BT-1000

Operation manual

BT-1000

Keep this manual for future reference

P/N: 1000-ENG-OPM-USA-R01

Proprietary Material

Revision R01
November, 2024

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1. Safety information

1.1. Instructions for the Safe Operation and Use

Symbols used:

The following symbols identify all instructions that are important to safety. Failure to follow these instructions can lead to injury or damage to the device. When used in conjunction with the following words, the symbols indicate:

WARNING • Can lead to serious injury or product/property damage.

The following symbols are placed on product, label, packing and this manual in order to stand for the information about:

Symbol	Standard/Symbol Reference no.	Description
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / W001	Used to display safety information for warnings. Before using the BT-1000, please be fully understand the information provided with the device.
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.4	Used to identify safety information for caution. Be well-known this information thoroughly before using the device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5333	Indicates the BF applied part. It is applicable to Doppler probe.
IP22	IEC 60529 Degrees of protection provided by enclosures	Indicates the protection level against the ingress of solid object and liquid. IPX7 is protection against the effects of temporary immersion in water.
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.1	Indicates the manufacturer.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5031	This symbol means a DC power adapter.
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / M002	Refer to the operation manual. Read the manual before placing the device.
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.3	Refer to the operation manual. Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.3	Indicates the date when the medical device was manufactured

SN	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.7	Indicates the serial number of the device.
REF	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.6	This symbol indicates a reference number.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.4	This symbol indicates to keep the device dry.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.1	This symbol indicates the medical device that can be broken or damaged if not handled carefully.
	ISO 7000 — Graphical symbols for use on equipment -- Registered symbols / 0623	This symbol indicates to keep upright
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.2	This symbol indicates to keep the device away from sunlight.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.7	Indicates the temperature limitation for transport and storage.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.8	Indicates the humidity limitation for transport and storage.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.9	This symbol indicates the range of atmospheric pressure to which the medical device can be safely exposed for transport and storage.
	Universal Recycling symbol	This symbol indicates the packing material is recyclable.
	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) EN 50419 Marking of electrical and electronic equipment	This product may contain material which could be hazardous to human health and the environment. DO NOT DISPOSE of this product as unsorted municipal waste. This product needs to be RECYCLED in accordance with local regulations, contact your local authorities for more information. This product may

		be returnable to your distributor for recycling - contact the distributor for details.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.2	Do not re-use Indicates a medical device that is intended for one single use only
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.4	Use-by date Indicates the date after which the medical device is not to be used
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.7.7	This symbol indicates the item is a medical device
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.7.10	This symbol indicates a carrier that contains unique device identifier information.
	Indicates that the product is a medical device as defined in 21 CFR 801.15(c)(1)(i)(F) and Federal Law (USA) restricts this device to sale by or on the order of a licensed physician (21 CFR 801.109)	Prescription only

※ According to IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard: Usability, the definition and using these symbols is adjusted.

1.2. Warnings

⚠WARNING

- Be sure to thoroughly read the contents of the user manual before use.
- Follow general safety precautions.
- Do not use this product for any purpose other than its intended use.
- Do not immerse this product in water or other liquids.
- Follow the instructions in <Cleaning and disinfection> for cleaning and disinfection.
- Be careful not to get dust or especially metal objects into the device.
- Do not use for patients with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.
- The device is only for use on healthy, clean, intact skin.
- Do not place in a place with high humidity or large temperature changes.
- Do not use the product where the environmental conditions for humidity, temperature and atmospheric pressure exceed those specified in this manual.
- Do not place in a hazardous location where chemicals or explosive gases leak.
- If you experience an allergic reaction while using the product, discontinue use.
- Children 7 to 12 years receiving the treatment through this device should be closely

supervised by an adult who has read the user manual and is familiar with this device.

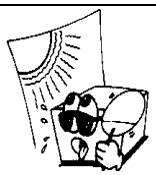
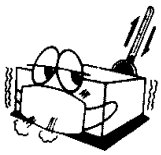
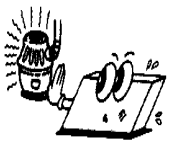
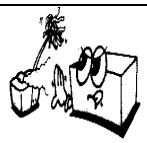
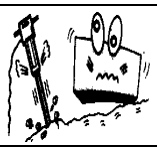
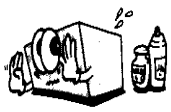
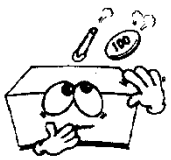
- The device is only intended to be used on one patient. Do not apply to two patients, apply one CH to one patient only.
- If the product is damaged or does not operate normally, stop using it and request repair through the place of purchase or Bistos Co., Ltd.
- Please do not modify or repair the product arbitrarily. We are not responsible for malfunction or damage caused by disassembly.
- If the product is not used for a long period of time, keep the battery fully charged.
- This equipment is used according to the prescription of a specialist, so if you experience discomfort such as pain or itching at the site where the disposable electric stimulation electrode is attached, or symptoms such as dizziness or insomnia, be sure to consult with a specialist.
- Do not apply stimulation to any part of the body other than the location of the patient's head as specified and shown in "Chapter 3.2.5 Electrode connect" of this manual. Do not apply stimulation to any other part of the patient's head.
- Do not attach disposable electric stimulation pads to areas with inflammation, burns, or wounds.
- Patients must not be connected to high frequency surgical medical devices, or other electronic medical equipment, while using the stimulator because burns may occur at the stimulator electrode area or malfunction may occur.
- Electrodes are not to be placed near the chest as this may increase the risk of heart failure.
- Do not place electrodes over the eyes, mouth, front of the neck (especially on the carotid artery), chest, upper back, or heart.
- Not to twist or coil the electrode cable. In particular, not to wrap the cable around the patient's or user's neck.
- Do not use the device with a position that electrode cable or other lines are possible to be entangled
- When disposing of packaging materials, comply with local waste disposal laws and regulations. Keep the packaging material out of reach of children.
- BT-1000 can only be repaired or replaced by qualified personnel. For details, refer to the service manual. Bistos will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to qualified service personnel in parts repair.
- BT-1000 should be kept out of the reach of infants and children under the age of 7 years.
- Not to let small parts being inhaled or swallowed. Risk of asphyxiation.
- Always use only accessories supplied by Bistos Co., Ltd.
- If a patient are receiving treatment from a doctor for an acute disease, malignant disease, infectious disease, heart disorder, high fever, abnormal blood pressure, skin perception disorder, or skin abnormality, or if you feel any abnormality, be sure to consult with your doctor before use.
- Long-term effects of using the BT-1000 device is unknown.
- Do not use in patients with body-worn device (e.g., insulin pumps, t-VNS)
- The BT-1000 should not be used with other electronic therapeutic device.

NOTE

- This product is a medical device and should be used according to a specialist's prescription. Do not use it for any purpose other than its intended use.

1.3 General Precaution on Environment

- Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 30% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

2. Introduction

2.1. Intended use and Product description

The BT-1000 external Trigeminal Nerve Stimulation System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.
The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

The BT-1000 is a medical device that is not connected to any other device or networks. It is used only in a single location, it does not transmit or communicate any data.

2.2. Product Configuration

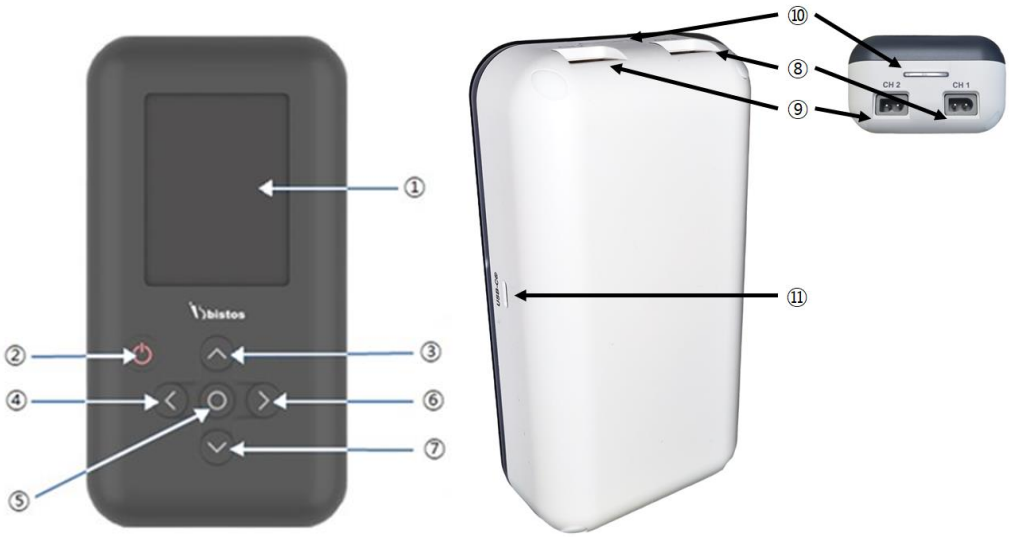
When unpacking, ensure that all of the following components are present. Standard components include:

Name	Operation Manual	Main body	Electrode	Electrode extension cable	Carrying case (Pouch)
Shape					
Quantity	1	1	1 (disposable)	1	1

WARNING

- For consumables, inspect them for wear or damage before use and replace them if necessary. Contact Bistos Service Center.
- The electrode is disposable, so multiple uses are prohibited. And contact Bistos Service Center if you need to order new electrode.

- The composition of BT-1000 is as shown below.

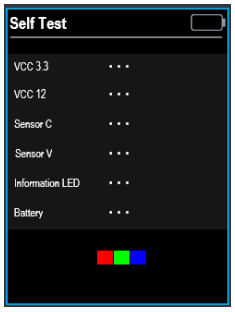
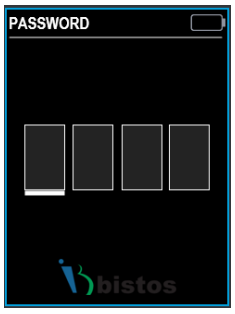


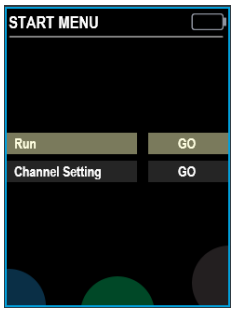
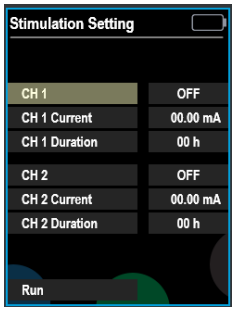
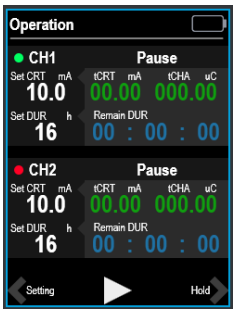
No.	Name	Description		
①	LCD display	Electronic stimulation signal setting status, stimulation status, Error information display		
②	Power button	Main body power ON/OFF		
③	Button(Up)	Up		
④	Button (Left)	Left		
⑤	Button (Set)	Select / Save & Back		
⑥	Button (Right)	Right		
⑦	Button (Down)	Down		
⑧	CH1	Channel 1 stimulation signal output terminal		
⑨	CH2	Channel 2 stimulation signal output terminal		
⑩	Status LED	stimulation signal output status display LED		
		Normal Ready for use	Normal Operating status	Abnormal operating status
⑪	USB-C Connector	USB-C type terminal for charging		

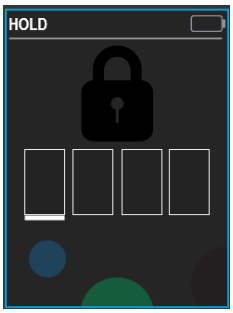
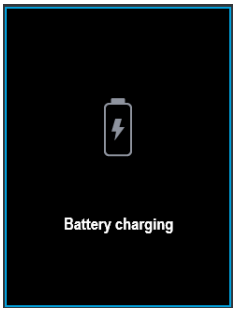
⚠ CAUTION

- The device applies only one channel to one patient. One channel is used for stimulation and the other channel is for reserve.

- Display Description

Figure	Name	Description
	Boot	Boot process and logo display when power on
	Self-test	Determination of system error of H/W that operates stimulus signal output and measurement function. System Error → Stop operation
	Password	When power is on, when hold is released Enter a 4-digit password using the combination of Up, Down, Left, Right, and Select buttons. - Initial Password ← ← ← ← - It can be changed in the system setting menu.

	Start menu	RUN – move to Operation screen Channel Setting – move to Stimulation Setting menu screen
	Stimulation Setting	- CH1, CH2: Set Stimulation channel 1 or 2 On/Off - Current: Setting the stimulation signal current level (1.0 - 10.0mA) - Duration: Setting the operation time of stimulation signal delivery (1, 2, 4, 8, 12, 16 hr)
	System Setting	Select, Down Key at Start Menu. - LCD Light : LCD brightness setting (1 ~ 3 level) - Date: Set the current date - Clock: Set the current time - Password: Password setting for stimulation signal output and system protection - F/W Ver: Main body firmware version information
	Operation	- Set CRT (Set current): Display the set current value - tCRT (True Current): Displays the measurement value of the stimulation signal actually transmitted to the brain (mA) - tCHA (True Charge): Converts current delivered to the brain into charge value and displays (μQ, mQ) - Set DUR (Set Duration) : Displays the set duration (hr) - Remain DUR (Duration): Displays remaining time during Duration (hr, min, sec)

		- Pause state while displaying the play button - Run status while displaying the pause button
	Power Off	Power Off indication
	Hold	Key Hold and LCD Off during Operation
	Battery Charge	When the charging cable is connected, Functions of the device cannot be operated.
	Battery	Indication of power status and charging status Low, 10%, 50%, 70% or more, 100% display during charging
Running	Running	Operating status
Pause	Pause	Pause status

RampOff	Ramp Off	A state in which the current value gradually decreases when changing to the pause state
OFF	Channel off	Channel off status
HIGH CURRENT	High Current	Overcurrent
HIGH IMPEDANCE	High Impedance	High impedance at the electrode pad attachment site
UNSTABLE	Unstable Current	Unstable current control
LOW BATTERY	Low Battery	Low voltage. Battery charging required.

- The electrode composition of BT-1000 is shown in the figure below.

No.	Name	Description
1	size / length	90 x 40 mm / 300 mm
2	composition	Liner, Electrode, Lead wire
3	Shelf-life	2 years (from the date of manufacture)

⚠ CAUTION

- Use only electrode supplied by Bistos Co., Ltd. Use of accessories not provided may result in personal injury or equipment damage.

3. Operation

3.1. Operating Principle

The operating principle of the BT-1000 external Trigeminal Nerve Stimulation System involves the delivery of low-level electrical pulses to the trigeminal nerve via an electrode placed on the forehead. The electrical pulses are generated by a controller unit and transmitted by wire to the electrode patch. This non-invasive stimulation activates the trigeminal nerve, which subsequently influences specific brain regions associated with conditions like ADHD.

3.2. How to use?

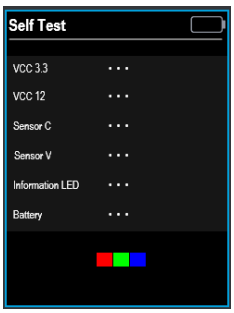
- Check that the product is not damaged.
- Connect the electrode extension cable to the stimulation output channel connector on the Main body.

3.2.1 Power On

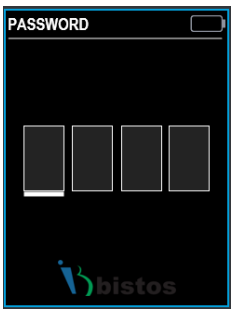
- If you press the power button () in the charged state and power off state, the boot screen is displayed for several seconds and then disappears and the start menu is displayed.

< Boot >

- The self-test is executed automatically and the password input window appears.



< Self-test >



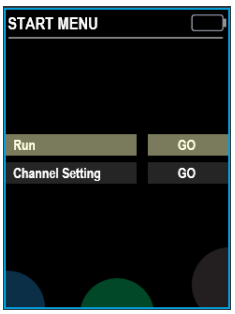
< Password >

3.2.2 Enter Password

- Enter the four passwords following the prompt you set before with a combination of five input buttons Up, Down, Select, Left, Right. 
  - Device default password is  .
- If the password matches move to the start window automatically.

3.2.3 Start window

- Use the up and down buttons  to select the Run or Channel settings menu (highlighted color indicates the menu selected) and press the select button  to go to the corresponding window.
- Select Run or Channel setting menu with Up, Down button, and (highlight selected menu is displayed) press select button  to move to the relevant window.
  - The device stores the stimulation settings of the previously set channel, so if no changes are required, you can go directly to the Operation window by selecting the Run menu. If you want to run the stimulation after changing the new stimulation settings, go to the Channel setting window.
- If you selected the Run menu (Section 3.2.5)
- If you selected the Channel settings menu (Section 3.2.4)
- If you press the select button and down button together for more than 2 seconds, it moves to system setting (Section 3.2.6)

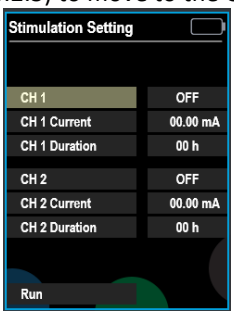


< Start menu >

3.2.4 Channel Setting window

- Move to the menu you want to change with the Up, Down buttons  .
- When the select button  is pressed (in the highlighted menu), the variable turns green and is activated. Change the value with the up and down buttons, and press the select button to set the value.

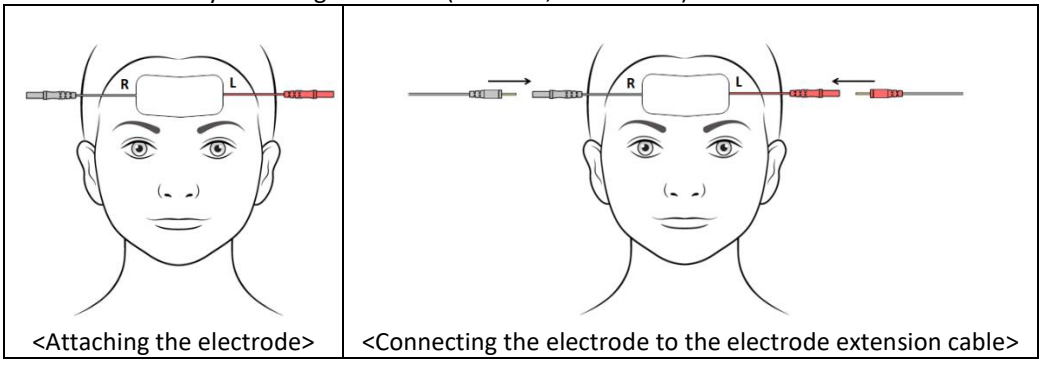
- When the parameters are set, move to the Run menu with the up and down buttons and press the select button (Section 3.2.5) to move to the Operation window.



< Simulation Setting >

3.2.5 Electrode connect

- Wipe the attachment site with soft gauze soaked in 70% alcohol solution and completely dry the skin.
- Remove the liner from the back of the electrode and attach it to the center of patient's forehead.
- Connect the connection terminals of the electrode to the terminals of the electrode extension cable by matching the colors (Red-Red, Black-Black)



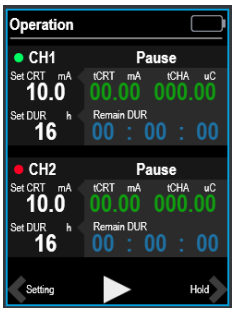
<Attaching the electrode> <Connecting the electrode to the electrode extension cable>

- Insert the electrode extension cable connected the electrode into one of the two output channel (CH 1 or CH 2) of the device.
  Be sure that the electrode extension cable is securely connected in one of the output channel.

< Connecting the electrode extension cable to the device >

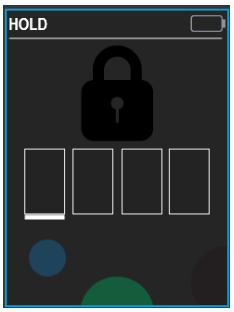
3.2.6 Operation window, Hold window

- Check the setting values such as Current and Duration again before outputting the electrical stimulation signal.
- When you enter the operation window, the default is pause mode, and run menu  appears at the bottom of the window and ready to run.
- While in pause mode, press select button Select  to activate run  then stimulation is starting. While in stimulation, the PAUSE menu  is displayed at the bottom of the window, allowing to pause the stimulation by pressing select button Select  if necessary.
- For 15 minutes from the first output of the electrical stimulation signal, it measures whether the impedance of the attachment part is appropriate, and if it is measured in a high impedance state, High Impedance information is displayed and operation is stopped. In this case, close the connection area and the disposable electric stimulation pad attachment area again, and after checking, try item 3.2.5 again.
- After 15 minutes from the first output of the electrical stimulation signal, it maintains operation even in a low impedance state and displays high impedance information.



< Operation >

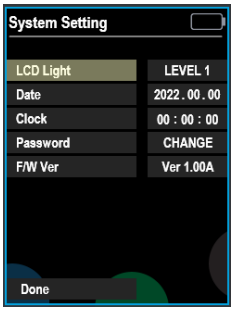
- After 30 seconds from the starting of stimulation, the screen turns off and enters the key-lock state.
- Or, if the right button  is pressed before 30 seconds after starting of stimulation, the screen turns off and enters the key-lock state.
  - In the key-lock state, if you press any of the five buttons, the password input screen appears, and if the password matches, the operation window screen is displayed.
- If an electric stimulation signal of ±20% at 0.1 mA ~ 0.4 mA to ±5% at 0.5 ~ 10.0 mA or more than the set value is output during RUN, a “High Current” message is displayed on the LCD and the output of the electric stimulation signal is blocked.



< Hold >

3.2.7 System Setting window

- In the Start window, press the Select and Down buttons  to move to the System Setting window.



< System setting >

- Move to the menu you want to change with the Up, Down buttons  ,  .
- When the select button  is pressed (in the highlighted menu), the variable turns green and is activated. Change the value with the up and down buttons , and press the select button to set the value.
- When the parameters are set, move to the Run menu with the up and down buttons and press the select button (Section 3.2.5) to move to the Operation window.

⚠ CAUTION

- During stimulation, the patient may feel a mild throbbing or tingling sensation at the electrode attached site. This is a common sensation that can be felt during electrical stimulation.

3.2.8 Charge window

- If connect a USB-C type charging cable with a rating of 5V, 1000 mA or more in the power ON state, the battery charging screen appears
- charging status is displayed
- When the USB-C type charging cable is disconnected, the power is turned OFF
- All functions of the device do not operate during charging

< Battery charging>

WARNING

- When charging the product, do not place the product in a position where it is difficult to disconnect the charger's plug or USB-C port.

3.2.9 Power Off

- Press and hold the power button ( ) for more than 2 seconds to turn off the device.

< Power Off >

3.3. Recommendation of the treatment

Bistos recommends to use the device with setting intensity to 2-4mA if there is no minor uncomfortable sensation such as itching or tingling for at least 8 hours during sleep. Consult your physician for recommended duration of treatment.
Before and during the use of the device, the caregivers should look for the setting value of the device and the skin irritation at the site where the electrode is placed.
Clinical trials related to Trigeminal Nerve Stimulation for Attention-deficit/Hyperactivity Disorder show that a clinical response to them would be seen within 4 weeks.
The disposable electrode should be discarded after single use for the treatment.

4. Cleaning and disinfection

The Electronic Stimulator System requires proper control and preventive maintenance. This ensures consistent operation and maintains the high level of performance necessary in monitoring procedures.

4.1 Main body

- Always keep it clean and undamaged.
- Do not immerse the product in liquid containers.
- If cleaning is required, wipe the exterior of the device carefully with a cotton swab or soft cloth soaked in a neutral cleaning solution. And wipe the device thoroughly with a soft cloth or a cotton swab to remove the neutral cleaning solution residue and dry it.
- Avoid direct sunlight and store the product in a place free of dust and contaminants.
- If not using for a long period of time, fully charge and turn off the power before storing.

WARNING

- Do not immerse the unit in water or allow liquids to enter the case. When using solutions, use sterile wipes to avoid pouring fluids directly.
- Take extra care when cleaning display surface, which is sensitive to rough handling. Rub the display surface with a soft and dry cloth.

5. Troubleshooting and maintenance

Observe all precautions to ensure the safety of the patient and those near the instrument.

- Examine the monitor and any accessories periodically to ensure that the cables, line cords and instruments do not have visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage and contact Bistos Service Center.
- The device and accessories do not require periodic calibration or adjustment.
- Do not operate the device if it fails to pass the power on self-test procedure. Contact Bistos Service Center.
- When the displayed condition is not stable, check the battery and charge them.

Issue	Resolution
If the power does not turn on	Check the charging status. Connect the charger to the product.
If the product comes into contact with a large amount of water	Turn off the product power. Wipe the product with a dry cloth and store for at least 12 hours in a cool, dry place.
If the stimulation	• After wiping the area (forehead) where the disposable electric stimulation electrode is to be attached with a 40% to 70%

signal output is not correct	ethanol solution, dry it for 1 to 2 minutes before attaching the electrode. • Use after removing hair, foreign substances or makeup from the attachment area. • Correctly attach the attachment part of the disposable electric stimulation electrode. • Make sure the cable is connected. • Make sure you have connected the channels correctly.

WARNING

- The incorrect battery replacement could cause danger such as excessive temperatures, fire or explosion.
- When not using the device for a long time (over three months), please store the device with the battery full charged.
- When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with leaked liquid, cleanse it with clean water at once. If the leaked liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

Shelf-life is not applicable to this BT-1000 because of low likelihood of time-dependent product degradation.

6. General information and specifications

Physical Characteristics	
Dimensions	(L)148.0 mm X (D) 78.0 mm X (H) 48.0 mm
Weight	Approx. 200 g
Display type	LCD (TFT Color LCD)

Safety	
Standard	EN 60601-1, EN 60601-1-2, EN 60601-1-11
Classification	Internal Powered Equipment
Mode of Operation	Continuous operation
Protection against electric shock	Type BF applied part
Protection against ingress of water	IP22
Service life (Main)	5 years accessories are consumables.

Power		
External	Input	5 Vdc, more than 1.0 A IEC 60335-2-29 Compatible
Internal	Battery	3.7 Vdc, 4200 mAh (Li-ion) Operating Time : 24hrs (when used continuously with the duration set to UnLimit) : 72hrs (when used 6 hrs a day) Charging Time (100 %): 8 hrs
Battery Service life		Maximum charge-discharge cycles: 300 cycles

Environment	
Operating temperature	10 °C ~ 40 °C (50 °F ~ 104 °F)
Operating humidity	5 ~ 85 %, Non condensing
Operating atmosphere / Altitude	80 kPa ~ 106 kPa / 2000 m
Storage temperature	-20 °C ~ 60°C (-4 °F ~ 140 °F) Electrode -10 °C ~ 40°C (14 °F ~ 104 °F)
Storage humidity	0 ~ 95 %, non-condensing
Storage Atmosphere	70 kPa ~ 106 kPa

Stimulation	
Output	0.0 mA – 10.0 mA (±5%) Maximum RMS Voltage 850 mV * at 500 Ω load
Pulse Width	250 uSec
Pulse frequencies	120 Hz
Intensity Step	0.1 mA
Duration	1, 4, 6, 8, 10, 12, 16 hour and UnLimit
Measurement	±20% at 0.0 mA ~ 0.4 mA to ±5% at 0.5 mA ~ 11.0 mA

7. Declaration on EMC

The Electronic stimulation System needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information provided in this user manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the Device and should be kept at least 1 m away from the equipment.

WARNING

- Use of accessories including electrode and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.

7.1. Electromagnetic emissions

<table>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The BT-1000 is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emission
IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fulctuations /flicker emissions
IEC61000-3-3</td><td>Complies</td></tr>
</table>

7.2. Recommended separation distances between portable and mobile RF communications equipment and the BT-1000

The BT-1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the

BT-1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-1000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter[M]		
	150 kHz to 80MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.3. Test specifications for enclosure port immunity to RF wireless communications equipment

The BT-1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of the BT-1000. Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band [a]	Service [a]	Modulation [b]	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation [b] 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation [b] 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation [b] 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900	Pulse modulation [b]	28 V/m	28V/m

		GSM 1900 DECT LTE Band 1,3,4,25 UMTS	217 Hz		
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation [b] 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation [b] 217 Hz	9 V/m	9 V/m

[a] For some services, only the uplink frequences are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

7.4. Electromagnetic immunity

The BT-1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-1000 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT (100% dip in UT) for 0.5/1 cyclesa) 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 23/30 cyclesa) (for 0.5sec) 0 % UT (100% dip in UT) for 250/300 cycles (for 5 sec)	0% UT (100% dip in UT) for 0.5/1 cyclesa) 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 23/30 cyclesa) (for 0.5sec) 0 % UT (100% dip in UT) for 250/300 cycles (for 5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-1000 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-1000 image intensifier be powered from a battery.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50 or 60 Hz	30 A/m, 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

The BT-1000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-1000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM bandsa) 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands 80% AM at 1kHz	3 Vrms 150 kHz to 80 MHz Outside ISM bandsc 6 Vrms 150 kHz to 80 MHz in ISM c and amateur radio bands 80% AM at 1kHz	Portable mobile RF communications equipment should be used no closer to any part of the BT-1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz ~ 2.5 GHz

Radiated RF IEC61000-4-3	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol : 
NOTE 1) At 80 ㎒ and 800 ㎒, the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BT-1000 is used exceeds the applicable RF compliance level above, the BT-1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BT-1000. [b] Over the frequency range 150 ㎑ to 80 ㎒, field strengths should be less than 3 V/m.			

Product Guarantee

Product Name	Electronic Stimulator
Model Name	BT-1000
Approval No.	
Approval Date	
Serial No.	
Warranty Period	1 Year
Date of Purchase	
Customer	Hospital: Address: Contact Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing BT-1000.

※ This product is manufactured and passed through strict quality control and inspection.

※ Compensation standard concerning repair, replacement, refund of the product complies with "**Framework Act on Consumers**" noticed by Fair Trade Commission of Republic of Korea

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