To all user of VD1X Sensis / Sensis Vibe systems

Product/Trade Name:	Sensis, Sensis Vibe Combo, Sensis Vibe Hemo	E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Model Number:	10764561, 11007642, 11007641	Date	September, 2021
		Corrective Action ID	AX066/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Missing regular reboot of the system may result in frozen vital signs

Dear Customer,

We would like to inform you about the following potential issues with your Sensis / Sensis Vibe system currently on VD1X software and a corrective action that will be performed.

What is the issue and when does it occur?

The system operator manual states that the system should be rebooted once, every 7 days. In some cases, users are not following these instructions and the system is running for more than 7 days. Under rare circumstances this may result in a partly freeze of the user interface which would no longer update the vital signs.

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

This may lead to incorrect or insufficient basis for diagnostic or therapeutic decisions.
If the user doesn´t follow the instructions for reacting to malfunctions, the system can partly freeze and would no longer update the vital signs until a reboot is performed or a service engineer is onsite.

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

The issue was identified by regular field observation. Root cause is the unintended long system runtime.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

Please restart the system to recover the system functionality as described in the system operating manual.

In any case, please make sure that patient treatment can be continued in other ways if there is any possible danger for the safety of the patient.

Please observe to reboot the system in regular intervals, at least once every seven days.

What actions are being taken by the manufacturer to mitigate possible risks?

The software in the affected systems will be updated to display a notification message after closing a study that reminds the operator to reboot the system since it's running already longer than advised without reboot once the system has reached a runtime of more than 7 days.

In addition, the system operating manual will include a warning message that the Sensis system can have performance issues when running for more than 7 days nonstop without a restart to inform the customer about the consequence to ignore a reboot of the system at least weekly. Furthermore, it will be stated that a system running nonstop for more than 7 days may display incorrect or delayed vital signs, the values might not be saved, the report generation might be incorrect, and the system could become unavailable before or during an examination. The warning message will also contain the statement that the Sensis system should be restarted at least once a week.

What is the efficiency of the corrective action(s)?

The software update will mitigate the occurrence of the issue.

How will the corrective action be implemented?

Our service organization will get in contact with you for an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX067/21/S.

What risks are there for patients who have previously been examined or treated using this system?

We do not consider it necessary to re-examine any patients in relation with the issue described above.

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.

Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,

Siemens Healthcare GmbH

Business Area Advanced Therapies (AT)

xxx