## Appendix E2 – All Recorded Maude Adverse Events

Table 1 Included (Relevant) MAUDE Reported Events

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| Manufacturer | Term | Event Type | Description |
| MC3 INC. | Urinary track stone removal | Malfunction |  |
| MC3 INC. | Urinary track stone removal | Malfunction | DURING AN OXYGENATOR SWAP FROM A COMPETITORS OXYGENATOR TO MC3, SN#(B)(4) WAS FOUND TO HAVE A LEAK. BLOOD WAS SEEN DRIPPING FROM THE GAS EXHAUST PORT ON THE BOTTOM OF THE DEVICE. THE OXYGENATOR WAS SWAPPED OUT FOR ANOTHER NAUTILUS AND NO PATIENT HARM WAS OBSERVED AS A RESULT. Manufacturer Narrative: THE DEVICE WAS RETURNED FOR ANALYSIS AT MANUFACTURER. THE DEVICE WAS TESTED WITH A PRESSURIZED WATER TEST (BLOOD PATH). THE DEVICE IS CURRENTLY ON TEST AND NO LEAK HAS BEEN OBSERVED AT THIS POINT (DEVICE HAS BEEN ON TEST FOR 2 DAYS). |
| MC3 INC. | Urinary track stone removal | Malfunction | OXYGENATOR STARTED LEAKING BLOOD FROM THE GAS OUTLET PORT. THIS LEAK WAS NOTICED BY THE USER ONE HOUR AFTER STARTING ECMO THERAPY. THE DEVICE WAS EXCHANGED WITH ANOTHER OXYGENATOR. THERE WAS NO PATIENT EFFECT. Manufacturer Narrative: THE DEVICE WAS RETURNED FOR ANALYSIS AT MANUFACTURER. THE DEVICE WAS TESTED AND THE LEAK WAS NOT CONFIRMED WITH A WATER TEST FOR THE BLOOD PATH. THE FIBER BUNDLE WAS EXAMINED AND THERE WAS EVIDENCE OF DRIED BLOOD ON THE DEVICE. THE DEVICE WAS FURTHER CLEANED WITH HYDROGEN PERIOXIDE WHICH REMOVED THE DRIED BLOOD. AFTER MORE THAN A DAY EXPOSED TO PEROXIDE-WATER, THE FIBER LEAK WAS CONFIRMED. DEVICES ARE 100% TESTED DURING THE MANUFACTURING FOR THIS TYPE OF LEAK WITHIN A SINGLE FIBER STRAND. IT IS INCONCLUSIVE AS TO WHY THE FIBER LEAK WAS NOT DETECTED DURING THE MANUFACTURING PROCESS. |
| MC3 INC. | Urinary track stone removal | Malfunction | THE PATIENT WAS PLACED ON ECMO AND FLOW WAS INITIATED AT 12:43 PM. FLOW AND PRESSURES WERE STABLE UPON GOING UP ON THE RPM AND FLOW. AFTER SEVERAL MINUTES, BLOOD WAS SEEN DRIPPING OUT OF THE EXHAUST PORT OF THE NAUTILUS OXYGENATOR. THE PATIENT WAS IMMEDIATELY CLAMPED OUT, AND A NEW NAUTILUS OXYGENATOR WAS BROUGHT IN AND REPLACED. THE PATIENT WENT BACK ON SUPPORT AT 13:16 WITH NO ISSUES. TOTAL BLOOD LOSS WAS 20ML. Manufacturer Narrative: IT IS UNCLEAR, FROM THE INFORMATION PROVIDED, WHAT CAUSED THE NAUTILUS OXYGENATOR TO LEAK BLOOD. THE DEVICE WAS DISCARDED AND NOT RETURNED THEREFORE, A DEFINITIVE ROOT CAUSE CANNOT BE DERIVED. |
| MC3 INC. | Urinary track stone removal | Malfunction | DURING THE ECMO PROCEDURE, AFTER 5 MINUTES, DRIPPING FROM THE GAS OUTLET BEGAN. INLET PRESSURE = 207 MMHG, OUTLET PRESSURE = 195 MMHG, FLOW 4.3 L/MIN, NORMOTHERMIA. Manufacturer Narrative: REVIEW OF PRODUCTION RECORDS FOUND THAT THE DEVICE PASSED ALL MANUFACTURING INSPECTIONS. THE DEVICE WAS RETURNED FOR ANALYSIS AT MANUFACTURER. VISUAL EXAMINATION SHOWED EVIDENCE OF BLOOD LEAK ON THE MANIFOLD CAPS. NO OTHER VISIBLE DEFECTS NOTED. THE DEVICE IS CURRENTLY ON TEST WITH PRESSURIZED HYDROGEN PEROXIDE AND NO LEAK HAS BEEN OBSERVED (DEVICE HAS BEEN ON TEST FOR 1 DAY) AT THIS POINT. |