2020-09-18

URGENT - FIELD SAFETY NOTICE

Type of Action	Replacement of the PCBA Connectors within affected BMU40
Subject:	FSCA-2020-07-30 BMU40 Replacement of PCBA Connector
Affected Product:	70104.0852 - Blood Monitoring Unit BMU 40
Affected Serial Numbers:	From 90002001 to 90002313 (see detailed information in Annex I – List of affected products)

Dear valued customer,

The medical device Blood Monitoring Unit BMU 40 is designed to monitor blood parameters during cardiopulmonary bypass (CPB) or similar procedures with extracorporeal circulation, which require continuous monitoring of the arterial and/or venous blood parameters: partial pressure of oxygen (pO2), temperature (TArt and TVen), oxygen saturation (SO2), hemoglobin (Hb) and hematocrit (Hct). Oxygen consumption (VO2) can also be calculated. Blood flow (QBlood) can be entered manually or values can be received from a connected heart-lung machine.

It has become known to Maquet Cardiopulmonary GmbH that the printed circuit board (PCBA Connector) of the BMU40 was designed with a short creepage distance. This PCBA Connector is positioned in the inner and backside of the metal enclosure of the BMU40.

Taking into consideration the product specifications, the mitigating design factors, as well as the factors that may contribute to product risk, the following potential health consequences (harms) could occur:

- Potential of electric shock
- Possible absence or potential loss of patient data during device replacement
- Procedural/use delay during device replacement
- User inconvenience during device replacement

The following

- design factors,
- the customary use of standard PPE by a user of the BMU40 (viz. nitrile gloves),
- functional healthcare facility protections,
- proper grounding of any accessory equipment connected to the BMU40, and
- IFU recommendations (e.g. a properly connected BMU40 to protective ground/earth, the use of equipotential bonding, noncontact of the device and the patient simultaneously, etc.),

would, more than likely, greatly attenuate the risk/ potential of electric shock passing through the BMU40 housing (backside) to a user.

Maquet Cardiopulmonary GmbH has not received any reports of serious injuries or death due to the malfunction of the PCBA Connector.

Based on the associated risk to the PCBA Connector with a shorter creepage distance, a general decommissioning of the affected BMU40 is therefore not required.

Corrective Action:

- The PCBA Connector within the affected BMU40 with the serial numbers mentioned above will be replaced by a new one.
- With a pending replacement of the PCBA Connector, the facility may continue to use the BMU40 by:
    - using the equipotential bonding connector on the backside of the BMU40, and
    - not connecting external devices to the BMU40 serial ports (Com 1 /Com 2) with an operational/ communication voltage outside the range of ±25Vdc

Advice on action to be taken by the User

- Your current stock may include products affected by this action.
- The PCBA Connector in the affected BMU40's shall be replaced by the new PCBA Connector as soon as possible, at the latest during the next annual preventive maintenance.
- Your local Getinge representative will contact you to arrange the replacement of the PCBA Connector of your BMU40.
- If you have an affected BMU40 unit, duly complete the enclosed Letter of Acknowledgement Customer and return it to your local Getinge representative as soon as possible by mentioning FSCA-2020-07-30 as a reference.

Referenced documents/ attachments:

- Letter of Acknowledgement Customer
- Annex I – List of affected products

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 could have an impact.
- Please maintain awareness of the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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 will provide this notification to the necessary Regulatory Agencies.

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

Sincerely,

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Maquet Cardiopulmonary GmbH
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GERMANY