CANON MEDICAL SYSTEMS EUROPE B.V.

Made For life

[redacted]
Ref: COM-0000000994

[redacted]

FIELD SAFETY NOTICE

REQUESTS FOR THE USE OF SUPERCONDUCTING MRI SYSTEM

Dear Customer,

Thank you for using a Canon Medical Systems superconducting MRI system.
With regard to the systems listed below, an incident in which fire and smoke generation occurred behind the front covers of the gantry was reported in a system (Vantage Galan 3T system MRT-3020) installed at a site in Japan. Detailed investigations are currently being conducted to identify the cause of this incident. In addition, to ensure safety, emergency inspections will be performed for all applicable systems. Systems using the same components as the applicable systems will also be included in the scope of these inspections.

Inspection of the system(s) installed at your institution will be scheduled immediately. In addition, we are issuing this document to inform you of the actions that should be taken if a similar incident occurs before inspection. Please read this document carefully and share the information with all relevant staff members at your institution.
We sincerely apologize for any concern or inconvenience this may cause you and very much appreciate your kind understanding and cooperation.

Affected systems/Model

- MRI system Vantage Galan 3T MRT-3020
- MRI system Vantage Centurian MRT-3020
- MRI system Vantage Titan 3T MRT-3010

The impacted serial numbers in your country is/are:

System model name	S/N	Country

Description of the Problem:
An error occurred during scanning. The operator heard abnormal sounds and entered the scan room. The operator smelled smoke and evacuated the patient to a safe place. Fire inside the system was visible through a gap in the system covers, and the emergency run down switch was pressed to de-energize the magnet. The operator extinguished the fire and called the fire department.
This incident did not result in the spread of fire or any personal injuries.

ACTION: We recommend to the following actions
Information concerning emergency inspection will be provided promptly by your service representative. If any unusual smell or smoke generation is observed before inspection, immediately stop using the system and contact your service representative.
For the precautions that should be observed if an error occurs during scanning, excerpts from the safety manual are provided in the **APPENDIX** section below. Read these precautions carefully and operate the system with special care.
Please keep this document together with the operation manuals.
If you have any questions regarding this matter, please contact your service representative.

APPENDIX
[Actions to be taken in the event of an emergency (excerpted from the safety manual)]

The safety manual describes the actions to be taken in the event of an emergency.
The relevant sections excerpted from the manual are provided below. Please read them carefully and operate the system with special care.

Electrical Fire

⚠WARNING	**Be sure to confirm that the correct type of fire extinguisher is available in every room in which electrical or electronic equipment is used. Be sure to use a fire extinguisher that has been specially approved for use on electrical fires, in accordance with the applicable local codes. The use of the wrong type of fire extinguisher can cause electric shocks or spread the fire.**

Emergencies requiring the Emergency Run Down switch to be pressed and actions to be taken

Emergencies requiring the Emergency Run Down switch to be pressed and the corresponding actions to be taken are outlined below.

(1) When a person wearing ferromagnetic material or a ferromagnetic object is seized by the gantry and cannot be separated

If an attempt is made to separate a person or an object forcibly from the magnet in the presence of the intense magnetic field, the injury or damage may become more serious as a result of the torque due to the magnetic field.

Before forcing a quench of the magnet by pressing the Emergency Run Down switch, prepare a support strong enough to support the load of the person or object when the attractive force is lost due to loss of the magnetic field.

(2) When a serious emergency or disaster (i.e., fire, earthquake, or flood) is imminent or has occurred and you consider a forced quench of the magnet to be the best way to prevent the damage from spreading.

⚠CAUTION

1. **Do not use the Emergency Run Down switch in cases other than emergencies. If the Emergency Run Down switch has been operated, immediately contact your service representative. Service work (replacement of the rupture disk, refilling of liquid helium, reenergization of the magnet) must be performed by the service engineer.**
2. **A battery is provided for the Emergency Run Down switch to supply power to the switch even in the case of power failure. Do not remove the battery from the Emergency Run Down switch. If the battery is removed, the Emergency Run Down switch will not operate in the event of a power failure.**
3. **Do not open the cover panel of the Emergency Run Down switch. Replacement of the internal parts can only be performed by authorized service personnel.**

System recovery

To use the system after the Emergency Run Down switch has been activated, special work must be done by service personnel. Contact your Canon Medical Systems representative.

Earthquake, Fire, or Flood

If an earthquake, fire, or flood occurs, remove the patient from the scan room to a safe place by following the procedure below.

(1) If an earthquake, fire, or flood occurs during scanning, stop scanning immediately.
(To stop scanning, press the ABORT button on the control pad or on the gantry operating panel or click the ABORT button on the sequence queue window.)

(2) Press the Emergency button.

When the Emergency button is pressed, the power supply to the gantry and the patient couch systems is immediately turned and the gradient power supply is set to stand-by mode. The magnet, the refrigerator, and the heat exchanger remain ON.

Emergency buttons are provided on the control box and gantry operating panel.

NOTE The Emergency button should be pressed only when the abnormal situation may continue to become more serious (earthquake, fire, flood, etc.) if power is supplied continuously to the system. After the Emergency button has been pressed, a period of approximately 10 to 20 minutes is required before the system is restarted. For the system resetting procedure, refer to "System recovery" (see below).

(3) Pull the emergency brake-release lever of the patient couch. The electromagnetic brake of the couchtop is released, allowing the couchtop to be pulled out manually.

(4) Manually pull out the couchtop from the magnet bore.

⚠CAUTION	**When removing the couchtop from the magnet bore, ensure that the patient's body does not come into contact with the system (in particular, the connector ports for RF coils and the side edges of the couchtop). Abrupt removal of the couchtop from the magnet bore can injure the patient's fingers, elbows, etc.**

(5) Remove the RF coil and the patient fixing bands from the patient.

(6) Move the patient from the scan room to a safe place.

(7) If there is a possibility of the magnet being damaged, quench the magnet by pressing the Emergency Run Down switch.

System recovery

Figure 1. Front of the control box

To recover the system after pressing an Emergency button, follow the procedure below. It takes about 15 minutes to start the system.

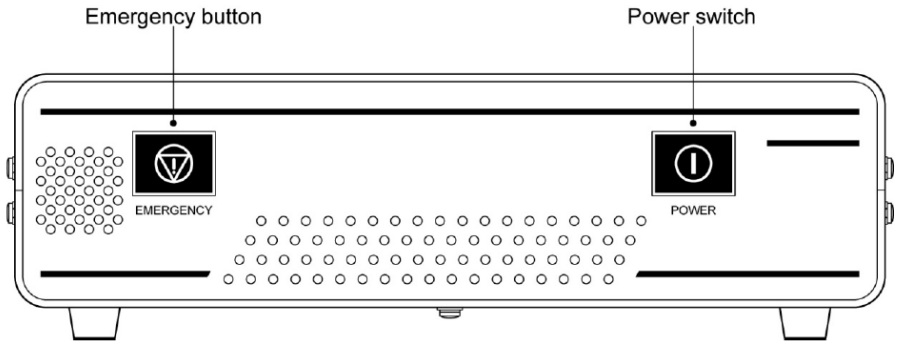
(1) Set the couchtop to the outermost position.

(2) Shut down the system.

(3) After the LED of the power switch on the control box goes out, set the power switch to OFF.

(4) Wait for approximately 30 seconds.

(5) Press the POWER switch (to ON). The system is started up.

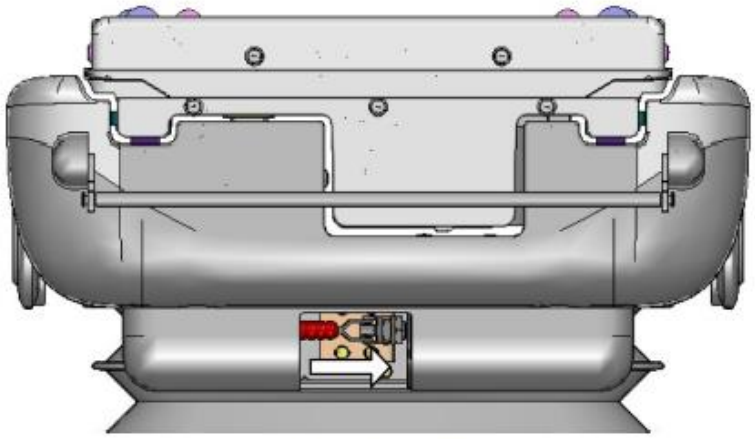


Procedure for extracting the patient from the gantry after the EMERGENCY button has been pressed

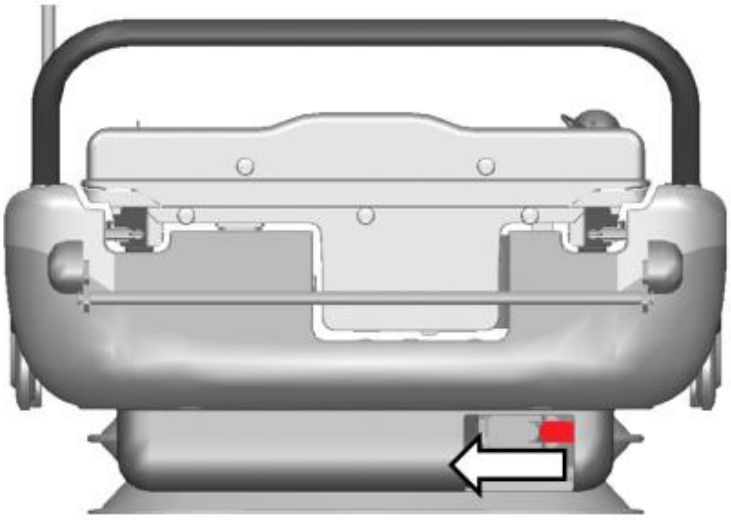
The brake release lever differs depending on the patient couch type. Operate the lever as shown in the figures below.

A)

1. Slide and open the cover on the rear of the couch.
2. Pull the red brake release lever on the rear of the couch.



Fixed couch



Dockable couch

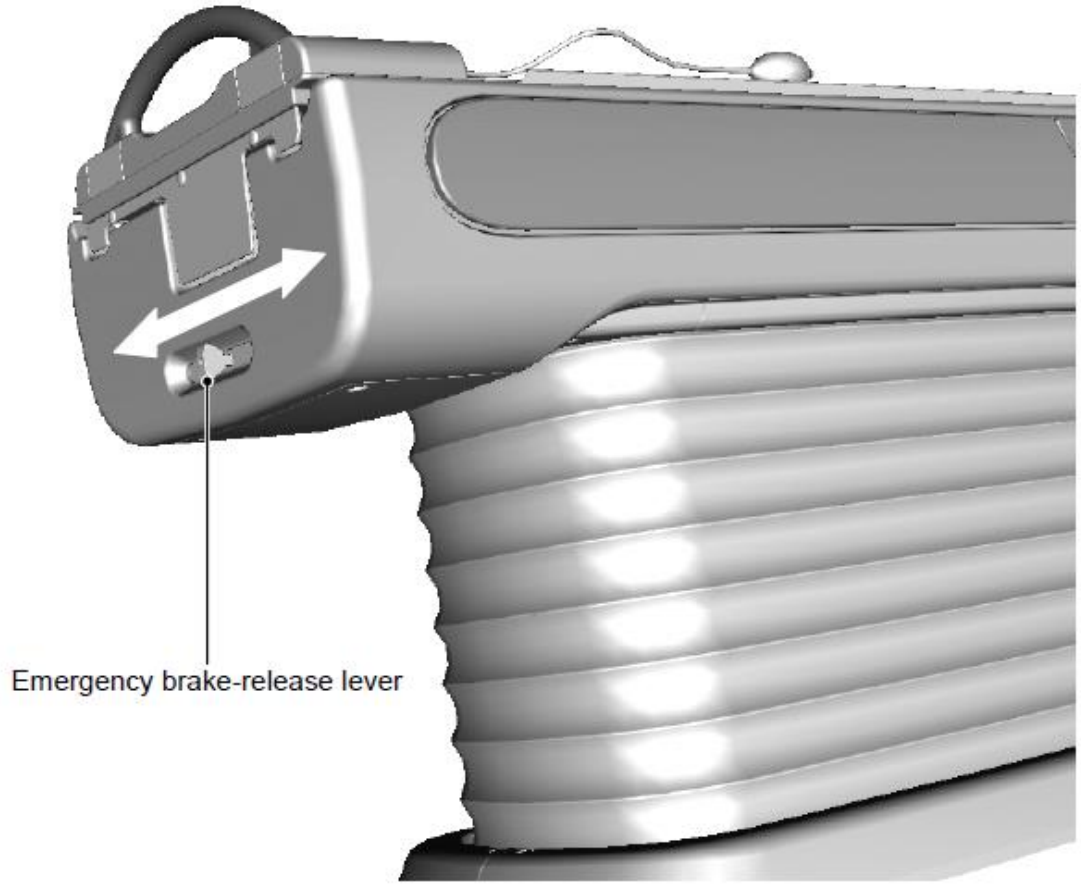
3. Make sure that the patient and any devices (needles, tubes, etc.) attached to the patient will not interfere with the surroundings, and then pull out the couchtop manually.
4. Return the brake release lever to its original position.

B)

(a) Tilt the emergency brake-release lever on the rear end of the couch to the right or left.

(b) Make sure that the patient and any devices (needles, tubes, etc.) attached to the patient will not interfere with the surroundings and then pull out the couchtop manually.

(c) Return the emergency brake-release lever to its original position.



Actions Being Taken by Canon

To ensure safety, emergency inspections will be performed for all applicable systems. Systems using the same components as the applicable systems will also be included in the scope of these inspections. Inspection of the system(s) installed at your institution will be scheduled immediately.

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, staff as well as clinical engineering or biomedical group 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.

[redacted]

EU.vigilance@eu.medical.canon

Thank you for your understanding and attention to this matter.

Yours sincerely,
For Canon Medical Systems Europe

[redacted]

Director of Regulatory Affairs and Quality Assurance

CANON MEDICAL SYSTEMS EUROPE B.V.

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USER REPLY FORM

Subject: REQUESTS FOR THE USE OF SUPERCONDUCTING MRI SYSTEM

Ref: COM-0000000994

Affected Systems:

- MRI system Vantage Galan 3T MRT-3020
- MRI system Vantage Centurian MRT-3020
- MRI system Vantage Titan 3T MRT-3010

Serial numbers:_____

Facility: _____

Contact Information:_____

Name:_____

Title:_____

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

Were the instruction 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 your staff? ☐ Yes ☐ No

If "No", please explain:

_____

_____

Signature:_____

Date:_____