Siemens Healthcare GmbH, SHS DI MR QT, Henkestr. 127, 91052 Erlangen, Germany

To all users of SIEMENS MAGNETOM Flow.Neo

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Customer Safety Advisory Notice MR056/25/S

CUSTOMER SAFETY ADVISORY NOTICE

Re: MAGNETOM Flow.Neo, UDI 04056869299594 and material number 11569839(ex-factory), UDI 04068151047943 and material number 11878344(upgrade) with Background recons e.g. COMPRESSED SENSING GRASP-VIBE, Compressed Sensing VIBE can sporadically lead to rescan with additional contrast media application

Dear Customer,

This letter is to inform you of an (potential) issue associated with the following product(s): using the background recons e.g. COMPRESSED SENSING GRASP-VIBE, Compressed Sensing VIBE of the MAGNETOM Flow.Neo with following serial numbers 256601, 229901, 256602, 229903, 229902 and 229906.

What is the problem and when does it occur?

A potential corruption of raw data has been identified. This sporadic event can occur when reconstruction algorithms that require high data rates (e.g. Compressed Sensing, EPI) are preceded by computationally intensive program steps.
In the event of a data corruption, the acquired raw data cannot be used for the final image reconstruction and the acquisition needs to be repeated. In the context of applications that utilize contrast media, e.g., Compressed Sensing GRASP-VIBE or Compressed Sensing VIBE, a rescan could result in the need of an additional dose of contrast agent.

What are the possible risks to health?

Missing images (as a result of corrupt data) may require a rescan. If contrast agent was administered, then an additional contrast media application could be required as well.

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

Avoid scanning with contrast media application especially involving background reconstructions e.g. COMPRESSED SENSING GRASP-VIBE and Compressed Sensing VIBE.

How will the issue finally be resolved?

Siemens Healthineers has resolved this issue. Roll out of resolution will be done via software update MR057/25/P. All affected systems will be updated by the end of August 2025.

Based on our investigation you can continue to use your system/device.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will 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 finalized.

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

Signature: *Electronically signed by: Sven Oliver Groezinger
Reason: i.V.
Date: Aug 11. 2025 14:08:47 GMT+2*

Email: svenoliver.groezinger@siemens-healthineers.com

Sven Grözinger
Head of QT Project, Processes & Strategy
Magnetic Resonance

Signature: *Electronically signed by: Friederike Hertle
Reason: i.V.
Date: Aug 11. 2025 14:12:06 GMT+2*

Email: friederike.hertle@siemens-healthineers.com

Friederike Hertle
Head of Regulatory Affairs
Magnetic Resonance