Field Correction Notice

APR-04-2022 | MX-8550 MCC/22/003/NU | Rev 01

Subject:
HL 40 Heart Lung Machine, Single Console Roller Pumps

Products affected:

Our records indicate that the below listed products were delivered to your location.
Please verify if you have the listed products and complete the information below.

Product	Article No.	Serial number	Manufacturing date
HL 40 Single Console Roller Pump (SCRP 150)	701057305	90 0000 006; 90 000 016; 90 000 004; 90 000 015.	N/A

Dear Customer,

The purpose of this letter is to inform you of potential issue related to Single Console Roller Pump (SCRP 150), and the necessary actions to be taken. Our records indicate that only one facility, Gemelli Hospital, Rome, Italy, has received two (2) HL 40 systems equipped with the (4) above-mentioned roller pumps.

The following has been observed

During production, a symmetry test was not fully performed to the extent that was intended. A roller head symmetry test was successfully performed on tube sizes: (1) 1/4´´ x 1/16´´ and (2) 3/8´´x 3/32´´.

An internal process audit revealed two additional symmetry tests for tube sizes (3) 3/8´´ x 1/16´´ and (4) 1/2`` x3/32 were not performed, and therefore Getinge cannot be assured the remaining tests would have passed.

Thus far there have been no reported complaints or negative outcomes associated with this finding.

Potential hazards

The immediate and/or long-term health consequences of asymmetric roller pump-heads and incorrect occlusion settings (over occlusion or under-occlusion) include any, some, or all of the following harms:

- Hemolysis,
- Mechanical hemolytic anemia,
- Acute Kidney Injury (AKI),
- Ischemia, Hypothermia,
- Air embolism,
- Systemic inflammation.

The most notable, immediate injuries/harms that are possible related to roller pump asymmetry include hemolysis, inadequate/inaccurate blood flow, and/or retrograde flow.

Precautions

The HL 40 Heart Lung machine can be used in accordance with the Instructions for Use (IFU), with extra attention to the following risk control measures that enable the user to reduce the risk for harm:

- Complete the pump flow calibration as per the Instructions for Use for the HL 40 Heart Lung machine at installation and with any changes to the disposable specifications.
- Perform roller-pump occlusion settings before each clinical use according to your local clinical guidelines, and according to the Instructions for Use for the HL 40 Heart Lung machine.
- Monitor arterial roller pump flow using the approved flow bubble sensor.

- Prepare a second Heart Lung machine to enable quick replacement in the event of system failure. Alternatively swap out the effected roller pump RP 150 with a replacement pump as per the instructions for use.

Corrective action

Getinge has initiated a field action of affected HL 40 Heart Lung machines. On site testing/replacement of the effected units will be performed. Gemelli Hospital's representative will be contacted by Getinge sales or service representative to schedule the required test and replacement of the devices, if necessary.

Getinge will inform you regarding the timeline of the test/replacement activities, in a timely manner. Maintain awareness on this notice and related actions until your HL 40 systems has been updated to ensure effectiveness of the corrective action.

Distribution

This Getinge Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. In the event your customer chooses not to proceed with ´the completion of the Field Safety Notice requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond. The competent authorities in each of the following countries have been informed about this communication and field action: Italy, Netherlands, France, Spain, Sweden, the Notified Body TüV Süd, South Africa and UAE.

Please complete & return the attached acknowledgement form [EVU-227349].

We apologize for any inconvenience this may cause and we will complete this field action as swiftly as possible. Should you have questions or require additional information, please let us know.

Sincerely,

Dr. Dušan Nikolić

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Enclosures:

1. EVU-227349 - Confirmation of receipt - MCC-22-003-NU