

2026 Pump Servoregulation (Cardioplegia)

Permission to print:	Yes
Category	Pump Servoregulation
Category 2	Cardioplegia
Severity	Good Catch No Harm Incident
Type of incident:	Equipment
Description:	<p>During an elective AVR for severe AS and AR, bypass was initiated using the Essenz Perfusion System of LivaNova. Root vent and LV vent were placed and cross clamp was applied. Cold blood cardioplegia in 4:1 ratio given through antegrade (1,000 mls) and retrograde (300 mls). Heart went to asystole within a minute. Succeeding cold blood cardioplegia was given in 8:1 ratio every 20 mins through retrograde (300 mls). The native aortic valve was replaced using a bioprosthetic valve. Started rewarming and gave hot shot before taking off the aortic cross clamp. Due to some bleeding/leaking from the aortic valve that is still causing aortic regurgitation, surgeon has to go back to fix the valve and requested another full dose of blood cardioplegia. After the cardioplegia system was switched from Manual mode to the 4:1 ratio setting, the cardioplegia blood pump (CPL-B) operated as expected; however, the crystalloid pump (CPL-C) did not rotate, resulting in no crystalloid flow delivery. The user verified proper pump setup, including confirmation that the pump lid was correctly closed, and evaluated multiple ratio settings to determine whether the issue was configuration related. The condition persisted despite these actions. To maintain cardioplegia delivery, the user reconfigured an available auxiliary roller pump, previously assigned as a root vent and labelled as a spare pump, to operate as CPL-C. Following reconfiguration, cardioplegia delivery was successfully restored and the procedure continued without further interruption. Reportedly, there was no impact on patients or users.</p>
GOOD CATCH - what went well	<p>The troubleshooting steps [previously practiced in simulation] performed by the perfusionist following this event were effective, and the CPL-C functionality was successfully restored without further impact on the patient and the procedure. As a potential workaround should a similar situation occur, and to avoid the need to configure a spare pump as a CPL-C, LivaNova recommends rotating clockwise the CPL-C pump control knob. This action may restore synchronization between the CPL-C and CPL-B pumps and re-establish ratio-controlled operation.</p>
What could we do better	<p>A quicker report from the company could have been helpful rather than waiting for 5 weeks to have the report from the Quality team of LivaNova in Germany. Investigation Details from LivaNova: EPM serial port log file was analyzed and confirmed that the CPL-B pump operated independently while CPL-C pump remained at 0 RPM. Essenz Cockpit event log files were collected; however, further log analysis could not be performed because the relevant event data had been overwritten during the Heart Lung Machine (HLM) software upgrade to version 1.6.1 performed on July 29. As no additional diagnostic information was available from the log files, it could not be determined whether the selected cardioplegia ratio setting was not retained by the HLM system or whether the CPL-B and CPL-C pumps remained in Manual mode. Consequently, the root cause of the reported behavior could not be conclusively established based on the available data. Although a definitive root cause could not be established, the available evidence suggests that the reported event is compatible with a loss of synchronization between the CPL-B and CPL-C pumps. The troubleshooting steps performed by the perfusionist following this event were effective, and the CPL-C functionality was</p>

successfully restored without further impact on the patient and the procedure. As a potential workaround should a similar situation occur, and to avoid the need to configure a spare pump as a CPL-C, LivaNova recommends rotating clockwise the CPL-C pump control knob. This action may restore synchronization between the CPL-C and CPL-B pumps and re-establish ratio-controlled operation. Post-market data review over the last 12 months has not identified any complaint trend suggesting that the same failure mechanism is indicative of a recurring or systematic product issue. The company sincerely apologizes for any inconvenience that the event may have caused.

Preventive actions A written step by step protocol/procedure in modifying the pumps was instituted in the unit. Practicing in a regular basis to modify the pumps in case this problem occurs again.

Manufacturer advised: Yes

Discussed with team: Yes

Hospital incident filed: Yes

Ext Authority Advised No

Patient outcome variance Nil