

Permission to print:	Yes
Near Miss or Accident	Accident
Type of incident:	Equipment
Catagory	Electrical / electronic
Knowledge Error	No
Protocol issue	No
Rule Error	No
Skill Error	No
Team Issue	No
Violation	No
Chance Chance event:	Yes
Description:	Stockert S5 HLM shut down 1 hr 49minutes into a 2hr 33min bypass. Completed power loss from mains and/or battery. Did not switch to battery - complete shut down.The HLM was off for one minute (Electronic data from Connect). The electronic gas blender was restarted after the brief interruption. The lowest SvO2 was 80.2% over the time of the event.
Contributing factors:	Mains power supply to HLM appeared OK. No known circuit breakers tripped. [Possible] Malfunction/faulty switch/circuit in HLM. [Possible the on off switch was partially deployed and flicked to the off position. The operator cannot be sure at the reboot of the HLM if the on of switch was in the on or off position]
Corrective action:	Called for help - hit the emergency call - Confirmed the power supply to the HLM was OK and commenced brief hand cranking (about 3 turns) while rebooting the HLM at the HLM on /off switch (twice). Once HLM rebooted the bypass continued without further incident.
Preventative action plan:	Notified service personnel. The HLM was quarantined and Bio engineers conducted extensive checking that included removal of the EP Pack - After long and extensive tests, no issue could be found or reproduced. The specific event log was sent to Sorin. Both Engineering- and R&D departments read out all logged messages and no fault was found. Considering the seriousness of the event, the supplier decided to fly in a new Power Supply Module as backup to be kept at the Auckland warehouse for 4 weeks. A flip chart has been designed for the HLM for use in a similar event with direction to re-set the on/off switch where there is power to the HLM and not battery power cut in.
Manufacturer advised:	Yes
Discussed with team:	Yes
Ext Authority Advised	No
Patient outcome variance f	Nil

Permission to print:	Yes
Near Miss or Accident	Accident
Type of incident:	Equipment
Catagory	Coagulation
Knowledge Error	No
Protocol issue	No
Rule Error	No
Skill Error	No
Team Issue	No
Violation	No
Chance Chance event:	No
Description:	High Trans Membrane pressure during By Pass, leading to a change out of the oxygenator We have experienced 3 different incidents of high TMP [in 2 procedures] all using Medtronic Fusion Balance coated oxygenators. All happened after being on Bypass for about 10 mins. The TMP has started to rise and the flow rate has decreased. We use a centrifugal pump. [In the first procedure we noticed decreasing flow, with increasing RPM and with no increase in the line pressure. The second procedure required two oxygenators to be changed out ].
Contributing factors:	No , ACT were all over 500 sec and there was not a common batch number. Patuient blood results were all within normal limits. We are advised that there have been at least 4 other reports of this problem all with Balance coating which may be a factor.
Corrective action:	[After the first instance intiated pre oxygenator pressure measurement]. Changed out all oxygenators without any problems. There was no adverse effects to patients
Preventative action plan:	All faulty Oxygenators were returned to the manufacturer . We have not had a report back yet . We have changed from Balance coating to Carmeda coating without a recurrence of the problem
Manufacturer advised:	Yes
Discussed with team:	Yes
Ext Authority Advised	Yes
Patient outcome variance f	Nil