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Extracorporeal Membrane Oxygenation (ECMO) Safety: Trouble Shooting, Root Cause Analysis and the Failure Mode Effect Analysis Closed Circuit, Hollow Fiber Oxygenator, Centrifugal Pump and Instrument Stack*

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ECMO safety is the avoidance of unnecessary incidents that result in adverse patient outcomes. These are mostly associated with:

1. Malfunctioning/defective equipment and supplies
2. Communication failure between healthcare professionals
3. Human error or incorrect execution of procedures
4. Failure to anticipate adverse events

There are eight steps to safety for any complex medical process like ECMO:

1. Policies, processes and procedures provide authorization and specific instructions to perform specific tasks in the safest, most effective manner.
2. Safety devices include hardware that can prevent injury or accidents.
3. Checklists ensure consistency and completeness of a task and compensate for limits of memory and attention.
4. Documented competency is used to ensure that personnel are fulfilling their duties properly as required by the appropriate authority.
5. Support staff that is adequately trained should be available on site to assist during complex procedures.
6. Trouble shooting is problem solving for failures as they occur.
7. Root cause analysis (RCA) identifies the cause of a serious failure after it occurs and proposes actions and conditions that could have prevented the failure.
8. Failure Modes and Effects Analysis (FMEA) examines how a system can fail before the failure occurs.

Definition: Competency is the ability of personnel to apply their skill, knowledge, and experience to correctly perform their duties. Competency assessment is used to ensure that personnel are fulfilling their duties as required by the appropriate authority.

Definition: Trouble shooting deals with an unanticipated failure while it is occurring using the following plan:

1. Identify what the failure is.
2. Devise an immediate plan to solve the failure.
3. Implement the plan the plan.
4. Assess results.

Definition: A RCA examines why a system failed, after the failure occurs. A system for performing RCA using the steps is listed below. Usually, the RCA recommends the implementation of an FMEA for the process and incident being investigated as a means to prevent future occurrences.

1. Choose investigators
2. Get the facts
3. Identify the hazards
4. Identify why controls failed
5. Plan for future events
6. Inform all players
7. Follow-up

Definition: An FMEA is a technique which 1) identifies potential problems in a design or process by itemizing the conceivable failures, 2) describes the consequences of a failure, 3) recognizes the specific configuration or action that can cause the failure, 4) lists specific actions that can prevent or mitigate the failure and 5) ranks the risk of each failure.

In 2001 the Joint Commission Leadership Standard LD 5.2: *Support of Patient Safety and Medical/Health Care Error Reduction* was implemented with the goal of reducing sentinel events and significant errors. Under this standard, hospitals are required to prevent adverse events and errors, rather than just react to them, by conducting proactive risk assessments. A sentinel event RCA is reactive and does not meet this standard on its own. Hospitals (and by implication ECMO programs) must provide a "failure mode analysis" for proactive process review. Analysis of a process in active use, such as the operation of an ECMO pump, with an FMEA can fulfill the Joint Commission accreditation requirement for proactive risk assessment.

This ECMO FMEA is inspired by an article from Wehrli-Veit et al*. Additional material has been added by various perfusionists. The table on subsequent pages details the FMEA.

Column I. Failure Mode: a list of potential failures.

Column II. Potential Effects of Failure: possible consequences of the failure.
Column III. Potential Cause of Failure: the circumstance that can result in the failure.
Column IV. Management: this column lists specific actions taken by the ECMO specialist to prevent or mitigate each failure mode.
Column V. Risk Priority Number (RPN): An RPN determines the risk priority using expert consensus to establish the probability that a failure will occur. Each failure mode has an assigned Harmfulness (A), Occurrence (B), Detectability (C) and Patient Frequency (D) value.

In addition ECMO RPNs have a Risk Time Factor (RTF); the longer a patient is on ECMO the greater the risk that a failure will occur. One day (24 hours) on ECMO is arbitrarily selected as one RTF. As examples, Day 1 (E1) and Day 10 (E10) RPNs can be determined subjectively by experienced perfusionists and ECMO specialists based on these categories. The Day 1 RPN is calculated by multiplying the numerical values of A, B, C, D and E1; the lowest Day 1 risk being 1*1*1*1 = 1*1day = 1. The highest Day 1 risk being 5*5*5*3 = 375*1 day = 375. The Day 10 RPN is calculated by multiplying the numerical values of A, B, C, D and E10; the lowest Day 10 risk being 1*1*1*1 = 1*10 days = 10, the highest Day 10 risk being 5*5*5*3 = 375*10 = 3750. A score of 375 or greater at Day 10 indicates a high confidence that the described risk will occur.

Obviously the longer the patient is on ECMO the greater the risk. Equipment and disposables are at greater risk for failure the longer they are in continual use. With multiple changes of personnel over time there is increased risk of a communication failure. Human errors or incorrect execution of procedures are more likely as the skill level of personnel varies from work shift to work shift. And less experienced personnel are less likely to anticipate adverse events.

****Disclaimer: See at end of table.

Sub-column A. Harmfulness Rating Scale: how harmful the failure can be. 1. Slightly harmful 2. Low level harm 3. Moderately harmful 4. Seriously harmful 5. Critically harmful	Sub-column B. Occurrence Rating Scale: how frequently the failure occurs. 1. Rarely occurs 2. Infrequently occurs 3. Moderate occurrence 4. Frequently occurs 5. Commonly occurs	Sub-column C. Detection Rating Scale: how easily the potential failure can be detected before it occurs. 1. Very easily detected 2. Easily detected 3. Moderately easy to detect 4. Difficult to detect 5. No means of detection	Sub-column D. Patient Frequency Rating Scale: how often the failure occurs in the total patient population. 1. Few patients are at risk 2. A significant number of patients are at risk 3. All patients are at risk	Sub-column E. Risk Time Factor (RTF): Time period during which the patient is exposed to the risk. E1 is an RTF equal to one day on ECMO. Additional days would multiply the RPN. Ten days (E10) is given as an example.
Calculated RPN: A*B*C*D*E* = Total RPN				

*Wehrli-Veit M, Riley JB, Austin JW. A Failure Mode Effect Analysis on Extracorporeal Circuits for Cardiopulmonary Bypass. JECT. 2004;36: 351-357.

FAILURE MODE / TROUBLE SHOOTING CATEGORIES (SEE TABLE BELOW)

A. BLOOD PUMP FAILURE
B. PRESSURE MONITOR FAILURE
C. CIRCUIT BLOOD LEAKS
D. INADEQUATE VENOUS RETURN
E. AIR IN THE CIRCUIT
F. WATER HEATER FAILURE
G. OXYGENATOR OR CIRCUIT FAILURE
H. PATIENT PROBLEMS
I. PROCEDURAL FAILURE

					V. RPN					
					A. Harmfulness	B. Occurrence	C. Detectability	D. Frequency	E1. Risk Priority Day 1	E10. Risk Priority Day 10
I. ECMO Circuit Failure Mode	**II. Potential Effects of Failure**	**III. Potential Cause of Failure**	**IV. Management**							
A. BLOOD PUMP FAILURE				.RPN	A.	B.	C.	D.	E1.	E10.
A1 Failure. Reduced or no apparent blood flow on centrifugal blood pump.	A1 Effect #1: Technical failure but no real loss of blood flow and no immediate danger to the patient. A1 Effect #2: Actual reduced blood flow can cause degradation of the patient's physiology. Stoppage of blood flow can result in the immediate death of the patient.	A1 Cause #1: Flow transducer not functioning properly. A1 Cause #2: Pre-pump pressure too negative: circuit kinked or clot obstruction in the venous line. A1 Cause #3: Post-pump pressure too positive: circuit kinked or clot obstruction post pump. A1 Cause #4: Inadequate patient circulating blood volume: 1. low CVP measurement, if available. 2. negative fluid balance. A1 Cause #5: Venous cannula displacement. A1 Cause #6: Cardiac tamponade: 1. High CVP measurement, if available	A1 Management #1: Adjust or replace flow transducer. A1 Management #2: Straighten out kinked line or remove obstructive clot. A1 Management #3: Straighten out kinked line or remove obstructive clot. SEE SECTION G. OXYGENATOR OR CIRCUIT FAILURE A1 Management #4: Give fluid volume. A1 Management #5: Adjust patient head and neck position: 1. Midline or extend head and neck 2. Prop up patient; R or L side	A1#1	1	3	1	3	9	90
				A1#2	4	5	1	3	60	600
				A1#3	3	3	1	3	27	270
				A1#4	3	4	3	3	108	1080
				A1#5	5	1	3	3	45	450
				A1#6	5	2	4	1	40	400
				A1#7	3	1	1	3	9	90
				A1#8	2	1	1	3	6	60
				A1#9	6	1	1	3	18	180

		2. CXR w/ cardiac silhouette abnormality 3. Tachycardia 4. Muffled heart sounds 5. Jugular vein distention (with chest or femoral cannulation) 6. Falling BP 7. Loss of pulsatility 8. Paradoxical pulse on inspiration 9. ST segment changes. A1 Cause #7: Excessive air de-primed the cone, stopping the blood flow. A1 Cause #8: Drive unit not properly locked into position, pulling on blood lines, kinking or disrupting them. A1 Cause #9: Unknown reason for stopped blood flow.	Check CXR for venous cannula position: 3. Call surgeon for cannula revision A1 Management #6: SEE SECTION H. PATIENT PROBLEMS : 1. Aggressively strip chest tubes if applicable. 2. Pericardial tap. 3. Contact surgeon for surgical intervention. A1 Management #7: SEE SECTION E. AIR IN CIRCUIT. A1 Management #8: Secure the drive unit 3 joint holder, fast clamp and locking knob in the proper position: 1. Position the drive unit, ensuring that the locking knob is tight. 2. Locate the drive unit with proper cone orientation and in close proximity to the emergency drive. 3. Position the drive unit to prevent fluid from entering the ventilation ports. A1 Management #9: Transfer cone to hand crank and begin manual operation: 1. Hand crank only if circuit pressures can be								

			maintained within normal limits and without alarms 2. DO NOT hand crank if blood flow is stopped due to excessively high post-pump or low pre-pump pressure alarms.							
A2 Failure: Centrifugal pump head (cone) not turning.	A2 Effect #1: Potential for retrograde blood flow in circuit with risk if hemodynamic collapse or air embolus. Clamp patient blood lines immediately.	A2 Cause #1: Power switch accidentally turned off. A2 Cause #2: Flow knob accidentally turned off: assess for pump RPMs. A2 Cause #3: Error code flashing on console. A2 Cause #4: Cone decoupled from drive unit. A2 Cause #5: Pump not properly connected to 110v outlet and the battery is depleted. A2 Cause #6: Fluid entry into drive unit through ventilation ports: electric motor damaged by water.	A2 Management #1: 1.Clamp either the venous or arterial blood line to prevent retrograde flow. * 2.Turn on power switch and set RPMs for forward flow. (*Perform this for each management intervention anytime blood flow is interrupted. Keep blood line clamped until appropriate RPMs are restored.) A2 Management #2: Turn up flow knob. A2 Management #3: Turn power switch to console off and then on to reset internal computer. A2 Management #4: Assess for abnormal sounds emanating from the cone/drive unit: 1. Decoupling may cause a humming, clicking or knocking sound. 2. Stop RPMs and re-seat the cone in the drive unit, then restart RPMs.	A2#1	3	1	1	3	9	90
				A2#2	2	2	1	3	12	120
				A2#3	1	1	1	3	3	30
				A2#4	3	1	1	3	9	90
				A2#5	1	1	1	3	3	30
				A2#6	3	1	4	3	36	360

			A2 Management #5: Secure the 110v power source and restart pump. A2 Management #6: Transfer cone to manual drive unit and hand crank until another drive unit can be obtained and installed.							
A3 Failure: Cavitation and blood damage from excessive RPMs as pump continues to turn	A3 Effect #1: Excessive RPMs will damage the blood causing hemolysis. This can lead to renal failure, electrolyte imbalance and renal failure.	A 3 Cause #1:Pre-pump pressure transducers not responding to pressure changes due to malfunction or clotting off. A3 Cause #2: Compliance chamber* full: pump outlet obstructions such as tubing kinks, twists, clots blocking the tubing/ oxygenator or too small of an arterial cannula requiring high RPMs. *The compliance chamber is a flexible venous line reservoir that collapses as the pre-pump pressure becomes negative. A3 Cause #3: Compliance chamber not full: pump inlet obstruction caused by tubing kinks, twists, clots blocking the venous line tubing or too small of a venous cannula requiring high RPMs.	A3 Management #1: 1.Flush, zero, replace pressure transducer. 2.Verify integrity of pressure transducer line or stopcock and replace as needed. A3 Management #2: Correct obstruction and modify pressure alarm limit. A3 Management #3: Correct obstruction and modify pressure alarm limit.	A3#1	2	2	3	3	36	360
				A#32	1	1	1	3	3	30
				A3#3	1	1	1	3	3	30
B. PRESSURE MONITOR FAILURE										
B1 Failure: No pressure alarm function	B1 Effect #1: The lack of adequate alarms may cause the ECMO specialist to assume that the circuit is performing properly	B1 Cause #1: Incorrect pressure alarm limit settings. B1 Cause #2: Pressure transducer not connected, stopcock turned off, or clots in tubing or connections.	B1 Management #1: Check and reset pressure limits on pre-pump and post-pump. B1 Management #2: Verify integrity of pressure	B1#1	1	1	1	3	3	30
				B1#2	1	4	1	3	12	120
				B1#3	1	1	1	3	3	30

	when it is not.	B1 Cause #3: Pressure transducer malfunction.	transducer lines or stopcocks and replace as needed. B1 Management #3: Flush, zero, and replace pressure transducers as needed.							
C. CIRCUIT BLOOD LEAKS										
C1 Failure: Blood dripping on the pump or the floor	C1 Effect #1: The risks depend on how much blood is leaking and include blood loss, air embolus, oxygenator failure and circuit disruption.	C1 Cause #1: Pre or post-cone leak in connector or other component. C1 Cause #2: Oxygenator leaking blood from tubing connection. C1 Cause #3: Oxygenator leaking blood from air vent port. C1 Cause #4: Oxygenator leaking blood from sweep gas exhaust port.	C1 Management #1: Change or repair the component that is leaking; the urgency depends on how much blood is leaking. 1. Patch leak with sterile bone wax plug secured with tape, if possible. 2. Call for assistance. C1 Management #2: Tubing connection leak: 1. Patch leak from a connection with sterile bone wax plug secured with tape, if indicated 2. Call for assistance C1 Management #3: Air vent port leak: 1. Close pigtail stopcock. 2. No additional action required. C1 Management #4: Sweep gas exhaust port: 1. Exhaust port condensate pink tinged: change oxygenator as convenient. 2. Exhaust port dripping red whole blood: change oxygenator ASAP.	C1#1	3	1	2	3	18	180
				C1#2	4	1	1	3	12	120
				C1#3	1	3	1	3	9	90
				C1#4	1	1	1	3	3	30

			3. Call for assistance.							
C.2 Failure: Blood detected in water lines. This is an emergency!	C2 Effect #1: Risk of hemolysis, infection and overt water infusion into the blood	C2 Cause #1: Leak in oxygenator heat exchanger.	C2 Management #1: 1. Turn off water heater and remove water lines ASAP. 2. Change the oxygenator ASAP. 3. Call for assistance.	C2#1	5	1	3	3	45	450
D. INADEQUATE VENOUS RETURN				.RPN	A.	B.	C.	D.	E1.	E10.
D1 Failure: Venous blood line jerking a/k/a chugging.	D1 Effect #1: The degradation of venous return can result in inadequate cardiovascular support and its associated complications, such as organ failure or organ damage.	D1 Cause #1: Venous/cephalic catheter mal-positioned. D1 Cause #2: Kink in venous blood tubing between the patient and the pump. D1 Cause #3: Flow knob inadvertently increased: assess RPMs D1 Cause #4: Inadequate venous return due to patient condition; patient agitated/active, hypovolemia, pericardial tamponade, increased abdominal pressure, seizures, etc. D1 Cause #5: Cannula kinked or obstructed: 1. Assess CXR. 2. Steel reinforcing wire within cannula compressed when inserted. 3. Securing suture is too tight around cannula. 4. Kinking commonly occurs spontaneously with VV double lumen cannulae. D1 Cause #6: Cannula too small: assess blood flow capacity of the cannula. See cannula flow chart.	D1 Management #1: Adjust patient head and neck position: 1. Midline or extend head and neck. 2. Prop up patient; R or L side. 3. Check CXR for venous cannula position. 4. Call surgeon for cannula revision. D1 Management #2: Remove kink and secure tubing to prevent further problems. D1 Management #3: Reduce RPMs in indicated D1 Management #4: This is not a condition related to the mechanical function of the ECMO pump. SEE SECTION H. PATIENT PROBLEMS: 1. Manipulate pump as indicated to optimize blood flow as much as possible. 2. Evaluate the patient as indicated. 3. Apply appropriate	D1#1	3	4	2	3	72	720
				D1#2	2	4	1	3	24	240
				D1#3	2	1	1	3	6	60
				D1#4	3	4	1	3	36	360
				D1#5	4	1	3	3	36	360
				D1#6	3	1	2	3	18	180

			medical/surgical remedies. D1 Management #5: l. If neck cannulation, extend neck. 2. May require surgical intervention to repair. D1 Management #6: 1. Reduce blood flow from target flow. 2. Increase medication or ventilator support to compensate for lower blood flow. 3. Surgical replacement, if applicable							
E. AIR IN CIRCUIT				.RPN	A.	B.	C.	D.	E1.	E10.
E1 Failure: Pre-pump air in the venous cannula, venous line and compliance chamber	E1 Effect #1: Air in the circuit will cause an air/blood interface that can lead to clotting, air embolus and de-priming of the centrifugal pump.	E1 Cause #1: Cracked or open stopcocks, pigtails, or connectors in venous line. E1 Cause #2: Pre-pump volume pushes into circuit. E1 Cause #3: Venous cannula connector loose or cracked. E1 Cause #4: Venous cannula side port dislodged from vein; side hole out of vessel. E1 Cause #5: Patient source of air coming from right atrium from central line or peripheral line infusion sites. E1 Cause #6: Patient source of air coming from right atrium from pulmonary-to-systemic (left atrial)	E1 Management #1: 1. Replace cracked components and adjust stopcocks. 2. Re-secure loose tubing and connector. 3. Temporarily patch crack with sterile bone wax and secure with tape. 4. Call for assistance. E1 Management #2: Give volume pushes post-pump. E1 Management #3: 1.Replace cracked cannula connector. 2.Cal for assistance. E1 Management #4: Contact surgery to reposition cannula.	E1#1	3	2	2	3	36	360
				E1#2	1	1	1	3	3	30
				E1#3	4	1	2	3	24	240
				E1#4	4	1	4	3	48	480
				E1#5	4	1	5	1	20	200
				E1#6	5	1	5	1	25	250

		air embolus potentially caused by interstitial pulmonary emphysema, acute respiratory distress syndrome or idiopathic alveolar rupture with air crossing into the right atrium during positive pressure ventilation. This is a rare occurrence and an emergency!	E1 Management #5: Secure peripheral infusion sites. E1 Management #6: 1. Stop any positive pressure pulmonary physiotherapy. 2. Reduce ventilator pressure to minimum. 3. Increase FiO2 on ventilator and sweep gas to 100% for a minimum of 2 hours to 'off gas' air emboli that have entered the systemic circulation from the left atrium.							
E2 Failure. Air in the blood pump cone	E2 Effect #1: Air trapped in the cone may cause hemolysis and reduced blood flow. If too much air accumulates, the cone could de-prime, causing the blood flow to completely stop.	E2 Cause #1: 1. Any air in the venous line should be walked down the line and into the spinning cone. 2. Air is trapped in the cone as it enters from the venous blood line. 3. The bubbles in the cone cause a swishing 'dishwasher' sound. 4. Efforts should be made to stop the air source to prevent its accumulation in the cone. 5. If only a small amount of air has entered the cone and no additional air is accumulating, it can be allowed to harmlessly absorb without any intervention. 6. However, accumulating air should be removed before de-priming of the cone occurs.	E2 Management #1 1. Remove the patient from ECMO by clamping the blood line between the cone and the oxygenator, placing the clamp nearer to the oxygenator. 2. Stop the pump and allow the air to rise into the outflow blood line of the cone. 3. Remove the cone from the drive unit, if necessary, to manipulate the air into the outflow blood line. 4. Restart the pump, remove the clamp and allow the air to enter the oxygenator. This should also place the patient back on ECMO. 5. Excessive air in the cone may require it to be re-	E2#1	2	3	2	3	36	360

			primed 6. Push fluid into the venous line towards the cone. The volume of the cone is approximately 50 ml. 7. This simultaneously pushes the air up towards the oxygenator. 8. Restart the pump, remove the clamp and allow the air to enter the oxygenator.							
E3. Air in the oxygenator and bubble trap.	E3 Effect #1: Air trapped in the oxygenator or bubble trap may cause hemolysis, clotting or reduced blood flow. If too much air accumulates, there is a risk of air embolus to the patient.	E 3 Cause #1: 1.Air accumulating in the oxygenator usually comes from the venous line or from the CDI shunt line. 2. However, if the post-pump pressure falls below the patient blood pressure, air can spontaneously cross the hollow fibers from the sweep gas and enter the ECMO circuit creating a risk of air embolus.	E3 Management #1: 1.Some air may not be removed automatically by the oxygenator hollow fibers or air vent port 2.After entering the oxygenator, the air can be aspirated by syringe from the oxygenator ports or the bubble trap without removing the patient from ECMO. 2. Excessive air removal may require an equal volume of fluid to be administered simultaneously to prevent patient hypovolemia. 3. Maintain a post-pump pressure higher than the patient's mean blood pressure at all times.	E3#1	2	3	2	3	36	360
E4 Failure: Air in the arterial blood line past the bubble trap; this is an emergency!	E4 Effect #1: Air that manages to enter the arterial blood line has an unimpeded path to enter the patient's	E4 Cause #1: Air that manages to enter the arterial blood line usually comes from an unnoticed or unknown source.	E4 Management #1: 1. Immediately, manually kink the arterial blood line between the air and the patient to stop the flow of	E4#1	5	1	3	3	45	450

	circulation and cause an air embolus, even during VV ECMO.		blood and air. Don't waste time looking for tubing clamps. 2. Quickly obtain tubing clamps and apply to both blood lines to prevent inadvertent air embolus while taking the patient off ECMO. 3. Find the point of entry of the air and stop it 3. Insert the bridge between the venous and arterial blood lines, recirculate and remove the air from the circuit. 4. Replace the oxygenator, if needed. 6. Removing excessive amounts of air from the ECMO circuit may require a long period of time to complete and a lot of volume to replace the air being removed. 7. Be prepared to resuscitate the patient during air removal. 8. Initiate the standard air embolus protocol, i.e., Trendelenburg, 100% O2 sweep gas and ventilator gas, steroids, barbiturates and core cooling.							
F. WATER HEATER FAILURE										
F1 Failure: Water dripping on the pump or floor	F1 Effect #1: The loss of adequate water to operate the unit and to wet floor slippage by personnel.	F1 Cause #1: Water only leak (no blood) at water hose connections. F1 Cause #2: Crack in outer plastic housing of the oxygenator not	F1 Management #1: 1. Turn water heater off, reseat the water hose connections. 2. Call for assistance to	F1#1	1	1	1	3	3	30
				F1#2	1	1	1	3	3	30

		involving blood leakage.	replace unit. F1 Management #2: 1. Try to seal leak with bone wax secured with tape for temporary repair. 2. Call for assistance to replace oxygenator							
F2 Failure: Temperature alarm	F2 Effect #1: Inadequate patient temperature control.	F2 Cause #1: Temperature set improperly. F2 Cause #2: Large amount of cold water added too quickly to the water reservoir. F2 Cause #3: Temperature recently adjusted. F2 Cause #4: Water level too low. F2 Cause #5: Heater or water pump malfunction.	F2 Management #1: 1. Water heater unit recently turned on, such as after a transport. 2. Readjust temperature setting. F2 Management #2: 1.Add water very slowly to the heater 2. Remove water lines from oxygenator and recirculate the water system to warm it up. F2 Management #3: Water heater unit will alarm as it warms or cools after any temperature change by the operator. F2 Management #4: Slowly add distilled water to the reservoir. F2 Management #5: Replacement of water heater may be indicated. 1.Turn unit off if indicated 2. Control patient temperature using external means.	F2#1	2	1	1	3	6	60
				F2#2	3	1	3	3	27	270
				F2#3	3	1	1	3	9	90
				F2#4	1	1	2	3	6	60
				F2#5	2	1	2	3	12	120

			3. Call for assistance to change unit..							
F3 Failure: Patient too cold or too hot	F3 Effect #1: The patient is enduring abnormal temperature ranges not intended to be part the ECMO support.	F3 Cause #1: Water heater unit malfunction: 1. Check water wheel; must be turning to indicate that water pump is operating. 2. Temperature LED malfunction after power interruption. 3. Reads letter characters rather than temperature number. F3 Cause #2: Water heater not turned on. F3 Cause #3: Temperature set point too low or too high. F3 Cause #4: No water flow to the oxygenator: 1. Water shut off valves on water line turned off. 2. Water hoses kinked, occluding water flow. F3 Cause #5: Heater unit set in FLUID mode without inline temperature probe. F3 Cause #6: Large amount of cold water rapidly added to water heater reservoir. F3 Cause #7: Radiant warmer above the bed malfunctioning.	F3 Management #1: 1. Turn water heater unit off, then on again to reset internal computer 2. Replacement of water heater may be indicated. Call for assistance to replace unit.. F3 Management #2: Check on/off switch after transporting patient. F3 Management #3: 1. Check after transporting patient. 2. Adjust set temperature on water bath or other external heat sources. F3 Management #4: 1. Open water shut off valves if closed. 2. Remove kink from water hoses. F3 Management #5: Water heater unit should be set in WATER mode for the internal temperature of the reservoir. F3 Management #6: 1. The 600 watt heater overloaded by excessive amount of cold water. Add water very slowly to the reservoir.	F3#1	2	1	2	3	12	120
				F3#2	1	1	1	3	3	30
				F3#3	2	1	1	3	6	60
				F3#4	2	1	2	3	12	120
				F3#5	1	1	1	3	3	30
				F3#6	2	1	2	3	12	120
				F3#7	2	1	1	3	6	60

			2. Check and reset temperature set point; turn heater off/on, then reset temperature set point. 3. Consider disconnection the heater from the oxygenator and recirculate the water until water warms. F3 Management #7: Check radiant warmer for malfunction.							
G. OXYGENATOR OR CIRCUIT FAILURE										
G1 Failure: Low or decreasing post-pump arterial pO2 (on ABG or CDI monitor) and/ or increased pCO2.	G1 Effect #1: Oxygenator failure from inadequate gas exchange can lead to poor oxygenation, respiratory acidosis, metabolic acidosis, inadequate organ gas exchange and death.	G1 Cause #1: Sweep gas line loose, disconnected or contains cracked connectors. G1 Cause #2: Oxygenator gas exchange failing due to condensation in the hollow fibers. G1 Cause #3: Blood clots in oxygenator reducing surface area for gas exchange. G1 Cause #4: Oxygenator blood flow or gas exchange rate exceeded: 1. Blood flow exceeding oxygenator rating 2. Elevated metabolism requiring excessive oxygenation or CO2 removal	G1 Management #1: 1.Utilize emergency E-tank O2 source with separate gas line. 2.Secure, repair or replace sweep gas line, blender/gas flow meter and/or gas lines. G1 Management #2: 1. “Sigh” oxygenator by increasing sweep gas flow to 10 L/min for 1 minute every 6 hours. 2. Readjust sweep gas or CO2 gas flow, if applicable. 3. Increase FiO2 on blender. G1 Management #3: 1. Readjust sweep gas or CO2 gas flow, if applicable. 2. Increase FiO2 on blender.	G1#1	3	1	3	3	27	270
				G1#2	1	4	2	3	24	240
				G1#3	3	2	4	3	72	720
				G1#4	4	2	3	1	24	240

			G1 Management #4: 1. Consider changing to a larger oxygenator. 2. Consider additional medical and ventilation support. 3. Consider mild hypothermia.							
G2 Failure: Increased post-pump, pre-oxygenator pressure, increased pressure gradient across membrane if monitoring trans-oxygenator pressures. See section on PRESSURE MONITOR FAILURE	G2 Effect #1: Oxygenator failure due to obstruction to blood flow can lead to poor oxygenation, respiratory acidosis, metabolic acidosis, inadequate organ gas exchange and death.	G2 Cause #1: Increased post-pump, pre-oxygenator pressure and the need for increased pump RPMs indicate a clotting oxygenator.	G2 Management #1: 1. Eliminate all other possible causes of post-pump, pre-oxygenator changes. (SEE SECTION B. PRESSURE MONITOR FAILURE) 2. Evaluate pressure and rpm changes over prior 24 hours 3. Change oxygenator before it becomes flow limited by excessive post-pump, pre-oxygenator pressure.	G2#1	3	2	2	3	36	360
PATIENT PROBLEMS										
H1 Failure: Increasing or decreasing patient arterial pO2.	H1 Effect #1: Cyanosis, acidosis, poor perfusion, lethargy, worsening blood gases. H1 Effect #2: 1. High CVP measurement, if available 2. CXR w/ cardiac silhouette abnormality 3. Tachycardia 4. Muffled heart sounds	H1 Cause #1: Inadequate VA ECMO blood flow. Significant recirculation on VV ECMO. H1 Cause #2: Pneumothorax. H1 Cause #3: Atelectasis, ventilator, or ETT problem. H1 Cause #4: Hemothorax or effusion. H1 Cause #5; Oxygenator failing Sweep gas line to oxygenator loose,	H1 Management #1: 1.Increase VA ECMO blood flow, if possible. 2.Increase ventilator and/or medical support. 3.Consider vasopressor support if VV ECMO. 4.Give volume to minimize recirculation if VV ECMO. 5.Consider conversion to VA if VV ECMO. H1 Management #2: 1. Reduce ventilator pressures.	H1#1	4	4	2	3	96	960
				H1#2	3	2	3	3	54	540
				H1#3	2	3	3	3	54	540
				H1#4	4	2	3	2	48	480
				H1#5	3	2	1	3	18	180
				H1#6	4	3	2	3	72	720
				H1#7	4	3	3	2	72	720
				H1#8	2	4	1	3	24	240
				H1#9	2	2	3	3	36	360
				H1#10	5	3	1	2	30	300
				H1#11	2	4	2	3	48	480
				H1#12	4	2	3	2	48	480
				H1#13	3	3	1	3	27	270
				H1#14	3	3	2	3	24	240
				H1#15	4	3	3	3	108	1080

	5. Jugular vein distention (difficult to assess with neck cannulation) 6. Falling BP 7. Loss of pulsatility 8. Paradoxical pulse on inspiration 9. ST segment changes. H1 Effect #3: Patient looks well.	disconnected or cracked H1 Cause #6: Seizures H1 Cause #7: Sepsis with or without peripheral shunting. H1 Cause #8: Agitated patient. H1 Cause #9: Hypervolemia, increased pulmonary perfusion prior to pulmonary recovery. H1 Cause #10: Decreased cardiac output on VV ECMO. H1 Cause # 11: Decreased patient hematocrit H1 Cause #12: Structural cardiac or pulmonary defect: 1.Diaphragmatic hernia 2.Co-arctation 3.Central shunt 4.Pulmonary stenosis 5.Single ventricle H1 Cause #13: Centrifugal pump: change in patient preload or afterload causing inadequate or altered blood flow. H1 Cause #14: Hypovolemia. H1 Cause #15: Cardiac stun with inadequate perfusion. H1 Cause #16: Tissue death with decreased O2 consumption.	2. Allow passive absorption of air. 3. DO NOT place intercostal chest tube unless hemodynamics are compromised. 4. Aggressively strip any chest tubes that are already in place. H1 Management #3: 1.Adjust ETT or ventilator as needed. 2. DO NOT use nasal intubation in children. It may result in excessive adenoidal bleeding. H1 Management #4: 1.Transfuse if hematocrit is low. 2.Evacuate hemothorax or effusion if hemodynamics are compromised. H1 Management #5: SEE SECTION G. OXYGENATOR OR CIRCUIT FAILURE. H1 Management #6: See H9 Failure Mode for seizures. Treat seizures. H1 Management #7: Treat sepsis. H1 Management #8: Calm or sedate patient.	H1#16	5	1	3	2	30	300
				H1#17	1	4	1	3	12	120
				H1#18	1	4	2	3	24	240
				H1#19	4	3	4	2	96	960
				H1#20	1	4	1	3	12	120

		H1 Cause #17: Improving respiratory function. H1 Cause #18: Cardiac stun on adequate VA flow. H1 Cause #19: Pneumopericardium or hemopericardium, pericardial tamponade. H1 Cause #20: Improving cardiac and/or pulmonary function.	H1 Management #9: Administer diuretics H1 Management #10: 1.Consider vasopressor support. 2.Consider conversion to VA ECMO. H1 Management #11: Transfuse. H1 Management #12: 1.Increase target blood flow. 2.Consider TEE/cardiac catheterization H1 Management #13: Interventions to increase patient right atrial volume or reduce patient blood pressure as indicated clinically. H1 Management #14: Evaluate blood volume and correct as needed. H1 Management # 15: 1.Increase VA ECMO blood flow, if possible. 2.Increase ventilator and/or medical support. 3.Consider vasopressor support if VV ECMO. 4.Consider conversion to VA if VV ECMO. H1 Management #16:							

			1.Evaluate organ systems for viability. 2. Consider termination of ECMO. H1 Management #17: 1.Adjust ventilator FIO2. 2.Consider weaning ECMO blood flow. H1 Management # 18: Continue full ECMO flow. H1 Management #19: 1. Aggressively strip chest tubes if applicable. 2. Pericardial tap. 3. Contact surgeon for surgical intervention. H1 Management #20: Consider weaning ECMO blood flow.							
H2 Failure: Increasing or decreasing patient arterial pCO2.	H2 Effect #1: 1.Apnea 2.Alkalosis Effect #2: 1.Tachypnea 2.Acidosis 3.Agitation 4. Hypertension	H2 Cause #1: Sweep gas flow too high. H2 Cause #2: CO2 titration too low. H2 Cause #3: Patient over ventilated. H2 Cause #4: Improving patient respiratory function. H2 Cause #5: Sweep gas flow too low H2 Cause #6: CO2 titration too high.	H2 Management #1: Decrease sweep gas flow. H2 Management #2: Increase CO2 titration. H2 Management #3: Wean patient ventilator. H2 Management #4: Consider ECMO weaning. H2 Management #5: Increase sweep gas flow. H2 Management #6:	H2#1	2	2	1	3	12	120
				H2#2	2	2	1	3	12	120
				H2#3	2	2	1	2	13	130
				H2#4	1	4	2	3	24	240
				H2#5	3	3	1	3	27	270
				H2#6	3	3	1	3	27	270
				H2#7	2	2	2	3	24	240
				H2#8	1	1	2	3	6	60
				H2#9	4	2	2	3	48	480
				H2#10	1	3	1	3	9	90
				H2#11	4	2	4	2	96	96

		H2 Cause #7: Patient under ventilated. H2 Cause #8: Endotracheal tube (ETT) problem. H2 Cause #9: Oxygenator failure. H2 Cause #10: Patient agitation. H2 Cause #11: 1.Pneumothorax 2.Hemothorax 3.Pulmonary effusion	Decrease CO2 titration. H2 Management #3: Adjust patient ventilator. H2 Management #8: 1.Adjust or replace ETT 2.DO NOT use nasal intubation in children. It may result in excessive adenoidal bleeding. Management #9: Replace oxygenator. SEE SECTION G. OXYGENATOR OR CIRCUIT FAILURE. H2 Management #10: Calm or sedate patient. H2 Management #11: 1.Transfuse if hematocrit low. 2.Evacuate hemothorax or effusion if hemodynamics are compromised.							
H3 Failure: Inconsistent or out of range activated clotting time (ACT) tests	H3 Effect #1: 1.Patient bleeding 2.Excessive blood loss 3.Circuit clotting 4.Thrombus formation	H3 Cause #1: Error or inconsistency in ACT technique or amount of blood used. H3 Cause #2: New heparin lot. H3 Cause #3: Infusion pump malfunction or pump set incorrectly. H3 Cause #4: Alteration or malfunction of ACT sampling site (e.g. clots or contamination of the	H3 Management #1: 1.Review sampling technique. 2. Repeat test H3 Management #2: 1.Consider replacement of heparin drip. 3.Consider checking heparin level. H3 Management #3: 1.Check infusion pump for	H3#1	2	1	1	3	6	60
				H3#2	1	1	4	3	12	120
				H3#3	3	1	1	3	9	90
				H3#4	1	1	1	3	3	30
				H3#5	3	1	1	3	9	90
				H3#6	2	3	2	3	36	360
				H3#7	1	1	1	3	3	30
				H3#8	1	1	1	3	3	30
				H3#9	3	1	4	3	36	360
				H3#10	4	2	4	3	96	960
				H3#11	5	2	3	2	60	600
				H3#12	1	4	1	3	12	120
				H3#13	3	2	4	3	72	720

		port). H3 Cause #5: ACT instrument or tubes/cartridges malfunction. H3 Cause #6: 1.Low or decreasing platelet counts. 2.Recent platelet transfusion. 3. Low fibrinogen. 4.Other coagulation factor deficiencies. H3 Cause #7: Sample mistakenly drawn in a heparinized syringe. H3 Cause #8: Heparin contamination from another source (e.g. TPN, line flushed). H3 Cause #9: Vitamin K deficiency. H3 Cause #10: Disseminated intravascular coagulation (DIC) due to circuit coagulopathy. H3 Cause #11: DIC due to sepsis. H3 Cause #12: Decreased or increased urine output. H3 Cause #13: Low Antithrombin III (AT III) level. H3 Cause #14: Recent Factor VII (NovoSeven) transfusion.	proper operation. 2. Consider replacement. H3 Management #4: 1.Change sampling port. 2.Change adaptors, stopcocks, and tubing as needed. H3 Cause #5: QC and replace ACT instrument and tubes/cartridges as needed. H3 Management #6: Check coagulation factors and correct as indicated. H3 Management #7: Repeat specimen in non-heparinized syringe. H3 Management #8: Look for heparin administered in other sources (minimal amounts by continuous infusions usually will not cause ACT alterations). H3 Management #9: Administer Vitamin K. H3 Management #10: 1.Check platelet count, coagulation tests, and correct as indicated. 2.Replace circuit.as needed. H3 Management #11:	H3#14	3	2	3	2	36	360

			Evaluate for and treat sepsis. H3 Management #12: Assess for changing urine output and address as clinically indicated. H3 Management #13: Consider fresh frozen plasma (FFP) or AT III transfusion for low AT III level. H3 Management #14: Check heparin level.							
H4 Failure: Oliguria.	H4 Effect #1: 1. Decreased Urine Output. 2. Edema. 3. Increased creatinine, BUN.	H4 Cause # 1: 1.Hypotension. 2.Hypovolemia. H4 Cause #2: Capillary leak syndrome. H4 Cause #3: Poor cardiac output. H4 Cause #4: Ischemic renal disease.	H4 Management #1: 1. Increase pump flow if on VA ECMO. 2. Give volume. 3. Consider inotrope if on VV ECMO. H4 Management #2: 1.Diuretics 2.Add replacement volume and attempt simultaneous removal with slow continuous ultrafiltration. H4 Management #3: 1.Increase pump flow if on VA ECMO. 2.Add volume or vasopressor support. H4 Management #4: 1.Increase paO2 with pump or ventilator. 2.Add diuretics. 3.Add slow continuous	H4#1	3	3	2	3	24	240
				H4#2	4	3	2	3	72	720
				H4#3	5	2	3	3	90	900
				H4#4	5	2	2	2	40	400

			ultrafiltration, hemofiltration or hemodialysis.							
H5. Failure: Hemolysis.	H5 Effect #1: 1. Plasma free hemoglobin > 100 mg/dl. 2. Tea colored urine. 3. Renal dysfunction	H5 Cause #1: Inaccurate sampling. H5 Cause #2. Centrifugal pump hemolysis, especially at high RPMs with low blood flows. H5 Cause #3: Water heater temperature too high. H5 Cause #4: Clots in patient. H5 Cause #5: 1. Clots, kinks or leaks in the ECMO circuit. 2. One or both cannulae are too small for desired blood flow.	H5 Management #1: 1. Repeat test - draw slowly, send specimen stat to lab. 2. Draw from end of pigtails with syringe. 3. Do not use a needle through a PRN adapter. H5 Management #2: 1.Manage RPMs to the minimum necessary 2.Convert to roller pump. H5 Management #3: Turn down water heater temperature. SEE SECTION F. WATER HEATER FAILURE. H5 Management #4: 1. Treat for DIC. 2. Replace circuit if needed to reduce free hemoglobin load. H5 Management #5: See the following sections: CENTRIFGUAL BLOOD PUMP FAILURE PRESSURE MONITOR FAILURE BLOOD LEAKS INADEQUATE VENOUS RETURN AIR IN THE CIRCUIT WATER HEATER	H5#1	1	1	1	3	3	30
				H5#2	3	2	2	3	24	240
				H5#3	3	1	1	3	9	90
				H5#4	3	3	4	3	108	1080
				H5#5	2	4	2	3	48	480

			FAILURE OXYGENATOR FAILURE							
H6 Failure: Non-surgical bleeding.	H6 Effect #1: 1.Blood loss. 2.Decreased hematocrit.	H6 Cause #1: Activated clotting time (ACT) too high due to excess heparin. H6 Cause #2: Platelet function poor or count too low. H6 Cause #3: Disseminated intravascular coagulation (DIC). H6 Cause #4: Sepsis. H6 Cause #5: Agitation. H6 Cause #6: Hypertension. H6 Cause #7: Cannula manipulation.	H6 Management #1: 1. Reduce heparin infusion rate. 2. Reduce ACT target value. 3. Evaluate heparin level. 4. Evaluate Antithrombin III level. 5. Change circuit if disseminated intravascular coagulation (DIC) suspected. 6. Consider aminocaproic acid, tranexamic acid or Novo 7 infusion. H6 Management #2: 1. Consider factor Xa, thromboelastography and antithrombin III assay. 2. Administer platelet transfusion H6 Management #3: Medically treat for DIC. H6 Management #4: Medically treat for sepsis. H6 Management #5: Calm, sedate or paralyze patient. H6 Management #6: Medically treat for hypertension. H6 Management #7:	H6#1	3	3	1	3	27	270
				H6#2	3	3	2	3	54	540
				H6#3	4	2	4	2	64	640
				H6#4	4	2	4	2	64	640
				H6#5	1	5	1	3	15	150
				H6#6	3	3	1	3	27	270
				H6#7	3	2	1	3	18	180

			1.Control bleeding topically if isolated site (sutures to cannula, Bioseal, QuikClot dressing, etc.). 2.May require surgical intervention to secure cannulae.							
H7 Failure: Hypertension.	H7 Effect #1: Complications from increased blood pressure.	H7 Cause #1: Fluid overload. H7 Cause #2: Pain. H7 Cause #3: Agitation. H7 Cause #4: Idiopathic cause. H7 Cause #5: Improved cardiac output. H7 Cause #6: Too high ECMO VA blood flow. H7 Cause #7: Recent steroid administration.	H7 Management #1: Consider diuretics or ultrafiltration. H7 Management #2: Treat pain. H7 Management #3: Calm or sedate. H7 Management #4: Anti-hypertensive medication. H7 Management #5: Decrease VA ECMO blood flow. H7 Management #6: 1.Decrease VA ECMO blood flow. 2.Consider increased ventilator or medical support. H7 Management #7: Wean inotropic or steroid support as appropriate.	H7#1	4	3	2	3	72	720
				H7#2	2	2	3	3	36	360
				H7#3	1	5	1	3	15	150
				H7#4	4	1	1	3	12	120
				H7#5	1	4	2	3	24	240
				H7#6	3	2	2	3	36	360
				H7#7	2	1	4	3	24	240
H8 Failure: Hypotension.	H8 Effect #1: Complications from decreased blood pressure.	H8 Cause #1: Decreased cardiac output. H8 Cause #2: Hypovolemia.	H8 Management #1: 1. Increase VA ECMO blood flow. 2. Administer volume. 3. Consider vasopressors if	H8#1	4	3	1	3	36	360
				H8#2	3	3	2	3	54	540
				H8#3	4	2	2	3	48	480
				H8#4	5	1	1	3	15	150
				H8#5	4	2	3	3	72	720

		H8 Cause #3: Capillary leak syndrome. H8 Cause #4: Massive hemorrhage. H8 Cause #5: Sepsis. H8 Cause #6: Low pump flow (VA ECMO).	on VV ECMO. H8 Management #2: Administer volume. H8 Management #3: Administer volume while removing volume by ultrafiltration as tolerated. H8 Management #4: Identify patient specific cause and treat as indicated. H8 Management #5: Medically treat for sepsis. H8 Management #6: Increase pump flow if adequate right atrial volume.	H8#6	5	1	1	3	15	150
H9 Failure: Seizures.	H9 Effect #1: 1.May be focal or generalized. 2.Increased blood pressure 3.Increased or decreased heart rate 4.Decreased SVO2 and/or SPO2 5.Hypoxia 6. Cyanosis	H9 Cause #1: 1. Ischemic brain injury. 2. Cerebral edema. 3. Brain infarction. 4. Intracranial hemorrhage.	H9 Management #1: 1. Administer anticonvulsants. 2. Treat as indicated for diagnosis based on reason for ECMO, time course of ECMO, and underlying cause of seizure: 3. Consider mild hypothermia. 4. Perform head ultrasound on infants. 5. Perform EEG. 6. Perform CT scan. 7. Consider ECMO discontinuance. 8. Revert to conventional medical management.	H9#1	5	2	3	3	90	900
H10 Failure: Arterial pressure line	H10 Effect #1: Patient	H10 Cause #1: Full cardiac output	H10 Management #1:	H10#1	1	3	1	3	9	90

tracing flat.	well perfused with narrow or absent pulse pressure. H10 Effect #2: 1.Cyanosis 2.Acidosis 3.Poor perfusion 4.Lethargy 5.Worsening blood gases	VA ECMO support. H10 Cause #2: Pressure transducer malfunction. H10 Cause #3: 1. Decreased cardiac output 2. Cardiac stun 3. Cardiac arrest 4. Pulseless electrical activity (PEA), also known by the older term electromechanical dissociation (EMD).	1.May be appropriate with full VA nonpulsatile support. 2.No intervention needed. H10 Management #2. Flush, zero or replace pressure transducers as needed. H10 Management #2: 1.Increase pump flow if on VA ECMO 2.Begin CPR resuscitation if on VV ECMO. 3. Consider conversion to VA ECMO.	H10#2	1	1	1	3	3	30
				H10#3	5	2	1	3	30	300
			‘I. PROCEDUREAL FAILURE							
I 1. Failure: Incorrect blood line marking resulting in incorrect connection of arterial and venous lines. (12/5/16: MAUDE Adverse Event Report: MEDTRONIC PERFUSION SYSTEMS MEDTRONIC TUBING PACK OXYGENATOR, CARDIOPULMONARY BYPASS)	I 1 Effect #1: During VA ECMO blood will be aspirated from the aorta and infused into the right heart causing hypotension and possible hypoxemia. I 1 Effect # 2: During VV ECMO blood will be aspirated and injected into the incorrect channels of the VV cannula resulting in excessive mixing of deoxygenated and oxygenated blood in the right heart.	I 1 Cause #1: Incorrect marking by the manufacturer. I 1 Cause # 2: Inattention on the part of the ECMO specialist to monitor proper flow of fluid in circuit during priming	I 1 Management #1: Inspect tubing pack for correct marking before set-up. I 1 Management #2. Communicate with surgeon to confirm proper tubing connection before initiating ECMO.	I 1#1	1	1	1	3	3	
				I 1#2	1	1	5	3	15	

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