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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 1-877-702-8488.

Place Implant Information Sticker Here



ReActiv8®

Implantable Electrical Stimulation System

User Manual

Model 5100 Implantable Pulse Generator

Model 8145 / 8165 Implantable Stimulation Leads

Model 7000 Activator

Model 4000 Magnet



RX ONLY

Place Implant Information Sticker Here

Place Implant Information Sticker Here

For medical questions, contact your physician:

Physician Name: _____
Telephone: _____
Hospital Name: _____
Hospital Address: _____

 My implanted medical device may set off your security system.



Customer Service 1-877-702-8488 (8am-5pm PST)
www.mainstaymedical.com/resources
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Issued 2025

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Label symbols

Explanation of symbols on products and packaging.

	Caution
	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
	Model Number
	Serial Number
	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
	MR conditional

	Ingress protection rating
	Type BF Applied Part

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) that establishes the electrical contact between the IPG and the tissue around it.

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

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

Implantable pulse generator (IPG) – The implanted ReActiv8 device that 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 that connects to the IPG and on the other end it has electrodes that deliver the pulses to the nerve.

Lockout Time – A safety feature that 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.

Parameter – One of the ReActiv8 programmable settings that controls, 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 that 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

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 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.

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. Your identification card may be required to avoid certain security devices (e.g. airport metal detectors).

 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.	Place Implant Information Sticker Here
 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 1-877-702-8488.	Place Implant Information Sticker Here
Place Implant Information Sticker Here	For medical questions, contact your physician: Physician Name: _____ Telephone: _____ Hospital Name: _____ Hospital Address: _____  My implanted medical device may set off your security system. Customer Service 1-877-702-8488 (8am-5pm PST) www.mainstaymedical.com/resources contact@mainstaymedical.com  Issued 2025

Carry this card with you at all times. If you move, change physician, or lose your card, contact your clinician for a replacement card.

2. Important information

Indication for ReActiv8

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 or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery.

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

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).

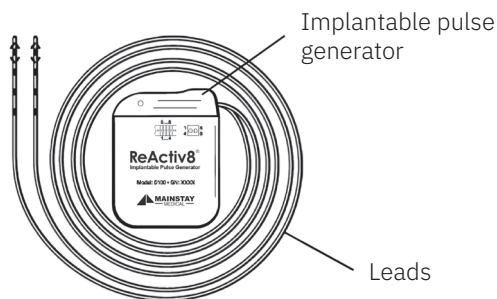


Figure 1: Implanted parts of ReActiv8

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

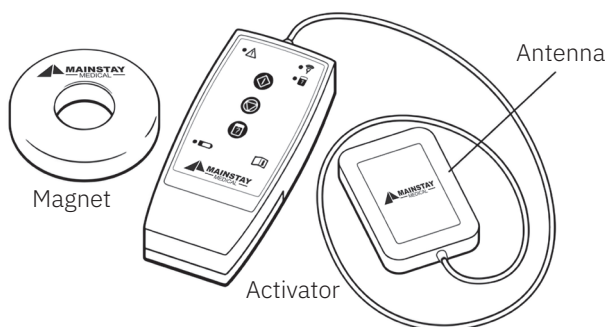


Figure 2: Magnet and Activator

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.

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.

Cellular and portable telephones, including base stations, are unlikely to interfere with ReActiv8. Avoid placing cellular or portable telephones directly over the IPG.

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.

Adverse Event Summary

The implantation of ReActiv8 involves risks similar to those of neurostimulators. In addition to risks commonly associated with surgery, implantation or use of ReActiv8 includes, but is not limited to, the following risks:

- Adverse Events (AEs) associated with the surgical procedure, including implant, revision, replacement, and removal, such as prolonged procedure, adverse drug reactions, bleeding, hematoma (bruising and swelling filled with blood), respiratory distress or asphyxiation (suffocation), infection, pain, inflammation, numbness, poor wound healing including wound reopening.
- Abandonment (stopping) of the implant procedure, including due to failure to achieve suitable stimulation thresholds (therapy) in one or both leads.
- Device fragments left behind in the body during device modification or removal procedure.
- Sharp or persistent pain including more pain than anticipated after surgery, and/or worsened low back pain, and/or pain and discomfort due to presence of the device.

- Accidental injury to nearby tissues, e.g., piercing structures such as muscle, blood vessels, or organs.
- Infection, including local infection of the surgical site, systemic infection, and sepsis (life-threatening infection).
- Slow, abnormal (unusual), or inadequate (incomplete) wound healing including wound dehiscence (slow healing).
- Tissue reaction and/or allergic reaction to the implanted device materials.
- Device extrusion (pushing out).
- Erosion (device coming out of the skin), threatened erosion or fistula (tunnelling) formation in skin over the device parts.
- Nerve irritation, impingement (catching), or damage, including that resulting from the physical presence of the device, exposure to electricity including electrical stimulation, or migration (unwanted movement) of the leads, suture sleeve, or IPG (battery). This may lead to pain, paralysis, sensory damage or changes to bowel, bladder, or reproductive function.
- Excessive fibrotic (scar) tissue growth.
- Stiffness, including restricted motion due to adhesions to the device.
- Tissue damage or irritation due to the physical presence of the device, including hematoma (swelling filled with blood), seroma (fluid under the skin), cyst, or swelling.
- Undesired sensations such as uncomfortable paraesthesia (tingling or prickling sensation), numbness, vibration, pressure, prickling, or uncomfortable contraction of the multifidus, or contraction or sensations in muscles other than the target muscle(s).
- Overstimulation of tissue, resulting in symptoms such as painful muscle contraction, paraesthesia, jolts, or shocks. In addition, injuries that occur as a consequence of stimulation, e.g., accidents that occur as a result of being startled.
- Muscle fatigue, spasm, or injury.
- Inability to deliver stimulation, including inadequate doses of stimulation. Causes include lead migration, lead fracture (breaking), device malfunction, stimulation threshold drift (changes in amount of stimulation needed), or exposure to electromagnetic fields, e.g., security screening devices.
- Inability to stop therapy, with possible complications such as anxiety, restriction of movement, pain, muscle fatigue, posture changes, difficulty in walking, sitting, or physical activity.
- Accidents, injuries, body movements, body positions, or biological processes that lead to device complications. Examples include a fall that may cause damage to the IPG, sit-ups or severe coughing leading to migration (unwanted movement) of the lead, or fracture of bones leading to device migration or damage.
- Injury to the person with the device as well as injury to other persons, including electrical, mechanical, chemical, and thermal injuries.
- Malfunction of other medical equipment, such as a pacemaker, due to the device.

Patients may also undergo medical and/or surgical intervention (such as revision or explant) to treat the issues identified above.

User activities

- **Physical activity** – 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. Failure to do so may result in migration of or damage to the leads, requiring a revision surgery to reposition or replace the leads.
- **Equipment operation** – During a Session you should remain in a prone position (lying on your stomach). 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. You should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.
- **Operating temperature** – Do not use the Activator when the air temperature is greater than 40° C or below 0° C.

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 they have an MR Conditional medical device during MR screening prior to the MR exam.

Refer to the document *ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines* for an up-to-date list of approved MR Conditional components, model numbers, and required conditions (including patient preparation) for safe use in the MR Environment. 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. Your physician may prescribe medication to help manage your post-surgical pain.

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. Avoid the following activities during the first few days after implant:

- 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 2 kilograms or 5 pounds).

As you begin to feel better, you should be able to increasingly perform more activities. 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.

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 items:

- 1 Activator
- 2 AA alkaline batteries

What the Activator does

The Activator (Figure 2, on page 9) 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.

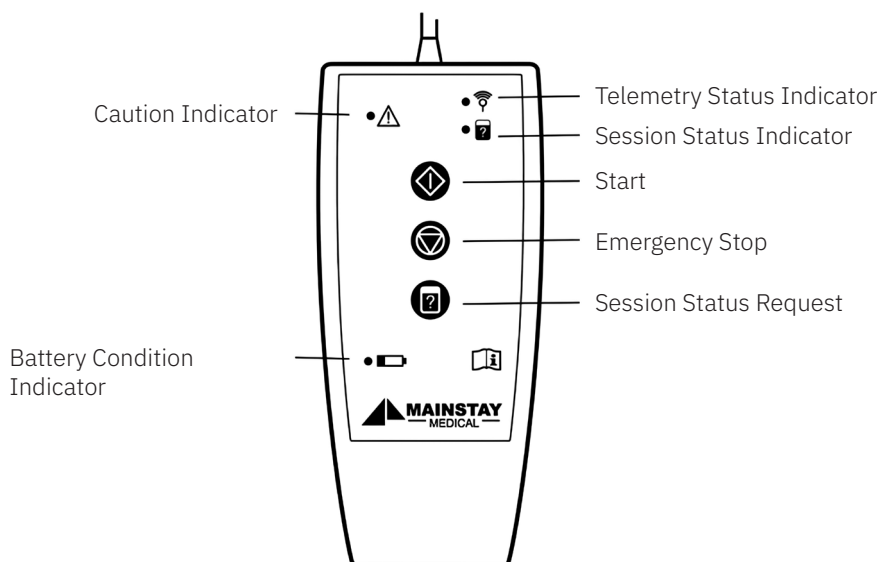


Figure 3: Activator control module

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.

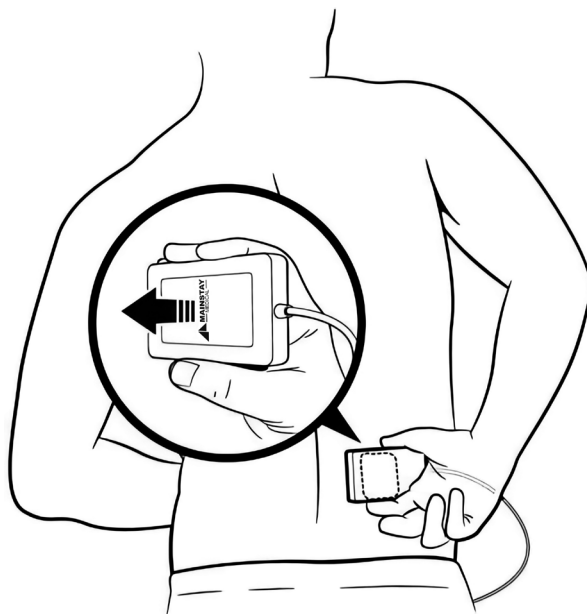


Figure 4: Placing the Activator antenna over the IPG

Controlling a Session with the Activator

Assume a comfortable prone position (lying on your stomach) 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:

- 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.

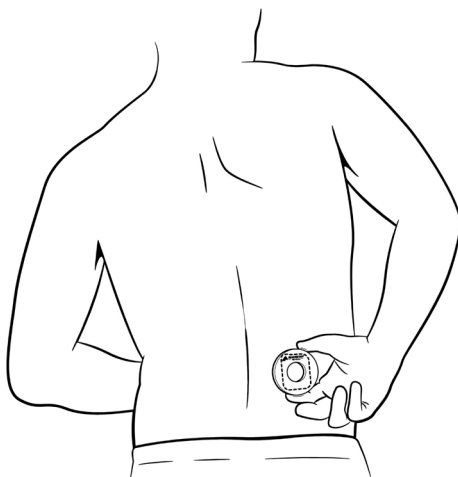


Figure 5: Placing the Magnet over the IPG

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 color and the Battery Condition Indicator  is not illuminated, the Activator batteries are acceptable for use.
 - If it illuminates with any color 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).

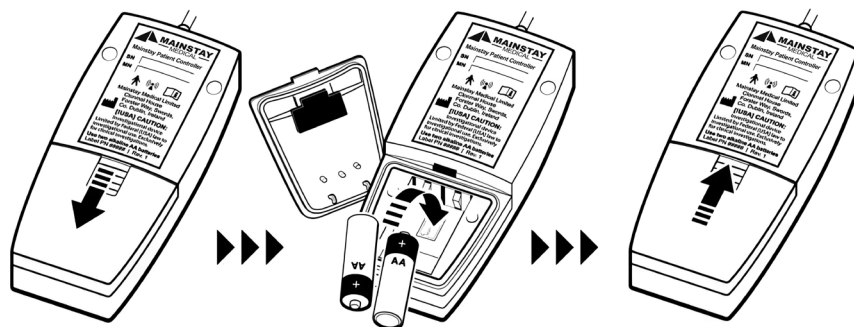


Figure 6: Installing or replacing the Activator batteries

- 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 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 should be removed before burial or cremation. 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)

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	- Platinum iridium - Epoxy - Silicone rubber - Stainless steel - 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, 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.

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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