



## **URGENT FIELD SAFETY NOTICE**

**Medtronic Navigation StealthStation<sup>®</sup> S7 and i7 Systems and Planning Station  
containing FrameLink Software Version 5.4**

### **Software Update**

12 July 2013

Medtronic reference: **FA585**

Dear Healthcare Professional (Hospital Administrator, OR Manager and Risk Manager),

This notification is to inform you of a voluntary Field Corrective Action Medtronic Navigation, Inc. is initiating related to the FrameLink software version 5.4 when running on a Medtronic StealthStation<sup>®</sup> S7 or i7 system or a Medtronic Planning Station. Our records indicate that your facility possesses one or more systems with FrameLink software version 5.4 covered by this corrective action.

#### **Details on affected devices:**

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

- Part Number 9734047 FrameLink S7 Applications Kit
- Part Number 9734066 FrameLink S7 Planning Station Kit
- Part Number 9733986 FrameLink Application Software

As noted above, FrameLink software version 5.4 can be used on Medtronic Navigation StealthStation<sup>®</sup> S7 and i7 systems or a Medtronic Planning Station. This corrective action covers only version 5.4 of this software. Earlier versions of the FrameLink software are not included in this action.

#### **Description of the problem:**

Medtronic Navigation, Inc. has identified that the use of high resolution exams (greater than 256 x 256) under certain use conditions may cause the Look-Ahead view labels to show user selected depths (displayed), but the corresponding images are shown at a depth twice the selected distance. Under these conditions, visualization of the planned trajectory could show the image at the incorrect depth. Medtronic Navigation, Inc. has received three customer reports related to this issue. None of the reports cited any patient injuries or adverse events.

Further internal investigation of similar or related views discovered that the use of high resolution exams (greater than 256 x 256) under certain use conditions may cause a similar discrepancy between the exam image and the displayed measurement or overlay. There have been no reported complaints or adverse events related to these additional views from the field.



**Medtronic**

Medtronic has taken prompt action to correct this issue and recommends the user take the action described below.

**Recommendations on action to be taken by the user:**

The FrameLink software version 5.4 has been revised to correct the software anomalies described in this letter. A new version will be installed on your system(s) by a Medtronic Navigation representative. **Until the software upgrade has been installed on your system, do not use high resolution examinations (greater than 256 x 256).** If you are not sure of the exam resolution being used, we recommend contacting your imaging department or your local Medtronic Navigation representative for assistance.

**Transmission of this Field Safety Notice:**

Please refer this Field Safety Notice to all those within your facility that use the StealthStation<sup>®</sup> S7 and i7 systems or Medtronic Planning Stations with FrameLink software version 5.4 for procedures. Please maintain awareness on this notice until a Medtronic Navigation representative has upgraded your software to the corrected version.

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

Medtronic Navigation has an ongoing commitment and interest in promoting better healthcare and patient outcomes by keeping you apprised of information related to our devices and associated therapies.

**Contact details:**

If you have any questions regarding this action, please contact your Medtronic Sales Representative at <XXXXXX>.

Sincerely,

Country/BU Manager