

ORN Exit Tool

Model 3886

User's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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Pat. <http://www.abbott.com/patents>

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Product Description

The Abbott ORN Exit Tool (OET) Model 3886, is an external, handheld device used to disable MRI Mode (set to Normal Mode) on select Abbott MR Conditional Implantable Pulse Generators (IPGs): Proclaim™ SCS Family, consisting of Proclaim™ XR 5 IPG, Proclaim™ XR 7 IPG, Proclaim™ Plus IPG 5, and Proclaim™ Plus IPG 7(3660, 3662, 3670, 3672), Infinity™ 5 IPG and Infinity™ 7 IPG (6660, 6662) or Proclaim™ DRG IPG(3664) when the Patient Controller (PC) and Clinician Programmer (CP) cannot be used to take the IPG out of MRI Mode.

Intended Use

The Abbott OET is intended for use with select Abbott MR Conditional IPGs. The OET is only intended to be used when the PC and CP cannot be used to take the IPG out of MRI Mode.

Intended Users

The intended users for this device are trained Abbott personnel or authorized representatives.

Indications for Use

Refer to the clinician's manual for the appropriate neurostimulation system.

Warnings

Electromagnetic interference (EMI). The OET has been tested to ensure its immunity from most common sources of electromagnetic disturbance. Extremely strong sources of electromagnetic disturbance may interfere with communication between the OET and the IPGs. If these conditions are encountered, moving away from the source of electromagnetic disturbance will allow the OET to resume normal operation. When

using the OET, patients should avoid being too close to these types of EMI sources, which include the following examples:

- **Communication equipment** such as microwave transmitters or high-power amateur transmitters, emergency service radio.
- **Wireless communication devices** such as computers that operate on a wireless network, handheld personal computers (PDA), cellular phones, and cordless phones.
- **Hospital and clinical equipment** used for electrocautery, diathermy, radiation therapy, lithotripsy, RF-ablation, X-ray, external defibrillation, blood pressure monitoring, and ECG.
- **Radiofrequency identification (RFID) devices** such as RFID patient wristbands, RFID equipment tags, etc. are all potential sources of RFID that may occur in a health care environment.

NOTE: If interference occurs, the effect can be minimized by reorienting or relocating the patient and device away from the interference source.

Precautions

Basic safety precautions should always be followed when using electrical products. These include the following:

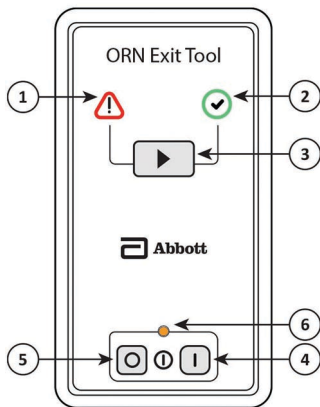
NOTE: Read all instructions before using.

- Do not place or drop the OET into water or other liquid.
- Use the OET only for its intended use as described in the manual.
- Never operate the OET if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water. Contact Technical Support for service or replacement instructions.

- Use only AA alkaline batteries and install the batteries as indicated on the OET.

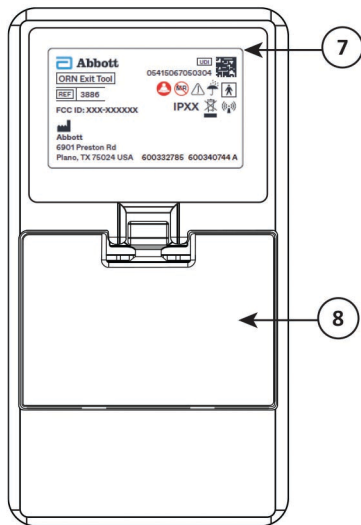
Using the Exit Tool

Figure 1. OET handheld device front view



1. Attention LED (solid amber) /timeout (flashing amber)
2. Checkmark LED (solid amber)
3. Function button (exit MRI Mode)
4. Power On button
5. Power Off button
6. Power LED (amber)
7. Label
8. Battery compartment door

Figure 2. OET handheld device back view



CAUTION: Do not bring the OET into the scanner magnet room. It is considered MR Unsafe. Doing so may cause injury or damage to the OET or MRI equipment.

NOTE: Before using, put on gloves, ensure the batteries are installed, and place the patient in a comfortable position based on their implant location. Additionally, ensure the patient and intended user are free of any metallic objects (i.e., metal belts, keys, cell phone, etc.) that may interfere with the device.

To disable MRI Mode on MR Conditional IPGs:

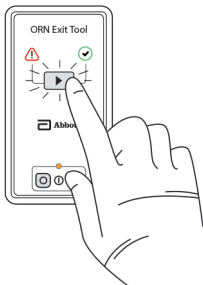
1. Hold the Power On button on the OET until the Power LED illuminates (solid amber) and a high tone followed by a low tone is emitted by the OET. This indicates the OET has turned on.

Figure 3. OET power on



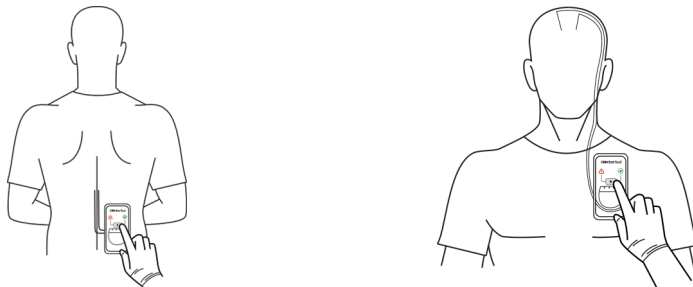
2. Press the OET Function button. The OET will start searching for the IPG by flashing both attention and checkmark amber LEDs simultaneously and emitting a beep from the speaker every second.

Figure 4. OET function button



3. Place the OET over the IPG. The OET should be positioned over the patient's clothing directly over the IPG. See MR Conditional Pulse Generator Implant Location (page 10).

Figure 5. Placing the OET over the IPG (SCS left and DBS right)



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- If the checkmark amber LED illuminates for 5 seconds and a high tone sounds, the IPG has successfully exited MRI mode. Follow instructions in the appropriate clinician programmer or patient controller manual to reestablish the pairing and restore therapy.
 - If the attention and checkmark amber LED lights keep flashing, and the OET keeps beeping, move the OET gently in the target area until the beeping stops, a high tone sounds, and checkmark amber LED is illuminated.
 - If the OET does not detect the IPG 5 seconds after pressing the function button, the attention amber LED will flash and a three-tone beep sequence (low, medium, then high) is emitted by the OET for 5 seconds. Repeat step 2.

4. If the OET still does not find the IPG, contact Abbott Technical Support (page 9).

NOTE: A trained Abbott representative should maintain physical custody of the OET at all times and return it to the Abbott development facility after use (See return instructions card in box).

The OET uses the following light patterns and sound tones to convey the status of the IPG.

Table 1. OET light patterns and sound tones

Action	Response		Condition
	Light	Sound	
Press the Power button on the OET (when amber LED is off).	Amber Power LED illuminates and stays on.	2 beeps: High tone then low tone	OET is turned on and awaiting user action.
	Amber Power LED illuminates briefly and fades away.	No beep.	The power button was not pressed long enough.
	Amber LED illuminates briefly and fades away.	Weak low tone beep every second.	Batteries are weak and may need replacing.
Press the Function button on the OET.	Attention and Checkmark LEDs both flash simultaneously.	Continuous beeps. Low tone at 1 second intervals.	OET is searching for the IPG.
	Checkmark LED is illuminated continuously for 5 seconds.	1 beep: High tone.	IPG is out of MRI Mode.

Table 1. OET light patterns and sound tones

Action	Response		Condition
	Light	Sound	
	Attention LED flashes continuously for 5 seconds.	3 beeps: Low tone, medium tone, then high tone. Sequence repeats 5 times.	The IPG is not in communication range of the OET.
	Attention LED illuminates continuously for 5 seconds.	2 beeps: Low tone, then high tone.	An error has occurred on the IPG.

Care, Cleaning, and Service

The OET is designed to be used as indicated; however, it is an electronic device and susceptible to many environmental stresses. Take care to avoid damaging the OET. If necessary, clean the outside of the OET with a cloth dampened with water.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Troubleshooting

Replace the batteries if:

- The Power On light does not turn on when you power on the OET.
- The OET does not respond to the function button.
- The OET shuts down before the requested operation is complete.

To replace the batteries:

1. Open the battery compartment door on the back of the OET.
2. Remove the AA batteries.
3. Insert 2 new AA batteries in the correct orientation as indicated on the OET.
4. Place battery compartment door back in position and lock in place.

MR Conditional Pulse Generator Implant Location

Common sites for generator implantation are under the skin, along the upper buttock, along the posterior axillary line, and in the area over the abdomen just below the lowermost rib (DRG and SCS), or under the skin in the upper right or left pectoral region (DBS).

Figure 6. Anatomical locations (shown in gray) for SCS/DRG implanted MR conditional IPGs

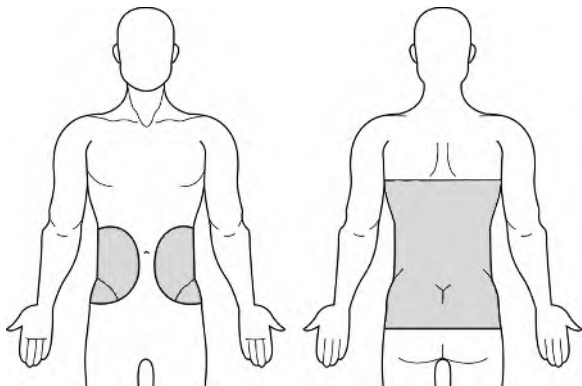
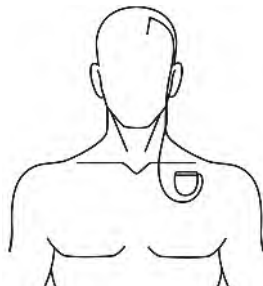
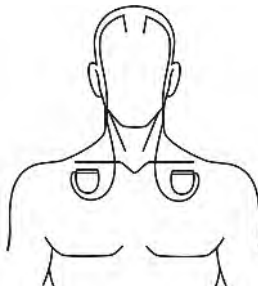


Figure 7. Anatomical locations for DBS implanted MR conditional IPG



Left Pectoral Region



Left and Right Pectoral Region

Appendices

Product Specifications

NOTE: Other than the battery compartment door on the back of the OET, there are no other user-serviceable parts in the OET. No calibration is required. Do not modify the OET.

Table 2. OET Specifications

Specifications	Model 3886
Height	11.45 cm (4.51 in.)
Width	6.1 cm (2.4 in.)
Depth	1.78 cm (0.7 in.)
Case material	High-impact plastic (PC-ABS)
Power source	2 AA Alkaline batteries
Audible output level	50dB (minimum) at 10.0 cm
Classification with respect to electric shock	Internally powered
Protection from electric shock (IEC 60601-1)	Type BF
Protection against ingress liquids	IPX0 (IEC 60529)
Mode of operation	Continuous

Storage and Operating Conditions

Table 3. Storage and Operating Conditions

Condition	Storage	Operating
Temperature	-20°C to 55°C (-4°F to 131°F)	15°C to 27°C (59°F to 81°F)
Humidity (non-condensing)	5% to 95% RH	20% to 60% RH

Regulatory Statements

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.