Instruction manual

Forehead Sleep Recorder

Specification Developer: Shenzhen BrainScience Bio-Info Technology Co., LTD.
Address:
1401, Building 7A, Wanke Yuncheng, Dashi 1 Road, Nanshan District, Shenzhen City, Guangdong Province, China.
Zip Code: 518057
Web site: http://www.eegsmart.com/contact.html
Phone number: +86-0755-86536023

Content

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

1. Declaration

This manual is a reference for product operation, maintenance and repair. The user should strictly follow the instructions under the guidance of the physician. For failures or accidents caused by failure to operate in accordance with the instructions, Shenzhen BrainScience Bio-Info Technology Co., LTD. (hereinafter referred to as "the company") does not assume any legal responsibility.

The copyright of the content in this manual solely belongs to the company. It is forbidden to take photo, copy, or translate to other language without the company's written permission.
This manual contains the proprietary information protected by the copyright law, including but not limit to technology secret, patent information and such trade secret. User shall bear confidentiality obligations, and shall not reveal any content of this manual to any irrelevant third party.
The user's holding of this product manual does not indicate that the company authorizes the intellectual property rights contained in the product.
The right to modify, update and interpret this manual belongs to the company.

2. Description

Thank you for purchasing this product, for correct use, please read the contents of this manual carefully before using it. After reading, please keep the instruction manual for reference when needed.
Product name: Forehead Sleep Recorder
Model: S1 or E1
The product acquires one channel EEG (electroencephalograph) signal , obtains SpO_2 and pulse rate signal via reflectance PPG (photoplethysmogram) technology, and body position and body movement via 6-axis motion sensor built in, then transmit these signals and values to tablet or smart mobile devices via BLE (Bluetooth Low Energy). The APP in tablet or smart mobile device generates a sleep report based on the signals data received, and the report is editable for healthcare practitioners.
The product was designed for use in the home or healthcare institute. The patient and healthcare practitioner both can be the operators of this product.

Specification Developer: Shenzhen BrainScience Bio-Info Technology Co., LTD.
Address: 1401, Building 7A, Wanke Yuncheng, Dashi 1 Road, Nanshan District, Shenzhen City, Guangdong Province, China.
Contract manufacturer: Shenzhen Med-link Electronics Tech Co., Ltd.
Production date: refer to the label on outer package.
Address of contract manufacturer: 4F and 5F, 2nd building, Hualian industry zone, Xinshi Community, Dalang street, Longhua district Shenzhen, Guangdong, China.
Copyright belongs to Shenzhen BrainScience Bio-Info Technology Co., LTD

3. Revision record

Product manual version: A0
Product manual issued date: 2019-06-18
Embeded software name: Umind sleep firmware
Embeded software version:V1.0
Embeded software issued date: 2019-06-05
Application software name: Sleep recorder
Application software version: V1.0
Application software issued date: 2019-06-12

4. Customer Service

Company name: Shenzhen BrainScience Bio-Info Technology Co., LTD
Address: Room 1401, Building 7A, Wanke Yuncheng, Dashi 1 Road, Nanshan District, Shenzhen City, Guangdong Province, China.
Web site: http://www.eegsmart.com/contact.html
Service phone number: +86-0755-86536023
Mail for Post-sale Service: ma@eegsmart.com

5. Direction for safety

5.1. Warning

1) Do not use it in the place with flammable gas, such as anesthetic. There is danger of explosion.
2) Do not throw the equipment into fire as it may cause an explosion.
3) Do not connect this product to a patient undergoing cardiac defibrillation.
4) Do not use this product in an MRI environment.
5) Clinicians are advised to instruct users on the proper use of this product.
6) Do not sterilize this product or accessories.
7) Pacemakers or other medical electronic equipment could interfere with the EEG signal and decrease sleep staging accuracy.
8) The function or safety of this product could be impaired if it has been subjected to unfavorable conditions or mishandling.
9) If, at any time, function or safety is thought to be impaired, damage to this product or accessories has been observed/suspected; this product should be taken out of operation and secured against unintended use. Contact after-sale service.
10) This product is designed for indoor use only. After shipping or transportation, allow this product to reach operation environment temperature before using.
11) Some users may experience skin irritation, hypersensitivity, or an allergic reaction to the self-stick sensors or adhesive tape. Advise patient that if this occurs, to discontinue use and

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

consult their healthcare provider.

12) Warning: Do not wear it continuously for more than 12 hours. Check the forehead skin condition at least once every 12 hours, and do not continue to use without intervals of more than one hour.
13) Don’t stare at the red light.
14) Place the device properly to avoid child can reach.

5.2. Cautions

1) The electrode sticker is a single-use product and forbidden to be reused.
2) Don't immerse this product in any liquid for cleaning or disinfection.
3) This product must be repaired by an authorized and qualified engineer. Users are not allowed to make any changes to the product.
4) When not in use for a long time, it should be stored after fully charged, and charge the device every three months afterwards; otherwise the product's built-in battery will be unusable due to over-discharge. The product should be fully charged immediately after each use. The recording process must ensure that the power of the terminal equipment can support the operation of the APP. At the same time, the APP is set to the locked state avoid accidental exit, and avoid incomplete recording data or data corruption.
5) Product operation and use can be used by the patient after training or reading the instructions carefully, but the conclusion should be given by qualified healthcare practitioner.
6) Federal Law (USA) restricts this device to sale by, or on the order of, a physician or other qualified healthcare practitioner licensed by the laws of the state in which he or she practices to use or order the use of this device.

5.3. Cleaning and disinfection

Cleaning: When the device is dirty, use a clean soft cloth moistened with a small amount of water or neutral detergent, and wipe it after wringing. ⚠ Note: Don’t use acid or alkaline cleaner.

5.4. Disinfection: Wipe the body with a clean, soft cloth moistened with a small amount of 75% medical alcohol, and air dry. Precautions to transportation and storage

Refer to the following table for requirements of device operation, transportation and storage environment.

Table1

Item	Work	Transportation and storage
Relative humidity	25%～80%（no condensation）	25%～93%（no condensation）
Temperature	5℃～40℃	-20℃～+55℃

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

barometric pressure	700hPa～1060hPa	700hPa～1060hPa

5.5. Warning symbol

Table2 description table for warning symbol

Symbol	Description
	IEC60601-1 BF type applied part
	Represent product series number
	Represent product lot number
	Model number
	General warning sign
	Must follow the product manual for use
	Nonionizing radiation
	Separate the collection for electronic equipment
	Production date
	Product manufacturer
	Direct current
	Support Bluetooth 4.2BLE protocol
	For single-use products, reuse is prohibited.
	Non-Sterile

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

Rx only	Federal Law (USA) restricts this device to sale by, or on the order of, a physician or other qualified healthcare practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

6. Product basic information

This product is a Class II, type BF, internally powered, medical device and is rated for continuous operation.

6.1. The device

6.1.1. Product name: Forehead sleep recorder

6.1.2. Model number: S1, E1,

6.1.3. The difference of these models is described as following:

Table3 - model difference

Model	Function			
	EEG	Body Position/movement	SpO_2	Pulse rate
S1	√	√	√	√
E1	√	√	×	×

Note: Mark √ represent this model has this function, mark × represent this model has no this function。

6.1.4. The device specification

1) Working voltage：DC 3.7V
2) Charging voltage：DC 5V
3) Effective distance for Bluetooth：2m
4) Operating hours：Continuous working no less than 15h after fully charged
5) Working current：Not exceed 7mA
6) Built-in battery capacity: DC 5V , 110mAh, rechargeable lithium batteryDevice size：68*38*14mm（L*W*H）
7) Device weight：16g

6.1.5. Bluetooth specification

Type of wireless technology	Bluetooth V4.2BLE
Wireless Function	Transmit patient biomedical information data from this device to terminal equipment, as well as ensuring the integrity and security of data during transmission.
Modulation Type	GFSK
Modulation Signal Type	Digital

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

RF Band Width	2402MHz～2480MHz
Data rate	1Mbps
Occupied ban wide	2MHz
Channel separation	2MHz
Maximum transmission distance	2m

6.2. Accessory 1:

Product name: electrode
Model number: EP3
Specification developer: Shenzhen BrainScience Bio-Info Technology Co., LTD
Specifications:
AC Impedance: The average value of 10-Hz impedance for at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) Peak to peak (P-P), shall not exceed 2 KΩ. None of the individual pair impedances shall exceed 3 KΩ.
Shelf life: 1 year
Shelf life after opening the bag: 2 weeks

6.3. Accessory 2:

Product name: Charging box
Model: S1-Dock-01
Specification developer: Shenzhen BrainScience Bio-Info Technology Co., LTD
Specifications:
Output 5V ⎓300mA
Input 5V ⎓300mA

6.4. Accessory 3:

Product name: USB cable
P/N: 4.03.000001
Specification developer: Shenzhen BrainScience Bio-Info Technology Co., LTD
Specifications:
Color,White.
26AWG*2C ;OD3.5; Length,80mm.

6.5. Packing list

Open the package, you should find the following supplies:

1) The device
2) Charging box
3) Electrode sticker(16PCS)

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

4) USB Charging cable
5) Manual
6) Warranty card

6.6. Product formation

6.6.1. Device

Figure 1

①Power button ②Indicator ③EEG electrode ④Window for Pulse rate and SpO2

6.6.2. Charging box

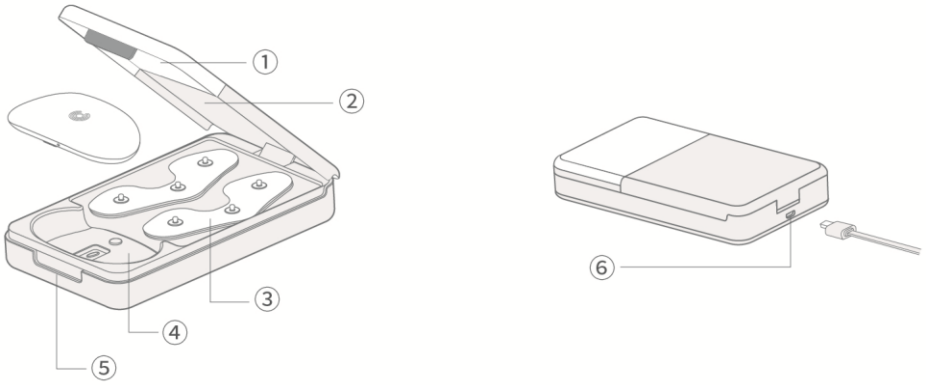

Figure 2

①Transparent window ②Mirror ③Electrode cabin
④Charging dock ⑤Magnetic fastener ⑥Micro-USB Charging socket

6.6.3. Electrode

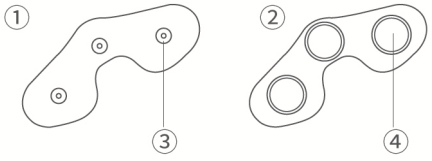

Figure 3

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

①Front side ②Back side ③Snap fastener ④Conductive gel

6.7. Product function

This product has following function

Table 5- Product function list

Function	Description
EEG	Monitoring and record the EEG data generated during sleep
Body position	Monitoring and recorder the sleep position: upright, left lateral, right lateral, supine, prone position
Body motion	Class the motion frequency in sleep to different grade.
Pulse rate	Model S1 can monitor and record the pulse rate data generated during sleep
SpO2	Model S1 can monitor and record the SpO2 data generated during sleep

7. Instructions for use

7.1. Intended use of the product

This product can record physiological signals like EEG、SpO2、Pulse Rate、Body Position and body movement signals during sleep. Under the guidance of healthcare practitioner, it can be used by adults at home or in medical institutions to assist healthcare practitioner in diagnosing sleep disorders.

7.2. Contraindication

Do not use this product on newborns, infants, or children. This product has only been tested on adults.
Do not use this product on the population with damaged frontal skin, with sensitive skin, or with involuntary behavior.

7.3. Intended user

This device is for the population with various types of sleep disorders or suspected sleep disorders.

7.4. Instructions for wearing this product

Users should use this product under the guidance of healthcare practitioner. Manual analysis, diagnosis and editing of recorded data must be performed by qualified healthcare practitioner. Operator can be the patient, also can be healthcare practitioner.

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

⚠ Before each use of this product, the smart mobile device or tablet running the APP for the product should be fully charged to ensure that there is enough power to support the operation of the APP during the recording. At the same time, the APP should be set to the locked state to prevent accidental exit and avoid incomplete recording data or data corruption.

Step 1: Before wearing the device, please clean subject' skin and wash away cosmetics, dirt and oil stains to prevent the device's adhesion from falling, and signal disruption.

Step 2: Take out an electrode sticker and install it onto the device tightly.

⚠Warning: Please purchase the electrode specified by the company, otherwise the accuracy of the signal and safety cannot be guaranteed, or it may cause allergic, irritating and other adverse reactions.

Step 3: Tear off the release film on the back of the electrode sticker to expose the gel part.

Step 4: Press the power button on top of the device, and the green light is always on. Here the device is in the startup state.

Step 5: With button on top side, align the device with the center of the forehead and attach it tightly, (be careful not to stick it to the hair).

Step1 Step2 Step3 Step4 Step5

Figure4 Figure5 Figure6 Figure7 Figure8

⚠The product should be fully charged immediately after each use, In order to facilitate the use of this product next time.

7.4.1. Descriptions for indicator lamp

Table 6 -Descriptions for device indicator lamp status

Power status	Battery status	Bluetooth status	Indicator lamp status
Charging	<100%	Any status	Yellow light breathing (5s stop, 5 breathing)
	100%		Steady green light
Stand by and Not charge	>5%	Connected	Any status
		Not connected	Steady green light
	0~5%	Any status	Yellow light flashes quickly
Shut down without charging	Any status		off

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

7.4.2. Charge

a) Use a Micro USB cable to connect the charging box to a USB interface power source (need to be equipped on your own).
b) Place the device into the charging box, and the device will automatically be attached. Here the device indicator is breathing yellow, indicating that the device is charging; green always on, indicating that charging is complete.
c) Low battery warning: When the power is on, if the power is less than 5%, then the yellow indicator light flashes quickly.

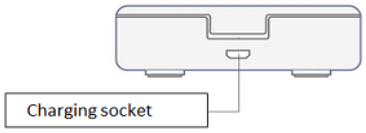

Figure 9

7.4.3. Power on / off

a) In the off state, press the power button of the device for short time, the green light of the device is always on, indicating that the device is in the state of being connected to the device.
b) Press and hold the power button of the device for more than 2 seconds. The device indicator flashes 3 times and then turns off, indicating that the shutdown was successful.

7.4.4. Mobile Terminal Device Connection

This product connects to a mobile terminal via Bluetooth. The steps are as following:
a) Turn on Bluetooth on the mobile terminal (some mobile terminals need to have the positioning function turned on at the same time).
b) Follow the guidance in the APP, select the Bluetooth number corresponding to the device label, in the nearby device list.
c) After the connection is successful, the device indicator flashes slowly in green.
d) For connection failure, Refer to Section 8 "Troubleshooting" of this manual.
e) Bluetooth specifications: 4.2BLE, working frequency 2.4000-2.4835GHz, modulation mode GFSK, automatic frequency hopping, effective distance within 2 meters (or depending on the specific environment)

7.4.5. Acquisition and operation of APP

Please contact your dealer to get the APP. For detailed installation method and operation guide, please refer to the APP instruction. The following is an overview of the work flow in the APP.
a） Connect the sleep recorder:
Turn on the sleep recorder, and then launch the sleep recorder APP in the customer's mobile

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

terminal device. Make sure the Bluetooth function of the device is enabled.

In the app, tap sleep recorder Connection, find the device by SN in the list and tap to connect. After connection, the EEG and other device information will be displayed.

b） Increase patient information:

In the main screen, enter patient management section, tap Add New Patient, and generate the patient information record.

c） Record sleep

In the main screen, tap Record Sleep, choose the corresponding patient, and tap start recording. After 30 seconds, you can tap End Record to generate a data record.

d） Data playback:

In the main screen, enter the data report and tap any data record. Then you can playback the EEG and other data recorded.

e） Sleep staging:

In the Record section, data playback interface, tap Sleep Staging to complete the EEG sleep staging manually or automatically.

7.4.6. Product use conditions

The use of this product during the operation in a strong electric field may cause abnormal EEG signal record.

This product should not enter the treatment or testing process in strong magnetic fields.

8. Troubleshooting

No.	Problem	Solution
1)	Device is unable to turn on	Try charging.
2)	Device is unable to shut down	Try to force reset by pressing and holding the button for more than 6 seconds.
3)	The device is unable to charge	Check the charger, charging cable, and try to reinsert the device to ensure that the electrode points are in good contact.
4)	No response after press the button	Long press the button for more than 6 seconds to force reset, and then shortly press the button to restart.
5)	Can't find Bluetooth device	Check if the Bluetooth function of the mobile device is normal. If it is normal, then try restarting the device or turning off and turn on the Bluetooth of the mobile device once.
6)	Bluetooth connection failed	Try restarting the device, or turning off and turn on the mobile device Bluetooth once
7)	The signal is abnormal after connection:	Try restarting the device and reconnecting.
8)	The electrode sticker cannot	Check whether the male buckle of the previous

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

	buckle the body:	electrode sticker has fallen off and remains on the device. If so, use a suitable tool to remove the remaining male buckle. Check whether the metal of the female buckle on the equipment is fatigued and aged, and if so, contact the after-sales service.

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

After the above problems are resolved, there are still problems that need to be handled, please contact the after-sales service unit. For contact details, please refer to "Customer Service" in Section 4 of this manual.

The user or anyone without written authorization are not permitted to conduct any form of repair or other treatment on the product.

9. Maintenance and Care

1) After use, put the device in the charging dock of the charging box and store it in a dry and ventilated environment. Avoid direct sunlight, storage and transportation environment should meet the requirements prescribed in the clause 5.3 of this manual.
2) Clean the product after use. If it is used by different patient, disinfect it. Both cleaning and disinfection can be performed by the patient. The cleaning and disinfecting components are the main unit and the charging case.
3) When not in use for a long time, it should be fully charged before storage, and the device should be charged every three months. Failure to comply with this may severely reduce the battery life.
4) Before using the electrode stickers, check whether they are within the validity period. It is forbidden to use the electrode stickers that have expired.The electrode stickers should be used up within 2 weeks after the electrode stickers are unsealed . Electrode stickers require no special maintenance.

10. Technical parameters

10.1. EEG performance requirements

EEG performance refers to "IEC 80601-2-26 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of electroencephalographs"

1) EEG performance requirements
   The error does not exceed ± 10%.
2) Time interval
   The error does not exceed ± 5%.
3) Amplitude-frequency characteristics
   1-60Hz (excluding 50Hz and 60Hz), the error does not exceed + 10% ~ -29%.
4) Noise level
   Not more than 5 μV (peak-to-peak).
5) Common mode rejection ratio
   Input frequency: 10Hz and 60Hz, not less than 80 dB.
6) Polarization withstand voltage
   Apply a DC polarization voltage of ± 300 mV, and the error should not exceed ± 5%.
7) Input impedance
   For a 10 Hz sine wave signal, the input impedance should not be less than 1MΩ.

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

10.2. SpO_2 and Pulse rate measurement performance

10.2.1. SpO_2 measurement section

(1) Measurement method
Use a headband or medical headgear to fix the device and ensure that it is tightly worn by keeping proper pressure, with the user in a supine position.
(2) SpO_2 measurement range
From 70%SpO_2 to 100% SpO_2.
(3) SpO_2 accuracy
In the range of 70% ~ 100%, the measurement error of SpO_2 ≤3 %.

10.2.2. Pulse rate measurement section

(1) Measurement method
Use a headband or medical headgear to fix the device and ensure that it is tightly worn by keeping proper pressure, with the user in a supine position.
(2) Measurement range
40 bpm to 240 bpm.
(3) Accuracy
Not exceed ±3% or 3BPM of the input pulse rate (Whichever is greater).

10.3. Body position requirements

Correctly identify typical left lateral, right lateral, supine, prone position.

11. User Agreement

Any user decide to buy this product, that represent the user has agreed this User Agreement (“ Agreement”). This agreement is to unify the opinion related to the use of the product between Shenzhen BrainScience Bio-Info Technology Co., LTD (“ BSBT”), whose address is 1401, Building 7A, Wanke Yuncheng, Dashi 1 Road, Nanshan District, Shenzhen City, Guangdong Province, China, and the user of the product (“ User”).The agreement is following:

1) The warranty period of this productis one-year from the date of its shipment to User.
2) User agrees that the product will be used according to this instruction manual for the purpose for which it was designed.
3) The product will be free for repair and replacement if the defects in workmanship or materials, that is found within 1 year “ Warranty Period” . The single use accessory is not included in this warranty in terms. The product with defects caused by accident ,misuse, neglect, or the use in violation of this instructions will be exclude from this warranty.
4) Repair or replacement of the product under this warranty does not extend the Warranty Period.
5) In order to request repair or replacement under this warranty, User should contact BSBT directly. BSBT will provide User with a Return Material Authorization (RMA) number to

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

return the product.

6) BSBT shall determine whether to repair or replace the Warranted Product; In the course of warranty service, BSBT may, but shall not be required to, make engineering improvements to the Warranted Product.
7) If BSBT reasonably determines that a repair or replacement is covered by the warranty, BSBT shall bear the costs of shipping the repaired or replaced product to User. All other shipping costs shall be paid by User.
8) The loss or damage during shipments under this warranty shall be paid by the party shipping the product. Products shipped by User under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the product. If User ships a product to BSBT in unsuitable packaging, any physical damage present in the Product on receipt by BSBT (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of User.
9) The service life of this product is 3 years. Exceed 3 years from the date shipping to user, BSBT reserve the right to reject to repair the product.
10) The product contains an embedded software and APP (hereinafter referred to as "Licensed Software") which is licensed, these software are not sold to User.
11) While a user may possess the product, the user is hereby granted the non-exclusive right to use the Licensed Software solely with the product on which the Licensed Software was provided to the user. The user shall not transfer the Licensed Software in any manner , and shall not modify or translate the Licensed Software.

12. Privacy policy agreement

For purposes of this Agreement (□Agreement□), the following terms have the following meanings: □User□ means anyone using the product, or any associated systems or software. □De-identified Information□ shall mean Information that has been de-identified in accordance with the requirements for de-identification of protected health information under 45 CFR §164.514(b). □Information□ shall mean written or electronic health information or data received by BSBT from a User and includes Information or data provided in any form, including De-Identified Information and Limited Data Sets. □Limited Data Set□ shall have the same meaning as the term □limited data set□ in 45 CFR §164.514(e), and shall include Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers (including finger and voice prints), full face photographic images, and any comparable images.

□Protected Health Information□ or □PHI□ shall have the same meaning as the term □protected health information□ in 45 CFR § 164.501. BSBT has created and established a data repository to receive and store Information received from a User. The Information submitted by a User, may be stored by BSBT in in one or more data repositories. De-identified Information from the data

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

repositories may be moved to a separate data repository for use as set forth herein. User agrees that BSBT may use such De-identified Information for any purpose. User agrees that BSBT is the exclusive owner of the De-Identified Information.

User licenses BSBT to store the data identified as PHI for the purposes of carrying out the operations as requested by User. Unless otherwise permitted in this Agreement, no User shall have direct access to Information in the data repository. Requests, if any, from User to access or amend PHI shall be referred to BSBT.

13. Electromagnetic compatibility

Forehead sleep recorders can generate, use, and radiate radio frequency energy. This equipment can cause electromagnetic interference between other medical or non-medical equipment and radio communications. According to the statement of IEC 60601-1-2: 2014, this product belongs to the first group, Class B medical equipment, to provide corresponding protection from interference. However, there is no guarantee that electromagnetic interference will not occur under certain installation conditions.

When this equipment is found to cause interference (requires switching equipment on and off for confirmation), the operator or authorized maintenance personnel can eliminate the interference according to the following measures:

1) adjust or relocate the affected equipment;
2) Increase the distance between this equipment and the affected equipment;
3) Use another power source to power this device;
4) Consult a maintenance engineer for more suggestions.

⚠ Note: Before using this equipment, please ensure that all EMC requirements in the manual have been met;

⚠ Note: This section will list the content described in the table of IEC 60601-1-2: 2014. It is the user's responsibility to ensure that this equipment and its nearby equipment meet the radio frequency interference parameters indicated in the general safety requirements.

⚠ Caution: Do not intentionally transmit RF signals (smart mobile devices, radio transceivers, or radio control products) while this equipment is in use. This may cause the operation to exceed the specified value. When near this device, turn off this type of device. It is the responsibility of the operator to remind patients or other personnel associated with this device to fully comply with the above requirements.

⚠ Note: The manufacturer will not be held responsible for any interference caused by the use of non-recommended internal connection cables or unauthorized changes or modifications to this equipment.

For forehead sleep recorders, special precautions regarding electromagnetic compatibility (EMC) are taken and must be installed and used according to the electromagnetic compatibility information specified in this manual.

Portable and mobile RF communications equipment may affect this equipment.

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

Use of accessories other than those specified may result in increased equipment or system emissions or reduced immunity.

⚠Note:

1) This equipment complies with the electromagnetic compatibility requirements of the IEC 60601-1-2: 2014 standard;
2) Users should install and use this product according to the information related the electromagnetic compatibility prescribed in this manual.
3) Portable and mobile RF communication equipment may affect the performance of this equipment. Avoid strong electromagnetic interference when using it, such as near smart mobile devices, microwave ovens, etc.;
4) Guidance and manufacturer's declaration are detailed as following:

⚠Warning:

1) This equipment should not be used close to or stacked with other equipment.
2) Even if other equipment meets the emission requirements of corresponding national standards, this equipment may still be interfered by them.

Table 7- Guidance and manufacturer's declaration - electromagnetic emission

The forehead sleep recorder and its use in the electromagnetic environment specified below, the purchaser or user of the device should ensure that it is used in this electromagnetic environment.		
emission test	Compliance	Electromagnetic environment- guidance
Radio frequency emission IEC/CISPR 11:2010	2group	The forehead sleep recorder communicates with a mobile phone or tablet via Bluetooth, and the transmission frequency is about 2.4GHz.
Radio frequency emission IEC/CISPR 11:2010	Class B	The forehead sleep recorder is suitable for use in all facilities, including domestic facilities and public low-voltage power supply networks directly connected to homes
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuation / flicker emission IEC 61000-3-3	Not applicable	

Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

Table **8-** Guidance and manufacturer's declaration—Electromagnetic immunity

The sleep recorder is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment			
immunity test	IEC60601 test level	Test level	electromagnetic environment guide
electrostatic discharge IEC 61000-4-2	±6kV Contact discharge ±8kV Air discharge	±6kV Contact discharge ±8kV Air discharge	The floor should be wood, concrete or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst IEC 61000 -4-4	±2kV on power line ±1kV On input/ output line	Not applicable	Not applicable
Surge IEC 61000 -4-5	±1kV Differential mode ±2kV Common mode	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	＜5% U_T, (＞95% dip in U_T) for 0.5 cycle 40% U_T, (60 % dip in U_T) for 5 cycles 70% U_T, (30% dip in U_T) for 25 cycles ＜5% U_T, (＞95% dip in U_T) for 5 seconds	Not applicable	Not applicable
Power frequency magnetic field (50/60Hz) IEC61000-4-8	3A/m	3A/m	Power frequency magnetic field should have power frequency magnetic field level characteristics in a typical place in a typical commercial or hospital environment
Note: U_T refers to the AC network voltage before the test voltage is applied			

Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

Table **9-** Guidance and manufacturer's declaration - Electromagnetic immunity

<table>
<tr><td colspan="4">The forehead sleep recorder is intended use in the electromagnetic environment specified below, the consumer or user of the device should assure that it is used in such an electromagnetic environment.</td></tr>
<tr><td>IMMUNITY test</td><td>IEC60601 TEST LEVEL</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Radio frequency conduction

IEC 61000-4-6</td><td>3V/m Effective value
150kHz~80MHz</td><td>Not applicable</td><td rowspan="2">Portable and mobile RF communications equipment should not be closer to any part of the frontal sleep recorder than the recommended isolation distance. This distance should be calculated by the formula corresponding to the frequency of the transmitter.
$d = 1.2\sqrt{p}$
$d = 1.2\sqrt{p}(80MHz \sim 800MHz)$
$d = 2.3\sqrt{p}(800MHz \sim 2.5GHz)$
In the formula:
P -- According to the transmitter's maximum rated output power provided by the transmitter manufacturer, in watts (w)；
d -- Recommended isolation distance in meters (m).
The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field a, in each frequency range.
b Both should be lower than the compliance level.
Interference may occur near the equipment marked with the following symbol:
  </td></tr>
<tr><td>Radio frequency radiation
IEC 61000-4-3</td><td>3V/m
80MHz~2.5GHz</td><td>3V/m</td></tr>
<tr><td colspan="4">Note1: At 80MHz and 800MHz, use the higher frequency band formula
Note2: These guidelines may not be suitable for all situations, and electromagnetic propagation is affected by absorption and reflection from buildings, objects and Population.</td></tr>
<tr><td colspan="4">a) The field strength of fixed transmitters, such as: wireless (cellular / cordless) telephones and base stations for ground mobile radios, amateur radios, AM and FM radio broadcasts, cannot be accurately predicted theoretically.
b) To assess the electromagnetic environment of fixed RF transmitters, surveys of</td></tr>
</table>

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

electromagnetic sites should be considered. If it is measured that the field strength of the Forehead sleep recorder is higher than the applicable RF compliance level above, the Forehead sleep recorder should be observed to verify that it can work normally. If normal performance is not observed, supplementary measures may be necessary, such as reorienting or repositioning the Forehead sleep recorder.

c) In the entire frequency range of 150kHz ~ 80MHz, the field strength should be lower than 3V / m

Table **10**- Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and forehead sleep recorders			
Forehead sleep recorders are intended for use in an electromagnetic environment where radio frequency interference is controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile radio frequency communication devices (transmitters) and forehead sleep recorders as recommended below.			
Transmitter's rated maximum output power (W)	(Unit: m) Calculate the separation distance based on the frequency of the transmitter		
	$d = 1.2\sqrt{p}$	$d = 1.2\sqrt{p}(80MHz \sim 800MHz)$	$d = 2.3\sqrt{p}(800MHz \sim 2.5GHz)$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	73
100	Not applicable	12	23
For the transmitter's rated maximum output power not listed in the table above, the recommended separation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where p is provided by the transmitter manufacturer Maximum output rated power in watts (w). Note 1: At 80MHz and 800MHz, the higher frequency range formula is used. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and Population.			

14. FCC Regulatory Compliance statement

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

Note: 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

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD

guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

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

Warning: changes or modifications not expressly approved by the party responsible for compliance could void the user’ s authority to operate the equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

15. Discard and disposal

If this product needs to be discarded, please dispose of device, charging box, USB charging cable or electrode stickers in accordance with relevant local regulations.

 Copyright© Shenzhen BrainScience Bio-Info Technology Co., LTD