To all user of VD12A Sensis / Sensis Vibe systems

Product/Trade Name:	Sensis, Sensis Vibe Combo, Sensis Vibe Hemo	E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
		Date	March, 2021
Model Number:	10764561, 11007642, 11007641	Corrective Action ID	AX073/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: "Windows Service Permissions" software issue

Dear Customer,

This letter is to inform you of a corrective action that will be performed to increase the IT security of your system.

What is the issue and when does it occur?

Due to the configuration of certain "Windows Service Permissions" within the operating system of the Sensis / Sensis Vibe computer, there is a risk for exposure of sensitive information, manipulation of data, or "Denial of Service" attacks. An attack can take place externally via the hospital IT network and a known Sensis Windows user login or via direct physical access to the system.

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

In case of a cybersecurity attack, the manipulation of sensitive procedure information by an attacker could result in incorrect diagnostic or therapeutic decisions.
Such "Denial of Service" attacks could result in an unavailability of the system.

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

This issue was identified during a regular internal IT security vulnerability scan.

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

No workaround is available. 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.

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

“Windows Service Permissions” are getting restricted to the required level only.

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

The IT security vulnerability of your system is getting reduced.

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 AX074/20/S.

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

The manufacturer sees no risks for patients who have previously been examined or treated.

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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Vice President Project & Portfolio Management

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Safety Officer Medical Devices AT