To all user of Sensis Vibe Hemo systems with MicroPodTM $EtCO_2$

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Date	December, 2020
Corrective Action ID	AX044/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Sensis Vibe Hemo systems with MicroPodTM $EtCO_2$

Dear Customer,

We already informed you by our notification AX048/20/S about the MicroPod^{TM} $EtCO_2$ issue. Following this information, we inform you about the MicroPod^{TM} $EtCO_2$ module replacement as a Corrective Action solving the potential issue with your Sensis Vibe Hemo system.

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/connector. 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.

Siemens Healthcare GmbH
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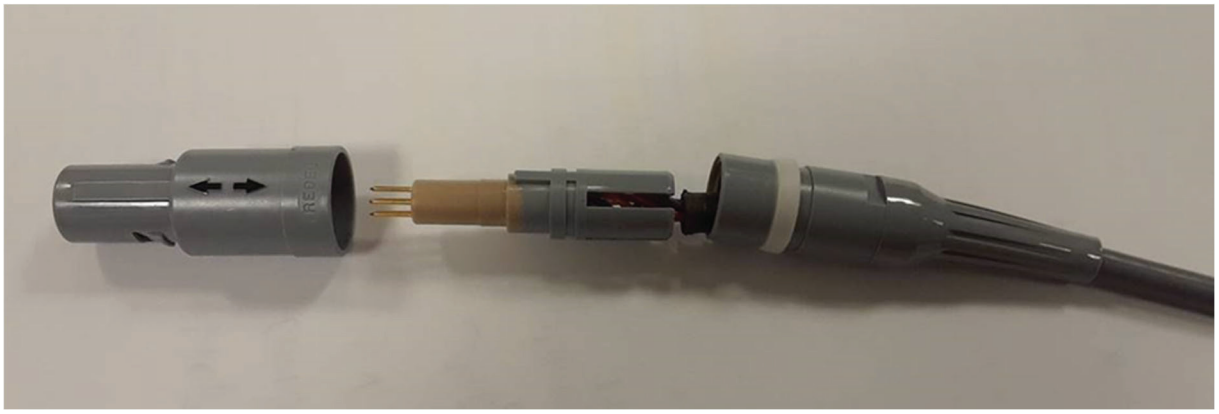

Figure 1: Example of broken connector

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 connector robustness got assessed as not sufficient.

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 a qualified electrician of Customer Service may resolve the issue.

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

The manufacturer optimized the assembly process of the connector resulting to increase the durability of the connector.

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

With the newly assembled connectors it is almost impossible that the connector joining the $EtCO_2$ module to the HemoBox may break and become damaged in the way, that it was damaged before.

How will the corrective action be implemented?

With this CSI, we provide the newly assembled MicroPod^{TM} $EtCO_2$ (Revision 02) which replaces the MicroPod^{TM} $EtCO_2$ (Revision 01).

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 is distributed to affected customers as update AX072/20/S.

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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