To all user of Sensis Vibe Hemo systems with MicroPod™ $EtCO_2$

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Corrective Action ID	AX048/20/S

Customer Safety Advisory Notice (CSAN) for Field Safety Corrective Action:

Subject: Sensis Vibe Hemo systems with MicroPod™ $EtCO_2$

Dear Customer,

We would like to inform you about a potential issue with your Sensis Vibe Hemo system in combination with the MicroPod™ $EtCO_2$ module.

What is the issue and when does it occur?

The connector joining the $EtCO_2$ module to the HemoBox may break and become damaged (see Figure 1). The damage to the connector may occur under certain conditions that place strain or unexpected force on the cable and/orconnector. Examples include (but are not limited to) stretching of the cable due to table movement, collision of the connector with other equipment, or incorrect plugging/unplugging of the connector. If the connector is re-connected to the HemoBox in this damaged state, the contact pins may not be in the proper alignment.

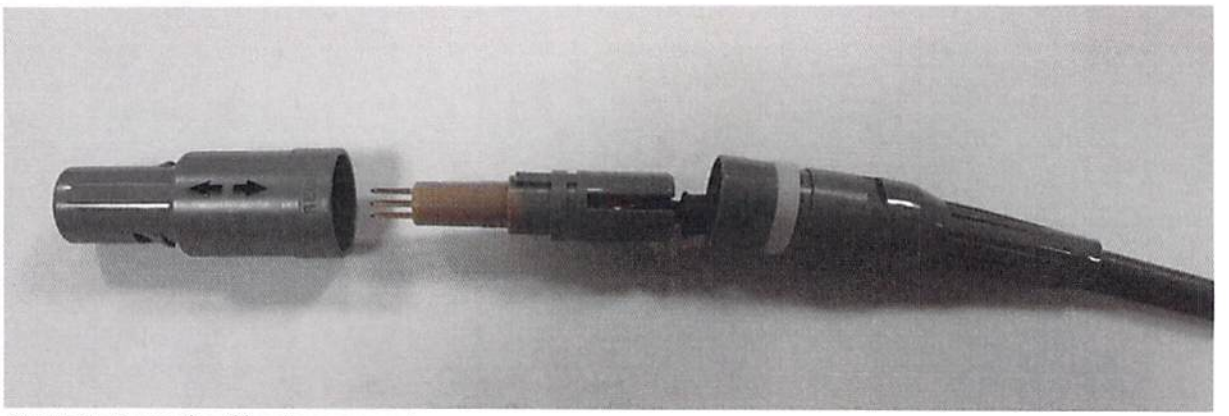

Figure 1: Example of broken connector

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

If the connector is re-connected to the HemoBox in this damaged state, under certain incorrect pin alignment conditions, the HemoBox may stop functioning and all vital signs are lost until the $EtCO_2$ module is disconnected. When the module is not connected, $EtCO_2$ monitoring is not available.

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

The problem was identified by regular field observation. The root cause is due to missing requirements in the connector assembly process.

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

If the connector joining the $EtCO_2$ module to the HemoBox should become damaged or break, the operator shall not attempt to fix the connector or re-connect the cable to the HemoBox. Only Siemens Healthineers' Customer Service or a service provider authorized by Siemens Healthineers may resolve the issue.

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

We are currently working on a solution to eliminate the root cause of this problem. As soon as a solution is available, our service organization will get in contact with you to schedule the corrective action.

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

There is no risk for patients who have previously been examined or treated using affected systems.

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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