LivaNova

Health innovation that matters

[redacted]

ENG

Our Ref: [redacted]

Dear Valued Customer,

On January 19, 2021, LivaNova received notice of a report, involving the following devices:

Item No.:	48-50-00
Article Description	S5 CONSOLE
Serial Number:	[redacted]

It was reported that a momentary interruption occurred on all the pumps of the S5 console and on the ERC during the procedure. No consequence on patient was reported.

To investigate the issue the device serial read-out (real time device parameters and setting recording file) was gathered and analyzed, determining that a specific event related to electrical communication interruption (CAN interruption) was triggered on the pumps involved in the claim.

Based on device reporting and complaint history reviews, it is very unlikely that a hardware fault occurs on all the pumps of the console simultaneously. However, in order to exclude this scenario, the entire S5 console (together with the centrifugal pump system), was checked and tested on site by the LivaNova field service representative.

The equipment was found working as expected and within specification: no hardware or software failures could be detected during the intensive tests performed.
Furthermore, LivaNova equipment have been designed to meet all the requirements of the standard IEC 60601-1-2:2014 for the Electromagnetic disturbances.

Based on the above facts, it was possible to exclude a hardware failure of the console, therefore, the most likely root cause of the reported event was traced back to external electromagnetic interferences from high frequency devices.

It is strongly recommended to check the operating theatre and the ambient of the operating theatre for emissions of high frequency emitting devices and to always have connected the potential equalization cable to earth (see IFU,