

## **URGENT FIELD SAFETY NOTICE**

### **Information about the recommended set up of the RAPID C-Spine Coil**

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**Dear customer ,**

This document contains important information for the continued safe and proper use of the MRI system: OASIS.

**Details of Affected Devices :**

Product Name : OASIS

**Description of problem :**

Hitachi had discovered that under rare circumstances, the balun attached the RAPID C-Spine coil cable can be overheated. Although there is no the suffering health harm at that time, it is possible to suffer the health harm depending on the degree of the heating surface temperature on balun cover.

Hitachi will be implementing a corrective action to replace the RAPID C-Spine Coil cable balun with an improved version.

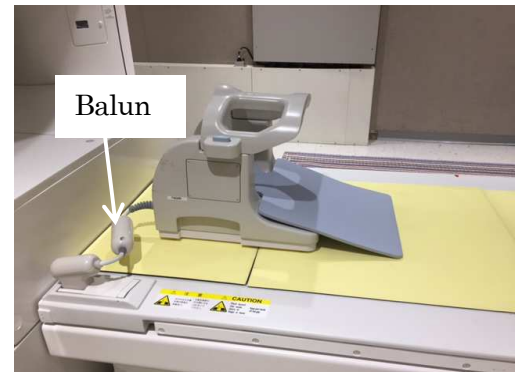


Fig.1 Balun of the RAPID C-Spine coil

**Advise on action to be taken by the users:**

Until such time that the corrective action can be performed at your facility, we ask that you connect the Coil Extension Cable for all exams using the RAPID C-Spine Coil. See Fig.2 for the recommended set up of the coil and extension cable on the OASIS patient table. All in the Coil Extension Cable Guide remains applicable.

Hitachi expects to begin replacing the coil cable baluns in the first quarter of 2017. Hitachi Service will contact you when the new baluns are available to schedule the corrective action at your facility.

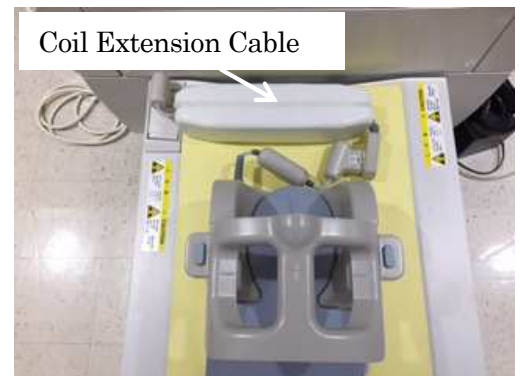


Fig.2 Recommended set up

**Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

**Geographic Distribution :**

**USA , Japan , Italy**

**Contact reference person:**

Please find your local contact person on the cover letter of our local sales organization to this "Urgent Field Safety Notice".

We confirm that this item has been reported to the responsible National Competent Authority.

Yours sincerely  
Hitachi, Ltd.