

Object: Reported Cases of Revolution Pump noise and overheating

Dear Valued Customer,

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

Following complaints have been reported from your facility:

COMPLAINT ID	DATE OF EVENT	PRODUCT DESCRIPTION	COMPLAINT DESCRIPTION	QTY COMPLAINED
2020-03335	Jun-10-2020	REVOLUTION PUMP	When the CP5 was powered up & revs increased, a noticeable noise was observed along with "vibration" of the inlet & outlet tubing from the pump head.	1
2020-03744	Jun-29-2020	REVOLUTION PUMP	On priming it was noted that there was vibration, noise and significant overheating from the Revolution head.	1
2020-03788	Jun-30-2020	REVOLUTION PUMP	Noisy Revolution head, with vibration and heat generation.	1
2020-03966	Jul-08-2020	REVOLUTION PUMP	Revolution head generating noise and heat.	1
2020-04374	Jul-27-2020	REVOLUTION PUMP	Very noisy, significant heat	1
2020-06132	Oct-07-2020	REVOLUTION PUMP	During priming it was noted that the Revolution head was noisy.	1

LivaNova has tested pump heads returned from Your center reporting noise and overheating. Additional testing has been performed on products from our inventory, as well as on pumps claimed for the same defect and returning from other centers.

Results confirmed that the generated pressures were aligned to the specification and the pumps were able to provide adequate flow. Endurance and heat generation tests by the maximum flow rate and the longest use time set in the IFU were performed, verifying no detachment, no damage and no difference in performance respect to the product specification.

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

Sede Legale:
Via Berignina Crespi, 17 - 20159 Milano - Italy
Sede Amministrativa:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel +39 0535 29811 Fax +39 0535 25229
Stabilimenti:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel +39 0535 29811 Fax +39 0535 25229
Via Crescentino sn - 13040 Salsuggia (VC) Italy
Tel +39 0161 487.1 Fax +39 0161 487.681

Sede Commerciale:
Via Statale 12 Nord, 86 - 41037 Mirandola (MO) Italy
Tel +39 0535 29811 Fax +39 0535 25229
Via Berignina Crespi, 17 - 20159 Milano - Italy
Tel +39 02 69465.211 - Fax +39 02 69465.300

Servizio Clienti Italia: +39 02 37014960
International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 - N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 - Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT0802000000823

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

Based on all evidences no influence on safety and performance was ascertained concluding that the pumps are fully safe to use.

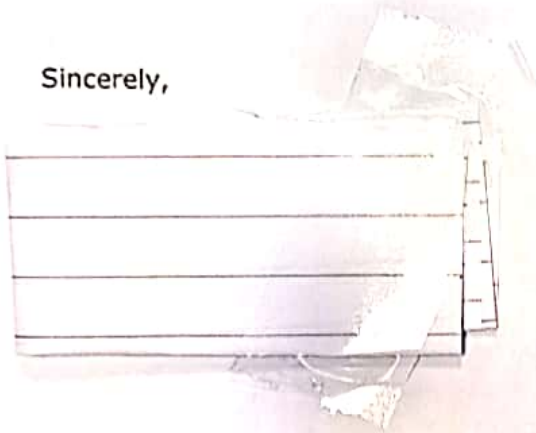
The investigation showed that noise is related to the change to the upper bearing configuration introduced in November 2019, in particular it was verified that the higher stiffness material performances introduced moved noise in the audible range.

To solve the issue a different bearing shape was introduced, whose production begun in November 2020.

We remain available in case you should need additional information.

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,



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Tel. +39 0535 29811 Fax +39 0535 25229
Via Benigno Crespi, 17 - 20159 Milano - Italy
Tel. +39 02 69465.211 - Fax +39 02 69465.300

Servizio Clienti Italia: +39 02 37014980
International Customer Services: +39 02 37027030

Capitale Sociale: € 6.580.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 - N. Mecc. Imp./Exp. MI 352423
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