

Kind attention of:

Mirandola, Italy, July 22<sup>nd</sup>, 2020

**Reference:** Reported Cases of Revolution Pump Noise

Dear Valued Customer,

This letter is to acknowledge the receipt of the complaint you submitted and provide with preliminary results of our investigation.

The following complaint has been reported into our database:

COMPLAINT ID	DATE EVENT	OF PRODUCT DESCRIPTION	COMPLAINT DESCRIPTION	QTY COMPLAINED
2020-03558	June 19, 2020	REVOLUTION PUMP	During priming, Revolution pump made unusual loud sound and vibration.	1

We have conducted magnetic coupling and performance testing on complained pump of similar cases, by measuring the related internal pressure at several speed steps.

As per investigation results, it was confirmed that the generated pressures were aligned to the specification and the pumps were able to provide adequate flow. We also conducted endurance testing by the maximum flow rate and the longest use time set in the IFU, no detachment, no damage and no difference in performance were observed.

Comparison on haemolysis between the reported pumps and inventory units was evaluated at the maximum flow rate and the longest use time set in the IFU. No significant difference in MIH was highlighted.

Based on those tests showing no influence on safety and performance, we can confirm that the pumps are fully safe to use and the generated noise could only affect acoustic comfort during the use.

We have been able to duplicate the noise described in your report during our laboratory test and investigation identified that a change introduced to the upper bearing design may trigger a resonant sound at a specific frequency.

Based on the investigation results and as part of continuous improvement process, LivaNova is improving the acoustic comfort of the product during use. LivaNova already completed the validation of this improved product and expects to start its production within end of September 2020.

In parallel, during April 2020, LivaNova has reintroduced the previous upper bearing configuration, which is not affected by the resonant sound.

We remain available in case you should need additional information.

Sorin Group Italia S.r.l.  
a wholly-owned subsidiary of LivaNova Plc

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**Servizio Clienti Italia:** +39 02 37014960  
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**Capitale Sociale: € 8.550.034,00**  
Registro Imprese di Milano N. 10556980158  
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Cod. Fisc. 10556980158 - Part. IVA 02109510368  
ISO CODE IT02109510368  
Registro Nazionale Produttori AEE N. IT08020000000823

<https://www.livanova.com>

Società soggetta all'attività di direzione e coordinamento da parte della capogruppo LivaNova Plc



Health innovation that matters

LivaNova is committed to provide quality products and service to its customers, and for this reason we kindly ask to provide us any additional information that may help to the investigate the reported cases.

Sincerely,

Alessandro Melchiorre  
Manager, Customer Quality  
LivaNova

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