2024 Oxygenator (?fibre leak)

Permission to print:	Yes
Category	Oxygenator
Severity	Good Catch Near Miss
Duration of incident:	minutes
Description:	On Monday morning June 24 as per out department protocol a Sorin Inspire 6 Oxygenator was primed at 0715. Protocol consists of CO2 flush of entire circuit with emphasis on the separate Dideco 731 Arterial line filter. The heat exchanger water lines are hooked up and the circuit is heated to 36C and the oxygenator observed for signs of any heat exchange leak. The prime consisting of 1200 mL of Plasmalyte A and (in this case 250 mL of 20 % Mannitol / 4 mL per kg of patient body weight). No other drugs were added at this time. The circuit ran at flows of 4 to 5 LPM for 45 minutes, arterial line occlusion checked, system maximum running line pressures were no greater than 325 mmHg which was during the arterial line occlusion check. Arterial line pressures were set at 260 warning and 280 mmHg stop pump. The operator had physically observed no abnormalities with the primed circuit at 0800. Physical hand on over the oxygenator unit was done to check for any fluid leakage signs. None was observed at 0800. The operator went to a meeting at 0800 and returned 20 minutes later. At approximately, 0836 just prior to entering into the operating theatre with the primed pump the operator observed approximately 25 to 30 ml of clear fluid on the floor under the oxygenator. The fluid was continuously dripping from the underside exhaust port of the unit. The circuit had been in continuous operation with the heater cooler unit at 36C since 0715. The whole area was checked for any signs of fluid leakage from shunt, lines, sampling ports. No other site of leakage was found, the only site of fluid leakage was the oxygenator exhaust port. The operator thought that perhaps housing around the heat exchanger inlet might be damaged? The unit was changed out for a new Inspire 6 and run for approximately 120 minutes prior to CPB. The second unit was fine during CPB. A heat exchanger pressure leak test with a manometer was performed on the defective unit and the unit passed. Also further running of the heater cooler unit with the defective oxygenator did not result in any leaks being observed. It appears that this may be an oxygenator fibre bundle leak. The manufacturer via distributer (LIVA NOVA) has been notified and the unit will return to Italy (Sorin) for testing and determination of the source of the leak. The scary issue it that the leak took so long to become apparent approximately 60 minutes after continuous running.
GOOD CATCH - what went well	Luckily the primed oxygenator had been running in the pump room for approximately 90 minutes, during the first 40 minutes no error was detected. Early recognition of the clear fluid leak from the exhaust port and operator checking the oxygenator on all sides for any signs of leakage as part of the operator's routine.
What could we do bette	Nothing noted
Preventive actions	Ensure that oxygenator is primed as early as possible and allowed to run continuously and then inspect unit for any signs of leakage after at least one hour of continuous running at 4 to 5 LPM. Inspection should be visual as well as hands on, placing hand over surface and under surface of oxygenator to check for and signs of leakage. This should also be done in the operating theatre pre-CPB with periodic observation during the bypass period.
Type of incident:	Equipment
Timing of incident:	Post Prime PreCannulation

Hospital incident filed	Yes
Ext Authority Advised	No
Discussed with team:	No
Manufacturer advise	Yes
Commentary	Oxygenator fibre leaks are rare - the last one reported to PIRS in 2022 - and usually minimal with reports where this has become apparent during the procedure but changeout has not been required, as adequate function has been maintained. This good catch describes a small continuing leak appearing quite some time after priming that suggests a potential significant problem fortuitously picked up prior to CPB. PIRS Ed