Medtronic

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# Urgent: Medical Device Correction

## Single Chamber Temporary External Pacemaker 53401

### All Serial Numbers Distributed February 2017- November 2017

21 June 2018

**Attention: Risk Management Director and O.R Materials Management**
**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Risk Manager or Health Care Professional:

This letter is to advise you of the potential that a subset of Medtronic Model 53401 Single Chamber External Pulse Generators (EPGs) may revert from programmed settings to nominal settings during use with a patient due to an unexpected Power on Reset (POR). Medtronic has received no (0) reports of patient deaths or complications as a result of this issue.

Medtronic records indicate that you have received one or more Medtronic EPGs that are affected by this Urgent Medical Device Correction. Affected devices include Model 53401 EPGs with serial numbers lower than MDB05000 that were distributed between February 2017 and November 2017 (see Appendix A: Serial Number List). This issue does not affect Model 53401 EPGs with serial numbers equal to and above MDB05000, any other Medtronic EPG models, or any Medtronic implantable devices.

**Issue Description**
The initial version of 53401 EPG firmware was configured to allow an unused, unterminated digital input/output pin to be an input. During investigation of this issue, this unterminated pin was found to act as an antenna, which could detect external electrical signals. The 53401 EPG microprocessor expects the unterminated pin to be silent. When this unterminated pin detects electrical signals, device firmware may lock up and cause a POR. When the EPG experiences a POR, by design, the device will cease functioning for approximately 7 seconds while it reboots, then resume functioning at nominal settings.

Medtronic engineers were able to reproduce this unexpected POR behavior in a lab environment outside of normal use conditions by striking the back of the unit, or by rubbing the unit on an article of clothing or other object that can result in static charge.

The estimated rate of occurrence in the field is 0.00075 per use. Through 21 May 2018, there have been seventeen (17) confirmed reports of this issue. Potential patient hazards are: insufficient cardiac output due to inappropriate pacing rate, loss of capture, or pro-arrhythmic pacing. Potential patient harms are: low cardiac output, cardiac arrhythmia, syncope or cardiac arrest. Medtronic has received no (0) reports of patient deaths or complications as a result of this issue.

Patients being treated with affected 53401 EPGs should be continuously monitored per labeled instructions for use.

Recently, Medtronic received FDA clearance for a firmware correction that prevents occurrence of this issue. Medtronic recommends customers send affected devices to Medtronic Service to update the firmware to prevent this issue and provide greater customer satisfaction.

**Customer Actions**
Medtronic recommends customers with 53401 EPG units take the following steps:

1. Verify whether 53401 EPGs in your possession are affected (See Appendix A: Serial Number List).
2. If your EPG is affected, complete the following:
    - Determine if the EPG firmware has been updated.
        - Power unit on and view firmware version (Figure 1 below).
        - If firmware version is 01.03.00 or greater, EPG firmware has been updated with correction for this issue. Continue to Step 3 to confirm that you were informed of the issue. No other action is recommended.

    If firmware version is 01.02.00, EPG firmware has not been updated. You may arrange to have your Medtronic Service Center update the EPG firmware at no charge.

3. Please complete the attached Confirmation Form in its entirety and return it as directed to confirm your receipt and understanding of this information. You must complete this form even if all units in your inventory have the correct firmware version.

During power up process, Firmware Version will be displayed for 2 seconds

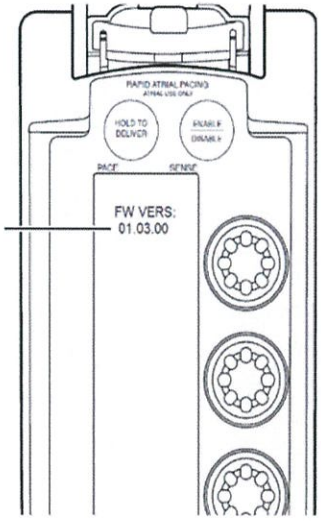


**FIGURE 1- updated firmware displayed in this image**

If you do not request service from Medtronic for this issue, the firmware update will be installed free of charge the next time your device is sent to your Medtronic Service Center. Per labeling, patients being treated with an EPG should be continuously monitored while the EPG is in use.

If you have multiple 53401 EPGs that require a firmware update, consider retaining a unit(s) while others are sent in for service. This will ensure you have devices to use while others are being serviced.

Please pass this notice to all those who need to be aware within your organization, or to any organization where potentially affected devices have been transferred. Please maintain a copy of this notice in your records to reference the firmware version.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic Representative.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

Sincerely,

[redacted]

Diana Teo
Quality System Manager
Medtronic

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# Customer Confirmation Form

## Medical Device Recall – CVG-19-Q1-02

## Single Chamber Temporary External Pacemaker 53401

### All Serial Numbers Distributed February 2017- November 2017

| Customer Contact Details | Medtronic Contact Details |
|---|---|
| Hospital / HCP: | By E-mail: |
| Address: | By Post: |
| Telephone no: | |
| Fax no: | |
| E-mail: | |

Indicate in the columns below all serial numbers you have in your facility and ensure all fields have been filled up

| Serial # of unit | Current Version # |
|---|---|
| | |
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| | |
| | |

**By signing this form, I confirm that I have read the Urgent: Medical Device Recall CVG-19-Q1-02 Single Chamber Temporary External Pacemaker 53401** Letter, dated **21 June 2018** from Medtronic. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____