SIEMENS

Healthcare

Safety Advisory Notice

To all users of the SIEMENS

SOMATOM Definition AS with
patient table PHS 1600 in combination with
software license for "Adaptive 4D Spiral"

Contact person of the Business Area:

Department:
Telephone:

E-Mail:
Date:

Re: SOMATOM DEFINTION AS with combination Patient table 1600 (material number 10643655) and perfusion scan mode "Adaptive 4D Spiral"

Dear customer,

This letter is to inform you of a potential malfunction and hence potential hazard to patients and personnel when using the perfusion scan mode "Adaptive 4D Spiral" in combination with your Patient Handling System PHS1600.

When does this malfunction occur and what are the potential risks?

We recently detected that the use of the combination of PHS1600 table with the perfusion scan mode "Adaptive 4D Spiral" could initiates scan aborts occasionally. Currently we are investigating the reason for this behavior. As this scan mode is typically used for critical diagnostic examinations, we do not want to miss to inform you about the risk of a scan abort while using this scan mode.

Please note that the decreased performance stability is not affecting any other scan modes or the mechanical stability of the table in general.

How can the operator help to avoid the potential risk of this issue ?

As operator you should be aware of the increased risk of a scan abort while using the perfusion scan mode in combination with the PHS1600 table, especially when applying contrast media.

How will the issue finally be resolved ?

Our experts still analyze the root cause of this issue and will develop a solution for the use of the patient table PHS1600 in combination with the "Adaptive 4D Spiral" scan mode. Currently we test mechanically improved components of the PHS1600 table with the objective to stabilize the performance.

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 placed in the medical device's instructions for use. Your personnel should maintain awareness until a solution is available.

If you have sold this medical device and it is no longer in your possession, we kindly ask you to forward this safety advisory notice to the new owner of this device. Please inform us about the new owner of the device.

The relevant National Competent Authority has been informed of this notice.

Sincerely Yours

[redacted]

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