Document Information

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Mainstay Medical

ReActiv8®

I have an implanted ReActiv8 neurostimulator. If I require medical treatment, please notify my physician listed on the back of this card.

My Name: _____

Implant Date: _____

Mainstay Medical Limited
Clonmel House, Forster Way
Swords, Co. Dublin K67F2K3
Ireland

Keep this card with you at all times.

MR Conditional

Important note: A patient implanted with a ReActiv8 neurostimulator can safely undergo an MRI exam only under very specific conditions. Scanning under different conditions may result in severe injury and/or device malfunction.

Full MRI safety information is available in the ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines, which can be obtained at **www.mainstaymedical.com/resources** or by calling **1300 128 000.**

Place implant information sticker here or write in:

This panel and patient ID card are removable from this user manual.

The patient ID card is to be filled out according to section labels on the card, and stickers from the implantable devices (leads and IPG) are to be placed in the labeled areas.

Symbol definitions can be found on pages 1-2.

Mainstay Medical

ReActiv8®

Implantable Electrical Stimulation System

User Manual

Model 5100 Implantable Pulse Generator

Model 8145 / 8165 Implantable Stimulation Leads

Model 7000 Activator

Model 4000 Magnet

Mainstay Medical

CE 2797

Place implant information sticker here or write in:

Place implant information sticker here or write in:

For medical questions, contact your physician:

Physician Name: _____

Telephone: _____

Hospital Name: _____

Hospital Address: _____

_____

⚠ My implanted medical device may set off your security system.

Issued 2024 4

Customer Service 1300 128 000
www.mainstaymedical.com/resources
contact@mainstaymedical.com

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990103-007, Rev. B, January 2025

Label Symbols

Explanation of symbols on products and packaging.

	Caution
	Warning
	Refer to instruction manual/booklet (Mandatory)
	Start
	Stop
	Telemetry Status Indicator
	Session Status
	Battery Condition Indicator
	2 x AA Battery
	Waste batteries should be separated from municipal waste for recycling
	Consult Instructions for Use
	Non-ionizing electromagnetic radiation
REF	Model Number
MD	Medical Device
SN	Serial Number
EC REP	European Union Authorized Representative

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	Temperature limitations in which the transport package has to be kept and handled
	Manufacturing Date
	Manufacturer
	CE mark of conformity with the identification of the notified body authorizing use of the mark.
	Ingress protection rating
	Type BF Applied Part
	MR Conditional
	MRI unsafe
	Double sterile barrier
	Unique Device Identifier
	Patient information website

Glossary

Activator – A hand-held device that communicates with the ReActiv8 IPG to start and stop stimulation.

Caution – A statement describing actions that could result in damage to or improper functioning of a device.

Clinician programmer – Device used to send instructions to the IPG and to receive information from the IPG.

Contraindication – A condition or circumstance under which a person should not have a ReActiv8.

Cumulative Max – The maximum amount of stimulation delivered over a specified time period (nominally set to 1 hour per day).

Diathermy – A medical treatment applied to the outside of the body that uses shortwave, microwave, or ultrasound energy. It generates penetrating warmth to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Electrode – A metal ring near the tip of the lead (described below) which establishes the electrical contact between the IPG and the tissue around it.

Electromagnetic interference (EMI) – An energy field which can be present near electrical or magnetic devices that could prevent ReActiv8 from functioning properly.

Intended Purpose/Indication – The purpose of ReActiv8 or the medical condition for which ReActiv8 may be considered in a person.

Implanted pulse generator (IPG) – The implanted ReActiv8 device which contains a battery and electronics to produce the electrical stimulation pulses.

Lead – The implanted electrical wire that carries the electrical pulses from the ReActiv8 IPG to the stimulation target. On one end it has a terminal which connects to the IPG and on the other end it has electrodes that deliver the pulses to the nerve.

Lockout Time – A safety feature which prevents over-stimulation. Lockout prevents starting a Session when the maximum amount of stimulation has been delivered over a specified time period (nominally set to 1 hour per day). It also prevents another Session from starting too quickly after the previous one. (Nominally set to 2 hours).

Magnet – ReActiv8 can be programmed such that the application of the Magnet over the IPG starts or stops a Session.

Magnetic Resonance (MR) Environment – The three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which a medical device might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.

MR Conditional – A medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields.

Parameter – One of the ReActiv8 programmable settings that control, for example, the strength of the electrical pulses and the duration of the Sessions.

Precaution – A statement that provides information about a potentially hazardous situation that may be harmful to the user, the equipment used, or the immediate environment.

Session – The period over which the stimulation treatment is delivered. A Session is started by the user using the Activator or the Magnet.

Stimulation – The delivery of electrical pulses to nerves.

Stimulation settings – The personalized program in the IPG which tailors ReActiv8 stimulation to your specific needs.

Therapy – Treatment of a disease or medical condition. ReActiv8 delivers stimulation to the nerves that control muscles in the back.

Warning – A statement describing an action or situation that could harm the user.

1. Introduction

How to use this manual

Intended Users:

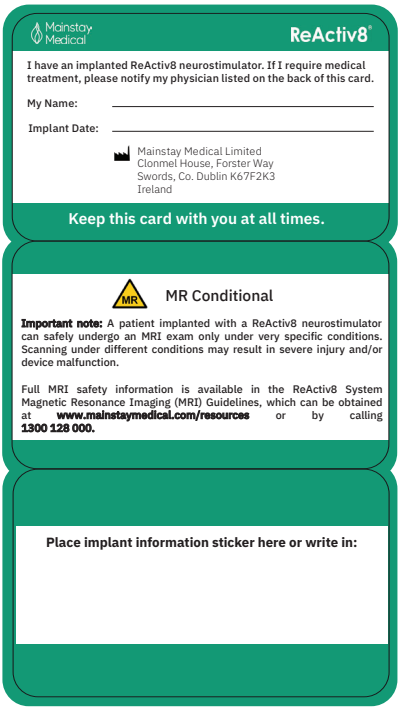
This manual is to be used by any person who has received a ReActiv8 system. Ask your clinician to explain anything that is unclear.

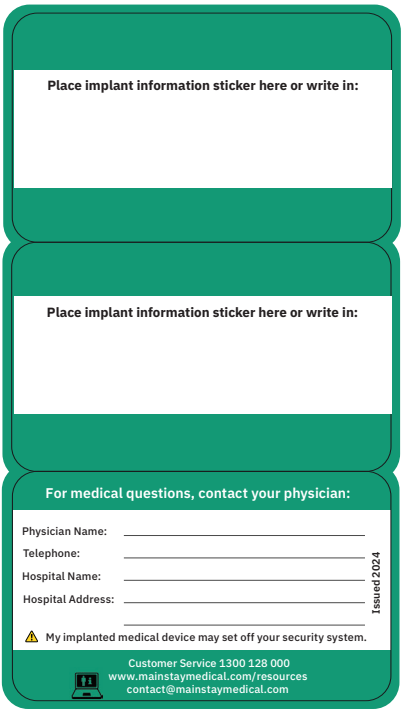
A glossary is included at the beginning of this manual.

- Section 1 “Introduction” explains how to use this manual and describes the documents provided to you, including this manual.
- Section 2 “Important information” describes how ReActiv8 works, the components of ReActiv8, when you should and should not use ReActiv8, and the benefits, warnings, precautions, adverse events and activities related to ReActiv8.
- Section 3 “Recovery and care after surgery” provides information about recovering from surgery, activity and care information, and when to contact your clinician.
- Section 4 “Using the Activator” describes the Activator and how to use it to control Sessions.
- Section 5 “Using the Magnet” describes the Magnet and how to use it to control Sessions.
- Section 6 “Maintenance” describes how to care for the Activator, including how to change the batteries, and lists the specifications for the Activator and the implanted components of ReActiv8.
- Section 7 “Troubleshooting” describes Activator warning and information indicators and how to solve possible problems.
- Section 8 “User assistance” describes where to find the Activator serial number and who to contact if the Activator is lost or broken.
- Section 9 “Radio Equipment” is a declaration that ReActiv8 is compliant with specific engineering standards.

Your identification card

When you leave the hospital, your clinician will give you an identification card containing medical alert information. This card supplies information about you, your physician, and the device. This card lets medical professionals, emergency first responders, and security personnel know that you have an implanted device.





Carry this card with you at all times. If your card is lost, damaged, or if you need to update any information, please contact your clinician for a replacement card.

2. Important Information

Intended purpose/indication for use

The ReActiv8 System is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the L3 transverse process as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging and associated physiological presentation.

Contraindications

ReActiv8 is contraindicated for patients who are:

- Unable to operate the system
- Unsuitable for ReActiv8 implant surgery (e.g., a patient with an infection near where the device would be surgically placed or any systemic infection, or a patient on blood thinners and cannot stop taking them for a surgical procedure)
- Current or planned pregnancy
- Current condition associated with muscle wasting
- Current neurological disease, deficit or disorder
- A Body Mass Index (BMI) greater than 35

Considerations for patient selection

ReActiv8 is not suitable for every patient with chronic low back pain. When selecting candidates for ReActiv8, consider the following:

- Moderate to severe chronic low back pain and disability despite medical management and attempting physical therapy.
- Able to operate the system.

What is the stimulation provided by ReActiv8?

ReActiv8 delivers electrical stimulation to certain nerves responsible for contracting some of the muscles that help stabilize the spine in your lower back. The electrical stimulation pulses are generated by an implantable pulse generator (IPG) and carried to the nerves via thin electrical wires that are implanted in your back. The implanted ReActiv8 IPG is wirelessly programmed by your physician to meet your specific needs.

You should administer the therapy as instructed by your physician. You will be able to start the Session with the Activator and it will automatically stop when complete. The Activator also allows you to discontinue or pause the Session at any time. ReActiv8 can also be programmed such that application of a provided magnet starts or stops stimulation.

Possible benefits of ReActiv8

The possible benefits associated with ReActiv8 include:

- Reduction in the severity of your low back pain;
- Improvement in your ability to handle regular daily activities (reduction of disability); and
- Improvement in your quality of life.

Alternate treatment options

There are other treatment options for mechanical chronic low back pain, although none are considered to completely stop the pain. Patients are typically treated with non-surgical therapies first. Non-surgical treatment options include, but are not limited to, oral medications, massage therapy, physical/occupational/exercise therapy, psychological therapies (e.g., behavior modification, hypnosis), lumbar extensor strengthening exercises, watchful waiting (ie., no therapy), traction therapy (relieving pressure), ultrasound therapy, transcutaneous electrical nerve stimulation (low voltage electric currents to treat pain), acupuncture (insertion of thin needles through your skin at strategic points), injections to relieve pain, osteopathic therapy, heat therapy, and lumbar stabilization exercises.

Description of ReActiv8

ReActiv8 consists of several implanted parts that generate and deliver electrical stimulation pulses to certain nerves in your lower back.

The implanted parts of ReActiv8 include an Implantable Pulse Generator (IPG) and two leads *(Figure 1)*.

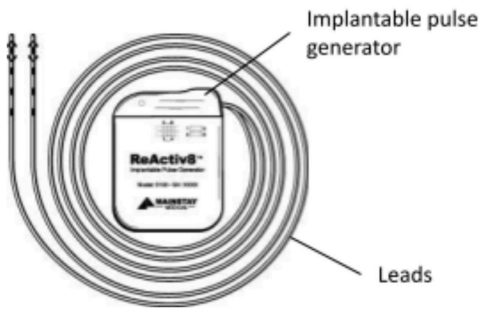


Figure 1: Implanted parts of ReActiv8

An Activator or Magnet is used for controlling delivery of electrical stimulation by the implanted parts *(Figure 2).*

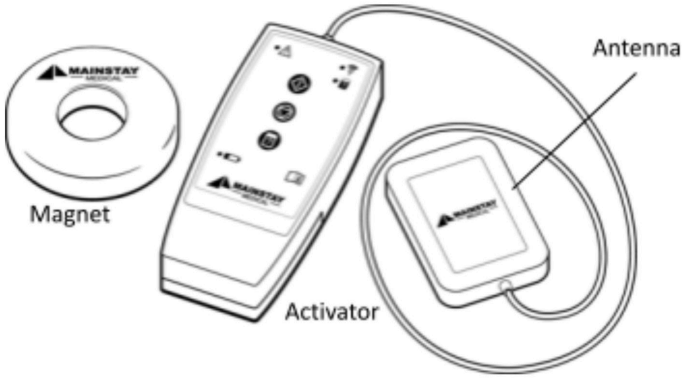


Figure 2: Magnet and Activator

Implantable pulse generator (IPG) – The device that contains the battery and electronics to generate the electrical stimulation pulses.

Lead(s) – A set of thin electrical wires that carry the electrical stimulation pulses from the IPG to nerves in your lower back.

Activator – The Activator is a device that you use to start or stop stimulation. It can also be used to check the status of the IPG, e.g. if the IPG is ready to deliver stimulation. The antenna, which is placed over the IPG to make wireless contact, is connected with a long cable to the hand-held Activator *(Figure 2)* for ease of operation and viewing.

Magnet – The IPG can be programmed such that the Magnet can be used to start and stop stimulation.

A copy of the Summary of Safety and Clinical Performance (SSCP) can be viewed by searching the device brand name on the Eudamed website at https://ec.europa.eu/tools/eudamed when it is available. A copy of the SSCP is also available at www.mainstaymedical.com/resources.

⚠ Warnings

- It is very important that you inform your physician or other healthcare professional (e.g., physical therapist, chiropractor, dentist, etc.) that you are implanted with the ReActiv8.
- **Magnetic Resonance Imaging (MRI)** – MRI compatibility of the ReActiv8 system is conditional on imaging parameters. Refer to the ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines.

- **Diathermy** – You SHOULD NOT receive diathermy therapy, as it may be hazardous for you.
- **Strangulation by cable** – When operating the Activator, keep the antenna cable away from your neck to avoid strangulation. Do not allow children to handle or play with the Activator.
- **Case damage** – In the case that the Activator is pierced or ruptured, burns could result from exposure to battery chemicals.

⚠ Precautions

Electromagnetic interference (EMI)

Electrical and/or electronic equipment emits energy when it is powered "ON". This energy is referred to as electromagnetic energy. Electromagnetic energy may be generated by equipment found in the home, work, medical, or public environments. In some cases, this energy may cause interference with other electrical or electronic equipment. Disturbance or interference resulting from exposure to energy emitted by other electrical or electronic equipment is referred to as electromagnetic interference (EMI). For example, some televisions may display a disrupted picture when an electrical appliance is operated nearby.

The ReActiv8 includes features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of the ReActiv8. Sources of strong EMI can exist near high power amateur radio transmitters, near television towers, electrical welders, or other equipment. Generally, the amount of EMI present in publicly accessible areas is at a level that is not likely to impact the ReActiv8. However, prior to entering controlled-access areas near these sources, please contact your physician for guidance.

Equipment such as retail theft prevention systems and airport metal detectors may interfere with the ReActiv8. Walk directly through such systems and do not remain near them any longer than necessary. The ReActiv8 in your body may set off security screening devices (e.g., at airports), so it will be necessary for you to carry your identification card to identify yourself to security screeners as a ReActiv8 user.

Exposure to strong sources of EMI can result in the following effects:
- Serious injury or death, resulting from heating of the implanted components of the ReActiv8 and damage to surrounding tissue.
- Damage to the ReActiv8, resulting in a loss of or change in stimulation delivery and requiring surgical replacement.
- Operational changes to the ReActiv8 IPG, causing it to turn ON or OFF (particularly if the IPG is enabled for magnet use) or to reset, resulting in loss of stimulation and requiring reprogramming by a clinician.

Electromagnetic interference (EMI) from household items

Most household appliances and equipment that are working properly and grounded properly will not interfere with ReActiv8. Many household items contain magnets or generate magnetic fields that are strong enough to activate the magnet switch inside the IPG, which can be programmed to start or stop therapy.

If interference is suspected, move away or turn off the household item.

Activator and Magnet

- **Activator handling** – To avoid damaging the Activator, do not immerse it in liquid; do not clean it with nail polish remover, mineral oil, or similar substances; avoid spilling fluids on it; and do not drop it or mishandle it in a way that may damage it.
- **Magnet use** – Depending on how the ReActiv8 IPG is programmed, the magnet may not be able to start or stop a Session. If this is the case, you must have an Activator to start or stop Sessions.
- **Magnet may damage items** – Do not place the ReActiv8 Magnet on or near computer monitors, magnetic storage disks or tapes, televisions, credit cards, or other items affected by strong magnetic fields. If the magnet is too close, these items may malfunction or be damaged.

Target Population

ReActiv8 is not suitable for every patient with chronic low back pain. When selecting candidates for ReActiv8, the following is considered:

- Chronic low back pain despite medical management and attempting at least one course of physical therapy.
- Able to operate the system.

The safety and effectiveness of the ReActiv8 system has not been established for:

- Pregnant women (including effects on a foetus, or during childbirth)
- Paediatric use (patients under the age of 18)
- Patients with worse leg pain than back pain
- Patients with radiculopathy below the knee

Adverse event summary

The implantation of ReActiv8 involves risks similar to those of peripheral nerve stimulators. In addition to risks commonly associated with surgery, implantation or use of ReActiv8 includes, but is not limited to, the risks below. The rates noted are based on 150 patients implanted in the ReActiv8-B Study (one of the main studies that tested the safety and

efficacy of the ReActiv8 system). Total follow-up duration is 5 years.

- Adverse Events (AEs) associated with the ReActiv8 surgical procedure (including implant, revision, replacement, and removal procedures). In the ReActiv8-B Study, events included:
  - Musculoskeletal pain (6%)
  - Complication of device removal (<1%)
- Adverse Events (AEs) that may be associated with any surgical procedure and not specific to the implant of the ReActiv8 system. In the ReActiv8-B Study events included:
  - Adverse drug reaction (3%)
  - Post-op nausea or vomiting (2%)
  - Anesthetic complication cardiac (<1%)
  - Complications wtih intubation (1%)
  - Post-operative dizziness (<1%)
- Accidental injury to adjacent tissues, e.g., piercing structures such as muscle, blood vessels, or organs. In the ReActiv8-B Study there were no instances (0%).
- Infection, including local infection of the surgical site, systemic infection, and sepsis. In the ReActiv8-B Study events included:
  - Infection at the IPG pocket (4%)
  - Superficial wound infection (<1%)
- Slow, abnormal, or inadequate wound healing, including wound dehiscence (slow healing), which may require surgical repair. In the ReActiv8-B Study events included:
  - Raised scar (<1%)
  - Open wound requiring additional sutures (<1%)
- Tissue reaction to the presence of the implanted device or materials in/on the implanted device such as response to residual material on device or an allergic response, e.g., previously unknown nickel or titanium allergy. Reaction may be local or systemic. In the ReActiv8-B Study there were no instances (0%).
- Nerve irritation, impingement, or damage, including that resulting from mechanical presence of device, exposure to electricity including electrical stimulation, or migration of the leads, suture sleeve, or IPG. This may lead to pain, paralysis, sensory deficits, or changes to bowel, bladder, or reproductive function. In the ReActiv8-B Study events included:
  - Numbness in leg (2%)
  - Neuropathic pain (1%)
  - Facial numbness (<1%)
  - Paralysis (0%)
  - Sensory deficit (0%)
  - Changes to bowel or bladder function (0%)
  - Changes to reproductive function (0%)
- Device extrusion. In the ReActiv8-B Study there were no instances (0%).

- Erosion, threatened erosion, or fistula formation in skin overlying device components. In the ReActiv8-B Study there were no instances (0%).
- Excessive fibrotic tissue growth. In the ReActiv8-B Study there were no instances (0%).
- Wound healing, such as hematoma, seroma, cyst, or swelling. In the ReActiv8-B Study events included:
  - Wound pain (5%)
  - Dermatitis (3%)
  - Hematoma (2%)
  - Swelling (1%)
  - Numbness (1%)
  - Redness (<1%)
  - Prickling sensation (<1%)
  - Seroma (<1%)
- Acute or persistent pain including worsened low back pain and/or pain and discomfort due to the surgical procedure or presence of the device. In the ReActiv8-B Study events included:
  - Temporary pain or discomfort at the IPG pocket (11%)
  - Pain or discomfort at the IPG pocket requiring additional surgery (5%)
  - Ongoing pain or discomfort at the IPG pocket (4%)
  - Pain at the lead site (2%)
  - Worsening backpain (2%)
  - Buttock pain (<1%)
  - Implant site warmth (<1%)
- Overstimulation of tissue or undesired sensations such as uncomfortable paraesthesia, numbness, vibration, pressure, prickling, or uncomfortable contraction of the multifidus, paraesthesia, jolts or shocks. In the ReActiv8-B Study events included:
  - Temporary pain or discomfort with stimulation (12%)
  - Long-term pain or discomfort with stimulation (3%)
- Tissue damage due to mechanical presence of device, or exposure to electricity including electrical stimulation. In the ReActiv8-B Study there were no instances (0%).
- Contraction of muscles other than the target muscle(s). In the ReActiv8-B Study there were no instances (0%).
- Muscle fatigue, spasm, or injury. In the ReActiv8-B Study there were no instances (0%).
- Stiffness, including restricted motion due to adhesions to the device. In the ReActiv8-B Study there were no instances (0%).
- Inability to deliver stimulation, including inadequate doses of stimulation. Causes include lead migration, device malfunction or exposure to electromagnetic fields, e.g., security screening devices. In the ReActiv8-B Study events included:

  - Lead conductor fracture requiring additional surgery (3%)
  - Lead migration (0%)
- Undesired electrical stimulation
- Inability to stop therapy, with possible sequelae such as anxiety, restriction of movement, pain, muscle fatigue, postural changes, difficulty in walking, sitting, or physical activity. In the ReActiv8-B Study there were no instances (0%).
- Accidents, injuries, body movements, body positions, or biological processes which lead to device complications. Examples include a fall which may cause damage to the IPG; sit-ups or severe coughing leading to migration of the lead; or fracture of bones leading to device migration or damage. In the ReActiv8-B Study events included:
  - Temporary pain due to bumping the area around the IPG (2%)
  - Temporary tingling sensation at the IPG with stimulation due to bumping the area around the IPG (<1%)
- Musculoskeletal pain or discomfort due to conducting stimulation sessions. In the ReActiv8-B Study events included:
  - Temporary shoulder pain (<1%)

Key safety events in the commercial setting include:

- Lead conductor fracture requiring additional surgery (<3%)
- Need for device explant (e.g., address other conditions unrelated to low back pain) (<2%)
- Lead migration (<1%)
- Pain or discomfort at the IPG pocket requiring additional surgery (<1%)
- Suboptimal lead placement requiring lead revision (<1%)
- Infection (<1%)

Limitations of Use

- **Very strenuous physical activity** – In general, very strenuous, high force activities including extreme range of motion of the arms should be performed with caution since it could impact the longevity of the lead (e.g., chopping wood, rowing, heavyweight lifting, and wrestling).
- **Equipment operation** – During a Session you should remain in a relaxed reclined, supine, or prone position. While receiving stimulation, you should not operate potentially dangerous equipment, such as power tools, automobiles, or other motor vehicles. You should not climb ladders or participate in other activities where postural change or an abrupt movement could alter the perception of stimulation intensity and cause you to fall or lose control of your equipment or vehicles or injure others.
- **Component manipulation** – You should avoid manipulating or rubbing the implanted

components of ReActiv8 through the skin. Manipulation may cause component damage, lead dislodgement, skin erosion, or unwanted stimulation at the implant site.

- **Scuba diving or hyperbaric chambers** – You should not dive below 5 meters (16 feet) of water or enter hyperbaric chambers above 1.48 atmospheres absolute (ATA). Pressures below 5 meters (16 feet) of water (or above 1.48 ATA) could damage the IPG. Before diving or using a hyperbaric chamber, you should discuss the effects of high pressure with your physician.
- **Skydiving, skiing, or hiking in the mountains** – The Activator will remain operational at altitudes <3000 meters (approximately 10,000 feet). However, you should consider the movements involved in any planned activity at high altitude and take precaution to avoid putting undue stress on the implanted parts.
- **Operating temperature** – Do not use the Activator when the air temperature is greater than 40°C or below 0°C.

Reporting Serious Incidents

In the case of a serious incident, consult your doctor immediately. Note that any serious incident that occurs in relation to the device should be reported to the manufacturer and to your national competent authority.

MRI safety information

Magnetic Resonance Imaging (MRI)

The ReActiv8 Implantable Pulse Generator (IPG) and implantable leads are MR Conditional devices with demonstrated safety in the MR environment only within specified conditions.

Consult with your healthcare provider prior to an MR exam and inform MRI site personnel that you have an MR Conditional medical device during MR screening prior to the MR exam.

Obtain the Latest MRI Guidelines

Refer to the document *ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines* for an list of approved MR Conditional components, model numbers and required conditions (including patient preparation) for safe use in the MR Environment. This document may be updated periodically. The latest version of these guidelines may be obtained at www.mainstaymedical.com/resources or through Mainstay Medical with the contact information provided at the beginning of this document. Referring to this document prior to an MRI scan is mandatory.

Failure to follow these guidelines for MRI scans may result in severe patient injury and/or device malfunction.

3. Recovery and Care After Surgery

Recovery from surgery

It may take several weeks to fully recover from implant surgery. It is normal to feel some discomfort from the incision(s) and to have some minor pain at the implant site. Use ice wrapped in a cloth and gentle compression as needed in the initial 2-4 days post surgery.

Your physician may prescribe medication to help manage your post-surgical pain.

When changing your dressings the first 24-48 hours after surgery, make sure to use sterile procedures such as washing hands. Do not soak your wound or sit in a bath. Your physician should follow up within 10-14 days to check on your incisions and to remove any sutures or staples if necessary.

Activities

Your clinician will advise you to limit your activities to low or moderate levels during the first few weeks after implantation of the IPG and leads. More strenuous activity may result in movement of or damage to the leads, requiring a revision surgery to reposition or replace the leads.

For the 2-4 days post implant avoid the following activities:

- Activities where you must bend, stretch, or twist your body; these movements can move the leads, which may affect stimulation.
- Reaching over your head.
- Bending forward, backward, or from side to side.
- Lifting heavy weights (e.g. more than 5 kilograms or 10 pounds).

After obtaining your incision check follow-up by your physician, for the next **month** refrain from the following activities:

- Activities where you must quickly bend, stretch, or twist your body using force.
- Fast or aggressive bending forward, backward, or from side to side.
- Lifting heavy weights (e.g., more than 10 kilograms or 25 pounds).

As you begin to feel better, you should be able to increasingly perform more activities. Get up and walk 5-10 minutes every 3-4 hours. Gradually increase walking, as you are able. Discuss your activity level with your physician.

When to call your clinician

Contact your clinician if any of the following events occur, or as directed by your physician:

- You have pain, redness, or swelling at the incision(s) later than 6 weeks after surgery.
- You feel discomfort or pain during a Session.
- You cannot start or stop a Session.
- The system is not working properly.

System activation and therapy training

Your system is inactive after surgery, and will be activated after you have been trained on the use of the system and its components by a Mainstay representative at your activation follow-up visit.

Care schedule

Your clinician will schedule follow-up visits with you to check on the most appropriate therapy for you and to make adjustments if needed.

4. Using the Activator

The Activator (Model 7000) package contains the following non-sterile items:

- 1 Activator
- 2 AA alkaline batteries

What the Activator does

The Activator *(Figure 2)* is a device that you use to start or stop stimulation. It can also be used to check the status of the IPG, e.g. if the IPG is ready to deliver stimulation. The antenna is connected with a long cable to the hand-held Activator control module *(Figure 3)* for ease of operation and viewing.

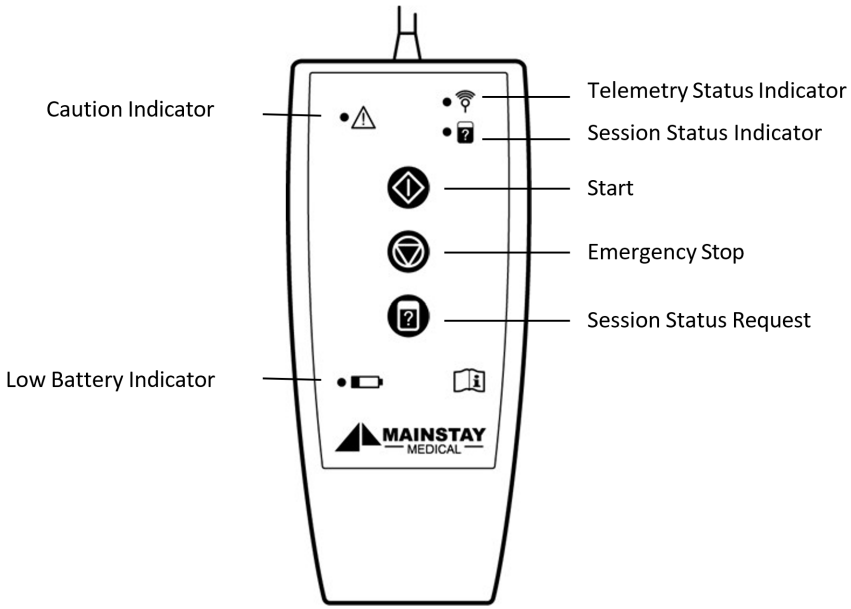


Figure 3: Activator control module

To start communication with the IPG, the antenna of the Activator must be placed directly over the IPG. Your physician will have placed the IPG in a location suited to your needs, and one example is shown in *Figure 4.* For best communication between the Activator and IPG, the Mainstay logo on the antenna should be positioned facing the IPG.

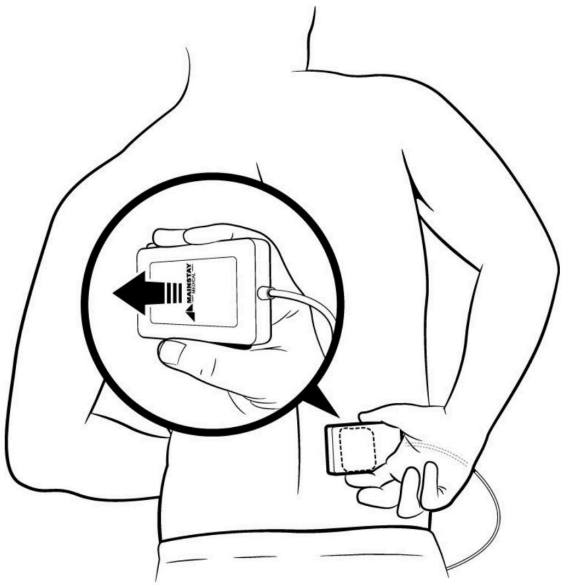


Figure 4: Placing the Activator antenna over the IPG

Controlling a Session with the Activator

Assume a comfortable prone position on a flat surface, such as a firm bed or exercise mattress. You may want to try propping a pillow underneath your stomach to find the most comfortable position.

Starting a Session

- Push the green Start button for at least 1 second and then release it.
- Place the antenna directly over the IPG and observe the Telemetry Status Indicator on the Activator.
  - If the Telemetry Status Indicator continues to flash yellow, reposition the Activator antenna. Thick clothing may interfere with communication. Placing the antenna directly on the skin or under thick clothing may improve communication between the Activator and IPG.
  - When the Telemetry Status Indicator is a solid green, you will hear a beep to inform you of successful communication. The antenna can now be removed.
- The stimulation will start after a delay that is programmed into the IPG (typically 40 seconds).

Stopping a Session

- The Session will automatically stop upon completion.
- In case the Session needs to be stopped sooner:
  - Push the red Emergency Stop button for at least 1 second and then release it.
  - If the Telemetry Status Indicator remains flashing yellow, reposition the Activator antenna.
  - When it is a solid green, you will hear a beep to tell you that communication has been established and the Session will stop.

Checking Session status

If you are unsure whether a Session is still in progress, you can check the Session status.

- Push the blue Session Status Request button for at least 1 second and then release it.
- Place the antenna over the IPG and observe the Telemetry Status Indicator on the Activator.
  - If the Telemetry Status Indicator remains flashing yellow, reposition the Activator antenna.
  - When it is a solid green, you will hear a beep, and the antenna can now be removed.
- The Session Status Indicator will indicate a status for 20 seconds. The explanation of the indication is listed in Table 1.

Table 1: IPG State

	Session Status Indicator	Session Status / Description
1	Alternate flashing of green and yellow	No Session is ongoing, and the IPG is available to start a Session.
2	Flashing green	The IPG has received a command to start a Session, and is in the time delay between receipt of the command, and the start of stimulation.
3	Solid green	The IPG is in a Session delivering stimulation.
4	Flashing yellow	The IPG is unavailable to start a Session. This could be because the daily maximum stimulation has been delivered, or a previous Session has been recently completed and a new Session cannot start until a programmed elapsed time has passed.

Other Activator indicators

The other indicators of the Activator are:

- If the IPG battery has reached its elective replacement level, the Caution indicator ⚠ will be solid red. Contact your clinician. Note: If the Start button has been pressed, stimulation will be delivered.
- If the caution indicator ⚠ flashes red the IPG needs to be checked. Contact your clinician. Note: In this case, no stimulation will be delivered.
- If the 2 AA batteries are near the end of life, the Battery Condition Indicator ▭ will light continuously during a Session. The Activator will function normally in this state.
- When the 2 AA batteries in the Activator need to be replaced, the Battery Condition Indicator ▭ will flash yellow. No other Session Status indications will appear and the Activator will not send commands to the IPG.
- A beeping sound accompanies the visual indications.

5. Using the Magnet

The Magnet (Model 4000) package contains the following non-sterile item:

- 1 Magnet

Starting or stopping a Session with the Magnet

To use the magnet, it should be placed over the location of the IPG, similar to what is shown in *Figure 5.* The Mainstay logo on the magnet can be oriented in either direction.

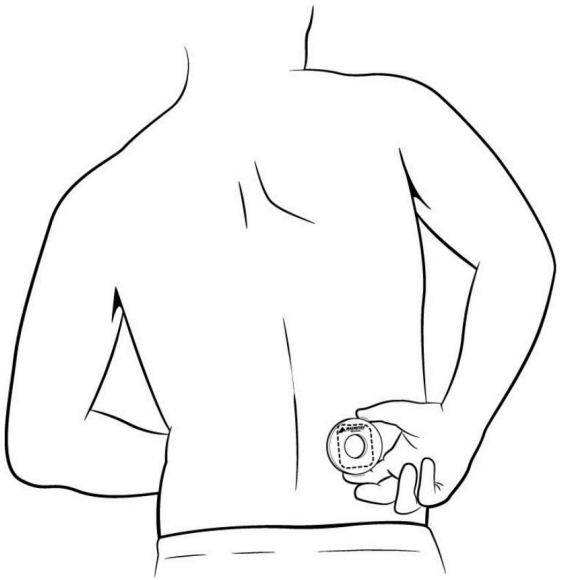


Figure 5: Placing the Magnet over the IPG

The IPG can be programmed so that Sessions can be controlled with the Magnet. There are three possible responses for the IPG when the Magnet is placed over it.

1. Stop Session (Default setting) – Placing the Magnet over the IPG only stops a Session. The Magnet cannot be used to start a Session.
2. Start/Stop Sessions – Placing the Magnet over the IPG starts or stops a Session.
3. None – Placing the Magnet over the IPG has no effect.

If the IPG is programmed such that the Magnet can stop Sessions:

- In case the Session needs to be stopped sooner, hold the Magnet over the IPG for at least 5 seconds.
- If the Magnet is not used, the Session will automatically stop upon completion.

If the IPG is programmed such that the Magnet can Start/Stop Sessions:

1. Start a Session
    - Hold the Magnet over the IPG for at least 5 seconds.
    - After a programmed Session delay of 40 seconds, the stimulation will start.
2. Stop a Session
    - In case the Session needs to be stopped early, hold the Magnet over the IPG for at least 5 seconds.
    - If the Magnet is not used, the Session will automatically stop upon completion.

If you are unsure of how the IPG is configured to interact with the Magnet, consult your clinician.

6. Maintenance

This section describes how to care for and dispose of the Activator and accessories.

Activator batteries

It is recommended to always keep two new AA alkaline batteries available for replacement. New batteries provide about 12 months of use, depending upon how often the Activator is used.

> ⚠ **Caution:** If the Activator will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, possibly causing damage to the electronic components.

Checking the Activator batteries

You can check the Activator batteries at any time with the following steps:

- Push the blue Session Status Request button, press down on the button for at least 1 second and then release it on the control module.
- Observe the Telemetry Status Indicator (see *Figure 3):*
  - If it illuminates with any colour and the Battery Condition Indicator is not illuminated, the Activator batteries are acceptable for use.
  - If it illuminates with any colour and the Battery Condition Indicator is illuminated solidly, the Activator batteries are acceptable for use, but are near the end of life and should be replaced.
  - If it does not illuminate and if the Battery Condition Indicator is flashing yellow, the AA Activator batteries are depleted and must be replaced.
  - If no indicators illuminate, the Activator batteries are completely discharged. The AA Activator batteries must be replaced.

Installing or replacing the Activator batteries

- Open the battery compartment cover *(Figure 6)*.

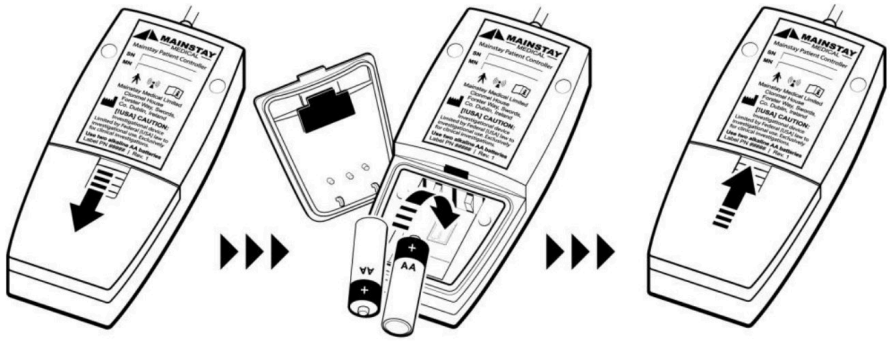


Figure 6: Installing or replacing the Activator batteries

- Remove the batteries.
- Insert the new batteries as shown on the battery compartment label.
- Close the battery compartment cover.
- Dispose of old batteries according to local requirements.

Cleaning and care

Follow these guidelines to help ensure that the Activator continues to function properly.

- The recommended cleaning process is to use a soft cloth, lightly dampened with distilled water. **DO NOT IMMERSE OR SOAK THE ACTIVATOR. ONLY WIPE THE ACTIVATOR.**
- Keep the Activator out of the reach of children and pets.
- Use the Activator only as explained to you by your clinician or as discussed in this manual.
- Follow all warnings and precautions in Section 2 “Important information”.
- Handle the Activator with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the Activator.
- The Activator is not waterproof. Do not allow moisture to get inside the Activator.
- Keep fresh batteries available.
- Replace low or depleted batteries.

Safety and technical checks

Periodic safety and technical checks, calibrations, or periodic maintenance of the Activator are not required. The Activator contains no user-serviceable parts. If repair or replacement is needed, contact your clinician. Do not attempt any repair or service (other than battery replacement) yourself.

Battery and Activator disposal

Dispose of discharged batteries according to local requirements. If you no longer need the Activator or it becomes non-functional, return it to your clinician.

ReActiv8 IPG disposal

If the ReActiv8 is explanted for any reason, it needs to be returned to the clinician identified on the Patient Identification Card. The IPG is not reusable. The IPG should be removed before burial or cremation. Explanted IPG and lead components may be contaminated with potentially infectious substances of human origin. In some countries, removal of battery-powered implantable devices is required before burial because of environmental concerns. The cremation process may cause the battery to explode.

Specifications

Table 2: IPG nominal specifications

Item	Specification
Size	6.5 cm x 4.8 cm x 1.2 cm
Weight	52 g
Power source	Non-rechargeable battery
IPG Longevity	5 years (for 1 hour of stimulation per day at 5 mA, 20 Hz)

Expected service life for the IPG and Leads is 5 years at nominal use.

Table 3: Activator nominal specifications

Item	Specification
Power source	2 AA alkaline batteries
Operating temperature	0°C to +40°C
Storage temperature	-10°C to +55°C
Operating humidity	Relative humidity range of 15% to 93%, non-condensing
Operating pressure	70 kPa to 106 kPa
Size	14.0 cm x 6.3 cm x 3.1 cm
Weight, including batteries	250 g
Battery life	12 months for alkaline batteries (typical)
Expected service life	5 years
Environmental protection	Ingress protection rating IP22

Table 4: Materials in contact with human tissue*

Description	Specification
IPG	• Epoxy • Silicone rubber • Titanium
Lead	• Pellethane 2363-75D/90A • Stainless Steel • MP35N alloy • NuSil MED-4870 • Platinum/Iridium alloy
Activator	• ABS Plastic (UL 94 HB)

* For a complete list of materials in contact with human tissue, including % of contacting surface area, refer to the ReActiv8 Implant and Programming manual or contact your clinician.

ReActiv8 does not contain phthalates (potentially harmful chemical found in some plastics), latex, human blood derivatives or cells or tissues of human or animal origin.

7. Troubleshooting

- If no indicators light on the Activator display when a button is pressed, replace the AA batteries with new batteries (refer to “Installing or Replacing Activator Batteries”). If this does not resolve the issue, contact your clinician.
- If the Battery Condition Indicator flashes yellow when a button is pressed, replace the AA batteries with new batteries (refer to “Installing or Replacing Activator Batteries”). If this does not resolve the issue, contact your clinician.
- If the Battery Condition Indicator lights solidly when a button is pressed, consider replacing the AA batteries with new batteries (refer to “Installing or Replacing Activator Batteries”), especially if abnormal Activator indications are seen.
- If the Caution indicator on the Activator flashes or remains solid red after pressing a button on the Activator, contact your clinician. A solid red indicator indicates that stimulation can still be delivered. A flashing red indicator indicates that stimulation CANNOT be delivered.
- If the Telemetry Status Indicator does not illuminate a solid green after a button is pressed, ensure that the Activator antenna is placed directly over the implanted IPG with the Mainstay logo facing the skin.
    - Bulky clothing worn over the IPG implant site may increase the distance between the Activator antenna and the IPG. It may be necessary to place the Activator antenna under clothing to ensure successful communication.
- If the Telemetry Status Indicator does not illuminate a solid green after a button is pressed, and after repositioning of the antenna has been tried, move away from any electronic equipment or sources of magnetic fields and repeat the desired Activator function. Refer to “Notes – Electromagnetic interference (EMI)” for information on the types of equipment.
- If the Activator does not start or stop a Session, replace the AA batteries with new batteries (refer to “Installing or Replacing Activator Batteries”). If this does not resolve the issue, use the Magnet instead if the IPG is programmed to allow a Magnet to start a Session. Refer to Section 5 “Using the Magnet”. The ability to use the Magnet for these functions is dependent on the programming of the IPG.

8. User Assistance

User assistance

The Activator has been designed and tested to provide trouble-free service. If repair or replacement is needed, contact your clinician.

Refer to the serial number located on the label on the back of the Activator. This number identifies each Activator.

If the Activator stops working – First try the Troubleshooting steps detailed in Section 7. Otherwise, contact your clinician.

If you lose the Activator or Magnet – Contact your clinician.

9. Radio Equipment (RE)

Hereby, Mainstay Medical declares that for ReActiv8, the radio equipment type – Ultra Low Power Active Medical Implant and its Accessories (operating in the frequency range 9 – 315 kHz) is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.mainstaymedical.com

Appendix

IPG and Activator declaration

This device complies with part 15 of the FCC Rules.

This Category II radio-communication device complies with Industry Canada Standard RSS-310.

Ce dispositif de radiocommunication de catégorie II respecte la norme CNR-310 d'Industrie Canada.

Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

The Activator is classified as a TYPE BF APPLIED PART per IEC60601-1:2005.

The Activator and IPG communicate using radio waves at approximately 21 kHz. They transmit data using amplitude modulation. The transmission bandwidth is about 600 Hz. The reception bandwidth is from 10 kHz to 28 kHz. The transmission power is less than 2.0 dBµA/m at 3 meters.

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