

Siemens Healthineers AG, SHS DI MR QT, Allee am Roethelheimpark 2, 91052 Erlangen

To selected users of following Siemens Healthineers systems:

See Attachment 1

Name Joerg Teiche
Department SHS DI MR QT

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Date August 11, 2025

Customer Safety Advisory Notice MR040/25/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 Healthineers AG

Chairman of the Supervisory Board: Ralf P. Thomas;
Managing Board: Bernhard Montag, President and Chief Executive Officer;
Members of the Managing Board: Darleen Caron, Jochen Schmitz,
Elisabeth Staudinger-Leibrecht

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Germany

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Registered office: Munich, Germany; Commercial Registry: Munich, HRB 237558;
WEEE-Reg.-No. DE 64872105

- 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.

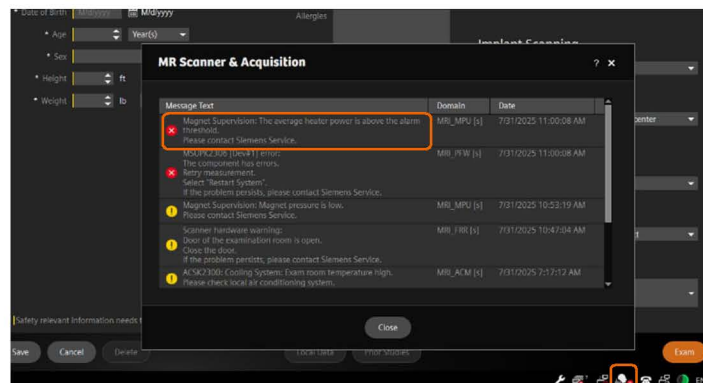


Figure 1 - Error message: “Magnet Supervision: The average heater power is above the alarm threshold. Please contact Siemens Healthineers Service.”

- 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.

To the extent Siemens Healthcare GmbH products are affected, this Customer Safety Advisory Notice is made in the name of and on behalf of Siemens Healthcare GmbH.

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

Sincerely yours,
Siemens Healthineers AG

*Electronically signed
by: Andreas Schneck
Reason: I am
approving this
document
Date: Aug 12, 2025
02:25:51 GMT+2*

Andreas Schneck
Executive Vice President Magnetic Resonance
Magnetic Resonance
Siemens Healthineers AG
Erlangen
Germany

*Electronically signed
by: Sven Oliver
Groezinger
Reason: signed on
behalf of Jörg Teiche
Date: Aug 11, 2025
15:53:48 GMT+2*

Joerg Teiche
Vice President Quality Management
Magnetic Resonance
Siemens Healthineers AG
Erlangen
Germany

Attachment 1

Product Name	Material Number	UDI-DI
MAGNETOM Verio	10276755	n.a.
MAGNETOM Skyra (DE)	10432915	04056869006703
Biograph mMR	10433372	04056869006741
MAGNETOM Verio Dot	10684333	04056869006673
MAGNETOM Prisma	10849582	04056869006727
MAGNETOM Skyra fit	10849580	04056869006710
MAGNETOM Verio Dot Upgr.	10684334	04056869006680
MAGNETOM Vida (DE)	11060815	04056869039176
MAGNETOM Skyra (CN)	11410327	04056869227139
MAGNETOM Lumina (DE)	11344916	04056869230740
MAGNETOM Vida Fit	11410481	04056869245188
MAGNETOM Vida (CN)	11516152	04056869260143
MAGNETOM Lumina (CN)	11516153	04056869260136
MAGNETOM Skyra Fit BioMatrix	11516217	04056869299273
MAGNETOM Cima.X Upgr. (DE)	11689304	04056869975245
MAGNETOM Cima.X (DE)	11647158	04056869975221
MAGNETOM Connectom.X	11371480	n.a.
BIOGRAPH One (DE)	11689172	04068151020472
MAGNETOM Cima.X Fit	11647159	04056869975238
MAGNETOM Cima.X (CN)	11689616	04056869996509