# MODEL 2696 INCHECK™

Patient Assistant

Physician's manual

! USA **Caution**: Investigational device. Limited by federal law (USA) to investigational use.



Printing instructions: doc#163256; refer to "Implant man." row in the applicable table.

## Explanation of symbols on the packaging and literature

| | |
|---|---|
|  | Attention: See accompanying documentation |
|  | Type BF equipment |
|  | Battery polarity as shown |
|  | Serial number |
|  | Storage temperature |
|  | For United States audiences only |
|  | **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician |
|  | Medical device |
|  | Telemetry (communication signal) status light lit |

## Explanation of symbols on the device

| | |
|---|---|
|  | Query button (Press to request implanted device to check for AF) |
| OK | OK symbol (AF is not present) |
| AF | AF symbol (AF is present) |
|  | Therapy button (Press to instruct implanted device to deliver atrial cardioversion therapy) |
|  | Record Symptoms button (Press to instruct the implanted device to record cardiac activity) |
|  | Record symbol (recorded cardiac activity) |
|  | Type BF equipment |
|  | Low Batteries symbol |
|  | Battery polarity as shown |
|  | Attention: See accompanying documents |
| ! USA | For United States audiences only |
| ℞ **only** | **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician |

# Table of contents

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Printing instructions: doc#163256; refer to “Implant man.” row in the applicable table.

# 1 Description and intended use

The Model 2696 InCheck™ Patient Assistant shown on Figure 1 is a hand-held, battery powered, radio frequency communication device. The Patient Assistant communicates with certain implantable Medtronic cardiac devices that provide patient-activated features. See the manual for the implanted device for compatibility information.

The Patient Assistant can send simple programming commands to the implanted device, and receive and display information about the patient's cardiac rhythm.

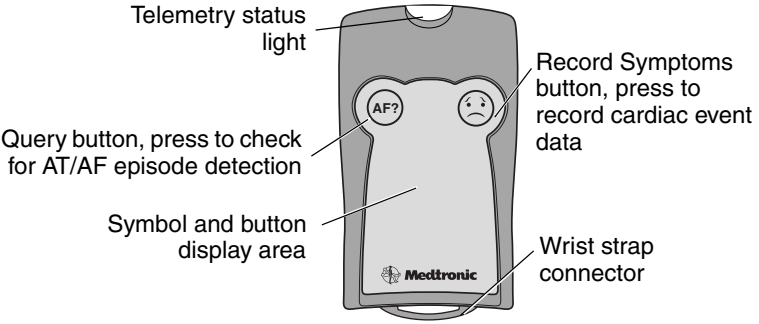


***Figure 1.*** *Patient Assistant (Not actual size)*

**Intended use –** The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the patient management features in the implanted device, depending on the implanted device model and the programmed features:

- To verify whether the implanted device has detected a suspected atrial arrhythmia.

- To initiate recording of cardiac event data in the implanted device memory.
- To request atrial cardioversion therapy, if supported by the implanted device and patient activated therapy has been previously programmed by the physician. Therapy is allowed when the implanted device is currently detecting an atrial arrhythmia episode and all conditions for delivering therapy have been met.

**Note:**

- Ventricular arrhythmia therapy cannot be patient activated using the Patient Assistant.

# 2 Contents of the Patient Assistant box

The following should be found in the Patient Assistant box:

- One Patient Assistant
- Two N-size 1.5 V batteries
- One carrying case
- One wrist strap
- One physician's manual
- One quick reference guide/patient ID card
- Two warranty cards (USA and outside USA)
- One patient manual

The Patient manual includes blank lines in sections 3 and 7 for the patient's prescription information. This information includes when to use the Patient Assistant, which button to press and what actions to take for each reply.

The Quick Reference Guide/Patient ID Card provides a more portable version of the basic instructions for using the Patient Assistant. Blank lines are provided for name and telephone number information.

## 2.1 Inspection

Inspect the Patient Assistant for damage or defects. If the case is cracked or other defects are discovered, return the Patient Assistant to Medtronic.

## 2.2 Installation and setup

Place new batteries in the Patient Assistant (see page 20).

Press either front panel button to test the Patient Assistant. The telemetry status light flashes green for about 15 seconds, and the Patient Assistant gives a short beep. This confirms that the batteries can operate correctly.

Provide the necessary information in the Patient manual and Quick Reference Guide/Patient ID Card.

Refer to the implantable device reference manual for information about its features that apply to the Patient Assistant.

# 3 Checking the patient's heart rhythm

## 3.1 How to check the patient's heart rhythm

**Note:** The Patient Assistant may not communicate at full strength outside the range of 8 °C (16 °F) to 43 °C (110 °F).

1. Press the Query button. Verify that the telemetry status light flashes green, and the Patient Assistant gives a short beep. If these responses do not occur, see page 23.

2. Place the Patient Assistant against the implanted device. See Figure 2.

***Figure 2.*** *Positioning the Patient Assistant*

3. Listen for a long beep or look to see if the telemetry status light is solid green. Lift the Patient Assistant to see what appears on the display area (Figure 3).

   **Note:** If the Patient Assistant does not respond in about 15 seconds, it did not communicate successfully with the implanted device. Repeat steps 1 through 3.

   **Note:** Pressing the Therapy button will cause the implanted device to deliver atrial cardioversion therapy. See page 16 for information about when the Therapy button will appear.

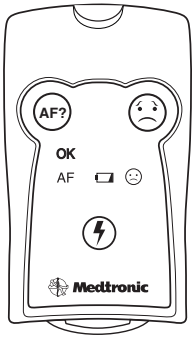


***Figure 3.*** *Patient Assistant with all symbols displayed for reference*

## 3.2 Response when a query is requested

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

| Display | Definition |
|---|---|
| OK | OK symbol: The implanted device **is not detecting** an atrial tachyarrhythmia episode. |
| AF | AF symbol: The implanted device **is detecting** an atrial tachyarrhythmia episode. |
|  | Therapy button: Atrial cardioversion therapy is allowed. See “Requesting atrial cardioversion therapy” on page 13 for more information. |
| Telemetry status light flashes for about 15 seconds and goes out. | The Patient Assistant did not communicate with the implanted device. |
|  | Low Batteries symbol: The Patient Assistant batteries are low and should be replaced soon. |

# 4 Requesting atrial cardioversion therapy

## 4.1 How to request cardioversion therapy

**Note:** The Patient Assistant may not communicate at full strength outside the range of 8 °C (16 °F) to 43 °C (110 °F).

**Note:** Pressing the Therapy button will cause the implanted device to deliver atrial cardioversion therapy. See page 16 for information about when the Therapy button will appear.

1. Instruct the patient to sit down or lie down in a comfortable position. Use the wrist strap if desired.
2. Press the Query button. Verify that the telemetry status light flashes green, and the Patient Assistant gives a short beep. If these responses do not occur, see page 23.
3. Place the Patient Assistant against the implanted device (see Figure 4).

***Figure 4.*** *Positioning the Patient Assistant*

4. Listen for a long beep or look to see if the telemetry status light is solid green. Lift the Patient Assistant to see what appears on the display area (Figure 5).

   **Note:** If the Patient Assistant does not respond in about 15 seconds, it did not communicate successfully with the implanted device. Repeat steps 1 through 4.

5. Press the Therapy button (if lit after pressing the Query button). The telemetry status light will flash red.

   **Note:** The Therapy button will stay lit for about 10 seconds after the query. If the Therapy button goes out before it can be pressed, repeat steps 1 through 4.

6. Place the Patient Assistant against the implanted device.

7. Listen for a long beep and look to see if the telemetry status light is solid red. Lift the Patient Assistant to see what appears on the display area (Figure 5).

   **Note:** If the Patient Assistant does not respond in about 15 seconds, it did not communicate successfully with the implanted device. Repeat steps 1 through 7.

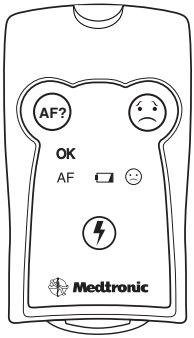


***Figure 5.*** *Patient Assistant with all symbols displayed for reference*

## 4.2 Response when therapy is requested

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

| Display | Definition |
|---|---|
| OK | OK symbol: The implanted device **is not detecting** an atrial tachyarrhythmia episode. Appears if the AF has stopped since pressing the Query button. |
| AF | AF symbol: The implanted device **is detecting** an atrial tachyarrhythmia episode. |
| (flashing) | Flashing Therapy button: **Therapy will be delivered soon.** In most cases, therapy will be delivered in about 10 seconds. The maximum time it takes the implanted device to prepare to deliver therapy is about 1 minute. |

| Display | Definition |
|---|---|
| No Therapy button. | **Therapy will not be delivered**. Telemetry status light is solid red with no flashing button. See section 4.4. |
| Telemetry status light flashes for about 15 seconds and goes out. | The Patient Assistant did not communicate with the implanted device. |
|  | Low Batteries symbol: The Patient Assistant batteries are low and should be replaced soon. |

## 4.3 When the Therapy button will appear

The Therapy button appears after pressing the Query button when the following conditions are met:

- The implanted device supports patient activated therapy.
- Patient activated therapy is enabled in the implanted device.
- The patient is in AT/AF.
- All conditions to deliver atrial therapy are met.

## 4.4 If therapy is not delivered

If the Patient Assistant gives a long beep and the Therapy button goes dark without flashing, the atrial cardioversion therapy was cancelled before delivery. The typical reasons are:

- The atrial rate cannot be confirmed.
- The ventricular rate is too fast.

Refer to the reference manual for the implanted device for more possible explanations and programming options.

# 5 Recording cardiac information

## 5.1 How to record cardiac information

**Note:** The Patient Assistant may not communicate at full strength outside the range of 8 °C (16 °F) to 43 °C (110 °F).

1. Press the Record Symptoms button. Verify that the telemetry status light flashes green, and the Patient Assistant gives a short beep. If these responses do not occur, see “Troubleshooting” on page 23.
2. Place the Patient Assistant against the implanted device. See Figure 6.

***Figure 6.*** *Positioning the Patient Assistant*

3. Listen for a long beep or look to see if the telemetry status light is solid green. Lift the Patient Assistant to see what appears on the display area (Figure 7).

   **Note:** If the Patient Assistant does not respond in about 15 seconds, it did not communicate successfully with the implanted device. Repeat steps 1 through 3.

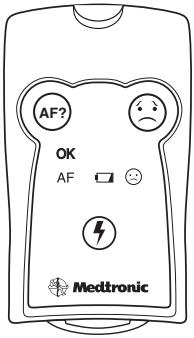


***Figure 7.*** *Patient Assistant with all symbols displayed for reference*

## 5.2 Response when record symptoms is requested

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

| Display | Definition |
|---|---|
| ☹ | Record symbol: The implanted device successfully recorded heart rhythm information. |
| Telemetry status light flashes for about 15 seconds and goes out. | The Patient Assistant did not communicate with the implanted device. |
| 🔋 | Low Batteries symbol: The Patient Assistant batteries are low and should be replaced soon. |

# 6 Battery information

## 6.1 Replacement batteries

The Patient Assistant operates with two N-size 1.5 volt batteries. The recommended battery type is alkaline manganese dioxide, type ANSI/NEDA 910A and IEC LR1. This battery is available from the following manufacturers:

- Duracell Model MN9100
- Kodak Model KN
- Rayovac Model RN-2
- Panasonic Model AM5
- Varta Model 4001
- Energizer Model E90

These batteries can be purchased at a retail store, camera store, battery speciality store, electronics store, or from an Internet retailer.

## 6.2 When to install batteries

- Install new batteries before giving the Patient Assistant to a patient.
- If the Low Batteries symbol appears, replace both batteries soon. The Patient Assistant will operate for several more uses after the initial appearance of the Low Batteries symbol.

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

## 6.3 How to install new batteries

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

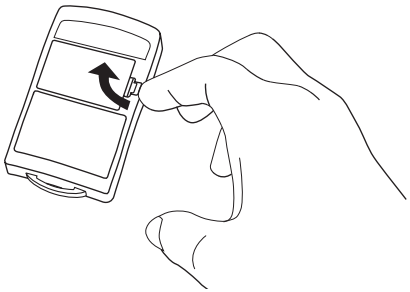

***Figure 8.*** *Replacing the batteries.*

2. Remove the old batteries.
3. Insert the new batteries according to the polarity shown on the battery compartment.
4. Snap the battery cover closed.
5. Verify that the Patient Assistant beeps and that the telemetry status light flashes when the Query button or the Record Symptoms button is pressed. This confirms that the new batteries have sufficient charge to operate the Patient Assistant.

# 7 Maintenance

## 7.1 Care and handling

The Patient Assistant is designed for robust use, to be carried and handled on a daily basis. However, it is a precision electronic instrument and precautions should be taken to avoid damage.

To preserve battery life, remove the batteries when the Patient Assistant is not used for long periods of time or exposed to temperatures below 15 °C (60 °F).

Electronic devices are susceptible to many environmental stresses. Precautions should be taken to avoid damage to the unit, including (but not limited to) those listed here.

**Precautions:**

- To prevent unintentional delivery of patient-activated therapy, instruct your patient not to carry the Patient Assistant in a pocket directly over the implanted device.
- Do not immerse the Patient Assistant in liquid.
- Do not clean the Patient Assistant with solvents or chlorine based cleansers (for example, nail polish remover or bleach).
- Do not drop the Patient Assistant or mishandle it in a way that might physically damage the Patient Assistant.
- Avoid spilling fluid on the Patient Assistant. Do not immerse in liquid.
- Do not open the Patient Assistant, except to install batteries.
- Do not sterilize the device by gamma irradiation and do not steam sterilize (autoclave) the Patient Assistant.

- Electromagnetic interference (EMI) can impair the proper performance of the Patient Assistant. Normal operation can be restored by moving away from the source of the interference.
- Other environmental factors may impact proper performance of the Patient Assistant. Use of good electronic device practices will help to prevent environmental damage to the unit.

## 7.2 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 cleaners will not damage the case or labels.

## 7.3 Service

The Medtronic Model 2696 InCheck™ Patient Assistant has been carefully engineered, manufactured and quality tested to provide long, trouble-free service. Should service or repair be necessary, contact your local Medtronic representative at the appropriate address or telephone number on the back cover of this document. Please refer to the model number (Model 2696) and serial number (located on the rear panel) when calling Medtronic.

## 7.4 Disposal

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

# 8 Troubleshooting

The following list can be used to help solve possible problems with the Model 2696 Patient Assistant.

| Problem | Possible causes | Possible solutions |
|---|---|---|
| Telemetry status light does not flash, no beep. | The batteries are inserted backwards. | Re-install the batteries. |
| | The batteries are depleted. | Replace the batteries. |
| | Wrong type batteries. | Verify that batteries are N-size, 1.5 V. |
| | A button is broken. | Replace the Patient Assistant. |
| | Component failure. | Replace the Patient Assistant. |
| Telemetry status light flashes, no beep. | The speaker has failed. | • Use response on the display area.<br>• Replace Patient Assistant. |

| Problem | Possible causes | Possible solutions |
|---|---|---|
| Telemetry status light stops flashing without a response after the button press. | Insufficient telemetry. Patient Assistant did not communicate with the implanted device. | Reposition Patient Assistant.<br>• Improve Patient Assistant position over implanted device.<br>• Circle the Patient Assistant slowly over the implanted device. |
| | Electromagnetic interference. | • Move away from the source of interference. |
| Repeated failures | Patient Assistant is outside its temperature range: 8 °C (16 °F) to 43 °C (110 °F). | Move to warmer or cooler surroundings. |
| | Patient Assistant needs repair. | Contact a Medtronic representative. |

# 9 Specifications

## 9.1 Device specifications

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

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

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

**Battery longevity:** 180 uses minimum, when used once a day at room temperature.[1]

**Operating temperature:** 8 °C (16 °F) to 43 °C (110 °F)

**Transport and storage (batteries not installed):**

Ambient temperature: -40 °C (-40 °F) to 66 °C (150 °F)
Relative humidity: up to 95%

**Audible output level:** 65 dBA minimum at 96 mm (6")

**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:** Short term

[1] Operating the Patient Assistant below 15 °C (60 °F) for extended periods of time will shorten battery longevity

## 9.2 Safety and compatibility standards

The Model 2696 Patient Assistant complies 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

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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