2024 Oxygenator - fibre leak

Permission to print:	Yes
Category	Oxygenator
Category 2	Circuit disruption
Severity	Good Catch No Harm Incident
Duration of incident:	minutes
Description:	IMAG x1, Ascending Aorta replacement bypass run 90 mins x clamp 70 mins S5 heart lung machine, Liva Nova Inspire 6F oxygenator, liva Nova BATCH #2407310130, MEMBRANE # 652799-0280 Just after delivering cardioplegia (hyperkalemic blood 4:1), 4 mins into the bypass run the patients arterial blood looked dark, the continuous gas monitor (Spectrum M4) was reading P02 at 270 mmHg , PCo2 was 30 mmHg, O2 saturation 80%. [True] Blood flow was 4.0LPM (CI 2.08 l/min/m2) and at 34.3 C, gas flow 2.6 LPM and FiO2 was 60% The gas line was checked - it was connected , with gas being delivered to the oxygenator. First thought it was maybe an oxygenator issue, so a blood gas sample was taken (but the AB1-90 portable blood gas machine was in ICU to replace a solution pack, so n+1 Perfusionist had to take it to icu- a 5 min task). At the same time as the gas sample taken, the gas flow was increase to 4 LPM, and Fio2 was increased to 80% , and immediately the arterial blood became red. At the same time a blood leak in the oxygenator gas outlet was discovered -this caused frothing blood to fall out of the gas outlet of the Inspire 6F onto the floor and also down the expired /gas out line that is connected to the gas measurement module of the M4. The first arterial blood gas results finally came back indicating suboptimal oxygenation pH 7.286, Po2 57.8mmHg, PC02 59.3 mmHg but this was taken prior to an increase in gas flow and Fio2. A second gas sample taken immediately (once again taken to ICU), and showed the patient had adequate gas exchange po2 164 mmHg , PC02 60 mmHg on bypass, hence there was a leak, but not a total failure of the oxygenator, so gas flows were increased to blow off excess Co2. hence decision what to do as it was a slow leak and in consultation with the surgeon, it was decided to continue using it, rather than an oxygenator change out where a patient would be subjected to no flow etc for 3- 5 mins while the change out occurred. In the mean time (luckily we still had another perfusionist on site) a spare oxygenator was set up in case of further issues and we did have to change the oxygenator out . The bypass continued without issue for the remainder of the procedure with minimal blood loss (maybe 50 -80 mls max if that at all) . This had no effect on patients post op Hb , nor did any blood products need to be given to compensate blood loss in the peri -operative period. The patient was extubated within 24 hrs and neurologically intact. Our unit earlier this year had decided to put a pronto line into our circuit , but due to using two different oxygenators on two HLMs this year, it was decided to wait until the end of the year when we use only one type, and hence only have one tubing pack modification. The M4 works on algorithms with the PO2 calculation predicted on blood temperature, blood flow rate, FiO2, Co2 and gas pressure. The blood and froth was filling up the expired CO2 line, so the initial gas results of Po2 of 270 mmHg was more than likely that of the prime going onto bypass, not the P02 at the time. The oxygenator was rinsed out and showed large areas of blood leakage in the fibres. This was returned to the manufacturer.
GOOD CATCH - what went well	noticed blood colour was dark -, even though gas value on M4 were [reading] correct. [This] highlights the down fall of using this device at times like these - with the blood dripping into the expired gas line - where values are calculated not actually measured.

What could we do bette	nothing really [apart from having a PRONTO option as is planned]
Preventive actions	Incorporate a pronto line
Type of incident:	Equipment
Timing of incident:	CPBhypothermic
Hospital incident filed	Yes
Ext Authority Advised	No
Discussed with team:	Yes
Manufacturer advise	Yes
Supplies Issue	Yes
Patient outcome varianc	Nil
Commentary	This is the second report of this oxygenator fibre leak to PIRS in the last 5 months which may well be an underestimation of frequency. The manufacturer's report subsequently received from the last PIRS report states "based on post market surveillance process for the last three years, the occurrence rate of this type of failure is extremely low (<0.003%)." Hence with an annual caseload of 500 or 1000 we might expect a fibre leak once or twice a rear respectively. While the author judiciously managed to this case without changeout, they suggest circumstances could easily have so required. They are to be applauded for scheduling inclusion of a PRONTO line in their circuit. As Gary Grist states in an article in Perfusion Theory, "By this time, all perfusion programs should be using a PRONTO line which enables an oxygenator to be changed out without taking the patient off CPB" . Grist G. 2021. Preventing perfusion incidents: an AMSECT risk register. AmSECT Today, 24(4), 16–18. https://perfusiontheory.com/preventing-perfusion-incidents-a-risk-register-by-gary-grist-rn-ccp-emeritus/