2025 Electrical Elecreonic (Pump servoregulation) #2

Permission to print:	Yes
Category	Electrical / electronic
Category 2	Pump Servoregulation
Severity	Good Catch No Harm Incident
Duration of incident:	minutes
Description:	Patient scheduled for elective CABG procedure, I am the assigned clinical perfusionist. My role is to prepare the heart-lung machine (HLM) (Essenz, Liva Nova - Italy) prior to use and institute, maintain and terminate cardiopulmonary bypass to enable to procedure to occur. These HLM are new to our institution (6 months old), replacing our previous iteration which had well surpassed its service life. This HLM can be divided into two key components - the Essenz Patient Manager (EPM - which manages all data logging) and the cockpit (responsible for all controls of heart lung machine, sends data for logging to EPM). For some context, since receiving these HLMs, our department has experienced numerous 'glitches' which have only impacted the EPM and data collection. While this type of 'glitch' remains unacceptable, it does not pose an imminent threat to patient safety providing the cockpit still allows the perfusionist enough information to complete the case. This morning, I set up the HLM and followed the manufacturer's instructions to prepare both the EPM and cockpit for use. I had no EPM issues on start-up and was able to take the HLM into theatres and connect up to medical gas supply, power and our heater-cooler. I was then able to begin priming the HLM without issue, while the surgical team commenced the operation. About 3/4 of the way through priming and completing my pre bypass safety checklists, the machines cockpit froze. I was able to change some of the HLM controls (arterial pump flow could be increased and decreased), however the cockpit's display was frozen (not allowing me to actually see how much I had increased or decreased flow) - analogous to driving a car with a speedometer stuck at 100km/h. The cockpit then RESET itself without warning - there was no discernible reason this series of events could not have happened while on bypass resulting in serious patient harm. As this was the first documented error impacting the cockpit of the HLM, I liaised with other senior colleagues and called the Liva Nova Clinical Support Specialist (who is also a perfusionist). I was instructed that Liva Nova had never seen this issue before and that if possible, I should not use this HLM. I immediately told the consultant cardiothoracic surgeon and anaesthetist. As the machine was close to being ready for CPB, I decided to complete the checklist in the event we had to emergently commence CPB. I then quickly set up and primed another Essenz HLM and switched the two bypass machines out. This process took at least 20 minutes, [potentially] exposing the patient to some level of risk. Fortunately, our decisions did not cause any delay to the operation and no actual harm was done to the patient. The cardiopulmonary bypass run was completed without issue. Following the case, the Liva Nova Engineer arrived promptly and collected the logs from the HLM. As a measure of caution, a new cockpit has been sourced from Melbourne, it is scheduled to arrive [the same day] and the engineer will return to carry out the replacement.
GOOD CATCH - what went well	A spare heart lung machine was available, allowing me to have a back up unit accessible. Understanding surgical and anaesthesia teams - despite the surgeon having repaired a type A dissection overnight and staying back to complete another case.
What could we do bette	We have 2 rooms operating simultaneously, with 3 heart lung machines in total.

	Normally when 2 rooms are in use, the spare HLM is set up ready for priming (allows it to be used for next case, emergency cases or return to CPB). As one of our perfusionists had been called in overnight to assist with an aortic dissection, we did not have supernumerary staff available to complete a spare pump set-up. Even if we completing priming before the patient was anaesthetised, there remains a risk that the HLM could seemingly restart or a component fail at any time. Besides further investigation and software updates by the company, I cannot think of anything the clinicians could do differently.
Preventive actions	Cockpit changed the following day, data logs sent to Liva Nova headquarters for investigation. The pump with the new cockpit planned to be kept as back-up until data logs reviewed by Liva Nova HQ. Note - the following day another incident occurred with another HLM (A separate PIRS to follow). This led to the cancellation of a cardiac theatre. Liva Nova to send a new HLM to us for use as a back up.
Type of incident:	Equipment
Manufacturer advise	Yes
Timing of incident:	Post Prime PreCannulation
Discussed with team:	Yes
Hospital incident filed	Yes
Ext Authority Advised	Yes
Patient outcome variance	Nil