

Complaint Summary # SUMM-13290

Created by Angelo Zaccardo on 01-Apr-2020 13:47

BasicSUMMARY NUMBER
SUMM-13290SITE
Mirandola**COMPLAINT INFORMATION**COMPLAINT NUMBER
2020-00079

EXT REFERENCE

HOSPITAL/CLINIC
[REDACTED]

RGA / RMA #

DATE OF SUBMISSION
07-Jan-2020**EVENT DETAILED DESCRIPTION**

Customer report: "We have a centrifugal disposable which was questionable during priming. It is just about visible in the video but the impeller was shaking side to side and making a humming sound. We have chopped it out and retained it for examination."

Video attached.

Available from Perfusion
Not contaminated.
Credit please.**PRODUCT INFORMATION**PRODUCT PART NUMBER
AB1579PRODUCT DESCRIPTION
[REDACTED]PRODUCT LOT
1908020195

PRODUCT SN

PRODUCT PART NUMBER
436980667PRODUCT DESCRIPTION
REVOLUTION PUMPPRODUCT LOT
1907260017

PRODUCT SN

INVESTIGATION**INVESTIGATION SUMMARY**

Returned units have been visually inspected and subsequently submitted to functional test. The pumps have been submitted to rotation test, checking the noise generated at several speed steps (from 1000 to 3500 RPM, at regular steps of 500 RPM). As per investigation results, the pressure generated by the complained pumps is aligned to the specification, showing that the pumps are able to provide adequate flow and the functionality is not impacted by the noise.

After the above described functional test, a further endurance test has been performed to evaluate the reliability and durability of the pump. Four complained units have been tested filling the circuit with water, increasing slowly the flow rate up to maximum flow rate intended (8 l/min) for the device: water was circulated for 6 hours with a back pressure of 150 mmHg. After 6 hours, the devices have been checked for eventual device detachment and/or damages of components. No differences in pumps performances have been noticed after 6 hours of test. No damages or detachment occurred during the test.

After the functional test, units have been sectioned to evaluate the components of the pump: Upper white bearing, Lower red bearing and Impeller. No defects nor wearing traces have been detected on these components.

Investigation details are reported in CP_MIR_MIS_001516.

Hemolysis test showed results aligned to units without the complained behavior. Refer to engineering report CP_DHF_1-009647.

Based on investigation results of similar complaints, it is possible to assume that the detected noise was generated by a restrained vibration of the impeller within its seats. Endurance tests confirmed pump safety and performance. Moreover, hemolysis test showed results aligned to units without the complained behavior. Based on the test conducted the issue appears to impact only the acoustic comfort and no impact on safety and performance has been observed.

DHR verification did not reveal any relevant information possibly linked with the claimed defect.

Refer to DHR activity #DHR-012820 for further details.

No modification of the initial reportability assessment

The present report has been reviewed as per reportability criteria described in current revision of CS_BU_GP_0023 and the review does not modify the initial reportability assessment for all applicable regulations.

ROOT CAUSES

LivaNova is undertaking a detailed investigation of all pump components potentially involved in the generation of the pump noise to determine the root cause and implement the needed actions to prevent the noise. Therefore CAPA-MIR-2020-0002 has been issued.

CORRECTIVE ACTIONS

Based on investigation results of similar complaints, it is possible to assume that the detected noise was generated by a restrained vibration of the impeller within its seats. Endurance tests confirmed pump safety and performance. Moreover, hemolysis test showed results aligned to units without the complained behavior. Based on the test conducted the issue appears to impact only the acoustic comfort. Despite no impact on safety and performance has been observed, CAPA-MIR-2020-0002 has been issued to determine the root cause and implement the needed actions to prevent the noise.

INVESTIGATION INFORMATION**CONCLUSION****CONCLUSION**

Thank you for contacting Livanova Group about the issue you experienced. We have completed our investigation and this report provides the root causes and the corrective actions we have taken. By partnering with us to provide the information about the event, together we can achieve improved product quality for patients around the world. If you have any questions, please contact your sales person.

MAIL ACTIVITY

SEND MAIL TO

SEND MAIL TO EMAILS
[REDACTED][Send Mail](#)

Angelo Zaccardo, Email: Investigation complete for Complaint 2020-00079, 01-Apr-2020 13:47

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Angelo Zaccardo [1622]:

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All Comments

Angelo Zaccardo [1622]:

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