Medtronic <vitatron · The Pace Makers >

URGENT FIELD SAFETY NOTICE

Medtronic Model 5348 and Vitatron MEP3000 Single-Chamber External Pulse Generator

Medical Device Recommendations

Medtronic/Vitatron Reference FA612

May 2014

Dear Health Care Professional (physician, Hospital Administrator, OR Manager, and Risk Manager),

Medtronic has identified a performance issue potentially affecting older Medtronic Model 5348 and Vitatron MEP3000 Single-Chamber External Pulse Generators (EPGs) manufactured between July 1995 and December 2007. You are receiving this communication as Medtronic/Vitatron records indicate your facility has received one or more potentially affected 5348 and/or MEP3000 EPGs. This issue does not affect any other Medtronic or Vitatron EPG models or any Medtronic or Vitatron implantable devices.

Issue Description: Through April 16, 2014, Medtronic has determined 49 events (out of approximately 30,000 potentially affected EPGs, or 0.16 percent), were related to a pacing rate outside of the intended setting, including events of sudden increased pacing rate up to the maximum setting of 180 pulses per minute (ppm). Of these 49 events, one was associated with a patient death with no other reports of critical injuries. An additional 85 reports of pacing rate outside of the intended setting have been received that may be related to this issue, but could not be confirmed due to insufficient data.

Root Cause: The root cause of this issue is the development of high resistance on internal electrical connector contacts due to oxidation over time.

Potentially affected Medtronic 5348 and Vitatron MEP3000 EPGs are within the Serial Number Ranges of:

- PEP001001P to PEP050019P and PEP001001K to PEP001714K

Malfunction Indications: Due to the unpredictable nature of the oxidation process on multiple electrical contacts, this issue may result in one or more of the following observations:

- Pacing rate outside of the intended setting, potentially including a sudden increase in pacing rate up to the maximum setting of 180 ppm.
- Output amplitude or sensitivity outside of intended setting.
- Pace, Sense, or Low Battery LED indicators not lighting during power on or reset functions.
- Rapid Atrial Pacing (RAP) display with intermittent functionality.
- Intermittent functionality of the On/Off and RAP control buttons.

Recommended Actions: After consulting with our Independent Physician Quality Panel, Medtronic and Vitatron recommends the following actions be taken when using a potentially affected Model 5348 and/or MEP3000 EPG:

- Monitor the EPG function and patient's heart rhythm continuously while the EPG is in use to ensure it is operating properly and delivering appropriate therapy to the patient.
- If any malfunction is observed with a 5348 and/or MEP3000 EPG, ensure the patient's condition is stabilized, discontinue use of the 5348 and/or MEP3000 EPG and contact your Medtronic /Vitatron representative.

Medtronic or Vitatron will no longer service or repair EPGs that are more than five years old, including these potentially affected 5348 and MEP3000 EPGs; which is consistent with the five-year service life of the new Model 5392 EPG. Medtronic will separately communicate additional details about this new EPG service policy. If you choose to replace your potentially affected 5348 and/or MEP3000 EPG, please contact your Medtronic /Vitatron representative for assistance with purchasing a replacement device.

Medtronic and Vitatron has communicated this information to the appropriate regulatory agencies and is committed to ensuring our products meet the highest quality standards and that our customers are fully supported.

For general questions related to EPG service policy or purchasing a replacement EPG, please contact your Medtronic /Vitatron representative; for technical questions, please call Technical Service.

Please share this notification with others in your organization as appropriate. If product within the scope of this notification has been forwarded to another facility, please alert the facility of this notification.

Sincerely,

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May 2014

Dear Health Care Professional (physician, Hospital Administrator, OR Manager, and Risk Manager),

On April 29, 2014, Medtronic distributed an Urgent Field Safety Notice (attached) to customers, who according to our records **currently possess** one or more specific 5348 and Vitatron MEP3000 External Pulse Generators (EPGs) potentially affected with a performance issue.

You are receiving this important notification because Medtronic is expanding communication to include additional customers who our records indicate purchased a model 5348 EPG from Medtronic and/or Vitatron MEP3000 or EPG Cable Leads. The age of these potentially affected 5348 EPGs ranges from 6 to 19 years old and your facility **may no longer possess, nor ever have possessed** a potentially affected 5348 and Vitatron MEP3000 EPG.

This issue **only applies to** Medtronic model 5348 and Vitatron MEP3000 EPGs with a serial number within the ranges of:

- **PEP001001P to PEP050019P** and
- **PEP001001K to PEP001714K**

Medtronic asks that you immediately initiate the following actions:

- Read the attached Urgent Field Safety Notice in its entirety and ensure that all applicable actions are taken in case of you possess any EPGs in the above serial number ranges.

For questions related to the Urgent Field Safety Notice, please contact your Medtronic/Vitatron representative; for technical questions, please call Technical Service.

Please share this communication within your organization as you deem necessary, which may include BioMedical Engineering.

Sincerely,