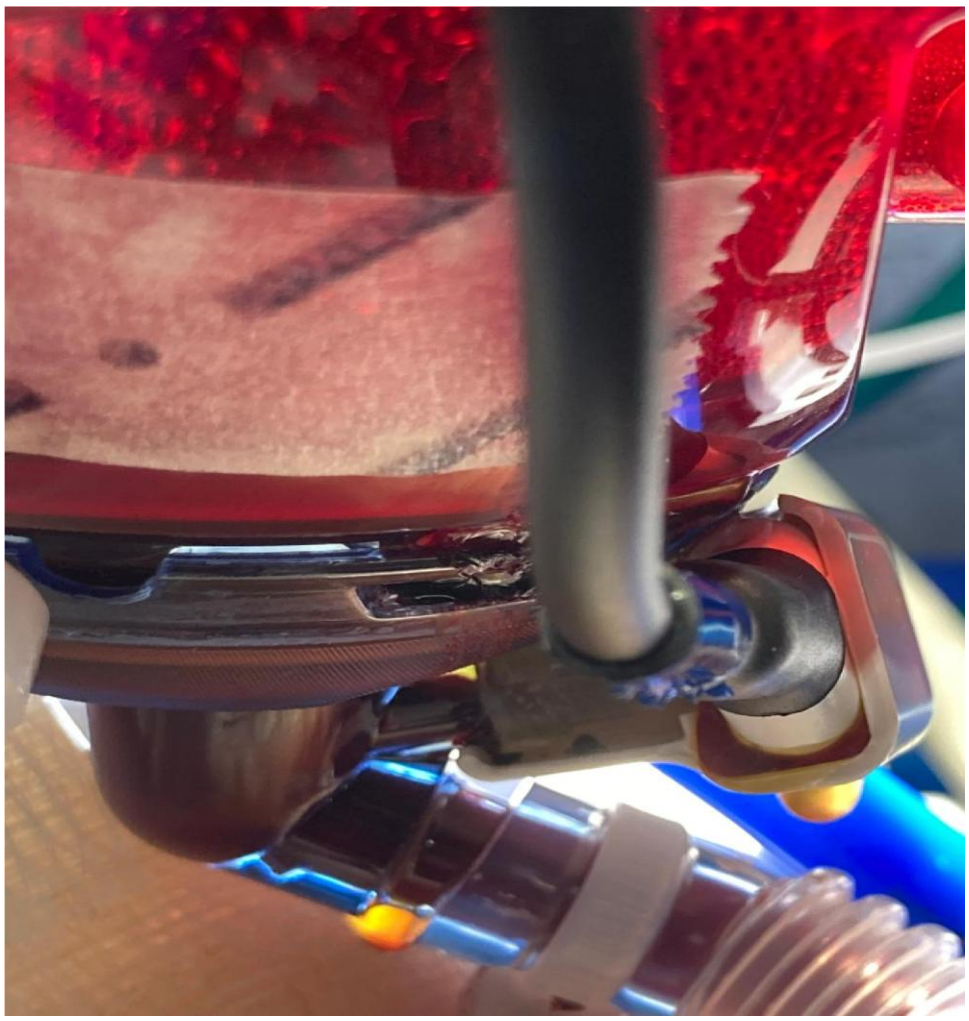
2026 Leaking ECMO Oxygenator

Permission to print:	Yes
Category	Consumables
Severity	Good Catch No Harm Incident
Description:	Over a four-month period, three separate blood leak incidents were observed involving the Eurosets ECMOLife NB ECMO Oxygenator. Incident 1: Immediately after initiating ECMO support, blood droplets were seen emerging from the bottom of the oxygenator and exiting through the venting holes at the base of the plastic housing. Support was discontinued, and the entire circuit was replaced. Incident 2: During the initial clear prime of a new circuit, a leak was again identified at the same location as in the first incident. The circuit was discarded prior to patient use. Incident 3: One week after the second event, a third leak occurred. The patient had been on ECMO support for approximately six hours when the bedside nurse notified the Perfusion team of blood droplets at the base of the oxygenator. Inspection confirmed the leak originated from the same site as the previous two incidents. Support was stopped and the circuit was replaced.
GOOD CATCH - what went well	In all three incidents, the leaks were detected before any significant patient harm occurred. However, in the two cases where patients were already on support, a fully blood primed replacement circuit was required, resulting in the associated negative impacts of an unplanned circuit change. The timely identification of each leak demonstrates that appropriate circuit monitoring and surveillance practices are in place.
What could we do better	Because the issue appears to stem from a manufacturing quality control defect, it is difficult to detect pre-emptively. Our circuits are typically clear primed, which provides an early opportunity to identify any visible abnormalities before patient use. However, following the second occurrence, it would have been appropriate to insist that the supplier replace all circuits from the affected batch.
Preventive actions	The distributor has now replaced all circuits with units from a new lot number. Further communication revealed that a manufacturing process change had been implemented approximately 18 months ago to address previously identified oxygenator leak concerns. All future circuits supplied to us will be from this updated manufacturing process. Internally, we have discussed the potential need to pressure test all ECMO oxygenators prior to use, similar to our practice in the bypass setting. Although the manufacturer has advised that such testing is not necessary, we are continuing to evaluate whether adopting this additional step would enhance safety
Type of incident:	Equipment

Manufacturer advised:	Yes
Discussed with team:	Yes
Hospital incident filed:	Yes
External Authority Advised:	Yes



Blood leak visible in attached photo. Movie of fluid leak during priming attached to email.