Medtronic

Urgent Field Safety Notice

NIM Vital™ Nerve Monitoring System

Notification in relation to Software version 1.3.2

May 2022

Medtronic Reference: FA1247

Dear Physician /Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily initiating a Field Safety Notice for specific production serial numbers of NIM Vital™ (P/N: NIM4CM01 & NIM4CPB1), with Software version 1.3.2, due to the potential for a false positive ground connection when completing the impedance check while an EMG Endotracheal tube is in use. The scope of this action includes only specific serial numbers of the products listed below (reference Table A for additional impacted product information) which have been distributed to your account.

Table A: Affected Product Information

Product Name	Model#	Material#	Serial #(s)
CONSOLE NIM4CM01 NIM 4.0	NIM4CM01	00763000395896 00763000002978	C2026233, C2026354, C2110208,
PATIENT INTERFACE NIM4CPB1 NIM 4.0	NIM4CPB1	00763000002985 00763000395902	P1910402, P1910404, P2026275, P2026329, P2026330, P2026981

Issue Description:

The NIM Vital™ system is an intraoperative EMG monitor that enables users to locate and confirm the integrity of nerves during surgical procedures. The system also has the capability to continuously monitor EMG activity from the muscles innervated by the nerve at risk.

Medtronic has become aware of a use error affecting the NIM Vital™ consoles while an EMG Endotracheal tube is in use. Failure to connect the ground electrode during case setup will incorrectly display a false passing ground impedance /electrode check. However, when proceeding to the monitoring screen the user will see a correct "Lead Off Detected" error message, indicating that one of the necessary electrode connections required for monitoring is not set-up correctly. This "Lead Off Detected" condition prevents the user from proceeding to monitoring until the ground electrode is appropriately connected. Thus, though there is potential for a false positive ground connection, use of the device for monitoring is not possible without the grounding electrode being connected and an actual positive ground connection being obtained. Error messages are in place to prompt the user to recheck all electrode connections.

A software update is currently being prepared for distribution to correct this issue. Upon availability of the software update (to be available within the next 6 months), Medtronic will notify your account and a Medtronic sales representative will work with your facility to apply and document the update of all affected systems.

Risk to Health:

From 01-May-2020 through 03-Mar-2022, Medtronic received 2 complaints worldwide. To date, Medtronic has not received any reports of patient harm attributed to this issue.

The potential risks associated with a ground electrode connection false-positive connection error if identified during surgery are:

- Functionality / Loss of Functionality of the NIM system, which could potentially result in:
  - Additional exposure to anesthesia if the case were to be canceled due to this issue.
  - Additional procedure needed to complete therapy; and
  - Prolonged/delayed surgery time.

Please follow the Instructions for Use regarding the setup and "Lead Off Detected" error message:

1. When using the NIM Vital system, be sure to connect the ground electrode as depicted in the setup instructions. A ground electrode has been provided with each EMG Endotracheal Tube for this purpose.
2. If "Lead Off Detected" is experienced while monitoring, be certain to check all connections, including the ground electrode, both at the patient and the patient interface.

As previously stated, though there is potential for a false positive ground connection, use of the device for monitoring is not possible without the grounding electrode being connected and an actual positive ground connection being obtained.

Transmission of this communication:

Please share this communication within your organization, with other organizations where impacted devices have been transferred, and any other associated organizations that may be impacted by this action. Please maintain a copy of this letter for your records.

Medtronic has notified the Competent Authority of your country of this action.

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

Sincerely,

Local / OU Manager