To all user of the Sensis and Sensis Vibe Combo systems with software version VD12A

Product/Trade Name:	Sensis Vibe Combo, Sensis	EU-SRN	DE-MF-000006122
Model Number:	11007642, 10764561	E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
		Date	November, 2021
		Corrective Action ID	AX077/21/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: ComboBox does no longer login automatically after several reboots

Dear Customer,

We would like to inform you about a potential issue with your Sensis Vibe Combo system currently with VD12A software and a corrective action that will be performed.

What is the issue and when does it occur?

The ComboBox software holds a configuration that determines how often the ComboBox automatically boots up. After a dedicated number of reboot and shutdown cycles the ComboBox will no longer boot up automatically.

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

The system will no longer be available for patient treatment due to no communication with the ComboBox.

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

The problem was identified by regular field observation. The root cause is a software issue.

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

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

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

The software in the affected systems will be updated to correct the issue.

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

The software update will resolve 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 AX081/21/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)

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Electronically signed by: Carsten Bertram Reason: I am approving this document Date: Nov 16, 2021 08:12 GMT+1

Carsten Bertram
President Advanced Therapies

i.V.

Electronically signed by: Johann Boeck Reason: I am approving this document Date: Nov 16, 2021 06:59 GMT+1

Johann Böck
Person Responsible for Regulatory Compliance