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Urgent Field Safety Notice

Subject: Real-time Image Display During Fluoroscopic Use of the O-ARM® Imaging System
Part # 9732719, 9733346, BI-700-00027-100, BI-700-00027-120, BI-700-00027-230

May 2010

Medtronic Reference: FA459

Dear O-ARM® Imaging System User,

Medtronic Navigation has identified a potential product problem with the O-ARM® Imaging System that has the ability to affect the real time image display which if not detected could in rare instances result in a frozen image being displayed during use of 2D continuous fluoroscopy.

Issue Description:

A faulty component connection that handles the image data transmission between the O-ARM® Imaging System stand and the Mobile Viewing Station during use of 2D continuous fluoroscopy has the potential to cause the real time image display to refresh at a rate that is slower than the specified 30 frames per second.

Action Requested:

While Medtronic Navigation remains confident in the reliability of your system we recommend that users of the O-arm Imaging System review the following information in order to ensure patient safety remains uncompromised during the use of the O-arm Imaging System:

- When utilizing 2D continuous fluoroscopy, please take note of the image quality as degradation may indicate a reduction in image update rate. When in question please validate that the system is performing correctly and is displaying the most current image by placing a high contrast object such as a surgical clamp in the beam.

- Procedures that require real time image feedback through continuous 2D fluoroscopy, such as vertebroplasty or kyphoplasty, should strictly adhere to any procedural treatment guidelines. The procedure should be conducted with an object in the field that will provide live feedback to the user.

- If the image is not updating as expected please discontinue use and contact your local Medtronic Navigation representative at (insert contact info).

- Please note that procedures that are performed under Image Guidance and do not require visual reliance on continuous 2D fluoroscopy, such as spinal fixation surgery are not affected by this issue.

Medtronic Navigation is committed to providing the greatest possible reliability and quality in our products. As such, a Medtronic Representative will be contacting you within the coming months to schedule a time to evaluate and service the potentially affected components within your system. A service visit will also be scheduled starting in November 2010 to update your system with a software based solution that will prevent this issue from occurring.

If you have any questions about this notification, please contact your local Medtronic Navigation representative at (insert contact info).

Sincerely,