Pain Therapy

疼痛療法

NeuroBlock Spinal Cord Stimulation System

NeuroBlock 脊髓電刺激系統

Models 1001, 1401, 2032

型號1001, 1401, 2032

User Manual

使用者手冊

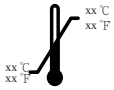
Rx only

2021-Feb

Label Symbols

Explanation of symbols on products and packaging. Refer to the appropriate product for symbols that apply.

Consult instructions for use



Temperature limitation

Use by

Manufacturer

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.

Magnetic Resonance (MR) Unsafe.

Serial number

Keep dry

IEC60601-1/EN60601-1, Type BF equipment

Non-ionizing electromagnetic radiation

Authorized Representative in the European Community

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FCC Information

The following is communications regulation information on the Model 1001 External Stimulator.

FCC ID:

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.

Table of Contents

1 INTRODUCTION

How to use this manual

Use this manual during trial phase and after receiving an Implantable Receiver. Ask your clinician to explain anything that is unclear.

- "1 INTRODUCTION", describes how to use this manual and information about the patient identification card.
- "2 IMPORTANT THERAPY INFORMATION", describes when you should and should not use a spinal cord stimulation system, the spinal cord stimulation system components, and the risks, benefits, warnings, precautions, and patient activities related to your spinal cord stimulation system.
- "3 RECOVERY AND CARE AFTER SURGERY", provides information about recovering from surgery, activity and care information, and when to contact your clinician.
- "4 USING YOUR CUBE", DESCRIBES THE CUBE, how to control and recharge the Cube.
- "5 USING CUBE TO START STIMULATION DURING TRIAL PHASE", describes how to adjust your stimulation using your Cube during trial phase.
- "6 USING CUBE TO START STIMULATION DURING PERMANENT IMPLANTATION PHASE", describes how to adjust your stimulation using your Cube during permanent implantation phase.
- "7 TROUBLESHOOTING", describes Cube warning, alert, and how to solve problems.
- "8 ADDITIONAL INFORMATION", describes how stimulation works, possible adverse effects, changes in therapy, and possible system complications.
- “9 MAINTENANCE AND ASSISTANCE” describes how to care for your Cube, and instructions on using accessories. This chapter also provides Cube specifications and information about who to call for assistance.

Patient Identification Card

A temporary patient identification card will be provided to you at the hospital during Trial Phase. This card supplies information about you, your implanted device, and your doctor. Your identification card may allow you to bypass security devices. If you move, change doctors, or lose your card, contact GiMER Medical for a replacement card. Refer to the GiMER Medical contacts at the end of this manual. After GiMER Medical receives your implant registration from the hospital, you will receive a permanent identification card.

2 IMPORTANT THERAPY INFORMATION

Purpose of the device

Cube (Model 2032) is designed to control the following components of GiMER Medical NeuroBlock SCS System:

- External Stimulator (Model 1001)
- Implantable Receiver (Model 1401)

Purpose of the spinal cord stimulation (SCS) system (indications)

The GiMER Medical NeuroBlock SCS System is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

Description of your system

A GiMER NeuroBlock SCS system has implanted parts that deliver the electrical pulses to block your pain signals.

GiMER NeuroBlock SCS system (Figure 1) includes: a Cube (an external controller, for controlling your system), an External Stimulator (ES), an Implantable Receiver (Receiver), and two lead kits (Medtronic, Vectris™ SureScan® MRI 1x8 Compact 977A260).

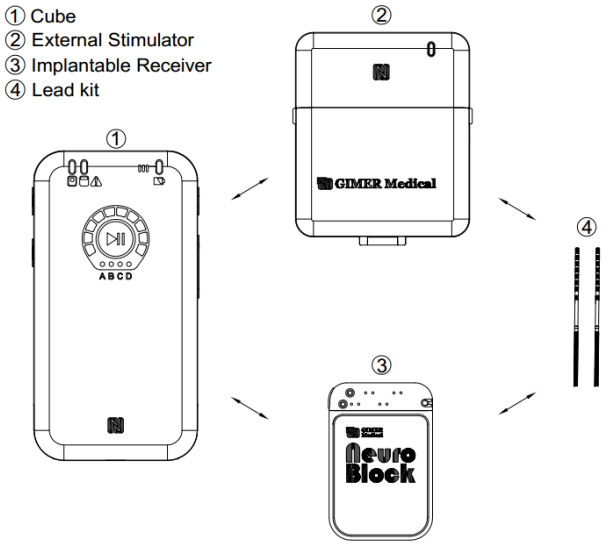


Figure 1. Schematic View of NeuroBlock SCS System

Note: This manual provides instructions for using the Cube only. For instructions about the External Stimulator and the implantable components, e.g., lead kit and the Implantable Receiver, the related manuals will be provided to the clinician.

1. **Cube** – (Model 2032) A hand-held controlling device that you use to, view, select, adjust, and control your stimulation. Refer to “USING YOUR CUBE” on page 18 for more information.
2. **External Stimulator (ES)** – (Model 1001) A disposable, single-use device delivers stimulation through leads. During trial phase, the External Stimulator is used to evaluate whether the GiMER NeuroBlock SCS System effectively relieves pain, prior to implantation of the permanent components of the NeuroBlock SCS System.
3. **Implantable Receiver (RS)** – (Model 1401) The permanent implanted component of the GiMER NeuroBlock SCS System. During treatment, the Implantable Receiver receives the control signals of stimulation and power from the Cube in order to generate stimulations to the leads.
4. **Lead(s)** – (Medtronic, Vectris™ SureScan® MRI 1x8 Compact 977A260) A lead is a set of thin wires, covered with a protective coating. A lead has small metal electrodes near the tip. The electrodes transmit electrical pulses to the area where your pain signals are blocked.
5. **Recharging Components** – The recharging component is used to charge the rechargeable Cube battery. Components included in the recharging component are: charger (adapter), and micro-USB cable. Refer to “Recharging Cube” on page 24 for more information.

Therapies that may not be used with the SCS system (contraindications)

The NeuroBlock SCS system should not be used for those patients who:

- Are poor surgical candidates.
- Fail to receive effective pain relief during trial period.
- Are unable to operate the SCS system.

Risks and benefits

It has been proven through research that stimulation can help patients to alleviate and control their pain and thus improve their quality of life. Your spinal cord stimulation system may be used with other pain treatments. Stimulation will not cure your pain. It can, however, reduce your pain to a tolerable level and allow you to resume many of your daily activities.

Risks of surgery

Implanting a spinal cord stimulation system has risks similar to spinal procedures, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis. If you are on anticoagulation therapy you might be at greater risk for postoperative complications such as hematomas that could result in paralysis.

For information about possible adverse effects, refer to “Adverse Events” on page 40.

General Warnings

Magnetic Resonance Imaging (MRI) –The NeuroBlock SCS System has not been tested under MRI and is currently not labeled as safe. If an MRI scan is required, the clinician must explant and remove all components of the NeuroBlock SCS System.

Electromagnetic interference (EMI) – Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with NeuroBlock SCS System function. NeuroBlock SCS System include features that provide protection from EMI. However, sources of strong EMI can result in the following:

- **Serious patient injury or death**, resulting from heating of the implanted components of the NeuroBlock SCS System and damage to surrounding tissue.
- **System damage,** resulting in a loss of or change in symptom control, and requiring surgical replacement.
- **Operational changes to the NeuroBlock SCS System,** causing it to reset and turn off stimulation, which may result in the return of underlying symptoms.
- **Unexpected changes in stimulation,** causing a momentary increase in

stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

If you suspect that other equipment is interfering with device function:

- Move the equipment or object away from the patient.
- Remove the external stimulator from the vicinity of the patient.

Electromagnetic equipment/environments – Avoidance of high electro-magnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High–power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics
- High–voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

Computed Tomography (CT) Scanning – Please inform your doctor and medical personnel conducting your CT scan that you have an implanted NeuroBlock SCS system. You must not operate any system device(s) while the scan is being conducted.

Machinery or heavy equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the NeuroBlock SCS System stimulation treatment. Malfunction of the system could result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

Case damage – If the Implantable Receiver case is ruptured or pierced due to outside forces, the Implantable Receiver fracture may damage the tissue around the Implantable Receiver and unexpected changes in stimulation could result.

Diathermy therapy – Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients

implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted components and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Electrocautery – If electrocautery tools are used near the device then the insulation can be damaged. The device may fail or conduct induced currents. Induced electrical currents can cause heating of the Implantable Receiver that results in tissue damage. When electrocautery is necessary, these precautions must be followed:

- The Cube should be turned off.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
  - Only low–voltage modes should be used.
  - The lowest possible power setting should be used.
  - The current path (ground plate) should be kept as far away as possible from the implanted device.
  - Full–length operating room table ground pads should not be used.
- After electrocautery, confirm that the device is working as intended.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have a NeuroBlock SCS System. Induced electrical currents may cause heating, or resulting in tissue damage.

NeuroBlock SCS System interaction with active implanted devices or body worn medical devices – The NeuroBlock SCS System may interfere with other active implanted medical devices or body worn medical devices, such as deep brain stimulators, peripheral nerve stimulators, transcutaneous electrical nerve stimulation, implanted drug delivery pumps, cardiac pacemakers, defibrillators, cochlear implants, transcranial magnetic stimulation and wearable medical sensors. The effect of other implanted medical devices on the NeuroBlock SCS System are unknown.

Theft detectors, security screening devices and radiofrequency identification (RFID) systems – Security checkpoints, metal detectors, screening systems at airports, and theft detectors all produce EMI. Any security system device may temporarily interrupt stimulation, or cause elevated levels of stimulation. Patients should avoid performing stimulation treatments in the area of security system devices. It is recommended that if a patient feels a change in stimulation near a potential security system device, they promptly move away from the area and remove the Cube from the body. Patients should not lean on scanners or linger in the area of security system device. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing any abovementioned devices/systems. If unavoidable, the patient should walk through the abovementioned devices/systems and promptly move away from the area.

Stimulation at vertebral levels above T8 – The safety of implantation of leads implanted above the T8 vertebral level have not been evaluated.

Pediatric Use – The safety and effectiveness of this therapy has not been established for use in children.

Pregnancy – The safety and effectiveness of this therapy has not been established for pregnancy, nursing, the unborn fetus, or delivery.

Wound contact – Do Not place the Cube directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The Cube must be placed overtop a thin layer of clothing at all times.

Emergency Procedures – The patient should be instructed to designate a representative (family member or close friend) to notify any emergency medical personnel of their NeuroBlock System External Stimulator, if emergency care is required. Each patient will be provided with a Patient Identification Card to carry with them that will inform emergency medical personnel of the patient's condition. The patient should be advised to remove the External Stimulator before undergoing any procedure that could include RF or microwave ablation, defibrillation or cardio version.

Warnings About Other Medical Treatments/Procedures – Safety has not been established for some medical treatments of patient with a stimulator (Implantable Receiver or External Stimulator) and the medical treatments/procedures includes:

- Electrolysis
- Lithotripsy
- External defibrillation
- Ultrasound scanning
- Radiation/Laser therapy
- Radiofrequency or microwave ablation

Precautions

System and therapy

Power Percentage Suggestion – When performing stimulation, ensure Cube power level is more than 50% to facilitate a smooth operation.

Component compatibility – For proper therapy, use only GiMER NeuroBlock SCS System components that are prescribed by your clinician.

Equipment modification – Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.

Patient control devices may affect other implanted devices – Do not place patient control devices (e.g., Cube, recharging components) over another device (e.g., pacemaker, defibrillator, cochlear implant, and another spinal cord stimulator). The patient control device could accidently change the operation of another device.

Patient device handling – To avoid damaging the device, do not immerse it in liquid; do not clean it with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or mishandle it in a way that may damage it.

Patient device use – When operating a patient control device (e.g., External Stimulator, Cube, recharging components), use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using NeuroBlock SCS system near flammable or explosive atmospheres are unknown.

Keep the Cube dry – The Cube is not waterproof. Keep it dry to avoid being damage. Do not use the Cube when engaging in water activities.

Cube interaction with metal – Keep the back side of Cube (Wireless Coupling Area) away from any metal for more than 10cm while using Cube during the stimulation therapy of permanent implantation phase. The metal may be coupled with Cube and therefore damage the Cube.

Medical tests and procedures – Before undergoing medical tests or procedures, contact the clinician to determine if the procedure will cause harm to the patient or damage to the System.

Do not dismantle the Cube – Do not dismantle or tamper with the device. Tampering with the device could result in harm.

Use of another patient's Cube – Never use another patient's Cube. The therapy program level maybe different for each patient. Use of another patient's Cube could result in ineffective therapy.

Handle the Cube with care – The Cube is a sensitive electronic device. Avoid dropping the device onto hard surfaces. Keep the Cube out of the reach of children and pets.

Storage temperature – The Cube should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to you or the component. Please contact GiMER Medical if a storage temperature is surpassed.

Use only GiMER system component – The compatibility of components other than GiMer NeuroBlock SCS system defined components is not verified; use only GiMER components unless otherwise specified.

Use only with GiMER devices – Do not use other non-GiMER wireless communication on the Cube, External Stimulator or Implantable Receiver, and do not use Cube on other non-GiMER devices for wireless power transmission.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase or uncomfortable in stimulation. Some patients have described this as a jolting or shocking sensation. Patients should stop using the NeuroBlock SCS system to administer stimulation before engaging into activities that could become unsafe.

Patient activities

Activities requiring excessive twisting, pressing or stretching – Avoid activities that may put undue stress on the implanted components of your spinal cord stimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, pressing, or stretching, such as massaging activities, can cause parts of your spinal cord stimulation system to fracture or migrate. This can result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery. Spinal cord stimulation patients, in particular, should avoid excessive bending of the torso.

Component manipulation (twiddler's syndrome) – Do not manipulate or rub your spinal cord stimulation system through the skin; this is sometimes called "twiddler's syndrome." Manipulation can cause damage to your system, lead dislodgement, skin erosion, or stimulation at the implant site.

Scuba diving or hyperbaric chambers – Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) can damage the spinal cord stimulation system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Skydiving, skiing, or hiking in the mountains – High altitudes should not affect the spinal cord stimulator; however, you should consider the movements involved in any planned activity and take precaution to not put undue stress on your implanted system. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the lead, requiring additional surgery to repair or replace the lead.

Discuss these activities with your doctor.

Individualization of treatment

Best results are achieved when you are fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the spinal cord stimulation system require long-term postsurgical management.

Patient selection – The spinal cord stimulation system should not be implanted if:

- your symptoms are not of physiological origin,
- you are not an appropriate candidate for surgery,
- you cannot properly operate the system, or
- you do not receive satisfactory results from trial period stimulation.

Use in specific populations – The safety and effectiveness of this therapy has not been established for the following:

- Pregnancy, unborn fetus, or delivery
- Pediatric use

Long–term effectiveness of neurostimulation

The long–term effectiveness of NeuroBlock SCS System has not been established. Long–term clinical data regarding the efficacy of GiMER Medical NeuroBlock SCS System is not yet available.

3 RECOVERY AND CARE AFTER SURGERY

Recovery from surgery

It takes several weeks to heal from surgery. It is normal to feel some discomfort from the incision(s) and to have some pain at the implant site for 2 to 6 weeks. Your doctor may also prescribe physical therapy or medication to help manage your pain. Always follow your doctor's instructions.

Activities

Some movements can cause changes in stimulation. For example, leaning back may cause the lead to move closer to your spinal cord; this may result in uncomfortable stimulation. Sudden changes in stimulation are most common while you are recovering from surgery.

- Avoid activities where you must bend, stretch, or twist your body; these movements can move your leads, which affects your stimulation.
- Avoid lying on your stomach.
- Avoid reaching over your head.
- Avoid turning from side to side.
- Avoid bending forward, backward, or from side to side.
- Avoid lifting more than 2 kilograms (5 pounds).

As you begin to feel better, you should be able to perform activities such as:

- Bathing or showering
- Sexual activity
- Working at home or at your business
- Hobbies or activities, such as walking, gardening, cycling, or swimming
- Traveling

Remember, returning to your daily activities should make you feel better, not worse.

Note: As you adjust to life with better pain management, you may want to try activities that you could not perform before your surgery. Discuss your activity level with your doctor.

When to call your clinician

Contact your clinician if any of the following events occur:

- You have pain, redness, or swelling at the incision(s) later than 6 weeks after surgery.
- You feel discomfort or pain during stimulation. Pause your stimulation and call your clinician.
- Your system is not working properly.
- You cannot start or pause stimulation.
- You cannot adjust stimulation using the Cube.
- Your External Stimulator requires battery replacement.
- Three or more Channel Indicators of your Cube start flashing during stimulation or treatment pause.
- The stimulation treatment does not effectively relieve your pain.

Care schedule

Your clinician will schedule follow-up visits to make sure you are receiving the most appropriate therapy.

4 USING YOUR CUBE

How your Cube works

The Cube communicates with External Stimulator and Implantable Receiver respectively and wirelessly transfers power to the Implantable Receiver for treatment. Your External Stimulator and Implantable Receiver only accept communications from the Cube, and the communication will only occur after the Cube is “paired” with External Stimulator or Implantable Receiver.

Use the Cube to:

- Start or pause your stimulation.
- View and adjust stimulation levels.
- View the remaining time for next treatment.
- Check the battery status.

Note: The Cube is an electronic device that should be used in accordance with any restrictions while traveling (e.g., airplane takeoffs).

Cube function keys and indicators

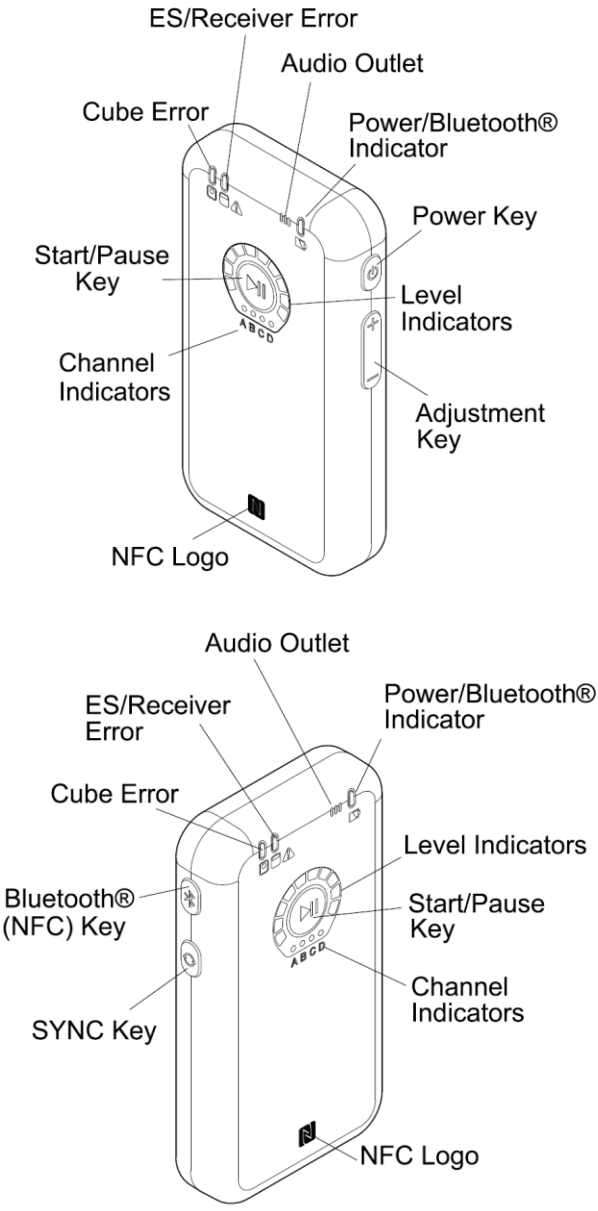


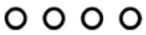
Figure 2. Parts of Cube

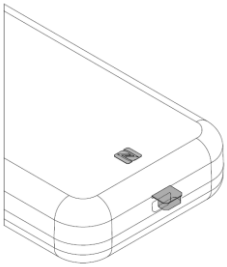
The following table provides a description of the functions of the Cube keys.

Table 1. Cube Function Keys

Function Keys	What it does or means
 **Power Key**	▪ Press and hold for 3 seconds to turn on or turn off Cube. ▪ When Cube is on, tap the key to see the power status.
 **Bluetooth® (NFC) Key**	▪ Press and hold the key for 3 seconds to activate NFC (near field communication) function to establish, or reset communication between Cube and External Stimulator.
 **SYNC Key**	▪ Tap to synchronize the data for the External Stimulator or Implantable Receiver.
 **Adjustment Key**	▪ Tap Adjustment key to Increase (+) and decrease (-) program level.
 **Start/Pause Key**	▪ Tap to start or pause stimulation.

Table 2. Cube Indicators and Outlets

Indicators	What it does or means
 **Power/Bluetooth® Indicator**	▪ Display device power status and notify if charging is required. ▪ Display Bluetooth® connection status.
 **Cube Error**	▪ Notify when Cube error occurs.
 **ES/Receiver Error**	▪ Notify when External Stimulator or Implantable Receiver error occurs.
 **Level Indicators**	▪ Display Cube program level, power level and communication status. ▪ Display External Stimulator & Receiver status (e.g., remaining restriction time or different phase status).
 **Channel Indicators**	▪ Display the status of lead channels.
 **Audio Outlet**	▪ The sound outlet for audio notifications.



- Connect the charger cable of adapter for power charging.

Micro USB Port (capped)

Turn on and off the Cube

1. Press and hold **Power** key for 3 seconds to turn on the Cube, and there will be several beeps. Power Indicator will flash yellow and blue alternately once.
2. The Cube will perform a self-test (all LED indicators will flash in the sequence of yellow and blue) in a few seconds after Cube turns on. Channel Indicators will light up and then go off. When self-test is completed, the Cube is operational, and Level Indicators will display as blue breathing light.

   Note: The default setting of Cube is for trial phase; during permanent implantation phase, Level Indicators will display as purple breathing light.
3. Press and hold **Power** key for 3 seconds to turn off the Cube, and there will be beeps.
4. All Level Indicators will light up and then go off counter-clockwise now.

   Notes:

- Stimulation will stop once the Cube is turned off.
- When stimulation ends, Cube will automatically turn off after 5 minutes without any operation.

Cube power status

1. When Cube is on, tap on **Power** key, Level Indicators of the power level (e.g., 1 LED indicates 10% power) will light up.
2. If Cube power is insufficient, Power Indicator will start flashing. When the power is below 10% or less, there will be 2 beeps, the Power Indicator will flash in yellow for 5 times, and the Cube will automatically shut down.
3. During stimulation, if Cube runs out of battery, stimulation will stop and the Cube may not communicate with the External Stimulator or Implantable Receiver.

   Note: To maintain uninterrupted therapy from the External Stimulator or Implantable Receiver, it is advised to recharge the Cube when the battery is lower than 50% (e.g., fewer than 5 LEDs light up).

Recharging Cube

For first time use, assemble the adapter by jointing the plug onto the base; follow the arrow direction of “Lock” to push the plug forward until a click sound is heard. (Refer to Figure 3)

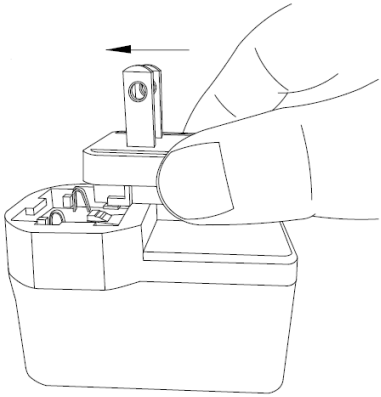


Figure 3. Assemble the Adapter

1. To start a charging session, connect the charger cable included in the Cube package to the micro-USB port at the bottom of the Cube, and plug the power adapter into wall socket (adaptable to 100–250V@60Hz).

⚠ **Caution:** Do not use any other non-GiMER micro-USB cable and/or adapter to recharge the Cube.

Note: Once the Cube starts charging, treatment is NOT available, the Power Indicator LED will remain on in yellow, and go off when the Cube is fully charged. Do not use your Cube during charging session.

2. For checking charging progress, when Cube is operational, tap **Power** key during the charging session, the current power level will show by flashing the corresponding Level Indicators.
3. For an uninterrupted treatment, allow the Cube to charge until at least five LEDs of Level Indicators lights up (50%); it takes about 2 hours to fully charge the Cube.
4. When the Cube is fully charged, Level Indicators will be off. After tapping the **Power** key, the Level Indicators will be all on, and the Cube is now ready to be used again.

Reboot the Cube

When the system freezes or hangs and Cube fail to respond to any operation (including pressing **Power** key to restart the device, see page 23), reboot the Cube by following the below procedures.

1. Press and hold **Power** key and **Start/Pause** key together for 10 seconds to reboot the Cube, and Cube will turn on automatically.

⚠**Caution:** Do not reboot the Cube during a charging session, the Cube will be unresponsive to this operation.

5 USING CUBE TO START STIMULATION DURING TRIAL PHASE

After the implantation surgery for placing two leads into your body and connecting External Stimulator with the leads by the clinician, you will receive Cube as a patient controller in the trial phase. Now you are ready to enter a test to see if this therapy works for you. You may refer to Chapter 4 “USING YOUR CUBE” to learn about Cube and familiarize with the operations better.

During trial phase, the stimulation is delivered by the External Stimulator, which is powered by a 9-volt alkaline battery. Under normal circumstance, you will not need to replace the battery of External Stimulator. However, if the battery power is low (i.e., Power Indicator flashes), contact your clinician to arrange an appointment for battery replacement.

There are ten program levels in the Cube. The default level for starting trial phase is level 1, which is the lowest energy level of the program. Most treatment duration is shorter than 10 minutes, but effective throughout the day (even for days) to relieve your pain.

After finishing one treatment, Cube will enter restriction period, a new treatment is available every 4 hours in trial phase. The purpose is to moderate your use frequency of the therapy. You can discuss with your doctor about the frequency of using the NeuroBlock SCS System.

For the following treatment, the permitted adjustment range is one level up or down from the previous level. (e.g., If you used Level 2 for previous treatment, you may stay in Level 2, or select Level 1 or Level 3 for the current treatment.) Whether to level up or down, it depends on your pain relief condition. If you still feel the pain, you can level up; if you do not feel any pain, (i.e., has found the effective program level), you can stay at the previous level. If you feel the pain at a new area or have complications, please level down or turn off the Cube then call your doctor for help.

Figure 4. External Stimulator

1. Turn on Cube and ensure Cube is operational (all Level Indicators will display as blue breathing light). Keep the Cube within 3 meters (10 feet) of the External Stimulator, tap **SYNC** key to synchronize Cube with External Stimulator. For the first use, the default program level is Level 1 and 1 LED will light up in blue.

   Note: After tapping **SYNC** key, if it is still within restriction time, Level Indicators will flash in yellow for the percentage of remaining time (e.g., 1 LED indicates 10% of 4 hours of trial phase restriction, which is 24 minutes).

   Note: After tapping **SYNC** key, if the External Stimulator battery is low, the ES Power Indicator on the upper right-hand corner of External Stimulator and the ES/Receiver Error on Cube will begin to flash.

△ **Caution:** Contact your clinician to arrange an appointment for battery replacement, do not try to replace the battery on your own.

2. After the synchronization is completed, there will be beeps, Level Indicators will display the last treatment level by lighting up the corresponding light in blue. Channel Indicators will light up for operational channels. Program level can be adjusted by tapping **Adjustment** Key to increase or reduce the stimulation intensity. (Skip this step, if the adjustment is not needed.)

- Level Up (Increase Strength): Tap "+", and the corresponding Level Indicators will begin to flash.
- Level Down (Reduce Strength): Tap "-", and the corresponding Level Indicators will begin to flash.

△ **Caution:** If it is noticed that three or more Channel Indicators of your Cube start flashing or didn't light up, contact your doctor immediately.

Note: The range of allowed level adjustment for each treatment during trial phase is one level up or down, you may also stay in current level.

3. When the desired level is selected, tap **SYNC** key first, after synchronization is finished, Level Indicators will light up in blue for the selected level, and then tap **Start/Pause** key to begin the stimulation. Now Level Indicators will light up in yellow and display the treatment remaining dosage by going off counterclockwise, and there will be 1 long beep at the beginning, and then 1 short beep every 5 seconds during the treatment.

   Note: It is advised to keep in upright and sitting position, and avoid any movements during the stimulation.

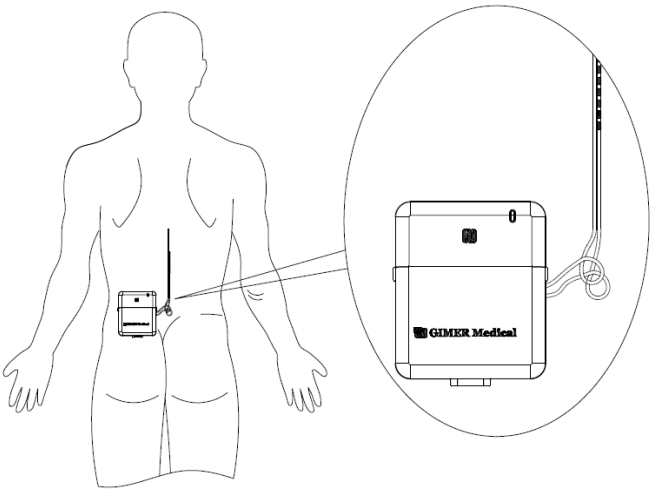


Figure 5. External Stimulator location during Trial Phase

4. To pause the stimulation as needed, tap **Start/Pause** key again. Level Indicators will flash in blue and yellow alternately and then display blue breathing light for the program level during the pause, and Channel Indicators will light up. To resume the treatment, tap **Start/Pause** key again.

Notes:

- During a treatment, if Bluetooth® connection is lost, External Stimulator will automatically postpone the treatment and wait for reconnection, Cube Power/Bluetooth® Indicator will start flashing in blue and yellow alternately (for reconnecting Bluetooth®). Once Cube and External Stimulator reconnected, there will be beeps, Power/Bluetooth® Indicator will flash in blue, Level Indicators will display the corresponding program level in blue light, then tap **Start/Pause** key to resume the treatment.
- If Cube fails at Bluetooth® reconnection and idles (without any operation) for 1 minute, Cube will return to standby mode, and Level Indicators will display blue breathing light. Tap **SYNC** key to reconnect the External Stimulator. If reconnection fails, press and hold **Bluetooth®** key to reset Bluetooth®. Refer to “TROUBLESHOOTING” on page 37. If the Bluetooth® connection still fails to resume, then leave the current environment since the failure might be due to EMI (electromagnetic interference).
- When treatment is paused for over 30 seconds, or, if accidentally **SYNC** key is pressed for 5 seconds during the pause, the Cube will return to standby mode, Level Indicators will display as blue breathing light. For resuming the unfinished treatment, tap **SYNC** key again to enter stimulation mode, Level Indicators will display blue breathing light for the program level paused, and then tap **Start/Pause** key again to start the stimulation; level adjustment is not allowed for the unfinished treatment.
- After five more minutes, Cube will automatically turn off itself without any operations. To continue the unfinished treatment, repeat step 1 and tap **Start/Pause** key.

5. When a treatment finishes, there will be beeps and the Level Indicators will flash blue and yellow interweavingly, then the Cube enters the restriction period for next treatment (4 hours during trial phase). The Level Indicators of Cube will display as breathing lights in blue.
6. After the restriction time ends, repeat step 1 to 3 for a new treatment if needed.

Notes:

- During restriction, to know the remaining time for next treatment, turn on the Cube and when Cube is operational, tap **SYNC** key, and Level Indicators will flash in yellow for the percentage of remaining time (e.g., 1 LED indicates 10% of 4 hours of restriction, which is 24 minutes).
- Restriction period begins once stimulation is started. If the stimulation is paused, it can be resumed any time before the restriction period ends. The paused or unfinished treatment will be omitted after a restriction period ends, and a new treatment can be started as step 1 to 3.
- When stimulation ends, Cube will automatically turn off after 5 minutes without any operation.
- Change External Stimulator battery: In rare cases, if External Stimulator power is insufficient, ES/Receiver Error on Cube will flash in a fast speed. Contact your clinician.

6 USING CUBE TO START STIMULATION DURING PERMANENT IMPLANTATION PHASE

After going through trial phase, it has been proven that this therapy works for you, and you must be very familiar with your Cube that you know how to turn Cube on and off, start and control the treatment. Now moving forward to next phase, with two leads and an Implantable Receiver implanted in your body, the operation of Cube remains the same, though you are advised to utilize the belt, pads and pouch assembly to support the Cube for aligning with the Implantable Receiver during the treatment. If you encounter any difficulty hearing the beeps or operating system device, please request assistance from your family member, friend, caregiver, or healthcare professionals.

You are advised to wear a thin layer of clothing for the treatment, and keep Cube away from any metal for more than 10cm distance. During the therapy, maintain yourself in an upright and sitting position, and avoid any movements. Implantable Receiver generates heat during the stimulation, your skin at the implant site may feel warm during the treatment, though it does not cause harm, please stop the treatment should you feel any discomfort, and contact your doctor immediately.

During permanent implantation phase, the stimulation is delivered by the Implantable Receiver, which is a battery-free device, powered by the energy transmitted wirelessly from the Cube. The battery-free feature not only ensures more safety, but also means your Implantable Receiver does not need charging session and maintenance. Under normal circumstance, you won't have to go through another surgery due to replacement of a depleted device battery.

There are ten new program levels in the Cube. Normally, each treatment duration is shorter than 10 minutes, but effective throughout the day (even for days) to relieve your pain.

After finishing the treatment, Cube will enter a restriction period. During permanent implantation phase, a new treatment is available every 6 hours, the purpose is to moderate your use of the therapy. You can discuss with your doctor about the frequency of using this pain therapy.

Figure 6. Implantable Receiver

1. Turn on the Cube, and when Cube is operational (all Level Indicators will display as purple breathing light), tap **SYNC** key to activate stimulation mode, Level Indicators of the previous program intensity will light up in blue. For the first use in the permanent implantation phase, the default program level is level 5.

   Note: If it is still within restriction time, Level Indicators will flash in yellow for the percentage of remaining time (e.g., 1 LED indicates 10% of 6 hours of permanent implantation phase restriction, which is 36 minutes).

2. Select desired level by tapping **Adjustment** key to choose level strength. (Skip this step, if the adjustment is not needed.)

- Level Up (Increase Strength): Tap “+”, and the corresponding Level Indicators will light up.
- Level Down (Reduce Strength): Tap “–”, and the corresponding Level Indicators will light up.

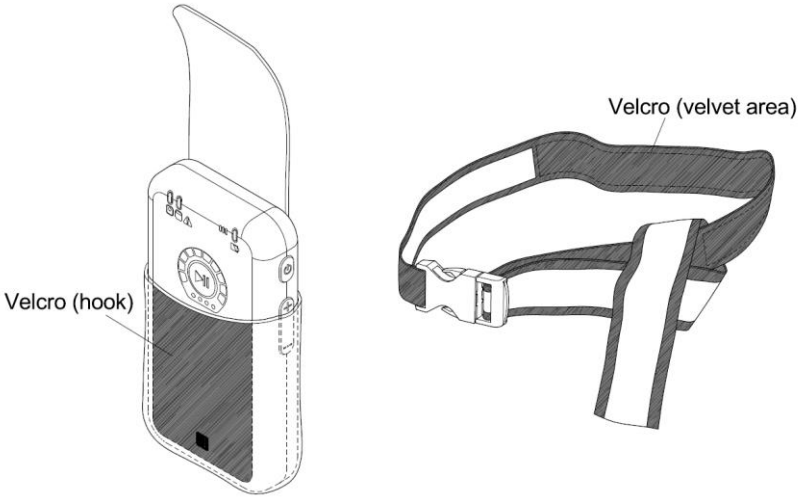


Figure 7. Belt and pouch assembly

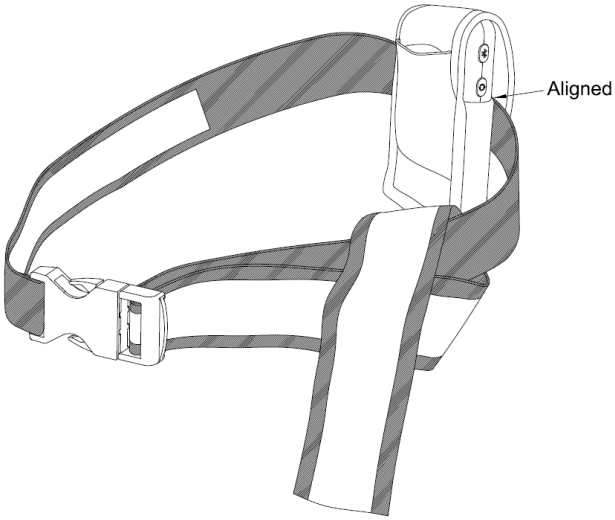


Figure 8. Align and attach pouch to the belt

3. Put on the belt with Velcro area (velvet at inner side of the belt) facing the body, buckle up, fasten the belt by adjusting the belt length, and tuck the excess belt in a knot. The belt should cover the implantation site.
4. Tap **Start/Pause** key, and place the Cube into the pouch, then attach the pouch Velcro area (hook) to the belt Velcro area (velvet at inner side of the

belt), where the Cube is at the inner side of belt and face outward, and the pouch front should be aligned with the upper seam of the belt (refer to Figure 7 and Figure 8).

Note: Insert the pads in the small pocket at the pouch to increase the proper distance for optimal communication between Cube and Implantable Receiver. Your clinician or nurse might have chosen the suitable pad for you before you left hospital.

5. Adjust the belt to allow Cube align with Implantable Receiver implantation site (refer to Figure 9 and Figure 10), there will be 2 short beeps repeatedly every 2 seconds; when Cube detects Implantable Receiver in the proximity, there will be repeated short beeps. When Cube is properly aligned with Implantable Receiver, there will be a long beep indicating the beginning of the treatment, and a short beep every 5 seconds during the treatment, maintain your position and avoid movements during the process.

⚠**Cautions**:

- While aligning Cube with Implantable Receiver or during stimulation treatment, do not suddenly remove Cube away from Implantable Receiver, and you should avoid any abrupt movement.
- If it is necessary to change the device relative position, tap **Start/Pause** key first for pausing the communication between the two devices to prevent the prickling sensation caused by the surge of transient power.

Note: After tapping **Start/Pause** key, Level Indicators will flash in blue light back and forth when Cube is searching for Implantable Receiver, and when Cube detects Implantable Receiver in the proximity, Level Indicators will flash clockwise in blue and counterclockwise in yellow, and then flash in blue and yellow alternately when Cube is establishing communication connection with Implantable Receiver.

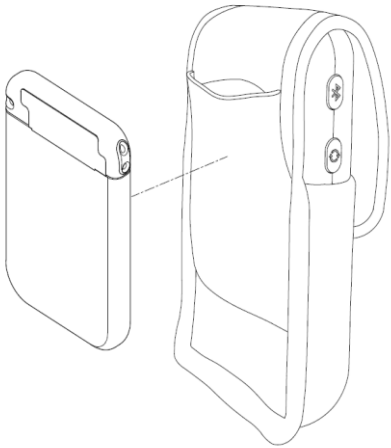


Figure 9. Align pad area with Implantable Receiver

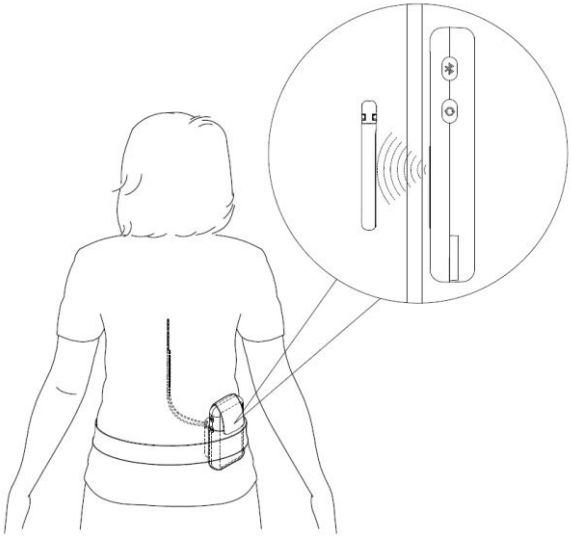


Figure 10. Stimulation during permernent implantation phase

6. During the treatment, Level Indicators will light up in yellow and reduce counterclockwise to display remaining dosage, and Channel Indicators of the lead(s) in use (operational channels) will light up.
7. Tap **Start/Pause** key to pause the treatment as needed; during the pause period, Level Indicators of the programmed intensity will display as blue breathing light, and Channel Indicators of operational channels will light up. Tap **Start/Pause** key again can resume the treatment.

△Cautions:

- If it is noticed that three or more Channel Indicators of your Cube start flashing during stimulation, or treatment pause, or after a treatment is complete, contact your doctor immediately.
- In rare cases, the temperature of Implantable Receiver may rise to maximum 43.5°C during stimulation. Although no damage will be caused, if the heat is unbearable or you feel any discomfort, stop the treatment and contact your doctor immediately.

Notes:

- During a treatment, if wireless communication is lost, Level Indicators will display as blue light repeatedly flashing clockwise, and there will be two short beeps repeatedly. Cube will automatically postpone the treatment and reconnect Implantable Receiver proactively. Once Cube and Receiver reconnected, there will be 3 beeps, Level Indicators will light up in blue for the treatment level, and after a long beep, treatment will be automatically resumed.

- If Cube fails to reconnect for 1 minute, repeat step 1 to 5 to reconnect the Implantable Receiver. If the reconnection still fails, make sure the Implantable Receiver and the Cube are aligned to each other or leave the current environment since the failure might be due to EMI (electromagnetic interference).

8. When the treatment is complete, there will be 6 beeps, Level Indicators will light up in blue for the finished program level, and Channel Indicators will light up for the channel just used. Abnormal channel(s) will flash if there's any open channel or impedance error. Cube enters the restriction period for next treatment (6 hours during permanent implantation phase). Then, Level Indicators of Cube will display as breathing lights in purple.
9. After the restriction time ends, repeat step 1 to 8 for a new treatment if needed.

Notes:

- During restriction, to know the remaining time for next treatment, turn on the Cube and tap **SYNC** key, and Level Indicators will flash in yellow for the percentage of remaining time (e.g., 1 LED indicates 10% of 6 hours of permanent implantation phase restriction time, which is 36 minutes).
- Restriction period begins once stimulation is started. If the stimulation is paused, it can be resumed any time before the restriction period ends. The paused or unfinished treatment will be omitted after a restriction period ends, and a new treatment can be started.
- When stimulation ends, Cube will automatically turn off after 5 minutes without any operation (inactivity).

7 TROUBLESHOOTING

If you are experiencing problems with your Cube, use the below table for troubleshooting. It also provides information on when to call your clinician.

Note: If you cannot solve a problem or if your problem is not described here, contact your clinician.

Table 3. Troubleshooting

Problem	Description
Uncomfortable stimulation:	**Possible Reasons:** ▪ The selected stimulation level is not suitable for your current activity or posture. **Possible Solutions:** ▪ Stop the stimulation. ▪ Stop the activity. ▪ Change your current posture and keep in upright sitting position. ▪ If this does not eliminate the problem, call your clinician.
Cube cannot communicate wirelessly with External Stimulator	Refer to "USING CUBE TO START STIMULATION DURING TRIAL PHASE" on page 27 for what the Cube displayed. **Possible Reasons:** ▪ You are in an environment where multiple devices are using Bluetooth® and thereby creating interference. ▪ You have moved into an environment where the use of Bluetooth® is prohibited. ▪ External Stimulator battery level is low. **Possible Solutions:** ▪ Make sure that the Cube and External Stimulator are within range of each other (within 3 meters). ▪ Make sure Cube is not in an environment of EMI (electromagnetic interference) or in a Bluetooth® prohibited environment. ▪ Tap **SYNC** key to reconnect the External Stimulator. ▪ Install a new battery for the External Stimulator (contact your clinician for battery replacement).
Cube cannot communicate with Implantable Receiver	Refer to " USING CUBE TO START STIMULATION DURING PERMEMANT IMPLANTATION PHASE" on page 30 for what the Cube displayed. **Possible Reasons:** ▪ Connection timeout and Cube idles. ▪ Cube is not properly aligned with Implantable Receiver within proper distance and/or the communication is out of range.

	Possible Solutions: ▪ If Cube idles, tap **SYNC** key, Level Indicators will become purple breathing light, and tap **SYNC** again, if Level Indicators light up in blue for program level, tap **Start/Pause** key to start the treatment. ▪ Make sure the Cube is aligned with the implantation site of Implantable Receiver with proper communication distance and range (using belt set and pad for support).
Cube error occurs during the treatment in permanent implantation phase (ES/Receiver Error lights up with two short beeps repeatedly)	**Possible Reasons:** ▪ Cube contacts or comes near metal objects while communicating with Implantable Receiver **Possible Solutions:** ▪ Keep Cube away from the metal object for more than 10cm distance. ▪ Tap **SYNC** key, Level Indicators will display as purple breathing light, then tap **SYNC** key again, Level Indicators will display breathing light in blue for the program level, tap **Start/Pause** key to resume the treatment.
Implantable Receiver Overheating (ES/Receiver Error and Level Indicators flash in yellow with two short beeps repeatedly)	**Possible Reasons:** ▪ If the temperature of the Implantation Receiver rises to 43.5°C, the treatment will pause, and ES/Receiver Error and Level Indicators will flash in yellow with 2 short beeps repeated. **Possible Solutions:** ▪ Tap **SYNC** key, Level Indicators will display as purple breathing light, and wait until the temperature drops (it is suggested to wait for about 20 minutes), then tap **SYNC** key again, Level Indicators will display breathing light in blue for the program level, tap **Start/Pause** key to resume the treatment.
Cube battery level is low	It is advised to recharge the Cube when the battery is lower than 50% for an uninterrupted treatment. Charge the Cube by using the recharging components. Refer to “Recharging Cube” on page 25.
Cube is unresponsive (Cube Error lights up)	**Possible Solutions:** ▪ Turn off the power for the Cube, then turn the power back on. (Reboot the Cube if the system is hung or frozen; refer to “Reboot the Cube” on page 26.) ▪ After rebooting, if Cube Error persists and there are 2 short beeps repeat for a few seconds, contact your clinician If you continue to have communication problems or cannot use the Cube to control stimulation, contact your clinician or GiMER representative using the contact information listed on the inside back cover of this manual.

Dropped Cube: Your Cube falls off a cabinet or table	**Possible Solutions:** ▪ Turn on the Cube to verify if all operations and indicators are normal; if the Cube is severely damaged, contact GiMER representative to arrange for a replacement. ▪ The Cube is designed to withstand a short drop to a hard surface and still operate normally, even if the case is chipped or nicked.
Fluid on the Cube: Fluid was spilled onto the Cube or the Cube was dropped into water	**Possible Reasons:** ▪ Cube is not waterproof, and water can damage the device. **Possible Solutions:** ▪ If fluid was spilled onto Cube case, pat dry the Cube with dry and clean towel and allow the Cube to air dry at room temperature. ▪ If Cube was dropped into water, contact GiMER representative to arrange for Cube replacement.

If the Cube requires repair, is damaged, or is nonfunctional and a replacement is needed, contact your GiMER representative using the contact information listed on the inside back cover of this manual.

8 ADDITIONAL INFORMATION

Adverse events

The implantation of a spinal cord stimulation system involves risks that are similar to other SCS system. In addition to those risks associated with surgery, the adverse events may occur with implantation or use of a NeuroBlock SCS system and underlying disease progression include but are not limited to the following. Please contact your physician if you experience any adverse events associated with the NeuroBlock SCS system.

- Abscess
- Allergic or rejection response to the implanted materials
- Cerebral spinal fluid (CSF) leakage
- Clumsiness
- Death
- Electrical shock, neurological effect, prickling, numbness, and/or uncomfortable sensation from stimulation
- Epidural hemorrhage
- Escalating pain symptoms
- Fibrosis
- Formation of reactive tissue around the lead in the epidural space
- Hyperesthesia
- Infection
- Inflammation/swelling
- Intermittent stimulation
- Lead migration(movement)
- Nerve damage
- Neurological deficits
- Neurostimulator pocket pain, infection, inflammation, hematoma, seroma, bleeding, and/or erosion
- Numbness
- Pain, bleeding, inflammation, and/or infection at the epidural needle insertion site
- Pain caused by overstimulation
- Pain caused by under stimulation
- Pain from a non-noxious stimulus to the skin (allodynia)
- Paralysis
- Persistent pain at the site of the implanted components
- Spinal cord compression
- Stimulation of the chest wall (radicular stimulation)
- Stimulation-dependent gastrointestinal symptoms such as diarrhea, incontinence, or constipation.
- Stimulation-dependent bladder symptoms such as urinary retention, incontinence, or frequency.
- Thrombosis (blood clot)
- Tissue damage

- Sensation of hearting or burn at the implant site
- Weakness

Subjects may require surgery. including revision, explant, and/or NeuroBlock system component replacement as a result of any of the above events.

Possible system complications

The lead, or Implantable Receiver could migrate within the body or erode through the skin. There could be undesirable changes in stimulation, possibly related to cellular changes around the electrode(s), changes in the position of the electrode(s), loose electrical connections, or lead fractures. It is also possible that the implanted materials could cause an allergic or immune system response. Your spinal cord stimulation system might unexpectedly cease to function due to other causes. These events, which can include electrical shorts or open circuits, conductor (wire) fractures, and insulation breaches, cannot be predicted.

9 MAINTAINENCE AND ASSISTANCE

This section provides information how to care for your Cube, and instructions on using accessories. This section also provides Cube specifications and information about who to call for assistance.

Cleaning and care

Follow these guidelines to ensure that the Cube and accessories function properly.

⚠Cautions:

- Keep the Cube out of the reach of children and pets. If children or pets swallow any components, contact a doctor at once.
- Use the SCS system components only as explained to you by your clinician or as discussed in this manual.
- Handle the Cube with care. Do not drop, strike, or step on the Cube.
- Do not dismantle or tamper with the Cube.
- Do not sterilize any parts of the Cube, sterilization may damage the Cube.
- Keep Cube away from any metal objects during therapy in permanent implantation phase.
- The Cube is not waterproof. Do not allow moisture to get inside the device. Use only dry and clean towel to wipe clean the Cube.

Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the Cube are not required. The Cube contains no user- serviceable parts. If repair or service is needed, contact your clinician or a GiMER representative for a replacement. Refer to the GiMER's contact information at the end of this manual.

Battery, Cube, and External Stimulator disposal

Return your Cube and your External Stimulator to your doctor or GiMER representative at the end of the trial phase or when no longer being used. Do not discard or burn the Cube or External Stimulator. Fire may cause the internal batteries of the Cube and External Stimulator to explode. Do not attempt to dispose of the Cube or External Stimulator yourself.

Implantable Receiver disposal

Explanted Implantable Receiver should not be resterilized or re-implanted. We suggest your explanted Implantable Receiver be returned to doctor or GiMER representative. Refer to the back cover for contact information if you or your doctor have any questions.

Specifications

The following table lists the specifications for the External Stimulator and Cube.

Table 4. Material of Model 1001 External Stimulator

Component	Material	Material contacts human tissue
Case	Polycarbonate	Yes
Cover	Polycarbonate	No
Contacts	Gold- and nickel-plated beryllium copper	No
Pad	Foam	No
Accessory		
Battery	PP3 9V alkaline battery	No

Table 5. Physical Characteristics of Model 1001 External Stimulator

Description	Value
Connector type	2 Octapolar, 16 electrodes contact
Height	81 mm
Width	68 mm
Thickness	22 mm
Weight	150 g
Power source	PP3 9V alkaline battery
Degree of protection against electrical shock	Type BF
Operating temperature range	10°C to 40°C
Storage temperature range	-10°C to 55°C
Humidity	30% to 90%
Pressure	75 to 150 kPa
ES Service Life	1 year

Table 6 . Physical Characteristics of Model 2032 Cube

Description	Value
Power Source	Rechargeable lithium battery
Service life	1 year
Operation temperature range	10°C to 40°C
Storage temperature range	-10°C to 55°C
Humidity	30% to 90%
Pressure	75 to 175 kPa
Size (approximate)	65 mm x 123 mm x 21.5 mm
Weight	250 g

User assistance

If repair or service is needed, contact your clinician or GiMER representative. Refer to the GiMER contacts at the end of this manual.

The serial number is located in the backside of the Cube. This number identifies each Cube. If you contact GiMER or GiMER representative about your Cube, refer to the serial number.

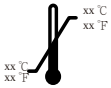
If your Cube stops working – First try the steps in "TROUBLESHOOTING" on page 37. Otherwise, contact GiMER representative or your clinician.

If you lose your Cube – Contact GiMER or your clinician to order a new Cube.

產品或包裝標籤上的標示說明

說明產品與包裝上的標籤。參照下列適用的產品標示。

諮詢使用說明



溫度限制

使用效期

製造商

勿將此產品丟棄至未分類的地方廢棄物分流系統。需根據當地法規丟棄此項產品。

核磁共振(MR)不安全

序號

保持乾燥

IEC60601-1/EN60601-1, BF 類別設備

非游離電磁輻射

歐盟授權代理

精能醫學為精能醫學股份有限公司於美國以及其他國家的註冊商標。**藍牙**®文字標誌與標誌為Bluetooth SIG所有之註冊商標，精能醫學經授權使用標誌。

FCC Information

The following is communications regulation information on the Model 1001 External Stimulator.

FCC ID:

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.

目錄

1 導引

如何使用本手冊

在試用期間以及接受植入接收器之後使用本手冊。有任何疑惑之處，請您的醫生協助釋疑。

- "1 導引", 敘述使用本手冊的方法以及病患識別卡的相關資訊。
- "2 重要治療相關資訊", 說明您應該與不該使用脊髓電刺激系統與零組件的時機，及與您的SCS系統相關的風險、益處、預防措施、病患活動等相關資訊。
- "3 術後復原與照護"，提供術後復原、活動與相關照護資訊，以及聯絡您的醫生的時機。
- "4 使用您的 控制器"，敘述介紹控制器，如何操作與將控制器充電。
- "5 試用期間使用控制器進行電刺激"，說明在試用期間使用控制器調整您的電刺激的方法。
- "6 永久植入期間使用控制器進行電刺激"，說明在永久植入期間使用控制器調整您的電刺激的方法。
- "7 故障排除"，敘述說明控制器的警告與警示，以及解決問題的方法。
- "8 附加資訊"，敘述說明電刺激的作動、可能的不良影響、療程的改變，以及可能的系統併發症。
- “9 維護與協助”，敘述說明保養控制器的方式，及使用配件的指示，也提供控制器規格與協助需求資訊。

病患識別卡

試用期間時，您的醫生將給您一張臨時病患識別卡，這張卡片記載您的相關資料，包括您的植入裝置與醫生，且可讓您越過安檢裝置。如果您搬家，換醫生，或者弄丟卡片，請參照本手冊封底內頁的資訊聯絡精能醫學以更換新卡。在精能醫學自院方收到您的植入註冊表後，您即會收到一張永久識別卡。

2 重要治療相關資訊

裝置目的

控制器 (Cube, 型號 2032) 設計用途為控制下列的精能醫學NeuroBlock脊髓電刺激系統裝置:

- 外部刺激器 (型號 1001)
- 植入接收器 (型號 1401)

脊髓電刺激(SCS)系統目的(適應症)

精能醫學的NeuroBlock脊髓電刺激系統適用於做為唯一的舒緩媒介，或其他治療模式的輔助療法，用來協助控制軀幹及/或下肢難以處理的慢性疼痛，包括單側或雙側疼痛。

系統敘述

精能NeuroBlock脊髓電刺激系統的植入部件可遞送電脈衝以阻斷疼痛訊號。

精能NeuroBlock脊髓電刺激系統包括: 一台控制器 (體外控制器，用以操控系統)、一台外部刺激器(ES)、一台植入接收器(RS)，以及兩份電極導線組 (美敦力, Vectris™ SureScan® MRI 1x8 Compact 977A260)。

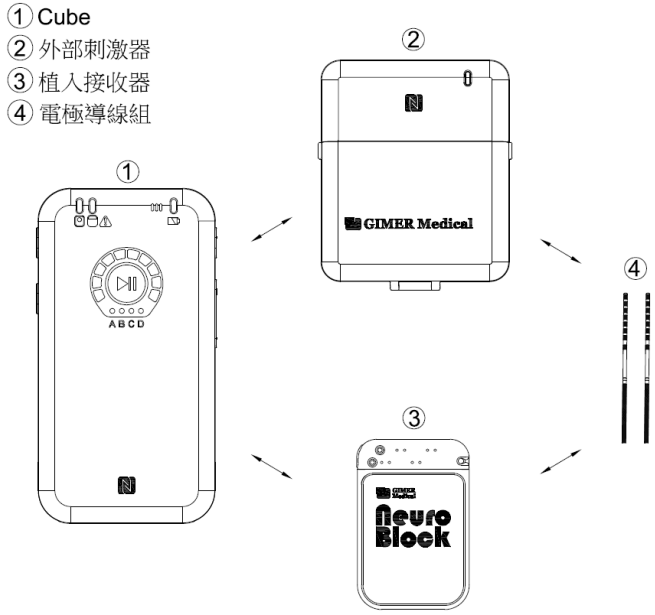


圖 1. NeuroBlock 脊髓電刺激系統

注意: 本手冊僅提供控制器的指示說明。關於外部刺激器與植入式零組件，例如電極導線與植入接收器，將提供相關手冊給醫生。

1. **控制器 (Cube)** – (型號2032) 為手持式控制裝置，用來檢視、選擇、調整，與操控您的電刺激。更多資訊請參照第61頁的"使用您的控制器"。

2. **外部刺激器 (External Stimulator, ES)** – (型號 1001) 為拋棄式，透過植入導線遞送電刺激的體外刺激產生裝置。外部刺激器使用於植入永久零組件前的試用期，用以評估精能 NeuroBlock 脊髓電刺激系統是否能有效緩解疼痛。

3. **植入接收器(Implantable Receiver, RS)** – (型號 1401)為精能 NeuroBlock 脊髓電刺激裝置的植入裝置。治療過程中，植入接收器接收來自控制器的電力與電刺激的控制訊號以產出電刺激傳送至導線。

4. **導線 (Lead)** – (美敦力, Vectris™ SureScan® MRI 1x8 Compact 977A260) 導線由一組以保護層覆蓋的細金屬線組成。導線靠近末端之處為小型的金屬電極，而電極負責傳送電性脈衝至您的疼痛訊號被阻斷的區域。

5. **充電零組件 (Recharging Components)** –充電零組件用於將控制器的電源充電。零組件包括: 充電器(整流器)與Micro USB線。更多資訊請參照第68頁的"控制器充電"。

不可與 SCS 系統共用的療法 (禁忌症)

NeuroBlock脊髓電刺激系統不得應用在下列病患上:

- 經醫師評估後不適合接受手術的人選
- 對試用期的電刺激沒有良好反應
- 無法適當操作系統

風險與益處

電刺激經研究證實可幫助病患緩解並管控他們的疼痛，進而改善了他們的生活品質。您的脊髓電刺激系統可與其他疼痛治療共用。電刺激不會治癒您的疼痛，但可緩減您的疼痛至可忍受程度，並使您重回許多日常活動。

手術風險

植入脊髓電刺激系統的風險與其他脊髓相關的程序類似，包括脊髓液滲漏、頭痛、腫脹、瘀傷、流血、感染，或者癱瘓。若您正接受抗凝血療法，您則有較高風險會面臨術後併發症，例如可能會造成癱瘓的血腫等。

關於可能的不良事件等相關資訊，參照第81頁的”不良事件。

一般警告

核磁共振造影(MRI) – NeuroBlock脊髓電刺激系統尚未進行核磁共振造影(MRI)的測試，目前並非標註為可安全進行核磁共振造影(MRI)的系統；如需進行MRI掃描，醫生須將所有的NeuroBlock脊髓電刺激系統零組件取出並移除。

電磁干擾(EMI) –電磁干擾(EMI)為家用、工作領域、醫療，或公共環境中的設備所產生的強大能量場，足以干擾NeuroBlock脊髓電刺激系統功能。NeuroBlock脊髓電刺激系統對於電磁干擾符合法規要求，然而，強力的電磁干擾來源可能造成的影響如下:

- **病患嚴重受傷或死亡**，由NeuroBlock脊髓電刺激系統的植入部件可能因該場域引起生熱而損傷其鄰近組織，致使嚴重不良反應。
- **系統受損**，造成症狀控制的喪失或變更，且須進行更換手術。
- **功能失效**，NeuroBlock脊髓電刺激系統的操作變更，造成系統重置或關閉電刺激，可能導致病人回到先前症狀。
- **預期外的電刺激改變**，造成短暫的刺激增強或間歇性刺激，部分病患形容為震顫或衝擊感。雖然預期外的刺激改變可能會帶來不適感，但不會損壞裝置或直接對病患造成傷害。在極少數案例中，病患因為預期外的刺激改變而跌倒受傷。

若您懷疑其他設備已干擾裝置功能:

- 建議遠離該設備或物品。
- 自病患身邊移開外部刺激器。

電磁設備/環境 – 儘可能避免高電磁輻射器設備環境。設備及/或環境舉例包括下列:

- 私人娛樂、通訊以及無線實驗用的強力業餘發送器/天線、民用波段(CB)電台或火腿電台
- 用於熔接金屬或塑膠的電弧焊或電阻焊設備
- 用於熔化金屬與塑膠的工業用感應電爐/加熱器或電弧爐/加熱器
- 以護欄圍起，限制進入標示與警告標示所界定出來的高電壓區域(護欄區以外為安全區域)
- 以護欄圍起，限制進入標示與警告標示所界定出來的微波發送器區域(護欄區以外為安全區域)
- 以護欄圍起，限制進入標示與警告標示所界定出來的電視與無線電塔區域(護欄區以外為安全區域)
- 用來增強無線電發送器、無線通訊軟體、音響設備或其他電子設備的電源輸出用的線性電源放大器(linear power amplifier)
- 用來追蹤車輛、設備或動物位置的無線電遙感偵測(telemetry)裝備

電腦斷層掃描 –請告知為您進行電腦斷層掃描的醫生與醫療相關人員您配有NeuroBlock 脊髓電刺激系統一事。進行掃描時，不可操作任何系統裝置。。

機具或沉重器械 – 使用 NeuroBlock 脊髓電刺激系統進行刺激治療時，請勿操作任何機具或沉重器械(含車輛)。系統異常可能會導致失去身體控制能力或功能，或者釋出讓病患有無法控制系統的感覺。

外殼損壞 – 若植入接收器的外殼因外力而破損或穿孔，植入接收器的碎片可能會損傷植入接收器附近的組織，並可能造成預期外的刺激改變。

電療(Diathermy) – 植入神經刺激系統的病患不可以使用短波電療、微波電療、或者超音波電療治療(統稱為電療)。電療的能量會透過神經刺激系統傳送，在植入的電極導線位置造成組織破壞，導致嚴重的傷害或死亡。

電燒 – 若在裝置附近使用電燒工具，裝置絕緣可能會受損，導致裝置異常或引發感應電流，進而造成刺激器生熱，導致組織損傷。若有必要進行電燒，須遵照下列預防措施:

- 需將控制器關閉。
- 需使用雙極電燒器。
- 若必須使用單極電燒器，則:
    - 僅能使用低電壓模式。
    - 必須使用最低電量設定。
    - 電流路徑(接地板)應盡可能遠離植入裝置。
    - 應使用完整長度的手術桌自黏性接地墊。
    - 電燒後，再次確認裝置運作如常。

心理治療程序 – 關於心理治療程序時使用的設備(例如: 電痙攣療法、穿顱磁刺激)，尚未建立其產生的電磁干擾對於 NeuroBlock 脊髓電刺激系統病患的安全性；引發的電流可能導致生熱或造成組織損傷。

NeuroBlock 脊髓電刺激系統與主動植入式裝置或其他人體穿戴醫療裝置的交互作用 – NeuroBlock脊髓電刺激系統可能會與其他的主動植入式裝置或其他人體穿戴醫療裝置互相干擾，例如深腦刺激器(DBS)、週邊神經刺激器、經皮神經電刺激器(Transcutaneous electrical stimulator)、植入式給藥幫浦、心律調節器、去顫器(Defibrillator)、植入式電子耳、經顱神經電刺激器、以及具有感測功能的穿戴式醫療裝置。關於其他植入式裝置或穿戴式裝置對於NeuroBlock脊髓電刺激系統的影響，目前仍屬未知。

防盜偵測器、安檢裝置、無線射頻辨識(RFID)系統 – 機場的安檢點、金屬感應器、掃瞄系統、防盜偵測器等皆會產生電磁干擾(EMI)。任何安檢系統裝置皆可能會暫時性地打斷刺激，或導致刺激強度上升。病患應避免在安檢系統裝置區域進行電刺激治療。病患若在潛在性的安檢系統裝置附近感到電刺激出現變化時，即刻遠離該區域，並將控制器移開身體。病患不應倚靠在掃描器上，或在安檢系統裝置區域逗留。配有植入式裝置的病患應告知相關人員，以需求協助通過上述裝置/系統。若無法避免，病患應步行通過上述裝置/系統後即刻遠離該區域。

胸椎T8節以上的電刺激 – 在胸椎T8節以上的區域植入導線的安全性尚未進行評估。

小兒科的使用 – 尚未建立關於孩童使用本療法的安全性與效能。

懷孕 – 此療法的安全性與功效尚未針對孕婦、哺乳、胎兒，或產婦建立。

傷口接觸 – 勿將控制器直接放置在皮膚上。直接性的皮膚接觸可能導致材質引起的過敏及/或敏感。使用在身體上時，務必將控制器隔一層薄衣物置放。

緊急程序 – 病患應按指示選定一位代理人(親友)，在需求緊急照護時告知緊急醫療人員該病患配有NeuroBlock脊髓電刺激系統之外部刺激器一事。將提供每位病患一張隨身攜帶用的病患識別卡，藉以知會緊急醫療人員該病患配有該裝置。當緊急醫療人員在進行任何可能涵蓋放射頻率、微波消融、除顫(defibrillation)或心律調整程序時，應先將外部刺激器移除。

關於其他醫療方式的警告 – 部分醫療方式尚未針對使用刺激器(植入接收器或外部刺激器)的使用者建立安全性，這些醫療方式包括:

- 電解治療(電針除痣)
- 體外震波碎石
- 外部除顫 (External defibrillation)
- 超音波掃描
- 放射線/雷射治療
- 放射頻率或微波消融術

預防措施

系統與療法

電量建議 – 進行電刺激時，確保控制器電量高於50%以利順暢無阻的操作。

零組件相容性 – 為求良好的治療，僅可使用您的醫生處方許可的精能醫學NeuroBlock脊髓電刺激系統的零組件。

設備修改 – 不可修改設備，此舉可能損壞裝置，導致設備功能異常或無法使用。

病患控制裝置可能影響其他植入裝置 – 勿將病患控制裝置(例如:控制器、充電零組件)放置在其他裝置上(例如 心律調節器、去顫器、植入式電子耳，以及其他的脊髓電刺激器)。病患控制裝置可能會意外的改變其他裝置的運作。

病患裝置操作 – 為避免損壞裝置，勿將裝置浸泡在液體中，勿以漂白水、去光水、礦物油或類似物質清潔裝置，並請勿摔落裝置，或以可能損壞裝置的方式操作及處置。

病患裝置使用 – 當進行病患控制裝置的操作(例如: 外部刺激器、控制器、充電零組件)時，請特別留意是否接近可燃性或爆炸性氣體。可燃性或爆炸性氣體與裝置內的電池可能會交互作用。在靠近可燃性或爆炸性氣體時使用NeuroBlock脊髓電刺激裝置的結果仍屬未知。

保持控制器乾燥 – 控制器並不防水，須保持乾燥以避免損壞。從事水上活動時，請勿使用控制器 。

控制器與金屬的交互作用 – 使用控制器進行永久植入期的刺激治療時，務必使控制器背面(無線連結區)遠離任何金屬10公分以上，以避免金屬與控制器電性耦合進而造成控制器損壞。

醫療測試與程序 –進行任何醫療測試或程序前，聯絡醫生以確定該程序是否會對病患造成傷害或損壞系統。

勿將 控制器拆裝 – 勿拆裝或竄改裝置。裝置竄改可能會造成傷害。

使用其他病患的控制器 – 絕對不要使用其他病患的控制器。每位病患的療程強度設定可能都不相同，使用他人的控制器可能會造成無效療程。

小心拿取 控制器 – 控制器為敏感的電子裝置，應避免摔落堅硬表面。將控制器遠離孩童與寵物可觸及的地方。

儲放溫度– 控制器應在產品包裝所標註的溫度下存放。儲放溫度範圍外可能會對您造成傷害或損壞零件。若儲放溫度超標，請聯絡精能醫學。

僅適用於精能系統零件 – 非精能NeuroBlock脊髓電刺激系統定義零組件之適用性尚未經過驗證；除非另行標註，僅可使用精能系統零組件。

僅可與精能裝置共用 – 勿在控制器、外部刺激器或植入接收器上使用其他非精能的

無線通訊裝置，且勿使用控制器對其他非精能的裝置進行無線傳能。

預期外的刺激改變 – 電磁干擾(EMI)，姿勢變更，以及其他的活動都可能造成可感知的電刺激變化，部分病患形容為震顫或衝擊感。病患應在進行活動前就停止電刺激，以免影響安危。

病患生活中的活動

需要大幅扭轉、加壓或伸展的活動 – 避免會在您的脊髓電刺激系統的植入零組件上施加不當壓力的活動，包括突然、過度、或重複性的彎腰、扭轉，上下跳躍，加壓或伸展等動作，例如按摩等等，都可能造成您的脊髓電刺激系統損壞或位移，進而導致喪失電刺激、間歇性刺激、損壞處刺激以及額外的手術。脊髓電刺激系統的病患，應格外避免過度彎曲上半身軀幹。

隨意撥弄零組件(twiddler 氏症候群) – 勿隨意撥弄或揉捏推拿您的脊髓電刺激系統處的皮膚，此舉稱為twiddler氏症候群。隨意玩弄可能會對系統造成損壞、導線脫落、皮膚糜爛，或者植入處刺激。

水肺潛水或高壓艙 – 勿潛水超過10公尺(33英尺)深，或者進入大於2.0 大氣絕對壓力(ATA)的高壓艙。水深超過10公尺(33英尺)的壓力或2.0大氣絕對壓力(ATA)皆可能損壞脊髓電刺激系統。潛水或使用高壓艙前，請與您的醫生討論高壓所帶來的影響。

跳傘、滑雪或山中健行 – 高海拔應該不至於對脊髓電刺激器造成影響，但您仍應考量任何所計畫的活動中會使用的肢體動作，且特別留意勿在您的植入系統上施加不當壓力。跳傘過程中，降落傘張開時所發生的猛急推拉可能會使導線脫落或損傷，進而需進行額外手術以修復或更換導線。請與醫生討論您的活動內容。

個別治療

達到最佳治療成果的前提為，您得知完整治療風險與效益、手術程序、後續需求，以及自我照護責任。如欲獲得NeuroBlock脊髓電刺激系統的最佳益處，則需長期的術後管理以利達成。

病患篩選 – 如有下列情形，不可植入脊髓電刺激系統:

- 您的症狀並非生理學起源
- 您不是適合進行手術的人選
- 您無法適當操作系統，或
- 您對試用期的電刺激沒有良好反應。

使用於特定族群 –此療法的安全性與功效尚未針對下列族群建立:

- 懷孕、未出生的胎兒，或產婦
- 小兒科使用

神經電刺激的長期功效 – 尚未建立NeuroBlock 脊髓電刺激系統的長期功效。目前尚無關於精能醫學NeuroBlock 脊髓電刺激系統功效的長期臨床資料。

3 術後復原與照護

術後復原

手術復原時間為時數週，而傷口處感到不適，以及植入位置感到輕微疼痛的情形長達2至6週等狀況，皆屬於正常情形。您的醫生可能會以物理治療或藥物處方來處理您的疼痛問題。請務必遵照您的醫生的指示。

活動

部分動作可能會改變電刺激，例如，後仰會使導線更靠近您的脊髓，因而可能造成不適的刺激感。在術後恢復期間，突然的電刺激改變則是最為常見的情形。

- 避免需要彎腰、伸展、或者扭轉身體的活動；這些動作可能會移動您的導線，進而影響電刺激。
- 避免趴姿。
- 避免手伸過頭。
- 避免左右彎腰。
- 避免前彎、後仰，或者左右彎曲。
- 避免提取2公斤以上重物(5磅).

當您開始感覺好轉，即可從事下列活動:

- 盆浴或淋浴
- 性行為
- 在家裡或您的事業場所工作
- 嗜好或活動，例如散步、園藝、騎自行車，或者游泳
- 旅行

切記，回到您的日常活動應該讓您感覺更良好，而不是更糟。

注意:當您以較佳的疼痛管理方式調整生活，您可能會想要從事一些手術前您無法進行的活動，請事先與您的醫生討論活動內容。

致電醫生的時機

請在下列任何一項事件發生時聯絡您的醫生:

- 超過術後6週，傷口處仍有疼痛，紅腫，或者腫脹情況。
- 在電刺激時有不適感或疼痛，即刻暫停電刺激並致電您的醫生。
- 您的系統沒有正常運作。
- 無法開始或暫停電刺激。
- 無法使用控制器調整電刺激。

- 您的外部刺激器必須更換電池。
- 進行電刺激或療程暫停時發現有三顆(含)以上的通道指示燈開始閃爍。
- 電刺激療程無法有效緩解您的疼痛。

關懷時程

您的醫生會安排回診的時間，以確保您正在接受最適當的療程。

4 使用您的控制器

您的控制器怎麼運作

控制器分別與外部刺激器及植入接收器進行通訊，並無線傳輸電力至植入接收器進行療程。您的外部刺激器及植入接收器僅接受來自控制器的通訊，且控制器的通訊僅始於與外部刺激器或植入接收器完成"配對"之後。

您的醫生會執行控制器與外部刺激器及/或植入接收器之間的配對。

使用控制器來:

- 開始或暫停您的電刺激療程。
- 檢視與調整刺激強度。
- 檢視進行下次療程前的剩餘時間。
- 檢視電量狀況。

注意: 控制器為電子裝置，須符合旅行時(例:飛機起降)的使用限制與規範。

控制器功能按鍵與指示燈

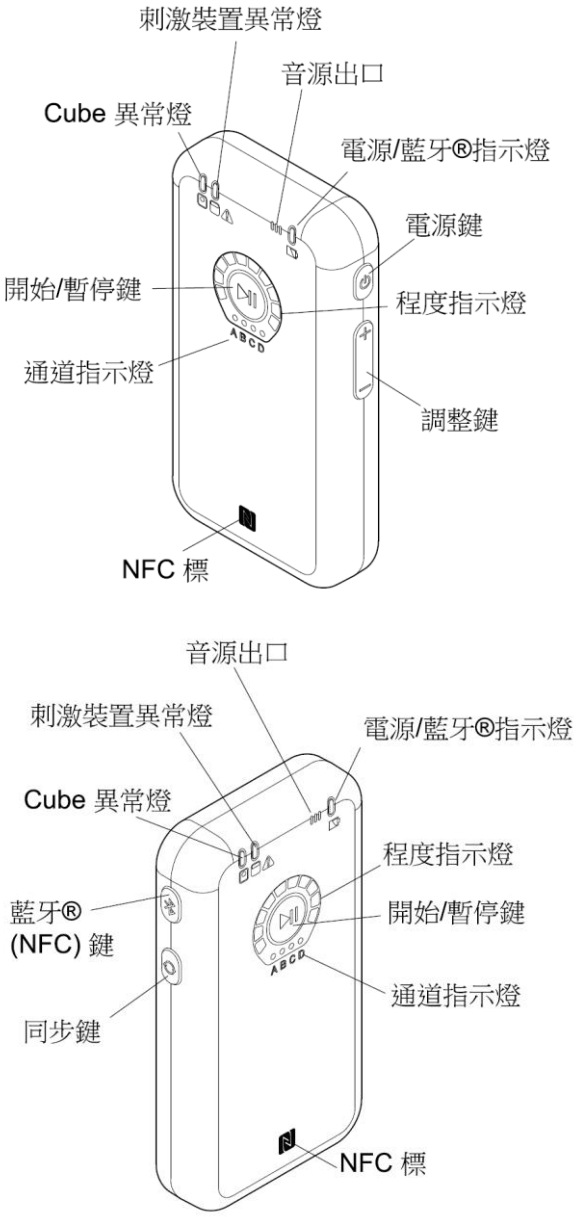


圖 2. 控制器示意圖

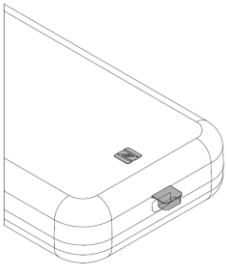
控制器各按鍵功能於下方列表中說明。

表 1. 控制器 按鍵功能

功能按鍵	作用或意指
 **電源鍵**	▪ 長按此鍵 3 秒鐘以啟動或關閉控制器。 ▪ 控制器為待機模式時，輕按電源鍵以檢視電量狀態。
 **藍牙®(NFC)鍵**	▪ 長按此鍵 3 秒鐘來啟用近場通訊(NFC)功能以建立或重置控制器與外部刺激器之間的通訊。
 **同步鍵**	▪ 輕按此鍵以同步外部刺激器或植入接收器的資料。
 **調整鍵**	▪ 輕按調整鍵以增加(+)或減少(-)療程的強度。
 **開始/暫停鍵**	▪ 輕按以開始或者暫停刺激。

表 2. 控制器 指示燈號與插孔

指示燈號	作用或代表意思
 **電源/藍牙®指示燈**	▪ 顯示裝置電源狀態並提示充電需求。 ▪ 顯示藍牙®連線狀態。
 **控制器 異常燈**	▪ 提示有控制器的異常發生。
 **刺激裝置異常燈**	▪ 提示有外部刺激器或植入接收器的異常發生。
 **程度指示燈**	▪ 顯示控制器療程強度、電量程度，以及通訊狀態。 ▪ 顯示外部刺激器或植入接收器狀態，例如: 剩餘的限制時間或不同時期的狀態。
 **通道指示燈**	▪ 顯示導線與刺激裝置的導通狀態。
 **音源出口**	▪ 聲音提示的輸出口。



- 連接充電器的插孔。

Micro USB 插孔 (有蓋)

控制器的開關機

1. 長按**電源鍵** 3 秒將控制器開機，同時會出現數聲嗶聲。電源指示燈會有黃藍燈交替閃爍一次。
2. 開機後的幾秒內，控制器將會進行自我檢測(所有程度指示燈將先閃起黃燈再閃起藍燈)，通道指示燈將亮起後熄滅。自我檢測結束後，控制器即可正常運作，程度指示燈將顯示為藍色呼吸燈。

   注意: 控制器的出廠設定預設為試用期狀態，在永久植入期時，程度指示燈將顯示為紫色呼吸燈。
3. 長按**電源鍵** 3 秒以將控制器關機，此時將有嗶聲出現。
4. 所有的程度指示燈將亮起，然後以逆時針方向熄滅。

注意:

- 控制器一旦關機，進行中的電刺激即會停止。
- 電刺激結束後，控制器將在閒置5分鐘(無操作)後自動關機。

電量狀態

1. 控制器為待機模式時，輕觸**電源鍵**，程度指示燈將亮黃燈以顯示對應的電量(例:1 顆燈為 10%電量)。
2. 若控制器電量不足，電源指示燈將開始閃爍。當控制器電量降至 10%以下，將出現 2 聲嗶聲，電源指示燈閃爍黃燈 5 次，接著控制器將自動關機。
3. 刺激過程中，若控制器電池耗盡，電刺激則會中斷，且控制器可能無法與外部刺激器或植入接收器進行通訊。

注意: 欲維持外部刺激器或植入接收器提供的連續電刺激，建議在控制器電量低於 50%時即進行充電(例如少於 5 顆 LED 燈亮起時)。

控制器充電

首次使用時，請先將插頭與充電器底座組合；遵照"Lock(鎖固)"的箭頭方向，將插頭向前推直到聽到一聲喀答聲。(參照圖3.)

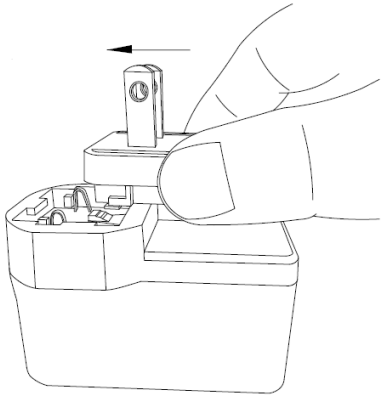


圖 3. 組合充電器

1. 如欲充電，請將控制器包裝內附的充電線接到控制器底部的插孔 (Micro USB)，且將充電器插頭插到插座上(適用範圍 100–250V@60Hz)。

△**小心:** 勿使用任何非精能的 Mircro USB 線及/或充電器插頭來將控制器充電。

注意:控制器一旦開始充電，電刺激即**無法**進行，電源指示燈將持續亮黃燈。充電時請勿使用控制器。

2. 欲查詢充電進度，在充電時輕觸**電源鍵**，程度指示燈將閃爍目前的電量。
3. 欲進行不中斷的療程，建議將控制器充電至 5 顆以上的程度指示燈亮(50% 電量)；控制器約需 2 小時將電量充滿。
4. 控制器充滿電時，程度指示燈會熄滅，若輕觸**電源鍵**查看電量，程度指示燈將全亮，此時控制器可供使用。

重新開機

若系統卡住或當機，控制器對任何操作皆無回應(包括按壓**電源鍵**重新啟動裝置，見第66頁)，發生此狀況時，則依下列程序將控制器重新開機。

1. 同時長按**電源鍵**與**開始/暫停鍵** 10 秒以將控制器重新開機，控制器會自動開機。

△**小心:** 勿在充電時將控制器重新開機，控制器對此操作將無回應。

5 試用期間使用控制器進行電刺激

在醫生進行將兩條電極導線置入您的身體並且連接外部刺激器的手術之後，您將會收到在試用期間做為病患控制器的控制器。現在您已就緒，可進入評估這套療法是否適用於您的測試。您可以參照第4章"使用您的控制器"來多認識您的控制器，並更熟悉它的操作方式。

試用期間的電刺激，以一顆9伏鹼性電池作為動力來源來對外部刺激器進行刺激遞送。在正常情形下，您並不需要更換外部刺激器的電池。倘若電池電量不足(例: 外部刺激器的電源指示燈閃爍)，請聯絡您的醫生，約診以進行電池更換。

控制器中包含10個療程強度，開始試用期的預設強度為第1級，為療程中能量最低的強度。多數的療程時間皆短於10分鐘，但可有效持續全日(甚至數日)緩解您的疼痛。

單次療程結束後，控制器會進入限制期間。試用期時，每隔4小時即可使用另一個新的療程，目的在於調控您對治療的使用頻率。您可與醫生討論NeuroBlock脊髓電刺激系統的使用頻率。

關於接下來的療程，許可的調整範圍以前次使用強度為基準，可增加或減少一級(例如，您上一次療程使用第2級，這次可以留在第2級，或選擇第1級或第3級進行治療)。是否升級或降級，可依照您的疼痛緩解狀況做選擇。如果您仍然感覺疼痛，您可以增幅現有強度；如果您沒有感覺任何疼痛，即表示您已經找到有效的強度，也可以停留在前次的強度。如果您有新的疼痛區域，或者出現併發症，請降級使用，或將控制器關機，然後聯絡您的醫生尋求協助。

圖 4. 外部刺激器

1. 將控制器開機，確認控制器為可操作狀態（程度指示燈全部顯示為藍色呼吸燈），且維持控制器在距離外部刺激器 3 公尺(10 英尺)以內的範圍，輕觸**同步鍵**以同步外部刺激器的資料。首次使用時，預設的療程強度為第 1 級，顯示為程度指示燈的 1 顆藍燈亮起。

注意: 輕觸同步鍵後，若仍處於限制時間內，程度指示燈將以黃燈閃爍顯示剩餘時間對應燈號(例: 1 顆燈表示試用期間 4 小時限制中的 10%時間，即為 24 分鐘)。

注意: 輕觸**同步鍵**後，若外部刺激器的電量不足，外部刺激器外部右上角的電源指示燈與控制器的刺激裝置異常燈皆會閃爍。

小心: 請聯絡您的醫生安排門診以更換電池，勿自行更換電池。

2. 完成同步後，會有數聲嗶聲，程度顯示燈會以藍色亮燈顯示最後一次使用的療程強度，通道顯示燈會亮燈顯示可運作的通道。可藉由輕觸**調整鍵**來增強或減弱電刺激強度（若無調整需求，可跳過此步驟）。

- 升級(強度增加): 輕觸"+"，此時對程度指示燈的對應燈號將開始閃爍。
- 降級(強度減弱): 輕觸"–"，此時對程度指示燈的對應燈號將開始閃爍。

小心: 若發現三顆(含)以上的通道指示燈開始閃燈或無亮燈，請立即連絡您的醫生。

注意: 在試用期間，您每次的療程可調整的強度範圍為升或降一級，您也可以選擇停留在目前使用的強度。

3. 選定療程強度後，先輕觸**同步鍵**，同步完成後，程度指示燈將亮藍燈顯示選定的強度，再輕觸**開始/暫停鍵**以開始電刺激。此時程度指示燈的燈號將轉成黃色，並以逆時針遞減熄燈方式顯示療程剩餘劑量，通道指示燈將亮起運作中通道之相對燈號。療程開始時出現一聲長嗶聲，之後則每 5 秒發出 1 聲嗶聲。

注意: 建議於刺激進行時保持直立坐姿，且避免任何移動。

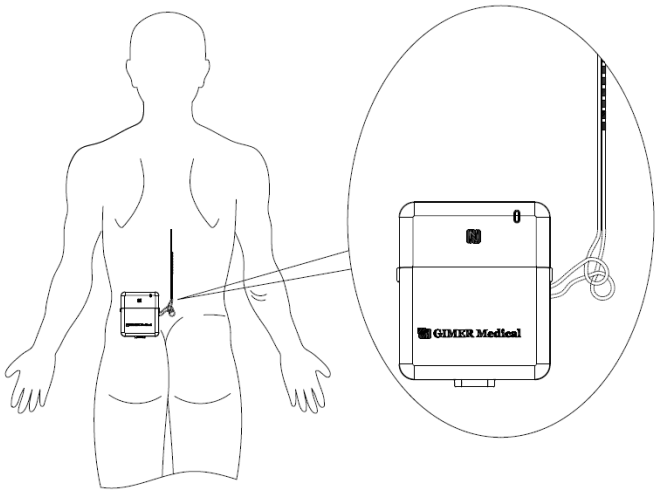


圖 5. 試用期間的外部刺激器位置

4. 療程中如欲暫停電刺激，輕按**開始/暫停鍵**，程度指示燈將先以藍黃燈交替閃爍，再轉為藍色呼吸燈顯示所暫停的強度，欲回到療程，則再次輕按**開始/暫停鍵**。

注意:

- 療程進行時，若藍牙®連線斷接，外部連接器會自動暫停療程等待重新連線，控制器的電源/藍牙®指示燈會黃藍燈交替閃爍(重新進行藍牙®連線)。控制器與外部刺激器重新連接後，會有數聲嗶聲，電源/藍牙®指示燈閃爍藍燈，此時輕觸**開始/暫停鍵**繼續療程。
- 若控制器無法重新進行藍牙®連結並閒置(無任何操作)達一分鐘，控制器將回到待機模式，程度指示燈將顯示藍色呼吸燈。輕觸**同步鍵**以重新連接外部刺激器，若仍連線失敗，則長按**藍牙®鍵**以重置藍牙®功能。參照第78頁的"故障排除"。倘若仍然無法回復藍牙®連線，離開當時的環境，因連線可能受到電磁干擾(EMI)。
- 療程暫停超過30秒時，或暫停時不小心長按**同步鍵**5秒，控制器會回到待機模式，程度指示燈將顯示藍色呼吸燈。如欲恢復未完成的療程，則先輕觸**同步鍵**以進入刺激模式，程度指示燈將以藍色呼吸燈顯示所暫停的強度，再輕按**開始/暫停鍵**繼續療程；未完成的療程不得進行強度調整。
- 控制器將在閒置5分鐘之後自動關機。如欲繼續未完成的療程，重複步驟1，再輕觸**開始/暫停鍵**。

5. 療程結束時，會有數聲嗶聲，程度指示燈顯示為黃藍燈交織燈號，控制器接下來則進入試用期間下一療程前的限制期 4 小時。程度指示燈則轉為顯示藍色呼吸燈。

6. 如欲在限制期結束後開始新療程，則重複步驟 1 到 3 來進行療程。

注意:

- 限制期時，如欲得知可開始新療程的剩餘時間，將控制器開機，於可運作時，輕觸**同步鍵**，程度指示燈將以黃燈閃爍表示剩餘時間的比例(例:1顆燈代表4小時限制期中10%的時間，即為24分鐘)。
- 限制期起始時間自啟用電刺激起算，中途若暫停電刺激，在限制期結束前可隨時再次開始。暫停或未使用完畢的療程在超過限制期後將被自動刪除，可按步驟1到3來進行新的療程。
- 電刺激結束後，控制器將在閒置(無動作)5分鐘之後自動關機。
- 需更換外部刺激器電池: 若出現罕見的外部刺激器電力不足情況，控制器上的刺激裝置異常燈將會快速閃爍，請連絡您的醫生。

6 永久植入期間使用控制器進行電刺激

經歷過試用期，已證實此療法適合您使用，您應該也已經熟悉控制器的操作方式，知道如何開關機與控制療程了。現在進入下一階段，兩條導線與植入接收器已植入您的體內，控制器的操作方式維持不變，但建議您在療程時利用腰帶、墊片與腰包組來輔助控制器對齊植入接收器位置。若您在聽取裝置提示音或操作系統方面遭遇困難之處，請向家人、朋友、照護者、或醫療專業人員尋求協助。

建議您穿著一層輕薄衣物進行療程，且必須使控制器遠離任何金屬物品或作用面，保持10公分以上的距離。療程進行時，請維持您的直立坐姿，並避免任何移動。植入接收器在電刺激時會產生熱度，您植入處的皮膚可能在療程時會感覺溫熱，這不會造成任何傷害，但若您有任何不適感，請停止療程並即刻聯絡您的醫生。

在永久植入期，電刺激由植入接收器(無電池裝置，其動力來自控制器無線傳送能量)遞送。無電池特徵不僅確保更佳的安全性，也表示您的植入接收器不需要進行充電或保養。在正常情況下，您不需要為了更換耗盡的裝置電池而進行額外手術。

控制器中設有10個療程強度，通常每次療程時間會在10分鐘內結束，但有效地全日(甚至數日)緩解您的疼痛。

療程結束後，控制器將進入限制期。在永久植入期，每隔6小時可使用新的療程，目的在於調控您對治療的使用頻率。您可與醫生討論這個疼痛療法的使用頻率。

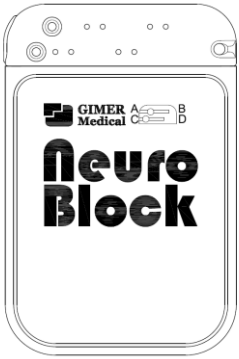


圖 6. 植入接收器

1. 將控制器開機，當控制器為可運作狀態時，(所有程度指示燈顯示為紫色呼吸燈)，輕觸**同步鍵**以啟用刺激模式，程度指示燈將以藍色燈號顯示先前的療程強度(初次療程時顯示系統預設強度 5)。

   注意: 若仍處於限制時間內，程度指示燈將以黃燈閃爍顯示剩餘時間對應燈號(例: 1 顆燈表示永久植入期間 6 小時限制中的 10%時間，即為 36 分鐘)。

2. 輕觸**調整鍵**來選取欲進行的療程強度 (如不需調整，則可跳過此步驟)。

- 強度向上(強度增加): 輕觸"+"，相對應的程度指示燈將亮起。
- 強度向下(強度減少): 輕觸"–"，相對應的程度指示燈將亮起。

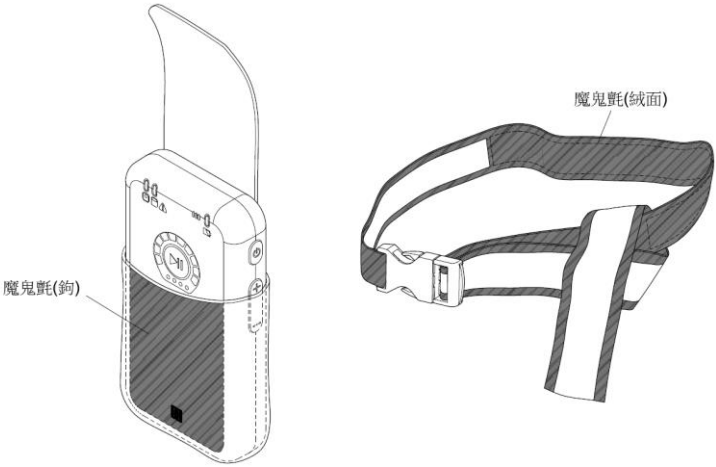


圖 7. 腰帶與腰包組合

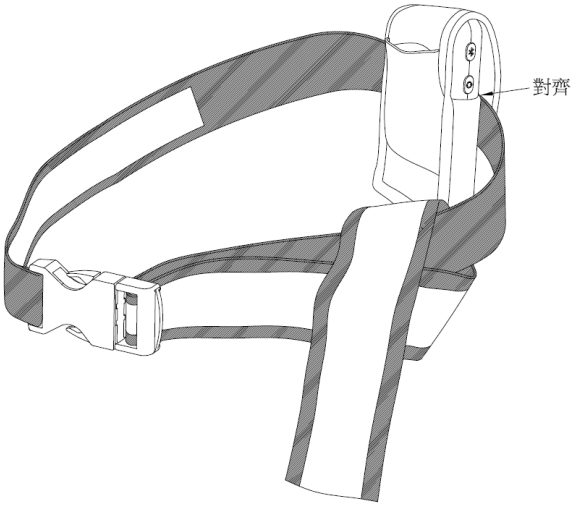


圖 8. 將腰包對齊後貼到腰帶上

3. 穿上腰帶，將魔鬼氈(腰帶內側絨面)朝向身體，扣上扣環，調整腰帶長度至合身程度，將多餘長度紮起成結。腰帶應蓋住植入區域。

4. 輕觸**開始/暫停鍵**，將控制器放至腰包內，並將腰包的魔鬼氈(鉤)區貼上腰帶魔鬼氈區(腰帶內側絨面)，則控制器位於腰帶內側且面朝外，腰包前側應對齊腰帶上側的邊緣(參照圖 7 與圖 8)。

   注意: 將墊片塞進腰包的小口袋用以達到控制器與植入接收器之間的最佳通訊距離。您的醫生或護士可能在您出院前已經替您挑好適合的厚度。

5. 調整腰帶位置，使控制器對齊植入接收器的植入位置(參照圖 9 及圖 10)。每兩秒會有兩短嗶聲重複出現；當控制器偵測到植入接收器在鄰近範圍，會有一短嗶聲重複出現。控制器與植入接收器正確對位後，會有一長嗶聲表示療程開始，療程進行中則每 5 秒會有一短嗶聲，在此過程中請保持您的姿勢並避免移動。

△小心:

- 將控制器對齊植入接收器時或者刺激療程進行時，請勿突然將控制器移開植入接收器的植入處，並避免任何突然的位移。
- 如有需要更動裝置的相對位置，務必先輕觸**開始/暫停鍵**來暫停兩裝置間的通訊，以避免因電源瞬變的突波而造成的刺痛感

注意: 輕觸**開始/暫停鍵**後，程度指示燈在控制器搜尋植入接收器時閃爍藍色跑馬燈，當控制器偵測到植入接收器在鄰近範圍，程度指示燈顯示為順時針藍色跑馬燈與逆時針黃色跑馬燈交替，接著，在控制器建立與植入接收器間的通訊連結時，來回交替閃爍黃藍燈。

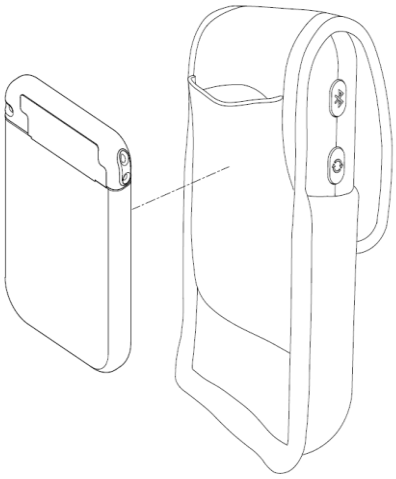


圖 9. 墊片區對齊植入接收器

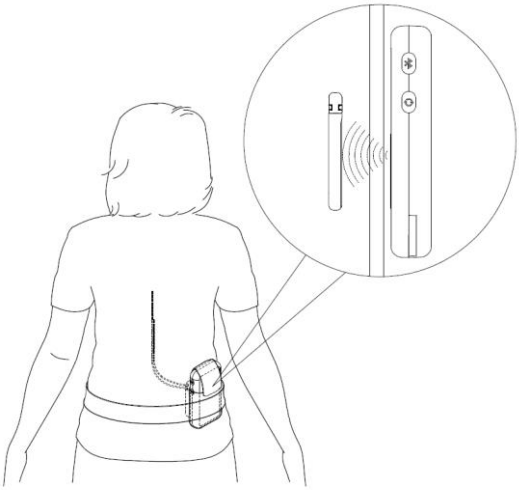


圖 10. 永久植入期間的電刺激

6. 療程進行時，程度指示燈會以黃燈遞減顯示療程剩餘劑量，通道指示燈會亮燈顯示使用中的電極導線(可運作通道)。

7. 如有需要時，可輕觸**開始/暫停鍵**來暫停療程。暫停期間的程度指示燈會以藍色呼吸燈顯示所選用的療程強度，通道指示燈會亮燈顯示正在運作的通道。欲回到療程，則再次輕按**開始/暫停鍵。**

△小心:

- 在療程進行時，療程暫停途中，或是療程結束後，如果發現有三顆(含)以上的通道指示燈開始閃燈，請立即聯絡您的醫生。
- 在極少數的情況下，植入接收器的溫度可能在電刺激時升溫至最高43.5°C。雖然此熱度並不會造成傷害，倘若您對此熱度感覺無法忍受，或是有任何不適感，請停止療程並立即聯絡您的醫生。

注意:

- 若無線通訊在療程進行時消失，程度指示燈將持續以藍色跑馬燈閃爍，伴以兩聲嗶聲重複出現。控制器會自動暫停療程並試圖重新連結植入接收器。控制器一旦與接收器重新連結上，會出現三聲嗶聲，程度指示燈將以藍燈亮起療程強度，在一道長嗶聲後，系統即會自動回到療程。
- 若控制器重新連結超過一分鐘仍失敗，重複步驟1至5以重新連結植入接收器。若仍無法成功連線，確認控制器與植入接收器的位置已相互對齊，或者離開當時有可能因為電磁干擾(EMI)而造成連線失敗的環境場所。

8. 當療程結束時，會出現 6 聲嗶聲，控制器的程度指示燈則以藍燈顯示剛結束的療程強度，通道指示燈則亮起所使用通道對應燈號。若有開路情況或通

道阻抗異常發生，則對應的通道指示燈將開始閃爍。控制器接著會進入下一次療程前的限制期(永久植入期時限為 6 小時)。程度指示燈將隨後轉為紫色呼吸燈。

9. 限制期結束後，如欲進行新的療程，重複步驟 1 至 8。

注意:

- 限制期間，欲得知下次療程前的限制期剩餘時間，將控制器開機並輕觸**同步鍵**，程度指示燈將以閃爍黃燈顯示所剩餘時間的百分比(例: 1顆燈為永久植入期限制期6小時中的10%時間，即為36分鐘)。
- 限制期起始時間自啟用電刺激起算，中途若暫停電刺激，在限制期結束前可隨時回復。暫停或未使用完畢的療程在限制期結束後將被自動刪除，可直接進行新的療程。
- 電刺激結束後，控制器將在閒置(無動作)5分鐘之後自動關機。

7 故障排除

如果您在使用控制器時遇到一些問題，使用下方表格來進行故障排除，裡面也提供了應該聯絡醫生處理的相關資訊。

注意: 如果您遇到無法解決的問題或是此處沒有說明的問題，請聯絡您的醫生。

表 3. 故障排除

問題	敘述
不適的電刺激	**可能原因:** ▪ 所選用的刺激強度不適合您現在的活動或姿勢。 **可能的解決方法:** ▪ 停止電刺激。 ▪ 停止活動。 ▪ 改變您目前的姿勢(建議採取直立坐姿。 ▪ 若上述皆無法消弭問題，請致電您的醫生。
控制器 無法與外部刺激器進行無線通訊	參照第 70 頁的"試用期間使用控制器進行電刺激"的控制器顯示狀態。 **可能原因:** ▪ 您可能身處一個同時有數裝置皆使用藍牙®，因而造成干擾的環境。 ▪ 您可能進到一個禁止使用藍牙®的環境。 ▪ 外部刺激器的電池電量不足。 **可能的解決方法:** ▪ 確認控制器與外部刺激器距離彼此範圍 3 公尺內。 ▪ 確認控制器環境沒有受到電磁干擾(EMI)且非位於禁止使用藍芽®的環境。 ▪ 輕觸**同步鍵**以重新連線外部刺激器。 ▪ 替外部刺激器換上新的電池 (請聯絡您的醫生以進行電池更換)。
控制器 無法與植入接收器進行通訊	參照第 73 頁的"永久植入期間使用控制器進行電刺激"的控制器顯示狀態。 **可能原因:** ▪ 連線逾時，控制器閒置。

	▪ 控制器沒有以適當距離對齊植入接收器，且/或超出通訊範圍。 **可能的解決方法:** ▪ 若控制器閒置，輕觸**同步鍵**，程度指示燈將顯示紫色呼吸燈，再次輕觸**同步鍵**，若程度指示燈以藍色燈號亮起對應的療程強度，則輕觸**開始/暫停**鍵以開始療程。 ▪ 確認控制器已在適當通訊距離及範圍內對齊植入接收器的植入位置(以腰帶墊片組作為輔助)。
永久植入期療程進行時控制器異常發生 (刺激裝置異常燈亮伴以兩聲重複性短嗶聲)	**可能原因:** ▪ 控制器在與植入接收器通訊過程中接觸或靠近金屬物品。 **可能的解決方法:** ▪ 使控制器遠離金屬或物品，保持 10 公分以上的距離。 ▪ 輕觸同步鍵，程度指示燈將顯示紫色呼吸燈，再次輕觸同步鍵，若程度指示燈以藍色亮燈顯示療程強度，則可輕觸開始/暫停鍵回復療程。
植入接收器過熱 (刺激裝置異常燈與程度指示燈以黃燈閃亮伴以兩聲重複性短嗶聲)	**可能原因:** ▪ 若植入接收器的溫度上升至 43.5°C，療程將暫停，刺激裝置異常燈與程度指示燈將以黃燈閃亮，同時會有兩聲重複短嗶聲。 **可能的解決方法:** ▪ 輕觸**同步鍵**，程度指示燈將顯示紫色呼吸燈，等待裝置降溫後(建議等待 20 分鐘)，再次輕觸**同步鍵**，若程度指示燈以藍色亮燈顯示療程強度，則可輕觸**開始/暫停鍵**回復療程。
控制器 低電量	建議在電量低於 50%時即進行控制器充電，以免療程受到干擾。請使用充電配件替控制器充電。參照第 68 頁的”控制器充電”。
控制器 無反應 (控制器 異常燈亮)	**可能的解決方法:** ▪ 將控制器關機後再次開機。(若系統卡住或當機則重新開機); 參照第 26 頁的”重新開機”。

	▪ 重新開機後，若控制器異常燈仍亮，且出現 2 聲嗶聲重複出現數秒，請立即聯絡您的醫生。 ▪ 若通訊問題持續發生，或無法使用控制器來控制電刺激，請聯絡您的醫生，或使用本手冊底頁內側的連絡資訊來聯絡精能醫學處理。
控制器摔落: 您的控制器 從櫃子或桌上掉落	**可能的解決方法:** ▪ 將控制器開機確認所有功能與燈號顯示仍正常運作；若控制器已嚴重受損，請聯絡精能代理安排換新。 ▪ 控制器的設計為可短距離抗摔硬質表面，即便外殼破損或缺角，仍可正常操作。
控制器上有液體: 液體潑濺至控制器上，或控制器掉進水裡	**可能原因:** ▪ 控制器並非防水裝置，水氣可能損壞裝置。 **可能的解決方法:** ▪ 若液體潑濺至控制器外殼上，以潔淨的乾毛巾將控制器拍乾後，放置於室溫下自然風乾。 ▪ 若控制器掉進水裡，請聯絡精能銷售代理處理換新。
若控制器在需要送修、損壞，或者無法作業的情況下需要換新，請使用本手冊底頁內側的連絡資訊來聯絡精能醫學處理。	

8 附加資訊

不良事件

植入脊髓電刺激系統涉及與其他脊髓電刺激系統類似的相關風險。除了與手術有關的風險之外，使用或植入NeuroBlock脊髓電刺激系統以及潛在的疾病惡化也可能導致的不良事件包括但不限於下列。若您經歷任何與NeuroBlock脊髓電刺激系統相關的不良事件，請聯絡您的醫生。

- 膿腫
- 過敏對植入材料起排斥反應
- 腦脊髓液滲漏
- 笨拙
- 死亡
- 電震、神經功能影響、刺痛、麻木，與/或來自電刺激的不適感
- 硬膜外出血
- 疼痛症狀加劇
- 纖維化
- 硬膜外導線周遭反應性組織增生
- 感覺過敏
- 感染
- 發炎/腫脹
- 間歇性刺激
- 導線位移(移動)
- 神經受損
- 神經性欠缺
- 神經刺激器的口袋疼痛、感染、發炎、血腫、血清腫、流血及/或潰爛
- 麻木
- 硬膜外的入針處疼痛、流血、發炎及/或感染
- 過度刺激造成的疼痛
- 刺激不足造成的疼痛
- 來自於非有毒刺激物接觸皮膚的疼痛(觸感痛)
- 癱瘓
- 零件植入位置感到持續性疼痛
- 脊椎壓迫
- 胸壁刺激(根端刺激)
- 與刺激相關的腸胃症狀為腹瀉、大便失禁，或便秘。
- 與刺激相關的膀胱症狀為尿液滯留、小便失禁，或頻率問題。
- 血栓
- 組織受損

- 植入處的炙熱或灼燒感
- 虛弱

患者可能因上述任何事件引發而須進行手術之項目，包括裝置改版、外植(植出)，及/或NeuroBlock系統零組件更換等等。

可能的系統併發症

導線或植入接收器可能在體內位移或者造成皮膚腐爛。電刺激可能會出現不良改變，起因可能與電極周邊的細胞變化，電極位置改變，鬆脫的電性連結(electrical connection)，或者導線破裂等有關。或許，也可能是植入材質引發了過敏或免疫系統反應而造成。您的脊髓電刺激系統可能會因為其他緣故而無預警的停止運作。這些事件可能包括了電路短路或開路，電導線(conductor wire)破裂，或者絕緣破損等等無法預測的情況。

9 維護與協助

本段落提供保養控制器的相關資訊，以及使用配件的指示說明。本段落同時提供控制器的規格，及有協助需求時的聯絡資訊。

清潔與保養

遵照下列指示以確保控制器與配件皆正常運作。

△小心：

- 將控制器遠離孩童與寵物可觸及之處；若孩童或寵物吞下任何零組件，請立即連絡醫生。
- 僅可按依照您的醫生解說內容或本手冊中提供的方式來使用脊髓電刺激系統零組件。
- 請小心拿取控制器，切勿摔落、敲擊，或者踩踏控制器。
- 勿拆裝或竄改控制器。
- 請勿消毒控制器的任何部位；消毒殺菌可能會損壞控制器。
- 進行永久植入期間療程時，確保控制器遠離任何金屬物。
- 控制器並非防水裝置，請勿讓濕氣進入裝置內部。僅可使用潔淨的乾毛巾擦拭清潔控制器。

安全性與技術性檢查

控制器不需要進行定期的安全性與技術性檢查或者保養。控制器中不含需要保養的零組件。若控制器有修復或服務需求，請聯絡您的醫生或精能代理以替換裝置。聯絡資訊請參照本手冊封底內頁。

電池、控制器及外部刺激器的廢棄處理

請將控制器與您的外部刺激器在試用期終了或不再使用時，歸還給您的醫生或精能醫學代理。請勿丟棄或燒毀控制器或外部刺激器；火焰可能導致控制器或外部刺激器內部的電池爆炸。請勿自行拋棄控制器或外部刺激器。

植入接收器的廢棄處理

已取出的植入接收器不可再次滅菌或重新植入。我們建議將取出的植入接收器歸還給醫生或者精能醫學代理。如果有任何疑問，請參照封底內頁的聯絡資訊。

規格

下方表格所列為外部刺激器與控制器相關規格。

表 4. 型號 1001 外部刺激器的材質

零組件	材質	接觸人體的材質
外殼	聚碳酸酯	是
蓋子	聚碳酸酯	否
金屬接點	鍍金與鎳的鈹銅合金	否
墊片	泡棉	否
配件		
電池	PP3 9伏鹼性電池	否

表 5. 型號 1001 外部刺激器的物理特質

敘述	數值
接頭類型	2 組八向電極, 16 個電極接點
高度	81 mm
寬度	68 mm
厚度	22 mm
重量	150 公克
電源	PP3 9V 鹼性電池
觸電防護的等級	BF 類型
操作溫度範圍	10°C 至 40°C (50 °F 至 104 °F)
存放溫度範圍	-10°C 至 55°C (14 °F 至 131 °F)
濕度	30% 至 90%
壓力	75 至 150 kPa
外部刺激器使用期限	1 年

表 6 . 型號 2032 控制器的物理特質

敘述	數值
電力來源	可充電式鋰電池
使用年限	1 年
操作溫度範圍	10°C 至 40°C
儲放溫度範圍	-10°C 至 55°C
濕度	30% 至 90%
壓力	75 至 150 kPa
尺寸 (約略)	65 mm x 123 mm x 21.5 mm
重量	250 公克

使用者協助

如果有維修保養需求，請聯絡您的醫生或精能代理。請參照本手冊底頁的精能聯絡方式。

序號標示於控制器的背面，用以區別每一台控制器。若您有控制器相關需求，可在聯絡精能醫學或精能代理時提供該組序號。

若您的控制器不能用了 – 先試試看第78頁的"故障排除"處理，再者，聯絡精能代理或您的醫生。

若您弄丟了 控制器 –聯絡精能或您的醫生以訂購一個新的控制器。

CE

Worldwide Testing Services (Taiwan) Co., Ltd.

ACCREDITED TEST HOUSE

CERTIFICATION OF TESTING

Under EU EMC - DIRECTIVE 2014/30/EU -

This certifies that the following designated product

External Stimulator
Model No. : 1001
Brand Name: NeuroBlock

(Product identification)

Has been tested in accordance to essential protection requirements of Council Directive 2014/30/EU and found the test results indeed meet the limitation of the relevant test standard(s) listed below:

EN 60601-1-2 (2015), IEC 60601-1-2: 2014,
CISPR 11: 2015/A2: 2019
(IEC/EN61000-4-2 (2009)/-3 (2006+A2:2010)/ -8 (2010))

(Identification of regulations / standards)

This certificate is issued for

Gimer medical co.,Ltd
9F.-5, No.97, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan

(Name / Address)

SPECIAL STATEMENT:

THE CERTIFICATION IS VALID ONLY IN CONNECTION TO THE TEST REPORT NUMBER **W6M22003-19791-E-11** AND TO THE SAMPLE HAS BEEN TESTED BY WORLDWIDE TESTING SERVICES (TAIWAN) CO., LTD.

August 31, 2020

(Date)

Rex Kao

Rex Kao, Laboratory Director

Worldwide Testing Services (Taiwan) Co., Ltd.
6F, NO. 58, LANE 188, RUEY-KUANG RD., NEIHU, TAIPEI 114, TAIWAN, R.O.C.

CE

Worldwide Testing Services (Taiwan) Co., Ltd.
ACCREDITED TEST HOUSE

CERTIFICATION OF TESTING

Under EU EMC - DIRECTIVE 2014/30/EU -

This certifies that the following designated product

CUBE
Model No. : 2032
Brand Name: NeuroBlock

(Product identification)

Has been tested in accordance to essential protection requirements of Council Directive 2014/30/EU and found the test results indeed meet the limitation of the relevant test standard(s) listed below:

EN 60601-1-2 (2015), IEC 60601-1-2: 2014,
CISPR 11: 2015/A2: 2019
IEC/EN 61000-3-2 (2018), IEC/EN 61000-3-3 (2013/A1: 2017)
(IEC/EN61000-4-2 (2009)/-3 (2006+A2:2010)/-4 (2012)/
-5 (2014+A1:2017)/-6 (2014)/-8 (2010)/-11 (2004/A1:2017))

(Identification of regulations / standards)

This certificate is issued for

Gimer medical co.,Ltd
9F.-5, No.97, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan

(Name / Address)

SPECIAL STATEMENT:

THE CERTIFICATION IS VALID ONLY IN CONNECTION TO THE TEST REPORT NUMBER W6M22003-19790-E-11 AND TO THE SAMPLE HAS BEEN TESTED BY WORLDWIDE TESTING SERVICES (TAIWAN) CO., LTD.

August 17, 2020

(Date)

Rex Kao

Rex Kao, Laboratory Director

Worldwide Testing Services (Taiwan) Co., Ltd.
6F, NO. 58, LANE 188, RUEY-KUANG RD., NEIHU, TAIPEI 114, TAIWAN, R.O.C.

Manufacturer

GiMER Medical Ltd. Co.

9F-7,No. 97, Sec. 1, Xintai 5th Rd., Xizhi Dist.,

New Taipei City 22175, Taiwan

www.GiMERmed.com

Tel. +886-2-2697-2680

Fax. +886-2-2697-2670

製造商

精能醫學股份有限公司

新北市汐止區新台五路一段97號9樓之7

22175, 台灣

www.GiMERmed.com

電話. +886-2-2697-2680

傳真. +886-2-2697-2670

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