Medtronic

REVEAL®

Patient Assistant 9538/9539

Clinician Manual

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

The following are trademarks of Medtronic:
Medtronic and Reveal

Explanation of symbols:

CE 0123 — Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD DIrective 90/385/EEC (NB 0123) and R&TTE 1999/5/EC.

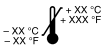
 — Package contents

 — Patient Assistant model 9538

 — Patient Assistant model 9539

 — Product documentation

! USA — For U.S. audiences only

 — Temperature limitation

EC REP — Authorized representative in the European Community

 — Manufacturer

 — Consult instructions for use

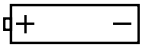
 — Date of manufacture

SN — Serial number

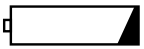
REF — Reorder number

 — Medical equipment with respect to electric shock, fire, and mechanical hazards, only in accordance with UL2601-1, and CAN/CSA C22.2 no. 601.1

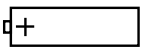
 — Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

 — Battery polarity as shown

 — Type BF equipment

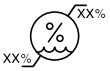


Battery condition



Position of Cell

RF transmitter



Humidity Limitation

Contents

1 Description and intended use

The Reveal Patient Assistant model 9538 and the Reveal XT Patient Assistant model 9539 are handheld, battery-operated, radio-frequency devices used to communicate with the Reveal Insertable Cardiac Monitor. See the Reveal Clinician Manual provided with the Insertable Cardiac Monitor for specific compatibility information.

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event.
- To initiate recording of cardiac event data in the implanted device memory.

The Patient Assistant is not intended to detect or indicate the presence or absence of medical conditions. Instruct the patient to seek immediate medical attention if he or she is feeling ill, regardless of indications from the Patient Assistant.

As directed by the clinician, the patient uses the Patient Assistant during or immediately after a symptomatic event. By pressing a button on the Patient Assistant and holding it in front of his or her implanted device, patients may record the event into the memory of the implanted device. At follow-up visits the implanted device recording is used to check the patient's cardiac rhythm and help determine if the patient's symptoms are cardiac related.

The patient should be advised to carry or keep their Patient Assistant nearby at all times to avoid the possibility of missing an opportunity to mark a symptomatic episode.

Caution: Do not take the Patient Assistant (handheld activator) into the MRI controlled room (magnet room). Doing so can damage the Patient Assistant or the MR scanner.

The physician should instruct the patient when to use the Record Symptoms button (both models) and Query button (model 9539) and what to do when a response indicator is received. The Reveal Patient Manual provides a place to record such instructions. See "Preparing the Patient Assistant for patient use" on page 10.

1.1 Reveal Patient Assistant model 9538

The Reveal Patient Assistant model 9538, shown in Figure 1, is identified by its single user-operated button located at the upper-right corner of the display area.

The Patient Assistant provides the patient with the ability to activate storage of cardiac data when a symptomatic event occurs or has occurred by pressing the Record Symptoms button [ ]. See “Recording cardiac rhythm data” on page 10. When the Record Symptoms button is pressed, the Patient Assistant also indicates if its battery voltage is low and if telemetry with the implanted device was successful.

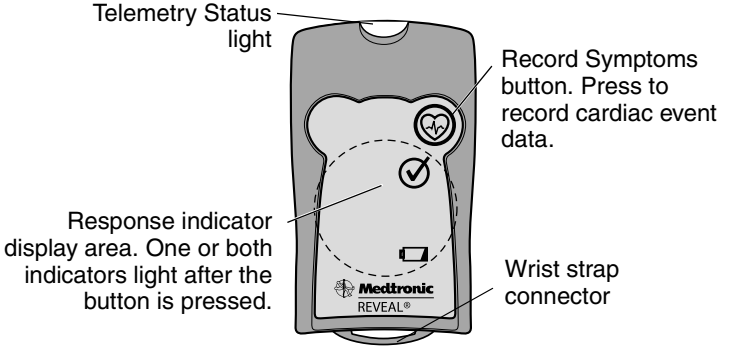


Figure 1. Reveal Patient Assistant model 9538 with all response indicators displayed for reference.

1.2 Reveal XT Patient Assistant model 9539

The Reveal XT Patient Assistant model 9539, shown in Figure 2, is identified by its 2 user-operated buttons, located at the upper-left and upper-right corners of the display area.

In addition to the features of the Reveal Patient Assistant model 9538, the Reveal XT Patient Assistant model 9539 has a Query button [ ]. The patient presses the Query button to check if the implanted device has detected important status information such as; low battery, if maximum auto-detected episodes have been reached, or if programmed criteria have been met for cardiac event data. Refer to the Reveal XT 9529 Clinician Manual for information on how to select and enable notification criteria.

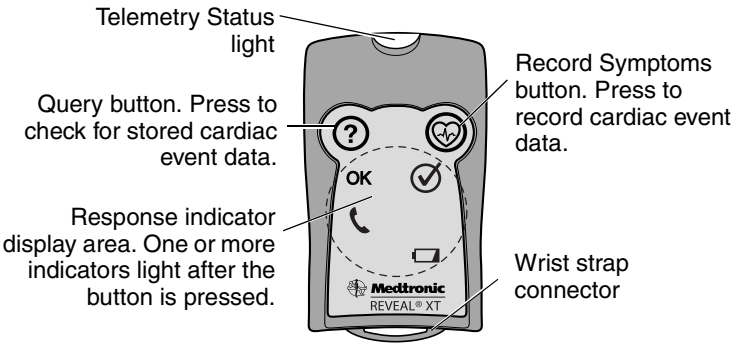


Figure 2. Reveal XT Patient Assistant model 9539 with all response indicators displayed for reference.

2 Package contents and inspection

2.1 Contents of the Patient Assistant package

The Patient Assistant package contains the following items:

- Patient Assistant
- N-size 1.5 V batteries
- Carrying case
- Wrist strap
- Reveal Patient Manual
- Quick reference card with attached ICM ID card
- Electromagnetic Compatibility Declaration
- Warranty card

2.2 Inspection

Inspect the Patient Assistant for damage or defects before giving the Patient Assistant to a patient. If the case is cracked or you discover other defects, return the Patient Assistant to Medtronic.

Check the battery date code before installing batteries to ensure there is six months or more of battery life remaining.

3 Preparing the Patient Assistant for patient use

The following steps should be completed before giving the Patient Assistant to a patient:

1. Place new batteries in the Patient Assistant. See “How to install new batteries” on page 16.
2. Record the necessary information in the Reveal Patient Manual. The Reveal Patient Manual provides a place to record instructions about using the Patient Assistant in the section “Instructions from your doctor,” found in the chapter “Using the Patient Assistant.” The instructions should indicate when the patient should press the Record Symptoms button (both models) and the Query button (model 9539), depending on what notification criteria have been programmed. The instructions should also include when and how the patient should contact the clinician.
3. Fill in both sides of the “Reveal ICM Device Identification Card,” which is attached to the Quick Reference Card.
4. Attach the provided wrist strap to the Patient Assistant or the loop on the provided carrying case. See “Attaching the optional wrist strap” on page 18.

Note: Refer to the Reveal DX 9528 Clinician Manual or the Reveal XT 9529 Clinician Manual for information about the particular features that apply to the Patient Assistant.

4 Recording cardiac rhythm data

4.1 How to record cardiac rhythm data

The patient should follow this procedure while experiencing symptoms or as soon as possible after experiencing symptoms:

1. Press the Record Symptoms button []. The Patient Assistant makes a short beep and the Telemetry Status light flashes green, which means the Patient Assistant is ready to initiate recording of cardiac rhythm data in the patient’s implanted device.

   Note: If the Patient Assistant does not respond within 15 seconds of pressing the button, see “Troubleshooting” on page 15.

2. Immediately after pressing the button, while the Telemetry Status light is flashing, the Patient Assistant should be held against the patient's skin or clothing directly in front of the implanted device. See Figure 3. The side with the buttons can be held facing the patient or away from the patient.

Figure 3. Hold the Patient Assistant in front of the implanted device. (The device may be implanted in a different location than is shown here.)

3. When the Telemetry Status light turns to a solid light and the Patient Assistant makes a long beep, remove the Patient Assistant from in front of the implanted device. A solid status light and long beep mean the implanted device has successfully responded.

   Note: If the Patient Assistant does not respond within 15 seconds, see "Troubleshooting" on page 15.

4. Immediately look at the Patient Assistant response indicator display area to see which indicator is lit (Figure 4). See "Response when a recording is requested" on page 12 for descriptions of the indicators.

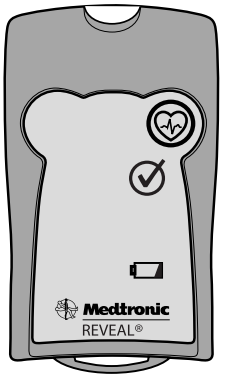


Figure 4. Reveal Patient Assistant model 9538 showing all possible response indicators when the Record Symptoms button is pressed.

4.2 Response when a recording is requested

The Patient Assistant displays the appropriate indicator for approximately 10 seconds after receiving a response from the implanted device.

Indicator	Description/Action to take (if any)
⊘	**Successful Recording indicator.** After pressing the Record Symptoms button, this indicator means that cardiac rhythm data has been successfully recorded into the implanted device memory.
▭	**Low Batteries indicator.** This indicator means that the batteries must be replaced in the Patient Assistant. See “Battery information” on page 16 for instructions.

5 Checking for cardiac rhythm events

5.1 How to check for cardiac rhythm data storage

Note: This feature is available only with the Reveal XT Patient Assistant model 9539. Refer to the Reveal XT 9529 Clinician Manual for information on how to enable notification criteria.

1. Press the Query button [?]. The Patient Assistant makes a short beep and the Telemetry Status light flashes green, which means the Patient Assistant is ready to query the implanted device.

   Note: If the Patient Assistant does not respond within 15 seconds of pressing the button, see “Troubleshooting” on page 15.

2. Immediately after pressing the button, while the Telemetry Status light is flashing, the Patient Assistant should be held against the patient’s skin or clothing, directly in front of the implanted device. See Figure 5. The side with the buttons can be held facing the patient or away from the patient.

Figure 5. Hold the Patient Assistant in front of the implanted device. (The device may be implanted in a different location than is shown here.)

3. When the Telemetry Status light turns to a solid light and the Patient Assistant makes a long beep, remove the Patient Assistant from in front of the implanted device. A solid status light and long beep mean the Patient Assistant has successfully queried the implanted device.

   Note: If the Patient Assistant does not respond within 15 seconds, see “Troubleshooting” on page 15.

4. Immediately look at the Patient Assistant response indicator display area to see which indicator is lit (Figure 6). See “Response when a query is requested” on page 14 for descriptions of the indicators.

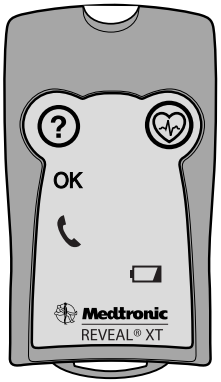


Figure 6. Reveal XT Patient Assistant model 9539 showing all possible response indicators when the Query button is pressed.

5.2 Response when a query is requested

The Patient Assistant displays the appropriate indicators for approximately 10 seconds after receiving a response from the implanted device.

Indicator	Description/Action to take (if any)
OK	**OK indicator.** This indicator means the implanted device has no recorded events that require follow-up; however, if the patient feels ill, instruct the patient to seek medical attention. **Note:** The OK indicator will also be received in the following situations: ▪ If notifications of the Patient Assistant query function are not enabled. ▪ If a Reveal Patient Assistant model 9539 is used with a Reveal DX 9528 ICM.
	**Event indicator.** This indicator means the implanted device has recorded events, and the patient should notify the clinician. These events include: ▪ Cardiac rhythm episodes matching selected notification criteria ▪ Implanted device requires attention (battery low or maximum auto-detected episodes reached)
	**Low Batteries indicator.** This indicator means that the batteries in the Patient Assistant must be replaced. See “Battery information” on page 16 for instructions.

6 Troubleshooting

Problem	Possible causes	Possible solutions
Telemetry Status light does not flash and no beep sounds.	The batteries are inserted incorrectly.	Reinstall the batteries.
	The batteries are depleted.	Replace the batteries.
	The wrong type batteries are inserted.	Verify that batteries are N-size, 1.5 V.
	There is a component failure.	Replace the Patient Assistant.
Telemetry Status light flashes, but no beep sounds.	The speaker has failed.	The response on the display area can be followed, but the Patient Assistant should be replaced.
Telemetry Status light stops flashing without a response after the button is pressed.	Insufficient telemetry: the Patient Assistant did not communicate with the implanted device.	Reposition the Patient Assistant directly over the implanted device, press the button again, and wait for a response.
	There is electromagnetic interference.	Move away from the source of interference.
	There is a component failure.	Replace the Patient Assistant.
Telemetry Status light turns a solid color, beeps, but no response indicator appears in the display area.	The light in display area is broken.	Contact a Medtronic representative.
	There is a component failure.	Replace the Patient Assistant.
Repeated failures occur.	The Patient Assistant is outside its temperature range: 49 °F (9 °C) to 110 °F (43 °C).	Move to warmer or cooler surroundings.
	There is electromagnetic interference.	Move away from the source of interference.
	The Patient Assistant needs to be replaced.	Contact a Medtronic representative.

7 Battery information

7.1 Replacement batteries

The Patient Assistant operates with 2 N-size 1.5 V batteries. The recommended battery type is alkaline manganese dioxide, type ANSI/NEDA 910A and IEC LR1, which can be purchased at retail and camera stores and from online merchants.

7.2 When to install batteries

- Install new batteries before giving the Patient Assistant to a patient.
- If the Low Batteries indicator appears, both batteries should be replaced as soon as possible. The Patient Assistant will operate for several more uses after the initial appearance of the Low Batteries indicator.

  Note: Follow local regulations for proper disposal of used batteries.

7.3 How to install new batteries

Note: Check the battery date code before installing batteries to ensure there is six months or more of battery life remaining.

Follow these steps to install batteries in the Patient Assistant:

1. Slide the battery cover tab toward the center of the Patient Assistant and push upward to open the battery compartment. See Figure 7.

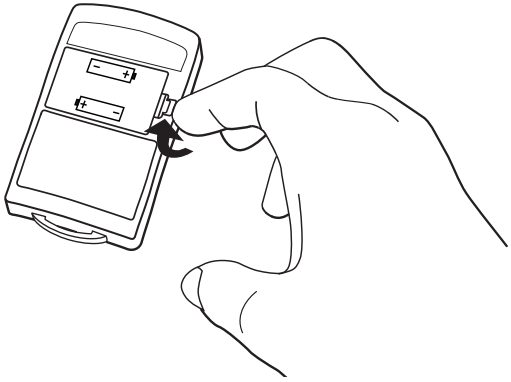


Figure 7. Opening the battery compartment.

2. Remove the old batteries.

3. Insert 2 new batteries (Figure 8). Follow the polarity diagram shown on the outside of the battery compartment.

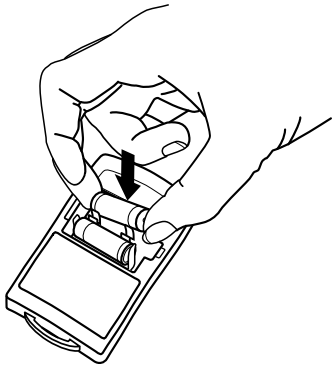


Figure 8. Replacing the batteries.

4. Snap the battery cover closed. See Figure 9.

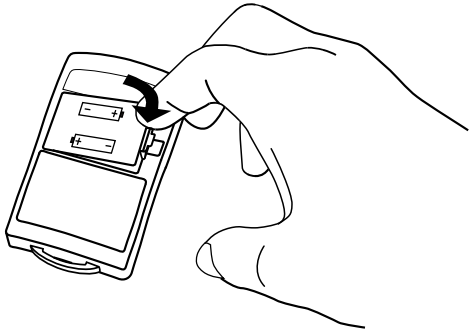


Figure 9. Closing the battery cover.

5. Make sure to test the Patient Assistant after installing batteries to determine if the batteries were installed correctly. Press a Patient Assistant button while the Patient Assistant is away from the implanted device. The Patient Assistant should beep and the Telemetry Status light should flash green, confirming correct battery installation. If you press a button and the Telemetry Status light does not flash green, make sure the new batteries have been installed correctly.

8 Attaching the optional wrist strap

The provided wrist strap can be attached to the Patient Assistant so the patient can hang the Patient Assistant around his or her wrist. This ensures the Patient Assistant is always accessible and not dropped. The wrist strap can be attached as shown in Figure 10. The strap can also be attached to the loop on the provided carrying case. See “Care and handling” on page 18.

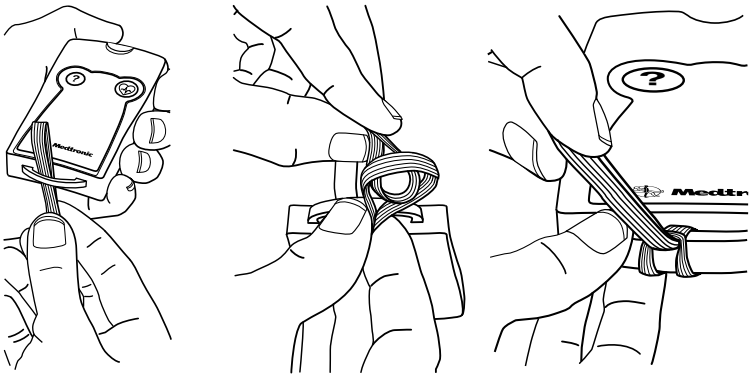


Figure 10. Attaching the optional wrist strap.

9 Maintenance

9.1 Care and handling

The Patient Assistant is designed to be used on a daily basis; however, it is an electronic device and susceptible to many environmental stresses. Precautions should be taken to avoid damage to the unit, including (but not limited to) those listed here.

Precautions:

- Do not immerse the Patient Assistant in liquid or spill fluid on it.
- Do not drop the Patient Assistant or mishandle it in a way that might cause damage.
- Do not open the Patient Assistant, except to install batteries.
- Do not sterilize the Patient Assistant.
- Do not carry the Patient Assistant in a pocket located directly over an implanted device. Use the supplied carrying case if the Patient Assistant is carried in a pocket or handbag.

- Do not “play” with the Patient Assistant. Doing so can cause previously recorded data to be lost.
- Electromagnetic interference (EMI) can impair the reliable performance of the Patient Assistant. Normal operation can be restored by moving away from the source of the interference.
- Although the instruction to the patient is to carry the Patient Assistant at all times, it is not allowed to take the Patient Assistant into the MRI controlled room (magnet room).
- Keep the Patient Assistant at room temperature. The Patient Assistant may not operate at full strength outside the range of 49 °F (9 °C) to 110°F (43 °C).

9.2 Cleaning

- Be careful to prevent moisture from entering the Patient Assistant. The Patient Assistant is moisture resistant but not waterproof.
- Clean the outside of the Patient Assistant with a slightly damp cloth. Mild household cleansers will not damage the case or labels.
- Do not clean the Patient Assistant with solvents (such as nail polish remover) or chlorine-based cleansers (such as bleach).

9.3 Service

All Medtronic Reveal Patient Assistant devices have been carefully engineered, manufactured, and quality tested to provide long, trouble-free service. Should service or replacement be necessary, contact your local Medtronic representative. Please refer to the model number and serial number (located on the back of the Patient Assistant) when calling Medtronic.

9.4 Disposal

Follow local regulations for proper disposal of the Patient Assistant at the end of its useful service life.

10 Specifications

10.1 Device specifications

Dimensions: Approximately 3.77 in x 2.20 in x 0.86 in (96 mm x 56 mm x 22 mm)

Power source: 2 N-size, 1.5 volt batteries, alkaline (manganese dioxide)

Battery dimensions: 0.39 in diameter x 1.18 in (10 mm x 30 mm)

Battery longevity: 180 uses minimum, when used once a day at room temperature. Operating the Patient Assistant below 60 °F (15 °C) for extended periods of time shortens battery longevity.

Operating temperature: 49 °F (9 °C) to 110 °F (43 °C)

Transport and storage (**batteries not installed):**
Ambient temperature: -40 °F (-40 °C) to 150 °F (65.5 °C)
Relative humidity: up to 95%

Audible output level: 65 dBA minimum at 3.77 in (96 mm)

Classification with respect to electric shock: Internally powered

Protection from electric shock (IEC 60601-1): Type BF

Protection against ingress of liquids: Ordinary equipment

Mode of operation: Non-continuous

10.2 Safety and compatibility standards

The Patient Assistant models 9538 and 9539 comply with the following standards:

IEC 60601-1, Medical electrical equipment safety

IEC 60601-1-2, Electromagnetic compatibility

EN45502-1, Safety, marking and information of medical devices

FCC Part 15

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M942629A001A
2010-08-03

M942629A001