

Urgent Field Safety Notice

Single Chamber Temporary External Pacemaker 53401

Important Device Information

June 2018

Medtronic reference: FA824

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 records indicate that you have received one or more Medtronic EPGs that are affected by this notification. Affected devices include Model 53401 EPGs with serial numbers lower than MDB05000 that were distributed between February 2017 and November 2017. 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. 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. Through 21 May 2018, there have been seventeen (17) confirmed reports of this issue. No patient deaths or complications have been reported 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 approval 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.

Customer Actions

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

1. Verify whether 53401 EPGs in your possession are affected
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. 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.

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

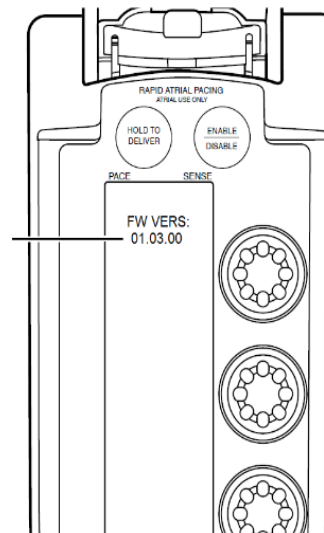


FIGURE 1- updated firmware displayed in this image

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.

This notice must be passed 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.

For questions related to this notice or EPG service, please contact your Medtronic representative.

The Competent Authority of your country has been notified of this action.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. We appreciate your prompt attention to this matter.

Sincerely,
Medtronic Saudi Arabia