2019 PIRS ALERT - Blood gas monitor

Permission to print:	Yes
Incident type	Good Catch Near Miss
Catagory	Blood gas
Type of incident:	Equipment
Procedure acuity:	Elective
Description:	We have been trialling a new Terumo CDI550 and have had a large number of failed shunt sensor calibrations (error message: Calibration slope error on pH, pCO2, pO2. Check sensors and gas bottles for correct placement and usage.) and inaccurate values being displayed by the monitor. Initially we thought it was a shunt sensor batch problem so changed batches and K+ values- with the same result. What we did notice was that the tangs on the large blue luer connection that must be unscrewed once the shunt sensor was snapped into the sensor head hit the sensor head body when either being loosened for calibration or tightened following calibration. Our investigation showed that the sensor array embedded in the head assembly sits lower in the CDI550 than the CDI500. This is leading to the shunt sensor marginally disengaging from the sensor head when you unscrew the large blue luer connection for calibration, or when retightening it following calibration. We believe this has possibly led to erroneous values being displayed by the CDI when not detected and remedied prior to CPB.
GOOD CATCH - what went well	Whilst the CDI unit was giving erroneous results we had an ABL900 in theatre and a Spectrum M4 alongside to check/verify results from the CDI550.
What could we do better	Product design process and quality control and remedial actions by manufacturer
Preventive actions	The manufacturer's solution is to loosen the large blue luer prior to snapping the shunt sensor into the sensor head for calibration. However they have no apparent solution for what to do after calibration as removing the calibrated sensor from the head to retighten the blue luer connector may result in a measurement inaccuracy of the system according the CDI550 operating manual.
Region	ANZ
Manufacturer advised:	Yes
Hospital incident filed:	No
Ext Authority Advised	No
Patient outcome variance	Nil
Discussed with team:	Yes
Commentary	This report fills the criteria of a PIRS ALERT.