

Urgent !
Field Safety Notice (FSN)



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2018-11-23

FSCA Number: FSCA-2018-11-19

FSCA Title: HCU 40 Flow Sensor Malfunction

Affected Product: Heater-Cooler Unit HCU 40

Affected Product details: The FSCA affects all models and all serial numbers of the below-mentioned HCU 40 device below S/N 90441598 :

- 70104.4054 HCU 40 High Voltage
- 70105.4917 HCU 40 Low Voltage

Description of the problem:

Dear valued colleagues and business partners,

The HCU 40 Heater-Cooler Unit is intended for cooling and warming a patient connected to the extracorporeal perfusion circuit and maintaining the patient temperature at the required level during cardiovascular interventions.

The system comprises two separate water circuits with temperature regulation. The first circuit is for connecting the oxygenator heat exchanger and/or the warming/cooling blanket, the second circuit is intended for connecting the cardioplegia heat exchanger.

Both water circuits of the HCU 40 contain a flow sensor which measures the water flow to ensure an adequate flow from the device to the connected accessories.

Maquet Cardiopulmonary GmbH has received complaints in relation to malfunctions of the HCU 40 flow sensors.

A malfunction of the flow sensor causes an error message that prevents further use of the device. The HCU 40 device software supervises the values detected by the flow sensor. A malfunction of the flow sensor generates a signal that is detected by the device firmware as out of range. To prevent further damage or use of a

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device where the water flow cannot be monitored, the software causes a shut-off of the affected water circuit not allowing desired patient temperature control by this water circuit. Typically, the use of the device is prohibited until the malfunction of the flow sensor is corrected by replacement. However the use of the HCU 40 with only one working water circuit is possible.

Maquet Cardiopulmonary has not received any complaints associated to serious injuries or deaths due to a malfunction of the flow sensors.

Corrective Action:

- Replacement of the flow sensors in both water circuits of the HCU 40

Advice on action to be taken by the User:

- As described, the use of a HCU 40 with only one working water circuit is possible. As a general precautionary measure in the instruction for use for HCU 40, please always keep a replacement unit on standby in order to ensure continuous full operation in the event of the described flow sensor malfunction.
- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- The update of your HCU 40 system(s) must be performed by authorized Getinge service personnel.
- Duly fill out the enclosed Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2018-11-19 as reference.

Referenced

documents/attachments:

- Letter of Acknowledgement Customer

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Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.
- According to our post-market surveillance following countries are directly affected by this FSCA: AE; AR; AU; AZ; BD; BO; BR; CA; CI; CN; CO; CR; CU; DZ; EC; EG; GE; HK; ID; IL; IN; IQ; IR; JO; KE; KR; KZ; LB; MA; MD; MM; MR; MV; MX; MY; NG; NP; NZ; PE; PH; PK; QA; RS; RU; SA; SD; SG; SY; TH; TW; UA; US; VN; XS; ZA

Your local Getinge representative will contact you for planning and performing the replacement of the flow sensors for your HCU 40 system(s).

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative.

Sincerely,

Managing Director

Safety Officer

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