

To affected users of Siemens Healthineers
MAGNETOM
 Free.Max/Free.Star/Amira/Sempra/Mica/Spectra

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Customer Safety Advisory Notice MR078/23/S

SAFETY ADVISORY NOTICE

Customer Information about possible artifacts from over-ear headphones during head examinations

Dear Customer,

This letter is to inform you about potential dot- or line-shaped artifacts caused by the presence of lubricating grease within the headband of the over-ear headphones listed below when used during head examinations with the MAGNETOM MRI systems listed in Table 1:

Name of the product	Siemens Model Number	Affected Headphones Serial Numbers
Over-ear headphones	11060845	7981 to 32200

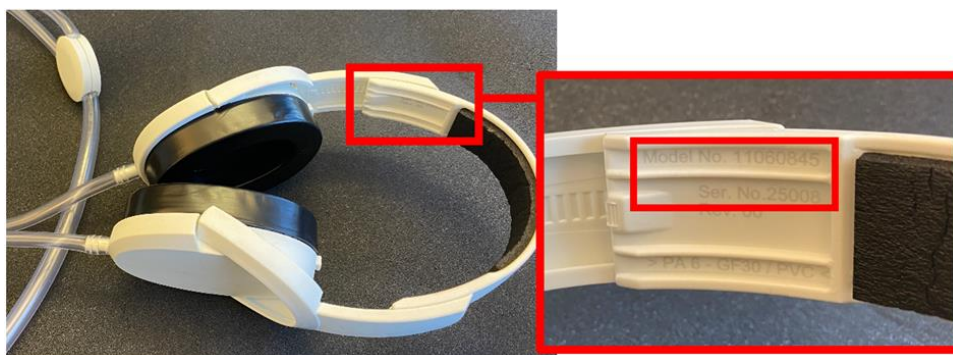


Figure 1: Location of model number and serial number on over-ear headphones

Table 1: List of systems

MAGNETOM Amira	MAGNETOM Free.Star	MAGNETOM Sempra
MAGNETOM Free.Max	MAGNETOM Mica	MAGNETOM Spectra

What is the problem and when does it occur?

In some cases, when lubricating grease is present within the headband of the over-ear headphones, it may cause visible, dot- or line-shaped, fat-isointense artifacts during **head examinations only**. These potential artifacts depend on the position of the headband, the amount of lubricating grease, as well as the sequence parameters used. This issue does not impact scans of other body regions.

In rare cases, when clumps of lubricating grease are present within the headband in combination with the use of T1-weighted sequences and high acquisition acceleration (e.g., PAT acceleration factor of 2 or more) the artifacts may fold in and be visible as dot or line shaped hyperintensities inside the skull anatomy. The following sequences are prone to the described behaviour:

- T1w SPACE sequences with non-selective excitation and total acceleration factor of 4 or more
- T1w MPRAGE with a total acceleration factor of 2 or more
- T1w VIBE with a total acceleration factor of 2 or more
- T1w TSE with transversal orientation and total acceleration factor of 3 or more

What is the impact to operation of the system and what are the possible risks?

The location of the folded in artifact depends on the positioning of the headphones and the sequence parameters (FOV, PAT, phase encoding direction / readout direction) used. Therefore, the hyperintensity can easily be validated as an artifact with the usage of additional sequences with varying parameters and orientations. With the generally known risk of artifacts in MR diagnostics, findings shall always be validated by at least one additional orientation/weighting.

How was the subject identified and what is the root cause?

Siemens Healthineers became aware of this issue during post market surveillance. The root cause has been identified as a manufacturing processing error.

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

The following steps can be taken to determine if the over-ear headphones are affected by the issue:

- Check the model number and serial number of your over-ear headphones. See *Figure 1* for their location on the over-ear headphones. If the model number is not identical or the serial number is outside the stated range (7981 – 32200), they are not affected.
 - If your over-ear headphones concur with the material number mentioned and are within the stated range of serial numbers, please perform phantom measurements with the following settings to evaluate whether your headphones are affected by the potential artifacts:
 - Set up with phantom bottle and headphones as shown in *Figure 2* below.
 - Use the standard sequence t1_fl3d_sag_p2_iso (from Siemens protocol tree: head -> library -> 3D) with the minimum possible echo time TE, repetition time TR of 10 ms, field of view (FOV) of 250 mm and coronal orientation.
 - Apply window values of approx. C=20 and W=10 to identify if artifacts from lubricating grease clumps are present outside of the skull at the position of the headband of the headphones.
- **If no artifacts are visible** during the described phantom measurements, your over-ear headphones are not affected and can continue to be used for MRI head examinations.
- **If artifacts are visible** during the described phantom measurements, your over-ear headphones are affected and must not be used for head examinations. In this case, please use the built-in loudspeaker in the scanner for patient communication or, if available, in-ear headphones which are also not affected by the described issue.

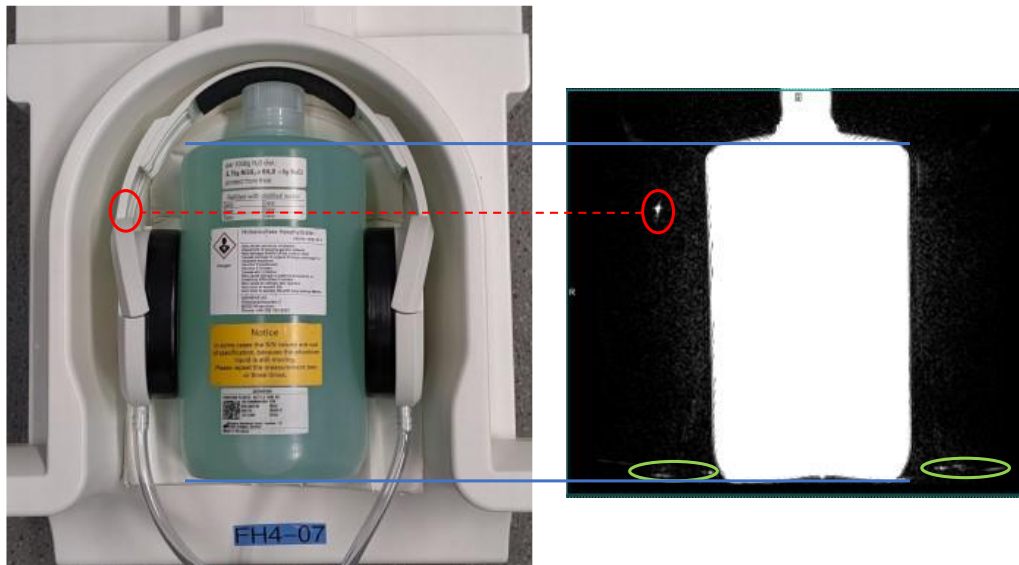


Figure 2

Left side: correct setup of phantom bottle and headphones in head coil

Right side: Example of signal from lubricating grease can be seen outside the phantom, marked with a red circle. The artifacts must be on the same height as the potential affected headbands of the headphone.

Please note: MR imaging often shows artifacts with phantom bottles in this extreme windowing e.g. at the top and/or bottom of the phantom. These artifacts are marked with green circles in the above example and can be ignored.

How will the corrective action be implemented and what is the efficiency of the corrective action?

Siemens Healthineers will correct the issue by exchanging the headband of the affected over-ear headphones at customer sites with the field update MR073/23/S. This replacement program will start in October 2023. With the exchange of the headband the root cause is eliminated.

In parallel the manufacturing error has been corrected for any new over-ear headphones with serial number > 32200. Those new headphones are not affected by the issue.

In case of further questions please contact your local service organization.

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 this 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.

Acknowledge Receipt of this Safety Advisory Notice

Please fill out the attached Acknowledgment of Receipt and follow the instructions for sending it back to Siemens via <insert appropriate confirmation method, e.g., by e-mail or other electronic ways of confirmation, print, fax or registered mail with return receipt>

What If the affected product is no longer on-site?

If these over-ear headphones are no longer in your possession, please forward this Safety Advisory Notice to the new owner of the headphones. If applicable, please inform us about the new owner of the headphones.

The <relevant National Competent Authority> will be informed of this notice, if required.

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

Sincerely yours,



*Electronically signed by: Tianshi Ma
Reason: I am approving this document
Date: Aug 21, 2023 09:24 GMT+8*



*Electronically signed by: Hai Ting Li
Reason: I am approving this document
Date: Aug 21, 2023 10:42 GMT+8*

Tian Shi Ma
General Manager
Siemens Shenzhen Magnetic Resonance Ltd.

Hai Ting Li
Quality Director
Siemens Shenzhen Magnetic Resonance Ltd.

To _____
Fax number _____

Acknowledgement of receipt

Customer address

I hereby confirm as the owner / responsible operator of the *MAGNETOM* _____ with the Serial number _____ that I have read and understood this notice and accept the implementation of the recommended measures.

Safety Advisory Notice

MAGNETOM Free.Max/Free.Star/Amira/Sempra/Mica/Spectra

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Place, Date _____

Name _____

Signature _____