Permission to print: Yes

Near Miss or Accident: Near Miss

Type of incident: Equipment

Catagory Oxygenator

No

No

Knowledge Error

Protocal issue No Rule Error No

Skill Error No

Team Issue No

Chance Chance event: Yes

Violation

Description: It was decided that a patient needed to be put on VV ECMO in a semi elective

situation in PICU. Perfusion prepared a circuit and primed it [the circuit] with plasmalyte. The circuit used was the Maquet BE-PLS-2051 set. I noted a small amount of clear fluid drip on to the floor but on further examination could not find where it came from an was unable to see any more fluid. When blood priming commenced and flows increased prior to patient being cannulated we saw more obvious drops of blood coming from a vent port at the bottom of the oxygenator. The company was phoned and it was advised that a small percentage of these oxygenators were affected due to a defect in the 'mats' within the oxygenator and they recommended that if it was safe to do so to change the oxygenator out. We opened another ECMO pack of the same type and lot number and changed out the oxy and uneventfully continued with the

procedure and safely initiated ECMO. Lot number 70099866

Contributing factors: N

Communication with the company and change out of the oxygenator prior to

ECMO commencing

Preventative action plan: None - company reported that this fault occurred in a small percentage of stock

and are now confident that the new stock does not have the same fault

Manufacturer advised: Yes
Discussed with team: Yes

Ext Authority Advised No

Patient outcome variance f Nil