Hz (EEG), 70/80/100/130/140(80~130Hz)(EMG)
- Waveform: Sine wave

Measurement method

- Test connection diagram is shown in the above diagram.
- Actual size of signal input is 106uVp.
- Measures the amplitude of detected waveform with a viewer program by changing frequency of the waveform generator.
- Obtain benefit (dB unit) per each frequency from the measured amplitude results.
- Benefit = 20*log (numerical benefit)

Measurement results

Results of brainwave signal channel and electromyogram signal channel measurement are shown in below figure.

(Measurement value at –3 dB passband in EEG, EMG frequency response characteristic test was at least 70.7 uVp.)

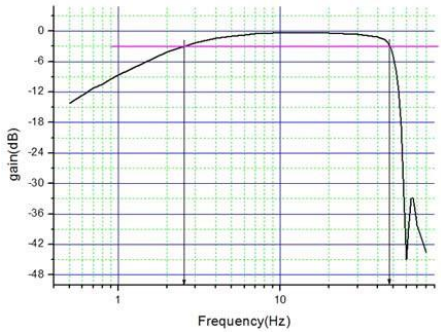


Figure 2.4 Frequency response curve of brainwave signal channel. -3dB passband: 2~48Hz

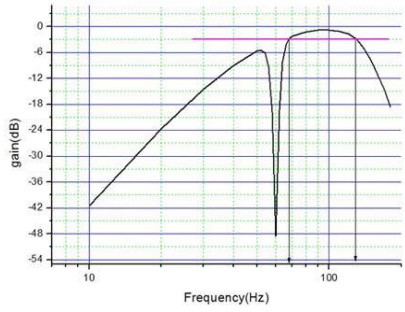


Figure 2.5 Frequency response curve of electromyogram signal channel. 70~130Hz at -3dB frequency band

2.1.4 Input Signal Range

Input signal condition

- Amplitude: Increase until output is saturated
- Frequency: 10Hz(EEG), 100Hz(EMG)
- Waveform: Sine wave

Measurement method

- Connect lines as shown in Fig. 2.1 waveform generator and obtain output signal amplitude with viewer program.
- Increase input signal until the output is saturated. Amplitude of output signal at this time is maximum input signal amplitude.

Measurement results

- Measurement value: +/-400uVp (EEG); less than +/-550uVp (EMG).

2.1.5 Input Referred Noise

Input signal condition: None

Measurement method

- Connect lines according to below diagram and obtain output signal amplitude with the viewer program. At this time, the signal amplitude should be obtained as rms. (rms is obtained from 1000 samples)

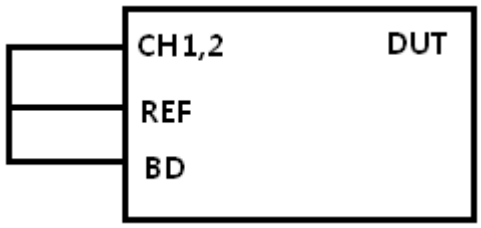


Figure 2.6 Connection diagram to obtain input referred noise size

Measurement results

- Measurement value: 0.49uVrms(EEG), 0.23uVrms(EMG)

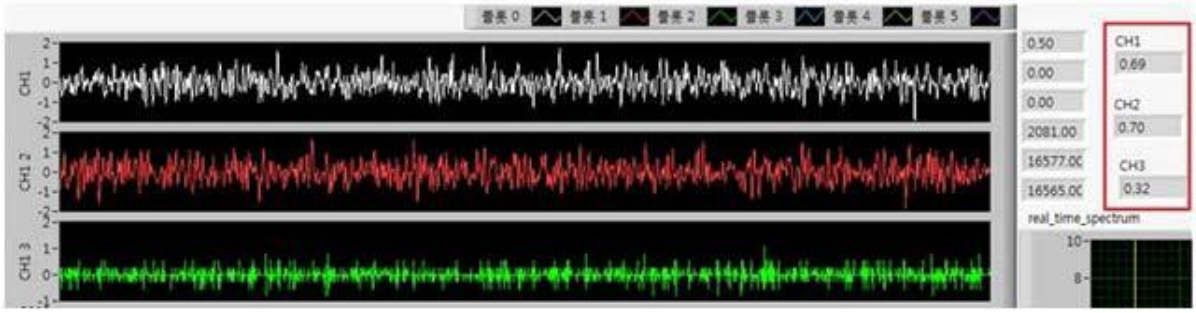


Figure 2.7 Input referred noise size. CH1=0.69/1.414=0.49uVrms, CH2=0.7/1.414=0.5uVrms. EMG=0.32/1.414=0.23uVrms.

2.2 CAI Product Specification

No.	SPECIFICATIONS	QUALITY
1	Channel Number	2 Channel
2	Measurement Type	Mono-Polar
3	Input amplifier range	EEG ±400uVp EMG ±550uVp
4	Noise	1uV RMS
5	Common Mode Rejection	80udB at 10Hz
6	Filter	EEG 2.5Hz ~ 48Hz(- 3dB) EMG 80Hz ~ 130Hz(- 3dB)
7	Resolution	EEG 15 bits EMG 12 bits
8	Sampling Rate	250Hz
9	Battery Backup	Lithium Polymer Battery 3.7V
10	Monitor OS	Windows, Android

Wireless (Bluetooth) Specification

Model name	CAI
Wireless output	Wireless 3 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.”	
Contact Information for Customers	
Marked separately on the device package box	
Manufacturer	Charm Engineering Co., Ltd.
Name of Apparatus	Specific low power radio apparatus for wireless data communication system
Year/Month of Assembly	Marked separately on the device package box
Manufacturer/Country	Charm Engineering Co., Ltd./Korea

2.3 Device Configuration

CAIx

Figure 2.8 CAIx

CAIx has built-in mainboard and Bluetooth communication module.
Also includes built-in 3.7V, 2000mAh Li-Polymer battery, Micro USB terminal for charging and CAIs connecting terminal.
The above devices are protected with an external casing.

CAI Connection Cable

Figure 2.9 CAI Connection Cable

It serves to connect CAIx and CAIs.

CAIs

Figure 2.10 CAIs

Sensor comprises with 4 electrodes and when CAIs is connected to CAIx, power of CAIx will be turned on automatically.
CAIs are components to be used as disposables in the CAI system and the used sensors must be replaced.
For instructions to attach sensors on a patient and instructins to connect them to CAIx, refer to instruction for use on the package of CAI sensor.
※ As the sensors are sold separately, contact customer service or local representative of Charm Engineering for purchase.

CAI Monitor

Figure 2.11 CAI Monitor

This is a monitor to display measured data values through Bluetooth communication after connecting CAIx and CAIs.

※ Note: CAI system is used according to IEC 60601-1-2 electromagnetic compatibility requirements.

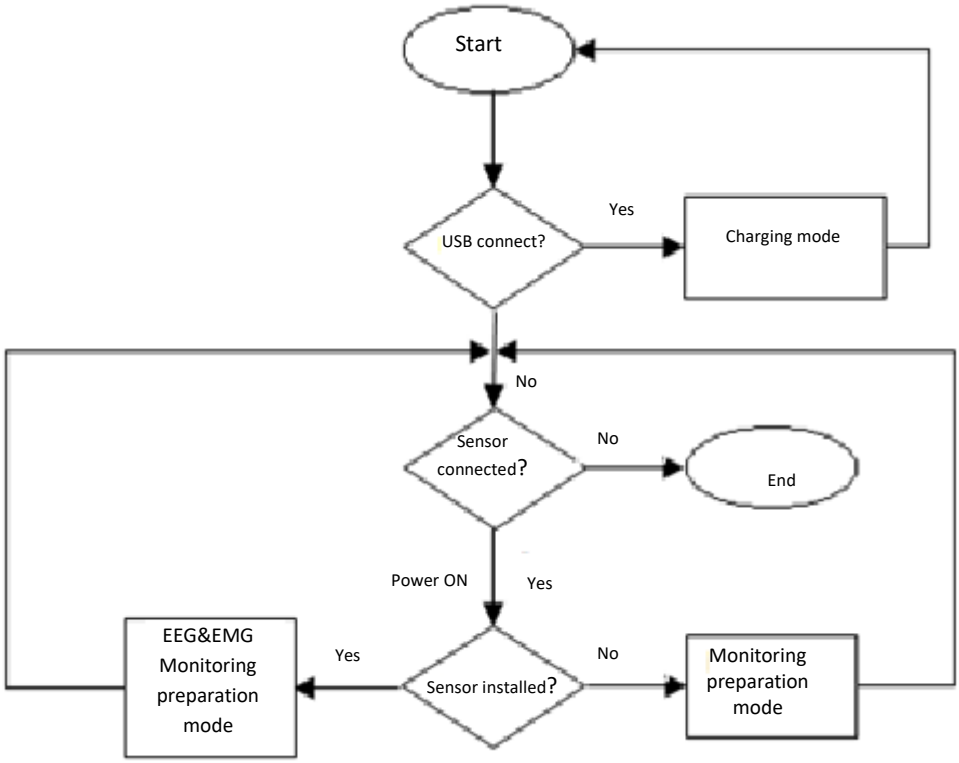
Any device usage within close distance from this device may give or receive effects from electromagnetic interferences. See Chapter 1 Caution "Prevention of EMI".

CAI monitor should be used only as CAI system.

(Do not install any suspicious applications to prevent malignant code and virus.)

2.4 Device Operation Diagram of CAI

CAI acts as charging and execution.



When u-USB power is plugged into CAIx, it acts as charging mode. In the charging mode, CAIx continuously monitors the USB connection. Charging status is displayed with 4 White LEDs on CAIx. The connected USB can be maintained even after completion of charging, but it is recommended to disconnect USB if possible.

In the monitoring preparation mode, contact of sensor to human body is monitored continuously to check access condition to EEG & EMG monitoring execution mode. Unless the sensor is disconnected, the device acts in this mode until the battery is exhausted. To block power to the board, it will be turned off automatically when the sensor is disconnected from the connector.

The EEG & EMG Monitoring execution mode is a mode to act only when all electrodes of CAIs contact human body and their installation state is confirmed. In this mode, CAIx provides brainwave poser spectrum values by bands (theta, alpha, L-beta, M-beta, H-beta, and gamma). Electromyogram (EMG) signal, which is measured between CH1 and REF electrode to detect muscular movement (forehead frowning) of subject.
Likewise in the monitoring preparation mode, the execution method will be maintained until

the battery is exhausted as long as the sensor is connected. When the board is not in use, it is required to disconnect the sensor to block power to the board.

As the brainwave and EMG signal are measured only in waiting and execution mode, these signals cannot be displayed when USB is connected. This is a factor to consider safety of subject against electric shock and once the electrodes are attached to human body directly, the board should be operated only by battery.

2.5 Using CAI

Turning on CAIx

When connecting CAIs with CAIx connector, power is supplied to CAIx. Remaining battery is indicated by number of illuminating white LEDs.

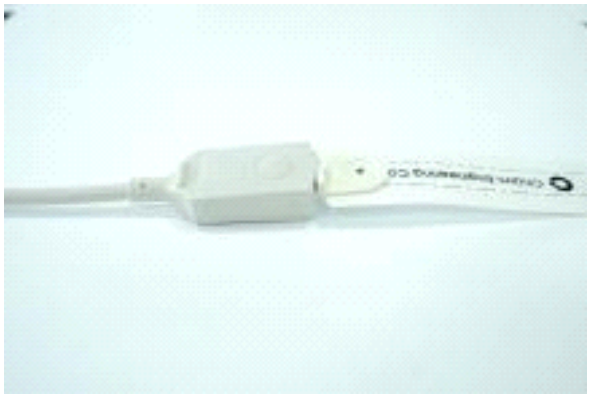


Figure 2.12 Turing on CAIx

Turning off CAIx

When disconnecting the CAIx cable from CAIs sensor, power is removed.

Power On/Off of CAIx depends on connection between the Cable and CAIs sensor.

Figure 2.13 Power removal of CAIx

Charging CAIx

When intending to charge CAIx, current is supplied using Micro USB power line and charging status is indicated according to number of illuminating White LEDs out of 4 LEDs. Due to features of the circuit, the indication of LED battery remain may not coincide accurately. (but the LED indication coincides after full charge)

Figure 2.14 CAIx charging state

Indication of White LED and its action state is as follow.

Mode	Details	LED ON/OFF Stuats
Charging	During charging	Charge status by number of white LED 1~4 lighting
	Charging completed	4 White LEDs On ○○○○
Check battery remains	75~100%	4 White LEDs On ○○○○
	50~75%	3 White LEDs On ○○◯◯
	25~50%	2 White LEDs On ○◯◯◯
	15~25%	1 White LEDs On ●◯◯◯

Charging status of CAI monitor and checking other information

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

→ When the battery level of CAI monitor is below 10%, "Low Battery power (Monitor)"alarm occurs.

On CAI monitor, battery remains and additional information of CAIx and CAI monitor will be displayed.

It is possible to check model name

It is possible to show battery remains,

It is possible to check model name and battery remaining of CAIx (CAI-WL-02-002).
It is possible to show battery remaining, charging state and current time of CAI monitor.

Attaching CAIs

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

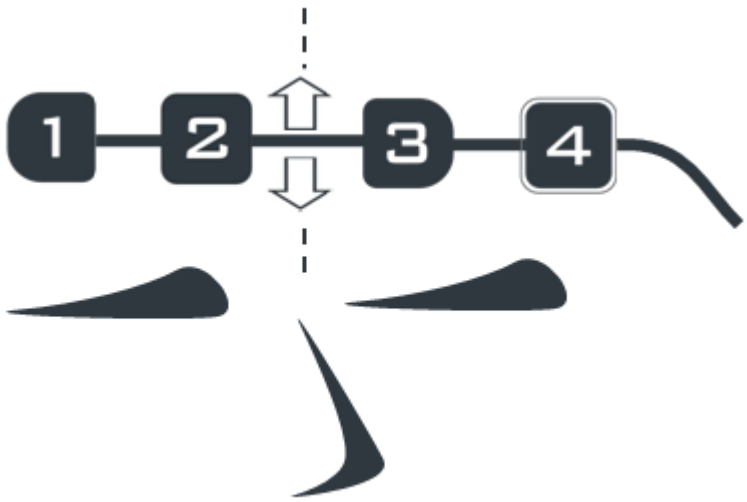


Figure 2.15 Example of CAIs Attachment

2.6 Use Environment

2.6.1 Storage

The monitor and other components can be shipped and stored under below conditions
Note: The following conditions are conditions for shipping and storage in state that the device is not under operation.

- Temperature 10 ℃ to 65 ℃
- Humidity 30% to 95% (without condensation)
- Atmospheric pressure 1060hPa to 700hPa

The CAI 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.

2.6.2 Use Environment of Device

CAI is not designed to be used in a place where flammable gas or steam exists. CAI is designed to be used safely in below conditions.
In environment out of below conditions, reliability of device may be affected.

- Temperature 10 ℃ to 65 ℃
- Humidity 30 % to 95 % (without condensation)
- Atmospheric pressure 1060hPa to 700hPa

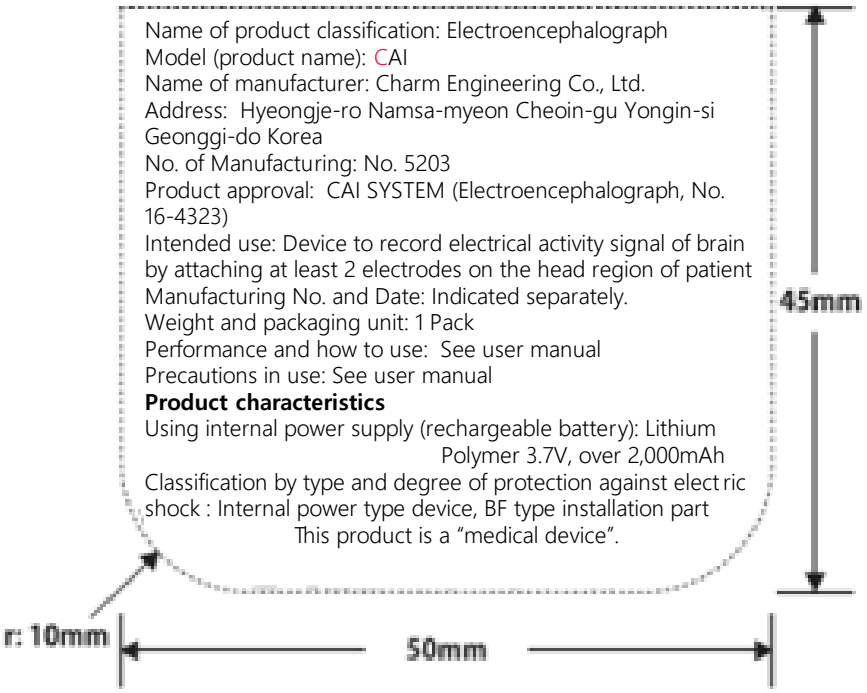
2.6.3 Electromagnetic compatibility (EMC) Conditions

CAI should use only a power supply (battery) supplied or recommended by Charm Engineering.
The device should be installed and used according to contents described in Chapter 5 "Electromagnetic compatibility guideline".
※ Caution: CAI system is used according to IEC 60601-1-2 electromagnetic compatibility requirements.
Using any devices within close distance from this device may give or receive effects from electromagnetic interferences (EMI). If EMI occurs, refer to Chapter 5 "Electromagnetic interference prevention".

2.6.4 Preparation for use : Installation of monitor

In order to improve safety and convenience of using Charm Engineering devices, it is recommended to install the CAI system to anesthetic device permanently. However when permanent installation is difficult, it can be fixed with tongs.

2.6.5 CAI Device Label



Chapter 3 Operation Method of CAI

Conductive component of electrode or sensor and connector should not be in contact with any other conductive parts including ground.
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 should 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 and CAIx connection cable should be located in a stable site to avoid discomfort of patients.

3.1 Connecting CAIs

Figure 3.1 Connecting CAIs

Step 1: Place the front side of CAIs sensor (side with sensor drawing) upward.
Step 2: Insert the CAIs sensor into CAIx connector until "click" is heard.
Step 3: Check the instruction indicated on the package of CAIs and attach CAIs to connection and body area (forehead) firmly as not to be detached.

3.2 Booting system/connecting CAIx/checking CAIs sensor

When booting of the monitor 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 search of Bluetooth, sensor check is started. When 2 or more amplifiers are searched, the screen (①) is displayed to allow selection of amplifier and when the amplifier is selected, sensor check (②) is started.

※ Bluetooth connection code: 1234

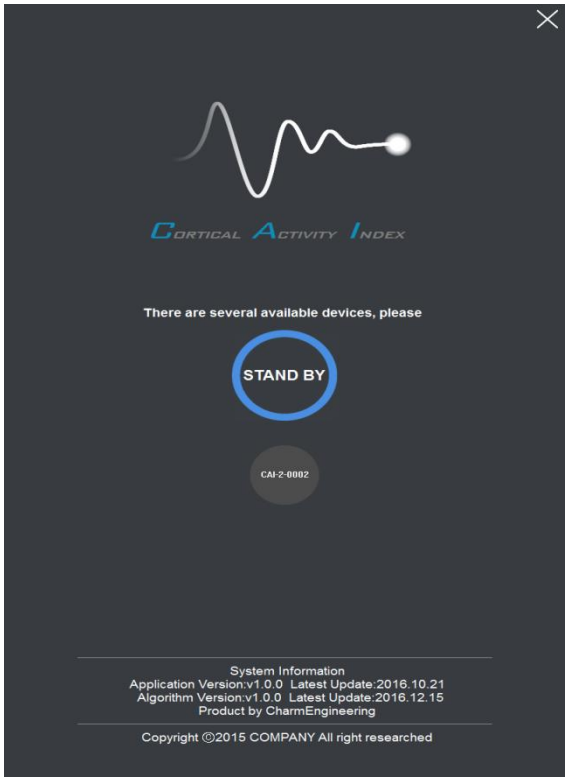


Figure 3.2 Launch screen

3.3 Inspecting sensor

To execute CAI monitoring system, check all sensors whether each CAIs sensor 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.

This symbol indicates that resistance of the electrode is within proper range. When all electrodes pass the inspection, monitoring will be started automatically.

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 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 the 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.

Figure 3.3 Sensor check screen

3.4 Displaying CAI index data

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

Figure 3.4 Main screen

3.4.1 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.

Calculates brain activity values within the range of 2.5Hz ~ 48Hz

Brain activity is calculated by measuring brainwave value above a certain level by dividing measured brainwave into certain time.

Calculates muscular activity by measuring electromyogram in the range of 80Hz ~ 130Hz.

3.4.2 CAI index value (range: 0-100)

CAI index is obtained by processing continuous EEG parameters and it is associated with hypnosis 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 be utilized as the only indicator to control anesthetic medicine dosage. In most individuals, awake state persists when the CAI index is over "80", however in specially calm and sedate individuals, awake state may be observed even when the CAI index decreases to as low as "60".

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

CAI	Clinical state
100	Awake
80	Sedate (sleep)
60	General anesthesia
30	

3.4.3 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.

3.4.4 Electromyogram (EMG, range 0 - 100)

CAI 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 center of screen. EMG activity may be increased in below cases during a surgical operation.

- Response to painful stimulus during operation.
- Body movement or muscle spams

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

When the 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.

3.4.5 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.

3.4.6 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.

3.4.7 Poor signal detection

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

3.4.8 CAI trend graph

Graph composition of CAI trend graph shows changes of CAI index over time.

CAI 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.

If a CAI value is moved out of the target range, a message is displayed on the screen and alarm sounds when audio alarm is set as on. (when no target alarm is set, no alarm will sound) the alarm sounds continuously until CAI index enters into the target range, can be silenced by touching [bell] icon on the bottom left screen, or terminated completely.
When intending to indicate other index values, users can do it by select "BSR", "EMG", or "SQI" on the upper left screen of CAI trend graph.

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

Users can capture and save the screen in specific situations of event, utilizing "Snapshot".

3.5 Main touch icons

On the screen, this anesthetic depth monitoring system composed 4 shortcut icons at the bottom of the screen to control main functions with a single touch while monitoring patient to provide convenience to users.

Figure 3.5 Main screen

3.5.1 Alarm On / Off

Alerting alarm is a function to notify possible issues of patient or of device to users in advance.

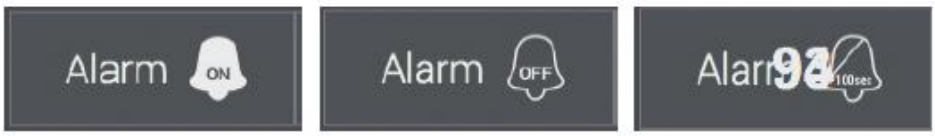


Figure 3.6 Alarm On (left), Alarm Off (center), Alarm Pause (right)

3.5.2 Target Range

When Target Range Activate is turned on, alarm will sound when values go outside of target range.

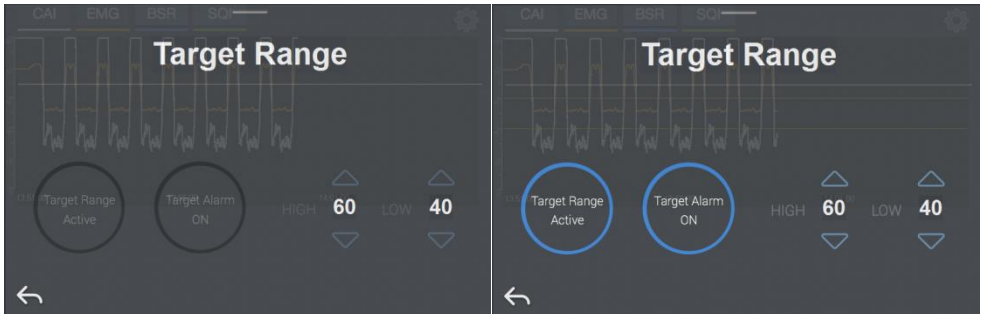


Figure 3.7 Target range ON (left), Target Range OFF (right)

3.5.3 Sensor Check

Checks current state of sensor attachment and displays it to users.

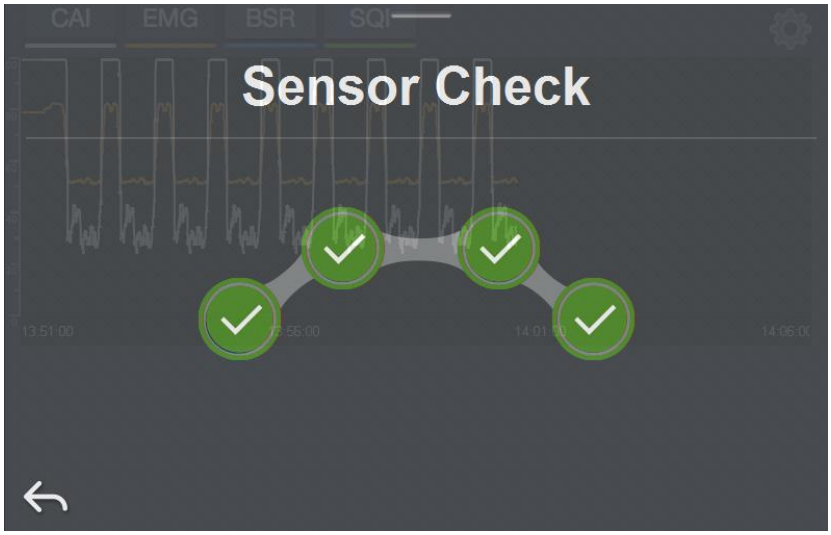


Figure 3.8 Sensor check

3.5.4 Snap Shot

Snapshot function saves current screen in JPEG format during monitoring of patient.
File format: MMDDHHmmss.jpg (CAI/bin/Image Data/mmddhhmmss.jpg)

3.6 Drag icons

When users drag bottom of the screen to top of CAI monitor, menu to explain each function appears. As this device has various functions, users should read this manual thoroughly prior to usage.

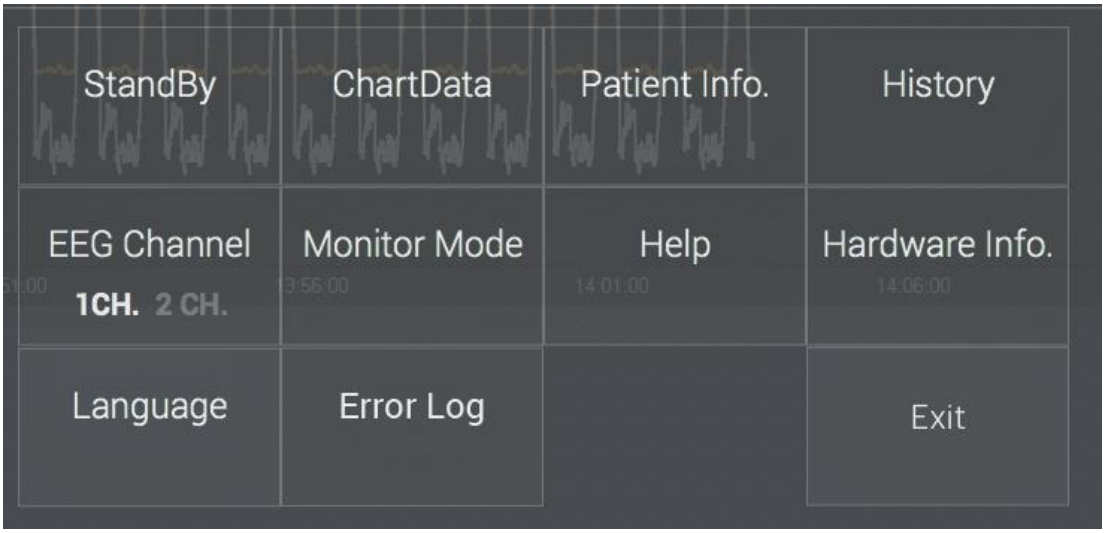


Figure 3.9 Drag icon

3.6.1 Stand by

When clicking StandBy icon at the end of surgery, a Pop-up window appears on the screen. After checking the Pop-up window, move back to initial screen.

3.6.2 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.

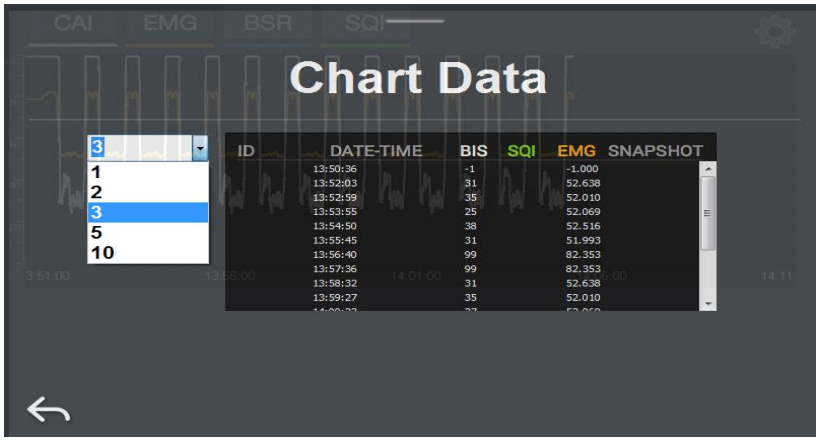


Figure 3.10 Chart data

3.6.3 Patient Information

Inputs and saves information of patient under operation.

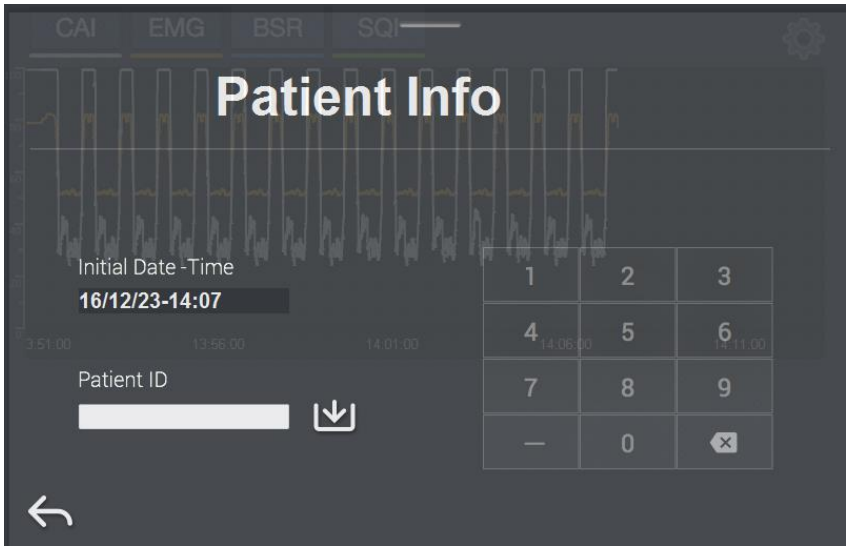


Figure 3.11 Patient Info.

3.6.4 History

Shows list of CAI_Data.csv and Raw_Data.csv saved in Export data.

File name /entered Patient ID / Start-End time/ file size

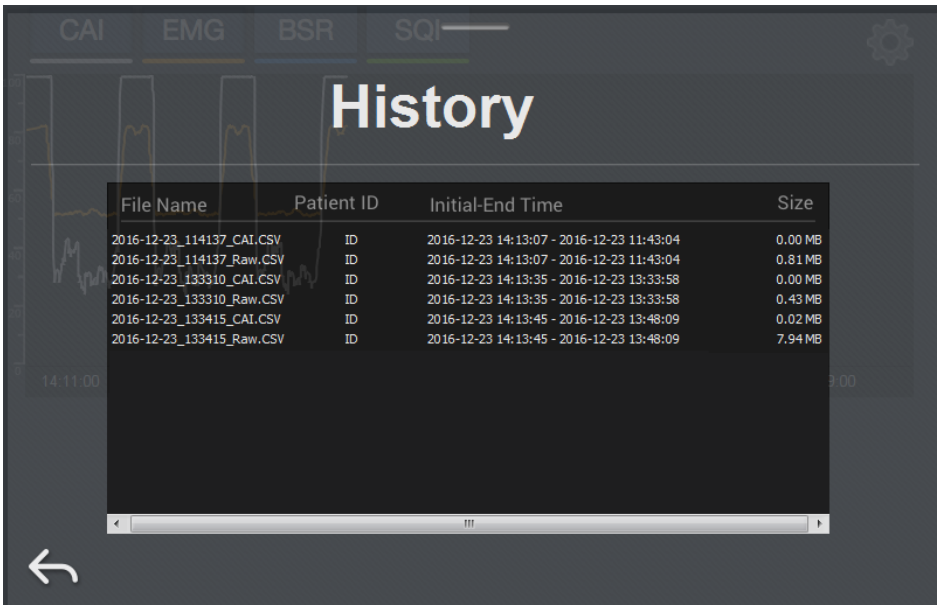


Figure 3.12 History

3.6.5 EEG Channel 1CH / 2CH

Selects either EEG channel 1 or 2, or both of them simultaneously and displays on the main screen.

3.6.6 Monitor Mode

Current setup conditions including Target Range (Min/Max), Alarm On/Off can be checked.

Figure 3.13 Monitor mode

3.6.7 Help

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

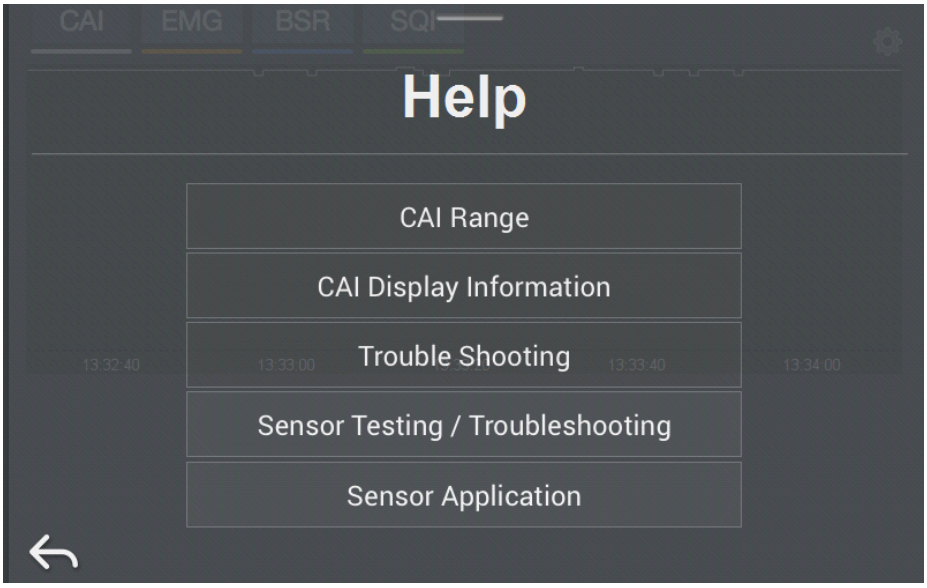


Figure 3.14 Help

3.6.7.1 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.

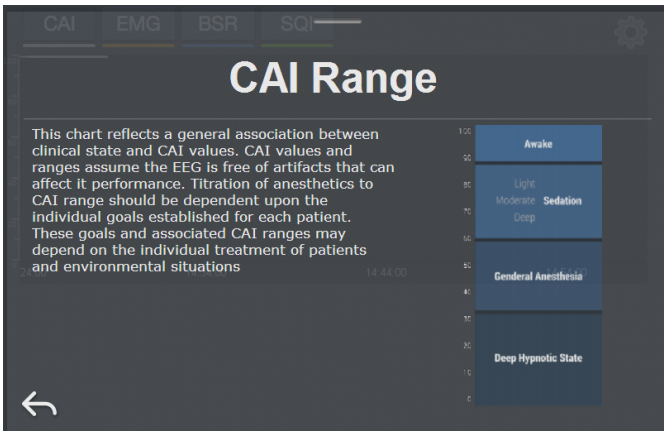


Figure 3.15 CAI Range

3.6.7.2 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.

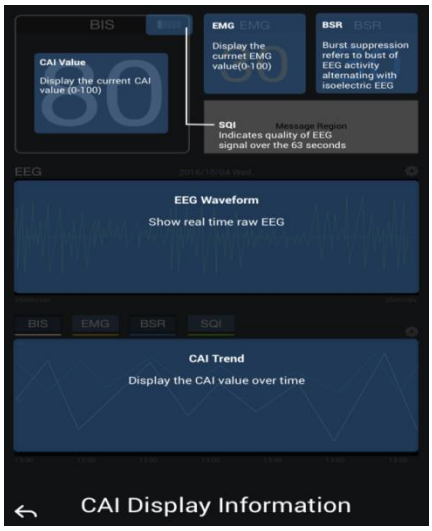


Figure 3.16 CAI Display Information

3.6.7.3 Trouble Shooting

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

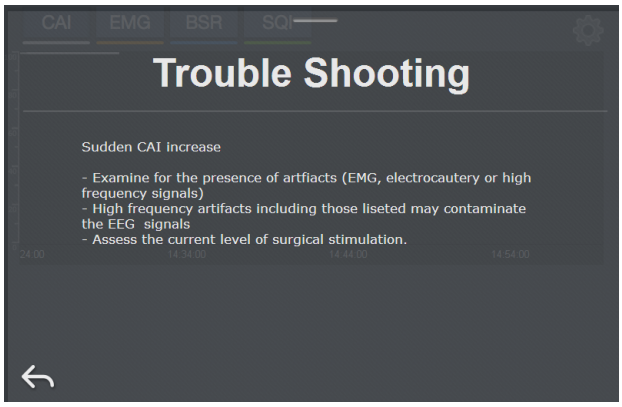


Figure 3.16 Trouble Shooting

3.6.7.4 Sensor Testing / Trouble Shooting

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

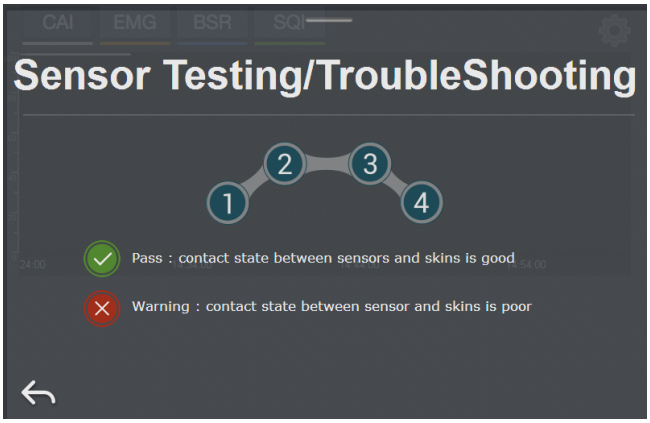


Figure 3.17 Sensor Testing / Trouble Shooting

3.6.7.4 Sensor Application.

This is an explanation about sensor attachment sequence

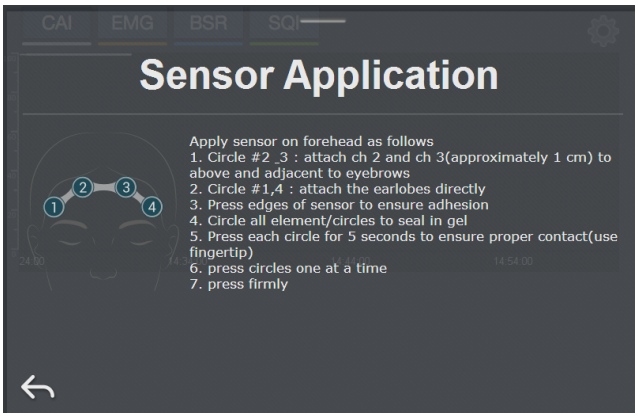


Figure 3.18 Sensor Application

3.6.8 Hardware Info.

This is display of software information of CAIx and CAI monitor hardware information

Figure 3.19 Hardware Info.

3.6.9 Language

CAI is displayed in English.

3.6.10 Error Log

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

※ Please refer to contents of Alarm in Chapter 1.

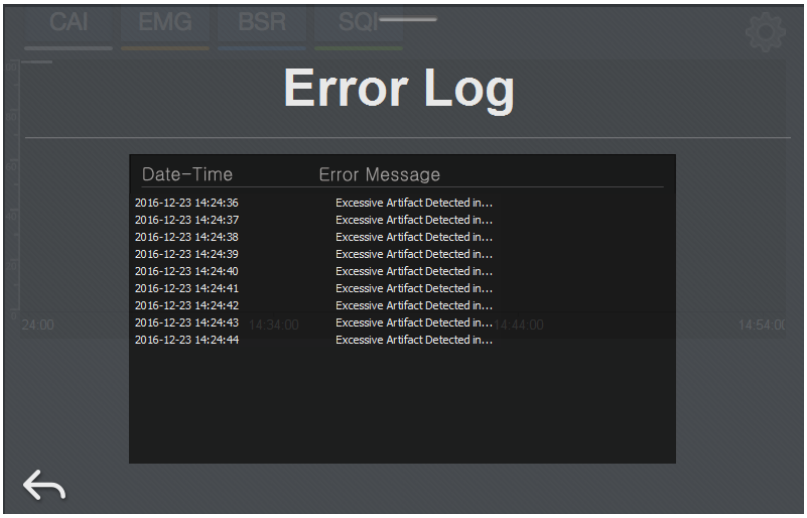


Figure 3.20 Error log

3.6.11 Exit

Terminates CAI system completely.

3.7 CAIx Replacement

There may be a case which is required to replace CAIx due to CAIs problems or physician's decision prior or during operation. In such a case, replace the main body of CAIx according to below sequence.

3.7.1 Prior to operation (by physician's own decision)

Step 1: Physiciam wants to replace new main body of CAIx.
Step 2: Bring new CAIx.
Step 3: Turn on the monitor and search new CAIx.
Step 4: Select the CAIx wanted by physician and use it after connecting Bluetooth.

3.7.1 During operation (by physician's own decision)

Step 1: Physician wants to replace new amplifier during operation.
Step 2: Bring new CAIx.
Step 3: Show Bluetooth connectible list on the monitor and search the new CAIx.
Step 4: Select the CAIx wanted by physician and use it after connecting Bluetooth.

3.7.3 During operation (due to device problem)

Step 1: During operation, a problem occurs in the system suddenly.
Step 2: Bring new CAIx.
Step 3: Show Bluetooth connectible list on the monitor and search the new CAIx.
Step 4: Select the CAIx wanted by physician and use it after connecting Bluetooth.

3.7.4 During operation (due to battery exhaustion of CAIx and CAI monitor)

Step 1: When the battery of CAIx or CAI monitor was exhausted suddenly during the operation. (When battery alarm message occurs)
Step 2: Bring new CAIx or CAI monitor.
Step 3: CAIx replacement: Show Bluetooth connectible list on the monitor, search and connect new CAIx. CAI monitor replacement: Turn on the monitor, select and connect CAIx or connect it to power case to use it
Step 4: Connect and use new CAIx or CAI monitor.

3.8 Battery Check

3.8.1 CAIx Battery Check

Power to CAIx is provided by battery, instead of direct connection from power outlet via power cord. Therefore, battery remains must be checked before using the device. The CAIx (main body – amplifier) in full battery state should be used and when battery available time is less than 1 hour, use it after replacing CAIx main body.
LED display on operation mode and battery charging state of CAIx is as follows.

Mode	Details	LED On/Off Status	
Charging	During charging	White LED 1~4 charge status On by number	
	Charging completed	4 White LEDs On	○○○○
Check battery remains	75~100%	4 White LEDs On	○○○○
	50~75%	3 White LEDs On	○○○◯
	25~50%	2 White LEDs On	○○◯◯
	15~25%	1 White LED ON	○◯◯◯
	1~15%	1 Orange LED ON	●◯◯◯

3.8.2 CAI Monitor Battery Check

CAI monitor is a universal display image device, which, can use both USB charging and battery mode. Although it is possible to use it by connecting with power cable when the remaining battery is insufficient, it is recommended to use the device after charging instead of connecting the power cable.

Battery power supply of CAI monitor is displayed on the upper right of the screen and it is recommended to use it at over 80% of power supply.

3.9 Termination of CAI

When intending to terminate use of CAI monitoring system,

- Push the CAIs sensor connected to the 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 is not reusable as it is produced for single use.
- Store CAIx in state that it is connected with CAIx cable to prevent loss of components.
- When use of CAI (surgery) is continuous, maintain stand-by mode on CAI monitor, and connect new CAIs for making it immediately usable state.
- When it is the last surgery of that day, disconnect CAIs sensor from CAIx connector and store the connecting cable and CAIx.
- After surgery, arrange the CAI system and store it in a designating place for next surgery. (When the device is contacted and/or contaminated with blood or other drugs, clean them up prior to storage and store the CAI in a designating place)

※ Caution: Do not disconnect power cord with wet hand. Check if the hands are clean and dry before touching the power cord.

3.10 Troubleshooting

Classification	Error situation	Error Message	Action to be taken
Sensor	When sensors are not attached firmly	Sensor Connect Error	1. Check sensor attachment on the patient. 2. Check connection between sensor and amplifier connector.
Signal	When Patient movement or strong noise in external environment occurs	Excessive Artifact Detected in Signal	1. Remove possible causes of noise around the sensor and amplifier.
CAI	When the BSR value is 100 for 63s	Isoelectric EEG Detected	1. Check the patient condition. 2. Check whether the sensor is disconnected. 3. Confirm sensor check.
	When the set CAI value is exceeded	CAI Out of Target Range	1. Check the patient condition. 2. Check the set range.
Battery	When battery remains of the monitor is below 10%	Low Battery Power (Monitor)	1. Recharge the CAI Monitor
	When battery remains of the amplifier is below 10%	Low Battery Power (Amplifier)	1. Recharge CAIx.

Chapter 4 Maintenance and Cleaning

This chapter describes preventive maintenance and cleaning of device for safe and correct use of device, which are essential contents.

4.1 Precautions

These are items that users must be aware for device safety, therefore provide training to comply the following contents prior to use.

- Do not replace some or all of components supplied without contacting or reporting to the manufacturer.
- Do not use the supplied cable which has any defect or problem in its sheath.
- When any liquid or similar material percolated into any component of CAI monitor or CAI, must turn off the device, disconnect the cable, and contact manufacturer.
- When there is any electrical defect in any form, do not use it.
- When there is any mechanical breakage, different performance from the initial state, or loosen assembly of components, do not use it.
- When any damage or loss of component is detected in inside and/or outside of the device, the device should not be used.

In all of the above mentioned situations, users must inform incidents to the manufacturer. As matters in the above listed or similar to, or modifications of device that may cause any problem in device safety are not part of manufacturer's warranty range, and the manufacturer holds no liability on them.

4.2 Cleaning and Maintenance of Device

This device should be inspected by personnel approved by the manufacturer at least once a year.

4.2.1 Cleaning of device

When blood or other potentially contaminating material is in contact with this device or its parts, users must maintain its cleanness and prevent its malfunction by cleaning prior to usage.

In addition when any liquid or blood is contacted with this device while in use, system inspection is also needed to prevent any error in future operation.

* Washing and cleaning of CAI system and its display monitor

- When any liquid or blood is in contact with the CAI system or the monitor, eliminate the contaminant immediately using lint-free absorbent towel. (For blood, it may be coagulated over time and become very difficult to remove)
- For overall cleaning, wipe with wet towel in detergent, tepid water, and with alcohol sequentially and dry it completely. (Residual moisture may affect inside of the connector)
- For disinfection, disinfect it with 10% bleach or bactericide (Lysol(R) professional disinfectant foam cleaner spray or PDI disposable wet tissue) on lint-free absorbent towel.
- When cleaning the display screen, wipe it with commercially available display screen cleaner or detergent and neutral solution. (However in order to prevent scratch on the screen, do not use an abrasive detergent)

* Caution: When the device is used continuously without removal of the blood or liquid, current leak may occur. When some disinfectants are mixed up (bleach and ammonia), harmful gas may develop.

* Do not use autoclave. Autoclaving may cause damage of product components.

* Avoid liquid ingress to the cable connected with patient. Performance of sensor connector may be disturbed.

4.2.2 Maintenance

Although CAI system is designed to avoid any need of regular adjustment or calibration, routine maintenance should be inspected regularly.

*** Regular inspection items**

- Check battery remains of CAIx and CAI monitor and contact the manufacturer when there is any defect in power supply of the battery. (Even though the battery has been stored after full charging (charging for at least 6 hours), it is necessary to inspect the battery regularly through operation of CAI monitor.)
- Check whether CAIs and CAIx operate properly after connecting them.
- As the connection cable is regarded as part of disposables, wearing of the cable is expected in its continuous usage. Check any contamination, poor contact, damage or breakage of the cable. (When the connection cable and its connector part have been used for at least 6 months, perform test on its operation and it is recommended to replace it when there is any defect.)
- Manufactured connection cable has manufacturing date on it to check its aging. (Cable Part Name-MMDDYY)
- Self-Check items for CAI system operation check

  Step 1 : Connect CAIs or Test kit and connection cable of CAIx and then turn CAIx on. When it is turned on, check its battery remains. (It is recommended to use it when its battery remains is over 80%).

  Step 2 : When CAIx and CAI monitor are not turned on after connecting CAIs or Test kit and CAIx or sensor connection is not identified on the CAI monitor, contact to customer service of Charm Engineering.

- When battery of CAIx and CAI monitor has not sufficient power output or is not continued for at least 1 hour, it is required to replace them with new one.

*** Inspection of leakage current**

- Leakage current is a basic indicator to indicate risk of electric shock for people who may be in contact with the exposed external surface of the device. CAI is inspected carefully in the factory for its leakage current to meet safety standards of IEC 60601-1-1 and IEC 60601-1-1. The device should receive inspection on leakage current at least once a year regularly.
- It should be noted that solutions such as salt water and Ringer solution as well as blood are all conductive. Touch no part of the system with wet hands. Work always with clean and dry hands.

As results of manufacturer's testing, its ground leakage current and patient safety current are lower than the limit established by the relevant safety standards. To maintain safety, the agency should conduct regular test to check the relevant current. When any leakage of blood or liquid occurs, test should be always performed again prior to use.

CAI Monitoring system complies with IEC60601-1, receiving KC certification and this content is indicated on the device label.

*** Device Identification**

The identification information is indicated on the device and its package box. This information includes device model, serial number, rated power, precautions, and manufacturer information.

*** Software information**

The software version is shown on the bottom of screen
Information on Application, Algorithm Version and latest Update are displayed respectively.

4.3 Warranty Information

Charm Engineering guarantees below items.

- This device has no defect of component and device, and is assembled without any problem to be used by medical professionals in general situation. The device has 12 months warranty period from the date when the device was supplied to the user.
- All parts and raw materials of this device has no defect, there is no problem in using it in general condition, and it has 60 days warranty period from the date when the device was supplied to the user.
- When device repair is necessary within its warranty period, users must inquire to the local representative or to the manufacturer.
- Depending on warranty period, repair or replacement may be made.
- When device service is needed, inquire to customer service of Charm Engineering.
- When sending a device for service, pack and send it to avoid loss or damage. Any damage or loss of device during shipment is not included in our warranty coverage.
- This warranty conditions are applied only to the initial buyer, its resale is beyond the warranty coverage.
- For the matters included in the warranty coverage, the manufacturer bears cost for delivery as well as repair and replacement. But, any damage caused by users' mishap or physical damage lies on the head of buyer.

Below items are beyond the coverage of this warranty.

A device damaged from abuse, negligence, or accident, the device damaged from any cause out of warranty coverage, device used by violating its precautions, device attached to nonstandard accessary device, device whose serial number is removed or unreadable, device revised or repaired by anyone who is not an engineer qualified or assigned for this device, or device disassembled, serviced, and reassembled by any person who is not approved by manufacturer is beyond the warranty coverage.

In addition, the manufacturer has no duty to repair, replace, and modify the device totally or partially due to routine wearing. Charm Engineering bears no liability on any device purchased from a person other than our official local representative or any device sold in brand other than Charm Engineering.

*** About software license**

The computer software ("license software") loaded on the CAI monitor ("System") is licensed to be used only in this condition and not sold separately. Charm Engineering has all rights not

granted you explicitly. Although you possess the system itself, Charm Engineering holds all ownership, right, and authority about the licensed software.

1. **License:** Concerning to specific system that licensed software is provided, nonexclusive right to use the licensed software is to be granted.
2. Restrictions: You should not transmit the licensed software from the system on this contract to another computer or system in any way without prior written permission of Charm Engineering. You should not distribute the license software or copies of its related document. You should not revise or translate the license software or copies of its related document without prior written permission of Charm Engineering. The license software contains trade secrets and it is prohibited to perform decompile, reverse engineering and decompose of license software or make it human recognizable format to protect it. When the system is transferred, you have a right to transfer the license software on the premise that the transferee agrees to application of this contract terms.
3. **Termination:** This license will be effective continuously until it terminates. When you do not comply with this license terms, this license will be terminated automatically without notice of Charm Engineering. In termination of this license, you cannot use this license software anymore.
4. **Limited Warranty:** This license software is provided in "current state" without any expressed or suggestive additional warranty such as warranty on commerciality or special purpose compatibility. Charm Engineering provides no warranty that functions included in the license software meet your requirement, there is no discontinuance or error in operation of license software, or such error of license software will be revised.
5. **Limitation of relief or liability for damage:** Regardless of causes, all liability and relief that Charm Engineering bears for your actual damage will be limited to the amount you paid in purchasing the system including the license software.

4.4 Customer Service and Service Center

For servicing of the device, contact customer service of Charm Engineering or local representative and receive unique ID for the service.
Prior to shipping the CAI monitoring system for servicing, prepare below items.

- Describe abnormal conditions of CAI monitoring system in detail.
- Clean the device to remove infectious hazards before shipping.
- Wrap the device with initial packaging material.
- Send it with all components and parts excluding the sensor used in malfunction or abnormal occurrence.
- Send CAI monitoring system to customer service of Charm Engineering or local representative.

Chapter 5 IEC 60601-1-2:2001 Electromagnetic Compatibility Guideline

This chapter describes specification of Electromagnetic Compatibility Guideline used by CAI monitoring system for user's reference. (IEC 60601-1-2.)

<table>
<tr><th colspan="3">Electromagnetic Interference</th></tr>
<tr><td colspan="3">When a user or purchaser intends to use model 002 in below specified electromagnetic conditions, t he user or the buyer should identify whether model 002 is used in the following conditions.</td></tr>
<tr><th>Interference Test</th><th>Compatibility</th><th>Electromagnetic conditions - guideline</th></tr>
<tr><td>Radioactive interference KN 11</td><td>Type 2</td><td>Model 002 must emit electromagnetic energy to perform intended function. Thus surrounding elec tronic device may be affected.</td></tr>
<tr><td>Radioactive interference KN 11</td><td>Grade A</td><td rowspan="3">Model 002 is compatible to use in all facilities ex cluding facility using power through direct conne ction to public low voltage power network suppli ed for household and self- use.</td></tr>
<tr><td>Harmonic interference IEC 61000-3-2</td><td>Not applied</td></tr>
<tr><td>Voltage fluctuation/ Flicker interference IEC 61000-3-3</td><td>Not applied</td></tr>
</table>

<table>
<tr><th colspan="4">Electromagnetic tolerance</th></tr>
<tr><td colspan="4">When the user or the buyer intends to use model 006 in below specified electromagnetic conditions, the user or the buyer should identify whether model 001 is used in the following conditions.</td></tr>
<tr><th>Tolerance test</th><th>IEC 60601 test level</th><th>Compatibility level</th><th>Electromagnetic conditions - guideline</th></tr>
<tr><td>Conductive RF
KN 61000-4-6

Radioactive RF
KN 61000-4-3</td><td>3 Vrms

150 kHz～80 MHz

3 V/m

80 MHz～2.5 GHz</td><td>3 Vrms

3 V/m</td><td>A portable or mobile communication device should not be closer than separation distance from any part of model 006 calculated by equation applied to transmitter radiofrequency.

Recommended separation distance
$d = 1.2\sqrt{F}$
$d = 1.2\sqrt{F}$ 80 MHz～800 MHz
$d = 2.3\sqrt{F}$ 800 MHz～2.5 GHz
Wherein, F is rated maximum output power expressed as watt (W) published by the manufacturer of transmitter and d is recommended separation distance expressed as (m).

The field intensity of fixed RF transmitter determined by field inspection[a] of electromagnetic environment should be below compatible level in each frequency range.[b]
Around medical devices having below symbol, there may be interference.
  </td></tr>
<tr><td colspan="4">Remark 1. Apply higher frequency range at 80 MHz and 800 MHz.
Remark 2. This guideline cannot be applied to all situations. Because electromagnetic wave may be affected by absorption and reflection by structure, object and human.</td></tr>
<tr><td colspan="4">[a] For the field intensity developed from fixed transmitter such as base station of wireless telephone (car phone/cordless phone), land mobile wireless, armature radiofrequency, AM and FM broadcast, and TV broadcasting, its precise theoretical prediction is difficult. In order to assess electromagnetic environment from the fixed RF transmitter, field section should be done. It is required to observe and validate whether the model 006 operates normally. It the field integrity measured in the place where the model 006 is used exceeds applicable RF compatible level, it is required to observe and validate whether the model 006 operates normally. When an abnormal operation is observed, additional action to adjust orientation of model 006 or transfer it to another place may be needed.

[b] In the frequency range of 150 kHz～80 MHz, the field integrity should be below 3 V/m.</td></tr>
</table>

Recommended separation distance between portable or mobile RF communication device and model 006

It is intended to use model 006 in electromagnetic environment where radioactive RF interference is controlled. The buyer or the user of model 006 can prevent electromagnetic interference by maintaining minimum distance between portable and mobile RF communication device (transmitter) and model 006 as recommended in below, on the basis maximum output power of the communication device.

Rated maximum output power of transmitter W	**Separation distance compatible to transmitter frequency (m)**		
	150 kHz～80 MHz $d = 1.2\sqrt{F}$	**80 MHz～800 MHz** $d = 1.2\sqrt{F}$	**150 kHz～80 MHz** $d = 1.2\sqrt{F}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Recommended separation distance for transmitter having rated maximum output power not listed in the above, α (m), can be determined using equation applicable to the frequency of transmitter. Also wherein *F* refers to rated maximum output power expresses as watt (W), which was published by the manufacturer of transmitter.

Remark 1. Apply higher frequency range at 80 MHz and 800 MHz.

Remark 2. This guideline cannot be applied to all situation. Because electromagnetic wave may be affected by absorption and reflection by structure, object and human.

FCC Information to User

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 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 con-nected.
• Consult the dealer or an experienced radio/TV technician for help.

Caution

Modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Compliance Information : 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.

IMPORTANT NOTE:

FCC RF Radiation Exposure Statement:

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Address : 5, Hyeongje-ro, Namsa-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, 17118, KOREA

Tel : + 82-31-330-8500 **FAX** : + 82-31-330-8600