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Urgent Field Safety Notice

Warning and Service

Warning Lamp Connectors & Chiller
Model 506A0107 / 506A0297 / 506A0298 / 506A0187 /506A0186

27 June 2016

Medtronic reference: FA725

Dear OR / Risk Manager,

This notification is to inform you of a voluntary Field Corrective Action Medtronic Navigation, Inc. is initiating related to a potential risk for Warning Lamp Connectors and/or Chiller grounding discontinuity. Our records indicate that your facility possesses a system with affected devices.

Details on affected devices

The part numbers included in this corrective action are as follows:

Affected Part Number:	506A0107 - Warning Lamps Control box 506A0297/506A0298/506A0187 /506A0186 - Chiller

Description of the issue

The Warning Lamp Box is an accessory to the PoleStar system and responsible for controlling the PoleStar warning lamps. The warning lamps are located outside the OR usually above the entrance door. The lamps provide two warning indications: One for PoleStar magnet out of the MSC, and the other is for PoleStar Scan in-progress. The Warning Lamp Control box unit is located in the PoleStar equipment room.

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The Chiller is an off the shelf product, accessory to the PoleStar system, and its function is to cool the gradient boards of the PoleStar system. The chiller is located in the equipment room outside of the operating room.

Recently Medtronic has identified during In-house testing a potential ground discontinuity in these sub-assemblies, leading to potential risk of User electrical shock upon direct contact with these sub-assemblies. The risk assessment conducted concluded that the risk of User electrical shock is low; In addition the system residual risk levels did not change and remain acceptable.

Our Risk evaluation determined there is no change in risk to the patient since the assemblies are located outside the OR.

Medtronic has taken prompt action to analyze and correct this issue and will perform inspection on site to verify and correct the grounding connection on your PoleStar system.

Transmission of the described information

Please ensure that all users of the above mentioned devices and all other persons who should be informed within your organization are aware of this urgent Field Safety Notice. If you delivered the devices to a third party, please forward also a copy of this information or inform the below mentioned contacts. Please retain this information at least as long as this action is closed.

The Bundesinstitut für Arzneimittel und Medizinprodukte has received a copy of this urgent Field Safety Notice.

We regret any inconvenience this action may cause. If you have questions regarding this action please contact your Medtronic representative or Daniel Essig under phone 0173 9213004.

Sincerely
Medtronic GmbH

Sales Manager
Navigation, Bildgebung und NIM Eclipse

Sr. Manager Regulatory & Quality