

# 2025 Oxygenator (Circuit Disruption)

Category	Oxygenator
Category 2	Circuit disruption
Severity	Good Catch Near Miss
Description:	We chose to electively set up and prime a neonatal ECMO circuit on two occasions in January using the EUROSETS NewBorn Oxygenator (Lot #009593103). On both occasions, during priming, it was identified that there was a fault in the membrane integrity and fluid was leaking from the blood phase into the gas phase. Due to the defect, these products could not be used. Instead, our primed emergency ECMO circuit, which incorporates the paediatric version of this oxygenator was used on both occasions.
GOOD CATCH - what went well	I believe this was the first occasion we had decided to use the New Born size of this oxygenator. Hence, we chose to use it in an elective environment and still had our standard 'paediatric' circuit primed (plasmalyte only) and ready as a backup. After a leak was identified on the first occasion (Mon 20/01/2025) we decided that we would electively set up and prime another circuit at an appropriate opportunity to determine if this was an isolated issue. 9 days later (Wed 29/01/2025) we set up and primed the second NewBorn oxygenator, that was going to be used as an 'emergency circuit'.
What could we do better	Reduced the time between first identifying the fault in the Lot and priming the second NewBorn Oxygenator.
Preventive actions	All of the Eurosets NewBorn Oxygenators from this Lot were pulled and returned to the manufacturer who has since replaced them. We have set up one of the replacements (from a different lot #) and have not had any issues so far. At the time a complaint was lodged with the supplier the incidents were reported to the hospital incident reporting system.
Type of incident:	Equipment
Timing of incident:	Prime
Procedure acuity:	Elective
Discussed with team:	Yes
Hospital incident filed	Yes
Ext Authority Advised	No

