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Instruction For Use (IFU)

Cranial Electrotherapy Stimulator (CES)

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User Notification

Before using this instrument, please carefully read the instructions. IFU provides important information on proper operation, highlighting steps to follow, incorrect operations that may cause device malfunctions, and hazardous actions that could result in harm to the user or damage to the device. The manufacturer shall not be responsible for any safety, reliability, or performance issues resulting from improper use, as outlined in IFU. Additionally, faults arising from such improper use will not qualify for free maintenance.

Please adhere to the following precautions when using this product:

Requirements for Installation Environment and Location:

- Ensure the installation environment is well-ventilated, with a temperature range of 20℃ to 24℃ and humidity between 20% and 80%.
- Keep the device away from electrical equipment, high-frequency radiation sources, and other potential sources of interference during operation.
- To prevent damage to the device or user from static electricity, wash your hands before using the instrument.
- Avoid exposure to moisture, water, extreme air pressure, excessive humidity or heat, poor ventilation, and areas containing alkaline dust or acidic gases.
- Do not install the device near chemicals or areas with a risk of gas leakage.
- Do not use the instrument near or in the presence of flammable anesthetics to avoid the risk of explosion caused by electric arcs.
- Do not use the instrument inside a medical hyperbaric oxygen chamber, as this could lead to explosions or fire.

Pre-Operational Precautions:

Ensure that all preparatory steps have been followed, as outlined in the manual, to guarantee safe and effective use of the device.

Pre-Operational Checks:

- Ensure that the instrument is in proper working condition.
- Verify that the instrument is correctly positioned.

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- Confirm that all wires are securely connected.
- When using this device in conjunction with other instruments, take care to avoid misdiagnosis or any operational issues.
- Inspect all wires connected to the patient for safety.
- If registering a new user with the software, make sure the Android device is connected to the internet to complete the verification process.
- Treatment and evaluation data will not be stored on the web server without an internet connection.

Precautions During Operation:

- Continuously monitor both the instrument and the patient with care and attention.
- If necessary, turn off the power or remove the electrodes to ensure patient safety.

Post-Use Shutdown Requirements:

- Gently remove the electrode wires without applying excessive force.
- Clean the instrument and its accessories, then organize and prepare them for the next use.

Additional Notes:

- It is prohibited to use this instrument for any purpose other than those specified in the instructions.
- Ensure that parts of the instrument that come into contact with the human body are only applied once the device is stable and operating properly.
- The power supply voltage and frequency must correspond to the specifications outlined in the manual.
- During treatment, avoid placing electrodes over wounds or areas of stasis. Electrodes should not be placed on the front and back of the heart and must maintain close and even contact with the skin. If unsure before or during use, it is recommended to consult a doctor or contact the manufacturer.
- If the stimulator is used within 1 meter of short-wave or microwave therapy equipment, the stimulator's output may become unstable.
- The disposal of this system’s equipment must comply with relevant national regulations and laws.

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- This manual describes all features of the highest software version and may not reflect the features of the version you have purchased or are using. The specific features of your version take precedence. The right of interpretation belongs to NCC. Updates to the software or manual may occur without prior notice from NCC.

Supply Voltage Requirements:

- **Special Power Supply:** 5V / 500 mA

Accessories Requirements:

- Only equipment and accessories approved by our company should be used with this instrument. The use of unapproved equipment or accessories may compromise the device's performance and safety. We are not liable for any personal injury or financial loss resulting from such unauthorized use.

Operator Requirements:

- The operator must carefully read the IFU before using the device or consult our personnel for a detailed introduction. All operational steps should be strictly followed.

Warnings:

1. **Do not open the instrument case** to avoid the risk of electric shock. Any repairs or upgrades must be carried out by personnel trained and authorized by NCC Medical Co., Ltd.
2. Do not use the instrument in environments containing flammable materials, such as anesthetics, to prevent the risk of explosion.
3. Before use, ensure that both the instrument and its accessories are functioning properly.
4. Do not use the device while bathing, and never immerse it in any liquid.
5. This device is designed as **supportive therapy** only.
6. Use the device according to the instructions for ear clip electrode placement.
7. Using this instrument in conjunction with electronic surgical instruments may cause electrode burns and damage to the equipment.

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8. The use of this device may affect the patient's physical condition and the administration of medication.
9. The long-term effects of regular electrical stimulation therapy on patients are not yet known.
10. The safety of using this device during pregnancy or childbirth has not been confirmed. Using electrodes near the chest increases the risk of cardiac fibrillation.
11. Keep the instrument and its accessories out of reach of children to prevent accidental ingestion or injury.
12. Using electrical surgical instruments alongside this device may cause the electrodes to burn and damage the equipment.
13. When the stimulator is used near shortwave or microwave therapy equipment (within 1 meter), the stimulator's output may become unstable.
14. **Do not open the instrument case**, as this may lead to electrical hazards. All maintenance and upgrades must be performed by authorized service personnel.
15. Excessive current can cause adverse reactions such as headaches, dizziness, and nausea. If such symptoms occur, immediately reduce the current.
16. This device is **prohibited** for use by patients with implanted electronic devices, such as pacemakers.
17. Use only accessories provided by NCC Medical Co., Ltd. Using accessories from other brands, or modifying wires (e.g., shortening or extending), may result in safety issues, for which NCC Medical is not liable.
18. Install the batteries according to the positive and negative markings inside the battery compartment. Incorrect battery installation can result in overheating, battery explosion, or damage to the instrument.

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Authority and Responsibility

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Chapter I: Composition and Connections

1.1 Hardware Composition

1.1.1 Main Unit

The main component of the device is the Microcurrent Stimulator unit, which is responsible for generating and delivering electrical stimulation.

Figure 1.Main unit

1.1.2 Power Supply

The device uses a special power supply of 5V/500mA, which is provided by an Android device. Do not use power supplies that do not meet these specifications, as doing so may result in malfunction or damage.

1.1.3 Connection Cables

Ear Clip Electrode Cable: As shown in Figure 2, one end of the cable features a plug that connects to the stimulator's main unit. The other end has two white ear clips that attach to the human body. The ear clips are not polarity-specific, meaning they do not distinguish between positive and negative.

OTG Cable with Pin Connector: As shown in Figure 3, one end of the cable is a pin connector that plugs into the stimulator's main unit. The other end is a USB Type-C plug that connects to the Android device.

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Figure 2.Ear Clip Electrode Cable

Figure 3.Pin OTG Cable

[1]: This refers to a smartphone or tablet, which must support OTG (On-The-Go) functionality. This feature allows the device to function either as a master device controlling other connected devices or as a slave device being controlled by another master device. The operating system must be Android 3.2 or higher.

1.1.4 Gasket

The gasket is placed on the ear clip electrodes, as shown in Figure 4, to ensure a secure and comfortable fit.

Figure 4.Gasket

1.2 Equipment Connection

Step 1:
Replace the Gasket:
Remove the used gasket from the electrode and replace it with a new one, as shown in Figure 5. Ensure the gasket is properly aligned and secured to guarantee optimal performance.

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Figure 5. Place the gasket

Step 2:
Apply Conductive Liquid:
Wet the gasket with the conductive liquid, as shown in Figure 6. This ensures proper conductivity between the electrode and the skin for effective stimulation.

Figure 6: Wetting the gasket with conductive fluid

Step 3:
Connect the Device:
Use the pin OTG cable to connect the stimulator main unit to the Android device. Insert the pin of the OTG cable into the round slot of the stimulator (as shown in Figure 7). Then, insert the USB Type-C plug into the USB Type-C port of the Android device (as shown in Figure 8).

Figure 7: Connecting the Stimulator Main Unit

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Figure 8: Connecting to the Android Device

Step 4:

Connect the Electrode Cable:

Attach the clip electrode wire to the corresponding port on the stimulator main unit, as shown in Figure 9.

Figure 9: The Electrode Cable Connected to the Main Unit.

Step 5

Before using the device, scan the QR code located on or inside the packaging to download and install the "HappySleep" application. After installation, open the "HappySleep" app and follow the registration steps as outlined in Chapter 3.

HappySleep Icon

Figure 10. QR code for HappySleep App

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Step 6

Log into the application. The main interface is divided into several sections: CES Therapy, More Functions, User Information, System Settings, Switch Users, and Exit. Users can navigate between these sections to access the respective functions. First, enter the **CES Therapy** interface, where you will find options to view the remaining treatment time, adjust stimulation intensity, display stimulation frequency, start/pause treatment, and access parameter settings. The default settings are: stimulation intensity of 2, stimulation frequency of 0.5Hz, and treatment time of 10 minutes.

Step 7

Place the Ear Clip Electrode:

Attach the ear clip electrodes to the earlobes, as shown in Figure 11.

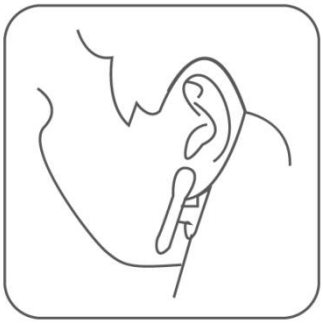

Figure 11: Placement of Ear Clip Electrodes.

Step 8

Adjust the Stimulation Intensity:

Adjust the stimulation intensity by either clicking the stimulation intensity bar or using the volume button. Gradually increase the intensity until you feel a slight tingling sensation in the ear. Do not increase the intensity too much, as this may lead to headaches, dizziness, or nausea. The recommended intensity is generally between levels 4 and 5, depending on personal tolerance.

Step 9

Set the Stimulation Frequency and Treatment Time:

The standard stimulation frequency is 0.5Hz. To adjust, click on the stimulation frequency bar and select the desired frequency. Treatment time depends on the intensity of stimulation. For stronger stimulation, a treatment time of 10-20 minutes is recommended. For moderate or weak stimulation, a time of 40-60 minutes can be selected by clicking on the treatment time bar.

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Step 10
Start the Treatment:
Click **Start** to begin the treatment. The device will operate according to the set parameters and will automatically enter energy-saving mode after a certain period. If another treatment is required while in energy-saving mode, unplug the OTG cable and reconnect it to the Android device.

Important Notes:

1. The device is intended for personal use. Please ensure that the equipment is connected and operated as instructed above. Do not connect the device to any other equipment not specified in this manual.
2. The electrodes are reusable. Please disinfect the electrodes according to the disinfection method outlined in section 3.3.2, and use them only for the same patient.

Additional Notes:

Please download and install the "HappySleep" app and register before using this device.

The application automatically records treatment parameters. Once familiar with the device, steps 4, 6, and 7 can be omitted.

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Chapter II: Software Introduction

2.1 Software Login

The application icon for the CES  is displayed on your Android device. Click the icon to open the login interface, as shown in Figure 12.

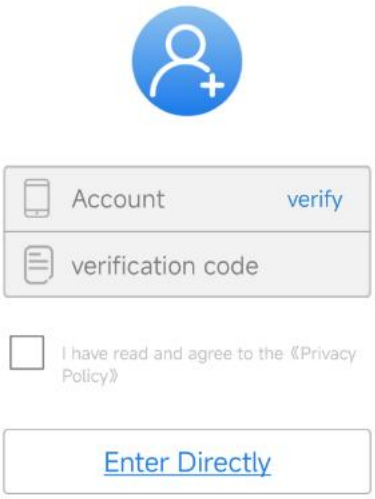
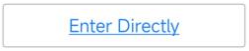


Figure 12. The login interface

Figure 12: The Login Interface

To log in, enter the correct mobile phone number and verification code. The software will automatically proceed to the main interface. If you prefer not to register, click the button  to bypass registration and directly enter the device's main interface.

Note:
When registering as a new user, ensure that the Android device is connected to the Internet to receive the verification code. Data related to treatment and assessment will not be saved on the web server when using visitor login mode.

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2.2 Function Overview

The main interface is divided into three modules: **CES Treatment**, **Sleep Assessment**, and **Data center module**. Additionally, a system menu is accessible from the main interface. The functions of these modules are as follows:

2.2.1 CES Treatment

This module allows you to set the treatment frequency, duration, and intensity. You can also control the indicator light and monitor the remaining treatment time.

2.2.2 Sleep Assessment

This feature provides a self-assessment questionnaire to evaluate recent sleep quality and offers corresponding sleep tips based on the results.

2.2.3 Data center module

Here, you can view historical data related to both treatment sessions and sleep assessments.

2.2.4 System Menu

The system menu allows you to modify personal information, adjust system settings, switch accounts, log out, and access help information. Under system settings, you can choose the language, change your password, update the software, and enable cloud storage and remote data download via data synchronization.

2.2.5 Actual Operation

Each module’s operation will follow the instructions provided on the specific software interface for detailed guidance.

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Chapter III: Equipment Maintenance and Care

This chapter provides instructions for maintaining your equipment and troubleshooting potential issues. Maintenance checks do not involve the internal structure of the instrument and can be performed by the user. For safety and regulatory reasons, internal maintenance and calibration must be handled by our authorized service personnel. If the instrument malfunctions, it should be clearly labeled to avoid use in an abnormal state.

3.1 Maintenance Inspections

Before using the device, the following inspections should be conducted:

- **3.1.1** Check for any mechanical damage.
- **3.1.2** Inspect all exposed conductors.
- **3.1.3** Check for any abnormal conditions in the instrument.

If you observe any signs of damage or malfunction, do not use the instrument, and promptly contact our service engineers. After any repair, the equipment must be thoroughly inspected, including a functional safety check, by qualified personnel. Any inspections requiring the instrument to be opened must be performed by authorized service personnel.

⚠ Failure to maintain the instrument as recommended can lead to equipment malfunction.

3.2 Failure Analysis and Troubleshooting

Problem	Cause Analysis	Solution
Device indicator does not light up after connecting to the phone	Pin OTG cable not properly connected	Reconnect the OTG cable
	Phone does not support OTG function	Use a phone with OTG functionality
	Faulty OTG cable	Contact the manufacturer for a replacement

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Problem	Cause Analysis	Solution
	Instrument malfunction	Contact the manufacturer for repair or replacement
No pulse output (no stimulation on electrode pads)	Current intensity set to zero or too low	Adjust the current strength using the app or volume buttons
	Electrode cord not plugged in	Reconnect the electrode wires
	Poor contact between ear clip and body	Check the positioning and fit of the ear clips
	Skin not cleansed before use	Clean the skin with alcohol pads or water
	Broken electrode wire	Contact the manufacturer for replacement
Blue light remains on after setting parameters and clicking start	Ear clip electrode cable not connected	Check the connection between the electrode cable and device
	Abnormal device connection	Restart the app and reconnect the OTG cable

Note: If your instrument still does not function correctly after following these steps, please contact the manufacturer or your nearest service center.

3.3 Cleaning and Maintenance

3.3.1 Regular Cleaning

Clean the external surfaces of the device using a dry cloth. To prevent damage to the unit, adhere to the following guidelines:

- **Do not use cleaning products that contain wax.**
- **Do not spray or splash water or cleaning solutions onto the device.** Ensure that no liquid enters switches, connectors, or vents.

Warning:
Failure to follow these cleaning guidelines may cause damage to the enclosure, obscure labeling, or result in equipment malfunction.

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3.3.2 Cleaning and Sanitizing Application Components

1. Clean the components before disinfecting, using a non-abrasive cloth dampened with mild soapy water.
2. After cleaning, use 70%-80% ethanol (medical alcohol) to disinfect the electrodes. Either spray the disinfectant evenly on the electrode surface and let it sit for 3 minutes, or wipe the surface twice with a clean, dry cloth.
3. Inspect the device for damage after each use.

3.3.3 Service and Maintenance Procedures

- The Company employs advanced production processes, reducing the need for frequent maintenance.
- We recommend that users perform annual maintenance on the instrument. Testing should be done at least once a year or whenever issues are suspected. Complex tests and calibrations should be performed by the manufacturer.
- Circuit diagrams, parts lists, and other detailed information are available to authorized service personnel only.

Note:
The warranty is valid only when using accessories approved or supplied by our company.

3.4 Transportation and Storage Conditions

- **Ambient temperature range:** -40℃ to 55℃
- **Relative humidity range:** ≤90%
- **Atmospheric pressure range:** 860hPa to 1060hPa

3.5 Packing List and Parts Replacement Cycle

Model	XCHSP-2S
S/N	See Warranty Voucher
Date of Manufacture	See Warranty Voucher

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No.	Component Name	Unit	Quantity	Replacement Cycle
1	Microcurrent Stimulator	Set	1	5 years
2	Pin OTG Cable	Pc	1	Depending on use, 1 year recommended
3	Ear Clip Electrode Wire	Pc	1	Depending on use, 6 months recommended
4	Warranty Certificate	Pc	1	N/A
5	Certificate of Conformity	Pc	1	N/A
6	Getting Started Guide	Pc	1	N/A
7	Operation Manual	Pc	1	N/A

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Chapter IV: Technical Parameters

The stimulus output is an asymmetric bipolar rectangular waveform where the positive and negative components cancel each other out, resulting in no net polarity. The waveform parameters are as follows:

4.1 Stimulating Waveforms

- **4.1.1** 0.5Hz waveform pulse width: 250ms to 1s.
- **4.1.2** 1.5Hz waveform pulse width: 40ms to 360ms.
- **4.1.3** 100Hz waveform pulse width: 5ms.

4.2 Stimulus Intensity

The selectable intensity steps at each stimulation frequency range from 0 to 600 μA, adjustable in increments of 50 μA.

4.3 Accuracy

- For the 50 μA range, the error in current output intensity is within ±10%.
- For the 100 μA to 600 μA range, the error is within ±5%.

4.4 Electrode Parameters

- **4.4.1** Electrode impedance is 0.6 Ω, with an allowable error of ±10% from the nominal value.
- **4.4.2** The cross-sectional area of the electrode connection wire is not less than 0.05mm².

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Chapter V: Important Security Information

5.1 Classification

According to GB9706.1-2020, the CES is classified as follows:

- **Degree of protection against electric shocks:** Type BF
- **Level of protection against ingress of fluids:** IPX0 (not protected against fluids)
- **Protection against the effects of defibrillator discharge:** Not protected
- **Degree of safety for use in the presence of flammable anesthetic gas mixtures (air, oxygen, or nitrous oxide):** Equipment not of type AP or APG
- **Operational mode:** Continuous operation
- **System supply voltage:** DC 5V
- **Manufacturer-recommended disinfection and sterilization methods:** Applicable

5.2 Equipment Symbols

- **5.2.1**  **:** BF-type equipment (Body Floating)
- **5.2.2**  **:** Attention, consult accompanying documents
- **5.2.3**  **:** Class II equipment

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Appendix 1: Manufacturer Information

- **Design Supervision:** Shanghai NCC Electronic Co., Ltd.
- **Company Name:** Jiangxi NCC Electronic Co., Ltd.
- **Enterprise Registration Number:** 360104110000958
- **Unified Social Credit Code:** 91360104563828231N
- **Medical Device Manufacturer License No.:** GSYJXSCX 20160160
- **Address:** Area A, 3rd Floor, Building 4, Science and Technology Innovation Center, No. 269 Aixi Hubei Road, Nanchang High-tech Industrial Development Zone, Nanchang City, Jiangxi Province
- **Tel:** +86 791-87521988
- **Postal Code:** 330000

Appendix 2: EMC-Related Considerations

This instrument has undergone electromagnetic compatibility (EMC) testing in accordance with the national standard **YY0505-2012**. However, electromagnetic environments exceeding the parameters specified in **YY0505-2012** may significantly interfere with the instrument's operation, reducing its performance or preventing it from functioning as intended. If adverse electromagnetic influences affect the instrument's performance, they should be identified, avoided, and resolved before continuing use.

If the instrument causes or is affected by electromagnetic interference (which should be confirmed by appropriate tests), the operator or authorized maintenance personnel can take the following measures to eliminate the interference:

a) Direct or Indirect Impacts

Before use, ensure that all operators and patients interacting with the instrument are free from static charges that could interfere with its performance.

b) Interference from Radio Wave Receivers (e.g., Radios or Televisions)

If the instrument experiences interference from nearby radio wave receivers, move the instrument or system further away from the receiver to minimize disruption.

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c) Lightning Interference

During lightning storms, nearby strikes may cause the instrument or system to experience over-voltage. In such cases, unplug the AC power cord and operate the instrument on battery power or with an uninterruptible power supply (UPS).

d) Use with Other Equipment

If the instrument is placed near or on top of other equipment, electromagnetic interference may occur between devices. Before use, confirm that the instrument and other equipment can function simultaneously without issues.

e) Use of Unspecified Accessories, Transducers, or Cables

Using non-specified accessories, transducers, or cables may result in increased electromagnetic emissions or decreased immunity. Ensure that all components conform to the specified configuration to meet the electromagnetic requirements of the system.

f) Consult Maintenance Engineers for Assistance

If necessary, consult a qualified maintenance engineer to further diagnose or resolve EMC-related issues.

Important Notes:

- ⚠**Note:** Before using this instrument, ensure that all EMC requirements outlined in this manual are satisfied.
- ⚠ **Note:** The manufacturer is not responsible for any interference caused by the use of unauthorized internal connection cables, accessories, or unauthorized modifications to this equipment.

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After-Sales Service Provisions

Warranty Commitment:
The company offers a **one-year free warranty** on the instrument (excluding consumables such as electrode wires, felt, and conductive liquid). Maintenance services will still be provided beyond the warranty period.

Technical Support:
The company is equipped with professional technical engineers. In the event of a machine failure, we will provide feedback within **24 hours** of receiving the repair report.

Maintenance Contact Information:

1. **Maintenance Center Tel:** +86 188 2116 5979 Email: export@cnnation.com
2. **Production Address:**
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