Field Safety Notice

2023-JULY-13 | MX-8905 | Rev 01

MCC-23-001-IU: Broken locking rings found in HL 40 roller pump heads

Products affected:

Our records indicate that one of the below listed products, parts of perfusion system HL 40 (701057656) were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Item number	Getinge Order Reference	Serial number	Manufacturing date
701057305	Single Console Roller Pump (SCRP 150)	900000033	N/A
701057423	Mast Roller Pump (MRP 150)	90000037	N/A

Description of the issue

During the production processes, a metallic rattling noise was detected in two of the pump heads for HL 40 Roller Pumps (150mm). When disassembled it was determined that locking rings were broken. Locking rings in HL 40 roller pumps are one means of preventing axial movement, but there is an additional press fit that prevents any axial movement as well. The root cause of the issue has been determined to be unfavorable manufacturing conditions, at one of two possible suppliers, leading to brittleness outside specification.

During root cause analysis we have not observed that this issue impacts pump performance.

There are no reports of this issue from either post market data or complaints.

A Risk Analysis of the issue concluded that the risk to patient safety is low.

Potential hazards

A broken locking ring could damage the pump and prevent the roller pumps from performing as intended, which may result in no or too low flow to the patient. This failure has however not been able to be produced during the root cause analysis.

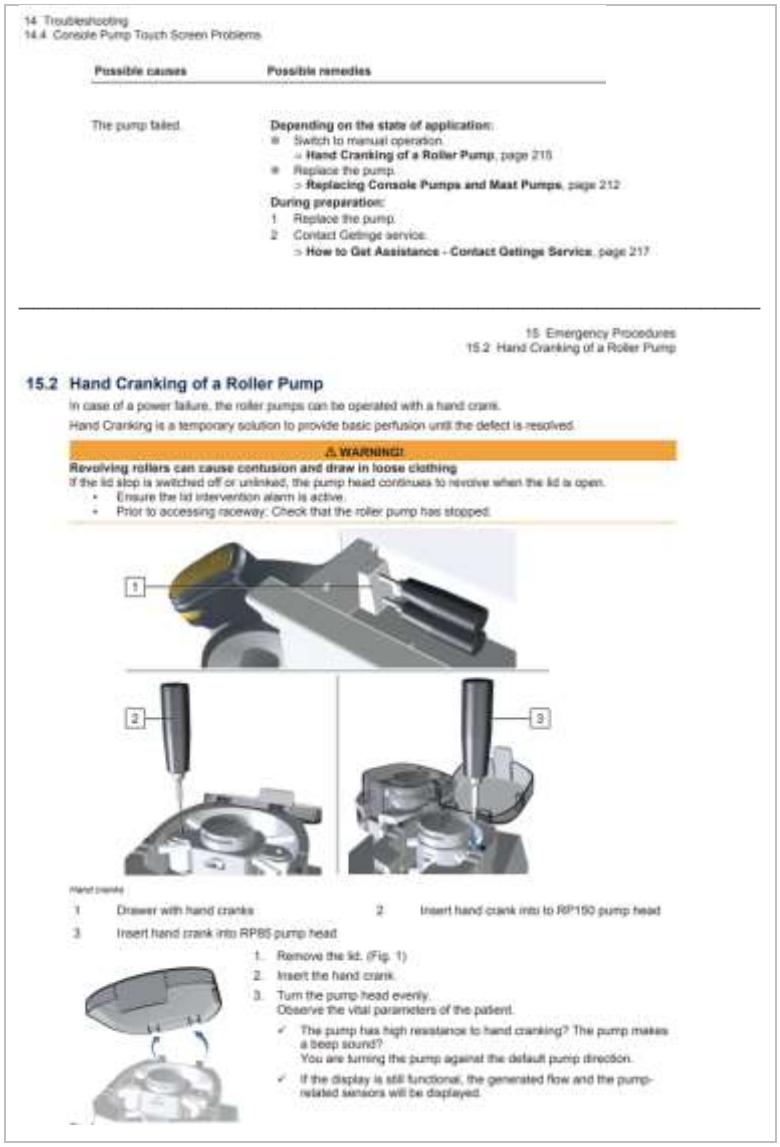
The immediate and/or long-term health consequences of the hazardous situation may include, either one, or both, of the following harms due to insufficient blood flow, no blood flow, or retrograde blood flow:

- Ischemia,
- Hypothermia

Precautions

The HL 40 Heart Lung machine, with its pumps, can continue to be used in accordance with the HL 40 Instructions for Use (IFU) and as described in the IFU:

- If an alarm message is elicited by the HL 40 user interface, please consider the contextual, recommended actions as indicated by the HL 40 Help screen displayed on the system monitor and the IFU.
- in the improbable event of a failure, or unrecoverable fault, of the roller pump the user should be prepared to deploy the hand crank as described in the HL40 IFU.



14 Troubleshooting
14.4 Console Pump Touch Screen Problems

Possible causes	Possible remedies
The pump failed.	**Depending on the state of application:** • Switch to manual operation. ⇒ **Hand Cranking of a Roller Pump**, page 215 • Replace the pump. ⇒ **Replacing Console Pumps and Mast Pumps**, page 212 **During preparation:** 1 Replace the pump. 2 Contact Getinge service. ⇒ **How to Get Assistance - Contact Getinge Service**, page 217

15 Emergency Procedures
15.2 Hand Cranking of a Roller Pump

15.2 Hand Cranking of a Roller Pump

In case of a power failure, the roller pumps can be operated with a hand crank.
Hand Cranking is a temporary solution to provide basic perfusion until the defect is resolved.

⚠ WARNING!
Revolving rollers can cause contusion and draw in loose clothing
If the lid stop is switched off or unlinked, the pump head continues to revolve when the lid is open.
- Ensure the lid intervention alarm is active.
- Prior to accessing raceway: Check that the roller pump has stopped.

Hand cranks
1 Drawer with hand cranks
2 Insert hand crank into to RP150 pump head
3 Insert hand crank into RP85 pump head

1. Remove the lid. (Fig. 1)
2. Insert the hand crank.
3. Turn the pump head evenly.
Observe the vital parameters of the patient.
✓ The pump has high resistance to hand cranking? The pump makes a beep sound?
You are turning the pump against the default pump direction.
✓ If the display is still functional, the generated flow and the pump-related sensors will be displayed.

Figure 1: Hand crank deployment as described in HL 40 IFU [70105.8274·2.1·NONUS·en·06·2021-02].

Corrective action

Getinge initiates this field action to address the affected roller pumps. The affected pumps shall be replaced as soon as pumps are available. You will be contacted by your Getinge representative for replacement of the pump.

Distribution

This Getinge Field Safety 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.

Please maintain awareness of this notice to ensure the effectiveness of the corrective action.

In the event you as customer choose not to proceed with completion of the corrective action requirements, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. A Field Safety Corrective Action report has been submitted to the Competent Authorities of Sweden, Spain, and Ireland. Our Notified Body TÜV SÜD have been informed of this issue.

Getinge apologizes for any inconvenience this may cause and will do its utmost to complete this Field Action as quickly as possible.

Should you have questions or require additional information, please let us know.

Sincerely,

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