

Siemens Shenzhen Magnetic Resonance Ltd., SHS DI MR QT,
Siemens MRI Center, Gaoxin C. Ave., 2nd Hi-Tech Industrial Park, 518057 Shenzhen

To selected users of following Siemens Healthineers
systems:

See Attachment 1

Name	Li, Hai Ting
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Date	August 12, 2025

Customer Safety Advisory Notice MR041/25/S

CUSTOMER SAFETY ADVISORY NOTICE

Inspection of Magnet Venting System

Dear Customer,

This letter is to inform you of a potential safety issue associated with the magnet venting paths of your 3 Tesla MRI system. To address this, an inspection will be carried out by our Customer Service Organization to prevent a possible hazard to patients, operators, or other persons.

What is the problem and when does it occur?

Potential error: an ice blockage may exist within the magnet venting system.

In the event of a quench, helium gas may be unable to escape through the designed vent paths, leading to a pressure build-up within the helium containment system. This pressure build-up could ultimately rupture the helium containment system, potentially resulting in a helium leak into the scanning room.

What are the possible risks to health?

In the event of a magnet quench combined with a complete ice blockage of the designed vent paths, vaporized helium gas could leak into the scanning room.

This poses a potential risk of asphyxiation to any person present in the scanning room. Furthermore, the sudden release of helium gas may cause cold burns and/or damage to persons or equipment.

Based on our internal investigation, you can continue to use your system until the inspection has been performed.

How was the subject identified?

Siemens Healthineers became aware of this issue during post-market surveillance.

What steps can the user take to avoid the possible risks associated with this issue?

This issue can only be identified by qualified personnel from our service organization. To help mitigate any potential risks please ensure the following:

Siemens Shenzhen Magnetic Resonance Ltd.

Gaoxin C. Ave., 2nd Hi-Tech Industrial Park, Tel.: (+86)755-26525421
518057 Shenzhen
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- If the error message shown in **Figure 1** appears on your host computer, **do not reboot the system**. Please call your local Siemens Healthineers service organization.

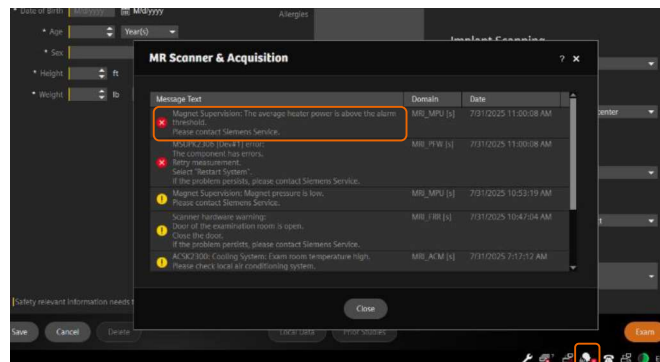


Figure 1 - Error message: "Magnet Supervision: The average heater power is above the alarm threshold. Please contact Siemens Healthineers Service."

- Grant access to the system so that the inspection can be carried out as directed by Siemens Healthineers service organization.

How will the issue finally be resolved?

Siemens Healthineers is preparing an inspection and, if necessary, a correction that will resolve this potential issue. The inspection MR042/25/S is planned to be available from August 2025.

Our service organization will contact you shortly to arrange a date to perform this inspection and, if necessary, a corrective action. Please feel free to contact your local service organization for an earlier appointment.

Dissemination of the content of this notice

Please ensure that your organization and others who may need to be informed receive the safety-relevant information provided within this notice and comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product-related records appropriately. Please keep this information at least until the measures have been completed.

Acknowledgment of Receipt of this Safety Advisory Notice

Please fill out the attached Acknowledgment of Receipt and follow the instructions for sending it back to Siemens Healthineers.

What if the affected product is no longer on site?

If this equipment is no longer in your possession, please forward this Safety Advisory Notice to the new owner of this equipment. If applicable, please inform us about the new owner of the equipment.

The relevant National Competent Authority will be informed of this notice.

We regret any inconvenience that this may cause and thank you in advance for your understanding.

Sincerely yours,
Siemens Shenzhen Magnetic Resonance Ltd.



*Electronically signed by: TIANSHI Ma
Reason: I am approving this document
Date: Aug 12, 2025 20:54:35 GMT+8*

Ma, Tian shi
General Manager
Siemens Shenzhen Magnetic Resonance Ltd.
Shenzhen

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*Electronically signed by: Hai Ting Li
Reason: I am approving this document
Date: Aug 12, 2025 18:26:20 GMT+8*

Li, Hai Ting
Head of Quality
Siemens Shenzhen Magnetic Resonance Ltd.
Shenzhen

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Attachment 1

Product Name	Material Number	UDI-DI
MAGNETOM Spectra	10655588	04056869006796
	10837643	04056869006802
MAGNETOM Vida	11647171	04056869297323
MAGNETOM Lumina	11647172	04056869297330
MAGNETOM Cima.X	11689617	04056869996516
MAGNETOM Seara	11570500	04056869975412

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