Permission to print:	Yes
Near Miss or Accident	Accident
Type of incident:	Management
Catagory	Pump Servoregulation
Knowledge Error	No
Protocol issue	No
Rule Error	Yes
Skill Error	No
Team Issue	Yes
Violation	Yes
Chance Chance event:	No
Description:	Bypass had been commenced and had been stable (full flow) for approximately 4 minutes (total bypass at this time 6 minutes). The level sensor alarm [on a Sorin S5 HLM] was activated prior to initiation of bypass. This [pre bypass level sensor check] involves the perfusionist who sets up the circuit and the perfusionist in charge of the case both checking the integrity of the pad and sensor, and the perfusionist doing the case doing the post prime level sensor test.[The level sensor alarm] had not alarmed in the first 6 minutes of bypass. At the 6 minute mark the level alarm activated, however there was not a low level incident as reservoir volume was in excess of 600 ml. I was unable to clear the alarm and recommence the arterial pump, and therefore notified the surgeon of an arterial pump issue. I then proceeded to change to the arterial back up pump (deployed as a sucker pump on our console).
Contributing factors:	[The initial thought was that]There are three possible mechanical causes plus human error. Those being [the] level sensor pad was faulty, the sensor itself was faulty or the module was faulty. We replaced the level sensor pad during the case and the low level alarm continued to function correctly. [The timing of] the replacement was not noted on the record, it was changed much later in the case. I was happy to proceed with patient support whilst the second perfusionist trouble shot the low level alarm situation. Being aware that no low level alarm sensor was in place additional precaution was taken with reservoir volumes. However our set up has a redundancy in place for the low level alarm function. We place the bubble detector on the outlet of the venous reservoir and it therefore serves as a surrogate to the low level alarm in situation where the low level alarm may fail. . Human error may have resulted in inability to clear level sensor error quickly. The record clearly shows the alarm system was on but does not indicate that the low level test was done prior to bypass. [On reflection]There are a couple of options [to explain the incident]: one is the test was not done, two that the test was done prior to the case record starting, three the fault with the sensor which lead to the pump stopping resulted in the record not being written.
Corrective action:	A back up perfusionist was present within 30s . A backup pump utilised for arterial pumping. the level sensor was reassigned to the new pump as was the slave cardioplegia delivery. Hand cranking used to return volume to patient. Bypass temporarily ceased as patient heart not pleged. Entire period of low pressure 2 minutes 20 seconds. Minimum pressure 29 mmHg. 20 s MAP's

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Preventative action plan:	On discussion most likely cause is either the sensor pad was not fitted correctly to the oxygenator, or the sensor was not connected to the pad correctly, or during the early stage of bypass this connection was disrupted.The level sensor is currently on two checklists. The possible improvement would be to look at reducing the degree of "clutter" from circuit components in the region of the level sensor.Unfortunately the original sensor was removed (and damaged) from the reservoir by the second perfusionist making it not possible to check whether the sensor was faulty. On advice from the manufacturer we followed the testing pattern that they advised prior to allowing the HLM back into service.
Manufacturer advised:	Yes
Discussed with team:	Yes
Ext Authority Advised	No
Patient outcome variance f	unknown