

Medtronic

Patient Assistant PA97000

DRAFT

Patient Manual

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

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How to contact Medtronic

Contact us online

Medtronic is dedicated to providing you with the most up-to-date information available about your Medtronic heart device. Information about your condition and device is available 24 hours a day on our website.

- Medtronic website: www.medtronic.com
- Patient Services website: www.medtronic.com/patients

If you would like to submit questions, suggestions, or requests to us online, you can use the online form provided at www.medtronic.com/contact-us.

Contact us by phone

Our experienced Patient Services group is available to answer any questions or concerns you have about your heart device. To speak directly with a Patient Services Specialist, call 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 7:00 PM (Central Time).

Contact us by mail or fax

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Using your Patient Assistant

Intended use

The Patient Assistant model PA97000 initiates the recording of cardiac event data in the device memory of compatible Medtronic cardiac implantable electronic devices. The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic.

What is the Patient Assistant?

The Patient Assistant is a handheld device that you use to prompt your cardiac monitor to begin recording symptoms. Your Patient Assistant connects wirelessly to your cardiac device. Data about your symptoms is stored in the cardiac device, not in the Patient Assistant. Your doctor uses the data to check your heart rhythm and to help determine if your symptoms are heart-related. Examples of heart-related symptoms (sometimes called “events”) include fainting, a fast heart rate, dizziness, and shortness of breath.

Carry the Patient Assistant with you at all times. Use it as instructed by your doctor while, or just after, you have symptoms.

This manual provides instructions on using, handling, and maintaining the Patient Assistant, and other information about it. If you have questions, contact your doctor or clinic, or contact Medtronic using the information on “How to contact Medtronic”.

Warning: The Patient Assistant can’t be used as an alarm system in situations where you need medical attention. Seek medical attention

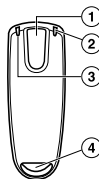
immediately if you are feeling ill and think you might need to go to the hospital. If there is an emergency, call your local emergency number. If your doctor has provided other instructions, follow them. Waiting to seek medical attention could be dangerous to your health.

Pediatric use – The Patient Assistant has not been tested specifically for pediatric use.

Patient Assistant button and lights

The Patient Assistant's button, lights, and Connector loop are shown in Figure 1. The lights do not turn on until you press the button. Use the Connector loop to attach the Patient Assistant to a key chain, lanyard, or other personal item.

Figure 1. Patient Assistant



1 Record Symptom button

2 Searching light (blue)

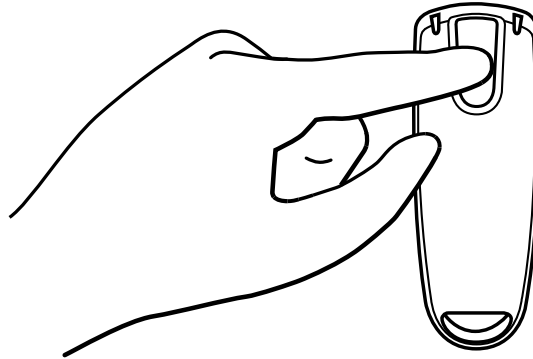
3 Success light (green)

4 Connector loop

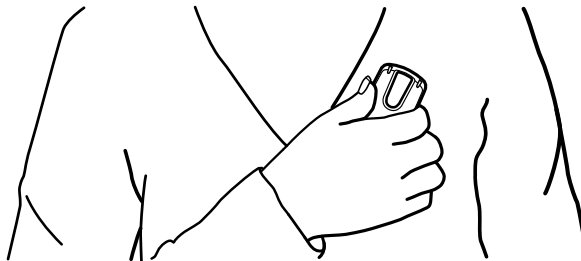
Instructions for using the Patient Assistant

You or a helper should follow these steps while you are having symptoms or as soon as possible afterward, as directed by your doctor.

1. Press and release the button. The Searching light will start flashing blue.



2. Quickly hold the Patient Assistant flat against your chest, directly over your cardiac device. (Your cardiac device may be in a different location than shown in this figure.)



3. When you successfully record an event in your cardiac device, two success signals will occur: a success tone will sound and the Success light will illuminate green.

Note: If the success signals do not occur within 15 s, reposition the Patient Assistant so that it is near your cardiac device but not directly on top of it. Then repeat Step 1 and Step 2. If you are wearing bulky clothing, such as a jacket or heavy sweatshirt, remove that item of clothing before repeating the steps.

Electrical interference and the Patient Assistant

Everything that uses electricity produces an electromagnetic energy field. This energy field surrounds an electrical item while it is connected to a source of electricity, such as an outlet or a battery. The energy field is strongest near the item and weakens with distance from the item. The relationship between these energy fields and the Patient Assistant PA97000 is called electromagnetic compatibility (EMC).

The energy fields from most electrical items are weak and won't affect your Patient Assistant. But strong magnets and electrical items such as cell phones and cordless phones can affect the connection between your Patient Assistant and your cardiac device. When you are trying to record a symptom, keep these items at least 15 cm (6 in) away from your Patient Assistant.

Troubleshooting

If you have difficulty using your Patient Assistant, see Table 1 to determine if one of the described problems occurred, and follow the corrective action provided. If you still have trouble, your Patient Assistant may not be working

correctly. Contact Medtronic Patient Services (see “How to contact Medtronic”), or your doctor or clinic, to troubleshoot further or to replace the Patient Assistant.

Table 1. Problems, possible causes, and possible solutions

Problem: You pressed the button, but the blue Searching light does not flash.

- **Possible cause and solution:** You didn't press the button hard enough. Retry recording the symptom, this time making sure to press the button firmly. Wait for a response. If you are unable to successfully record a symptom after 2 attempts, write down your symptom and the time it occurred. Then bring the note with you the next time you visit your doctor or clinic.
- **Possible cause and solution:** The Patient Assistant might have been in an environment that was too cold or hot. Write down your symptom and the time it occurred. Then bring the note with you the next time you visit your doctor or clinic. Meanwhile, allow the Patient Assistant to come to room temperature.

Table 1. Problems, possible causes, and possible solutions (continued)

- **Possible cause and solution:** The Patient Assistant might not be working correctly. Contact Medtronic Patient Services (see “How to contact Medtronic”) to replace the Patient Assistant.

Problem: You pressed the button and the blue Searching light flashes, but no success tone sounds and no green Success light illuminates.

- **Possible cause and solution:** The Patient Assistant did not communicate with the cardiac device. Reposition the Patient Assistant in a new location near, but not directly on top of, your cardiac device, retry recording the symptom, and wait for a response. If you are unable to successfully record a symptom after 2 attempts, write down your symptom and the time it occurred. Then bring the note with you the next time you visit your doctor or clinic.
- **Possible cause and solution:** Electromagnetic interference: move away from the source of interference (an electrical or magnetic item), retry recording the symptom, and wait for a response. If you are unable to successfully record a symptom after 2 attempts, write down your

Table 1. Problems, possible causes, and possible solutions (continued)

<p>symptom and the time it occurred. Then bring the note with you the next time you visit your doctor or clinic.</p>
<p>Problem: You pressed the button, the blue Searching light flashes, and the green Success light illuminates, but no success tone sounds.</p> <ul style="list-style-type: none"> • Possible cause and solution: Your current environment might be too loud to hear the success tone. If you saw the green Success light, then you successfully recorded a symptom, so don't worry that your symptoms weren't recorded. When you mark a symptom in a quieter environment, you should be able to hear the success tone. • Possible cause and solution: The Patient Assistant might not be working correctly. If you saw the green Success light, then you successfully recorded a symptom, so don't worry that your symptoms weren't recorded. Contact Medtronic Patient Services (see "How to contact Medtronic") to replace the Patient Assistant.
<p>Problem: You pressed the button, the blue Searching light flashes, the success tone sounds, but the green Success light does not illuminate.</p>

Table 1. Problems, possible causes, and possible solutions (continued)

- **Possible cause and solution:** Your current environment might be too bright to allow you to see the green Success light. If you heard the success tone, then you successfully marked the symptom, so don't worry that your symptoms weren't recorded. When you mark a symptom in a darker environment, you should be able to see the green Success light.
- **Possible cause and solution:** The Patient Assistant might not be working correctly. If you heard the success tone, then you successfully marked the symptom, so don't worry that your symptoms weren't recorded. Contact Medtronic Patient Services (see "How to contact Medtronic") to replace the Patient Assistant.

Handling your Patient Assistant

The Patient Assistant is designed for daily use. Take the following precautions in order to avoid damaging it:

- Do not immerse the Patient Assistant in liquid or spill fluid on it.

- Do not drop or mishandle the Patient Assistant in any way that might cause damage. Contact your doctor or clinic, or contact Medtronic (see “How to contact Medtronic”), if the Patient Assistant has been dropped and does not function.
- Do not open the Patient Assistant. The batteries cannot be replaced.
- To avoid accidental recordings, do not carry the Patient Assistant directly in front of your cardiac device, such as in the pocket of a shirt or coat that you are wearing.
- Keep the Patient Assistant away from children and pets.
- Keep the Patient Assistant at room temperature. See “Conditions for operating, transporting, and storing the Patient Assistant” for more information about the best conditions for transporting and storing your Patient Assistant.

Cleaning and maintenance

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 soft, slightly damp cloth, as needed. Do not

clean the Patient Assistant with solvents (for example, nail polish remover) or chlorine-based cleansers (for example, bleach).

Regularly inspect the Patient Assistant for damage or defects. If it is damaged or if you cannot fix the problem, contact your doctor or clinic, or contact Medtronic (see “How to contact Medtronic”) for assistance.

Patient Assistant disposal

Do not throw your Patient Assistant in the garbage. The Patient Assistant contains materials, such as batteries, that can harm the environment. Follow local regulations regarding how to throw it away.

Warnings and precautions

Warning: The Patient Assistant is not intended to be used as an alarm system for situations where medical attention is needed. Seek medical attention immediately if you are feeling ill and think you might need to go to the hospital. If there is an emergency, call your local emergency number. If your

doctor has provided other instructions, follow them. Waiting to seek medical attention could be dangerous to your health.

Caution: To prevent the risk of infection, do not place the Patient Assistant in direct contact with your incision site until the incision site is completely healed.

Caution: Do not modify the Patient Assistant. Modifications may impair its effectiveness.

Caution: Use the Patient Assistant only as directed by your doctor. Do not “play” with your Patient Assistant, including unnecessarily pressing the button, because doing so can cause inappropriate data to be recorded.

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

Contraindications

There are no known contraindications for the use of this device.

Patient Assistant specifications

- Dimensions: Approximately 10 cm x 4 cm x 1 cm (4 in x 1.5 in x 0.4 in)
 - Power source: Non-replaceable lithium coin-cell battery
 - Battery longevity (service life): When used within the recommended operating temperature range (5°C to 40°C [41°F to 104°F]), the button on your Patient Assistant can be pressed at least 200 times before the battery is depleted.
 - Protection from electric shock (IEC 60601-1): Type BF Applied Part
 - Protection from ingress: IP22. This means that the product is protected from ingress in the following 2 ways:
 - Against access to hazardous parts with a finger
 - Against vertically falling water drops when the enclosure is tilted up to 15°
- The Patient Assistant is moisture resistant but not waterproof.
- Mode of operation: Continuous

FCC compliance information

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.

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This portable transmitter and its antenna comply with FCC and Industry Canada radiofrequency (RF) exposure limits for the general population and for situations of uncontrolled exposure. These RF exposure limits apply when the general public may be exposed to radiofrequencies from the device. They also apply when people who are exposed to radiofrequencies from the device don't know about, don't understand, or can't control their exposure.

Conditions for operating, transporting, and storing the Patient Assistant

Operating Conditions

The Patient Assistant is designed to operate in the following conditions:

- Temperatures from 5 to 40°C (41 to 104°F)
- Relative humidity of 15% to 90%, non-condensing, but not requiring water vapor partial pressure greater than 50 hPa
- An atmospheric pressure of 700 to 1060 hPa

Store and use the Patient Assistant within the ranges listed here. If it's exposed to conditions outside these ranges, it may not work until it sits at room temperature for 10 minutes. If you experience a symptom and the Patient Assistant doesn't work, write down your symptom and the time it occurred. Then bring the note with you the next time you visit your doctor or clinic.

Transport and Storage Conditions

The Patient Assistant may not work correctly if it is exposed to heat, humidity, or atmospheric-pressure levels outside the following ranges:

Short-term storage and transport conditions – If the Patient Assistant is exposed to conditions in the following ranges for more than 24 hours, it may stop working entirely:

- Temperatures of -25 to 5°C (-13 to 41°F) at a relative humidity up to 90%, non-condensing
- Temperatures of 35 to 60°C (95 to 140°F)

Long-term storage conditions – The Patient Assistant is designed to be exposed to conditions in the following ranges for up to 2 years while still functioning:

- From 15 to 30°C (59 to 86°F) at a relative humidity up to 90%

Explanation of symbols

Table 2. Explanation of symbols on package labeling






Symbol	Explanation
	Conformité Européenne (European Conformity) This symbol means that the device fully complies with applicable European Union acts.
	For US audiences only
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
	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.
	Type BF applied part. The Patient Assistant is the applied part and the patient is the operator.

Table 2. Explanation of symbols on package labeling (continued)





Symbol	Explanation
	Medical equipment, with respect to electric shock, fire, and mechanical hazards, in accordance with AAMI ES60601- 1:2012, CSA C22.2 No 60601-1:2014, and IEC 60601-1:2012
	This symbol means that the device fully complies with the Australian Communications and Media Authority (ACMA) and the New Zealand Ministry of Economic Development Radio Spectrum Management standards for radio communications products.
	China RoHS
	Technical Conformity (Ministry of Internal Affairs and Communications) mark for Japan
IP22	The product complies with international electrical safety rating IP22 with regard to ingress of dust, other foreign objects, and water, as required by IEC 60601-1-11. This

Table 2. Explanation of symbols on package labeling (continued)


















Symbol	Explanation
	means that the product is protected both against access to hazardous parts with a finger and against vertically falling water drops when the enclosure is tilted up to 15°. The Patient Assistant is moisture resistant but not water-proof.
	Non-ionizing electromagnetic radiation
	Date of manufacture
	Serial number
	Caution
	Consult instructions for use
	Manufacturer
	Temperature limitation

Table 2. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Humidity limitation
	Storage temperature
	Transit temperature
	Package contents
	Product documentation
	Reorder number
	Use by
	Authorized representative in the European community
	Patient Assistant

Medtronic

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