

Date:

Ref: COM-0000001204

Contact Name:**E-mail:****Job Title:****Hospital Address:**

FIELD SAFETY NOTICE
Correction to Superconducting MRI Systems

Dear Customer,

Thank you for using a Canon Medical Systems superconducting MRI system.

The purpose of this letter is to bring to your attention the following problem:

There was an incident in which smoke was generated and fire occurred behind the front covers of the gantry of a Vantage Galan 3T MRT-3020 system installed in Japan. The cause of this incident has been determined to be the disconnection of the power cable within the system. We have already started replacement work for 3T systems. In addition, for 1.5T systems, we will perform safety inspections and replace the power cable securing parts of potentially affected systems with parts made of materials with a higher degree of flame retardance in order to prevent ignition due to arcing in the event of power cable disconnection.

We sincerely apologize for any concern or inconvenience this may cause you and appreciate your kind understanding and cooperation.

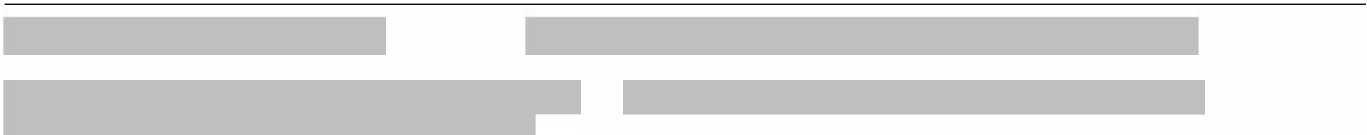
Affected systems/Model

- (1) MRI system Vantage Orian MRT-1550
- (2) MRI system Vantage Elan MRT-2020
- (3) MRI system Vantage Titan MRT-1504

Description of the Problem:

It has been determined that the terminal block used to secure the power supply cable for the gradient coil of the MRI system was not secured as designed. Because of this, the cable became disconnected, and arcing occurred. Melting of the cable due to this arcing caused the cable securing parts below it to ignite, resulting in a fire at the terminal block.

It has been discovered that steps to confirm secure fixing of the terminal block in question were



not part of the quality control process, from manufacturing of the terminal block at the contracted manufacturer to our pre-shipment testing.

Note that there are no reports of health hazards related to this incident.

ACTION: We recommend the following actions

Information concerning the replacement work will be provided promptly by your service representative. If any abnormalities such as unusual smells or smoke are observed before the work, immediately stop using the system and contact your service representative.

Actions Being Taken by Canon

In addition to strengthening quality control processes to prevent reoccurrence, we will perform safety inspections for delivered systems and replace the power cable securing parts that may cause smoke and fire with parts made of materials with a higher degree of flame retardance.

Device Vigilance

FSCA information has been shared with the related Authorities. FSN letters are shared with the related customers to warn about required actions to be taken.

Transmission of the Field Safety Notice

It is strongly requested that you share the contents of this letter with all users and review radiologists as well as clinical engineering or biomedical groups at your facility.

If you have any questions regarding this matter, please contact your service representative.

Confirmation of receipt

Please return the "User Reply Form" on the last page to Canon, either by fax, email or reply paid envelope.

Further information

Should you have further questions, please do not hesitate to contact our service and/or QA&RA department. Details you will find below.

Canon Medical Systems Europe B.V.





CANON MEDICAL SYSTEMS EUROPE B.V.

Made For life

Thank you for your understanding and attention to this matter.

Yours sincerely,
For Canon Medical Systems Europe

[Redacted signature]

[Redacted footer text]

USER REPLY FORM

Subject: Correction to Superconducting MRI Systems

Ref: COM-0000001204

Affected Systems:

- (1) MRI system Vantage Orian MRT-1550
- (2) MRI system Vantage Elan MRT-2020
- (3) MRI system Vantage Titan MRT-1504

Serial number(s): _____

Facility: _____

Contact Information: _____

Name: _____

Title: _____

Telephone Number: _____ **Fax Number:** _____

Were the instructions contained in the "**ACTION: We recommend to take the following actions:**" section of the attached letter understood?

- Yes No

If "No", please explain:

Was the information shared with all your staff? Yes No

If "No", please explain:

Signature: _____

Date: _____

