

# Medtronic, Inc. Recalls Dual Chamber Implantable Pulse Generators (IPGs) Due to Possible Circuit Error

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death*

## Recalled Product(s):

- Medtronic, Inc. Dual Chamber Implantable Pulse Generators (IPGs)
- Model Names:
  - Adapta, Versa, Sensia, Relia, Attesta, Sphera, and Vitatron A, E, G, Q series
- Manufacturing Dates: March 2, 2017, to December 18, 2018
- Distribution Dates: March 6, 2017, to January 7, 2019
- Devices Recalled in the U.S.: 13,440

## Device Use

Medtronic's Dual Chamber Implantable Pulse Generators (IPGs) are implanted cardiac pacemakers used to provide stimulation to increase heart rate in patients with a slow heart rhythm (bradycardia) or no heart rhythm. The pulse generator is the small implanted unit containing the battery and other electronic parts. The pulse generator must be used with insulated electrode wires called leads. These devices are designed to be used in addition to routine clinical monitoring by a health care professional.

## Reason for Recall

Medtronic is recalling its dual chamber IPGs due to the possibility of a software error that can result in a lack of pacing. Patients and physicians cannot predict whether and when this software error might occur. A lack of pacing could result in patients experiencing slow heart beating, low blood pressure, and symptoms such as light headedness, fainting, and even death.

## Who May be Affected

- Hospitals and health care professionals using Medtronic's Dual Chamber Implantable Pulse Generators to provide pacing support to treat patients with bradycardia.
- Patients and caregivers of patients receiving pacing support using a Medtronic Dual Chamber Implantable Pulse Generator.

## What to Do

Beginning January 17, 2019, Medtronic's Field Representatives have hand-delivered "Field Corrective Action Notification" letters to implanting and follow-up physicians. The notification provided the following instructions:

### Health Care Providers

- Medtronic recommends programming to a non-susceptible pacing mode as the primary mitigation for patients implanted with an affected device until the software update has been installed.
- Additional patient risk assessment and programming recommendations are included in [Medtronic's advisory letter](http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051) ([http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID\\_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051](http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051)) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>).
- In addition to the field correction notification, Medtronic's Field Representatives will:
  - Hand deliver an additional "Supplemental Letter" alongside an "Urgent Medical Device Recall" letter to physicians with patients whose devices have shown evidence of a pacing pause that may be related to this circuit error.
  - Request physicians return all unused and unopened affected product to Medtronic for replacement.
  - Confirm notifications are received by implanting or follow-up physicians using Medtronic's electronic tracking system in conjunction with confirmation via a paper form.
  - Conduct effectiveness checks to ensure that all identified implanting or follow-up physicians and risk managers have been notified or proof of at least three attempts to notify them is obtained.

### Patients

- Patients remaining in a susceptible mode should seek immediate medical attention if experiencing any new or unexpected symptoms consistent with a pause in pacing.

### Contact Information

Customers who have questions or need additional information regarding this recall may contact Medtronic's Technical Services at 1-800-505-4636.

### Date Recall Initiated

January 17, 2019

### Additional Resources:

- [Medtronic, Inc.: Urgent Medical Device Recall \(January 7, 2019\)](https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/dual-chamber-pacemaker-recall.html) (<https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/dual-chamber-pacemaker-recall.html>)
- [Medtronic, Inc. Advisory: Dual Chamber IPG Circuit Error \(January 7, 2019\)](http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051) ([http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID\\_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051](http://wwwp.medtronic.com/productperformance/document.html;JSESSIONID_productperformance=swpwcCdbQYh222HYT0LvWxp8XKMfLNT02lvZHmphpbRTyvNv4zvRr!1821005720!-1232079971?id=1100051))

### How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(/Safety/MedWatch/HowToReport/ucm2007306.htm\)](/Safety/MedWatch/HowToReport/ucm2007306.htm). Health care professionals employed by facilities that are subject to [FDA's user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm\)](/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

**More in Medical Device Recalls**  
[\(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

[2019 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm629347.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

[2018 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm590900.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

[2017 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

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