

Friends- Here is the narrative for the second ECMO FMEA.  
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#### Narrative #2

##### ECMO FMEA B1 FAILURE: NO PRESSURE ALARM FUNCTION

Go to the AmSECT Safety Page <http://www.amsect.org/page/perfusion-safety>, select ECMO FMEAs, open the PDF and scroll down to section B1 to find the detailed FMEA. This FMEA focuses on the failure of pressure alarms (servo-regulating or not) to function on centrifugal pumps (CBP). Many of these same problems can occur on roller blood pumps (RBP).

This failure is closely related to A1 except that blood flow which is unsuspectingly unmonitored by defective pressure transducing can cause a very sudden failure, catching the specialist by surprise. And nobody likes surprises on ECMO. Some would say that this could never happen to a well-trained team. I would then argue that my team was well trained and very savvy. And yet in the approximately 800 patients and 160,000 hours of ECMO I was associated with, perhaps there were two dozen times when experienced operators were blindsided by non-functioning pressure monitors. I estimate a failure rate of approximately 3% among patients and 0.015% for each ECMO hour. Most of these incidents occurred in the program's early years. It was finally realized that these incidents were not isolated flukes. Rather, they occurred as a result of the conjunction of three different factors: 1. Imperfect anticoagulation procedures, 2. defective circuit design and 3. the human response to many hours of tedious and boring ECMO pump operation involving shift changes of many different operators and ignoring the dampening or even freezing of the transducer pressure readout; a dead giveaway that something is wrong.

In response, the anti-coagulation techniques were improved over time (although never perfected during my time with the program). Monitoring lines were heparin-coated when the option finally became available. The tedium was fought by having two ECMO Specialists assigned to each patient; one as bedside nurse and the other as pump operator. (All of our ECMO Specialists were experienced ICU RNs capable of performing both roles.) These individuals traded roles half way through the shift to reduce the tedium and focus on changes in the pressure readouts. Finally, the hand off checklist and hourly checks were revised with this specific failure in mind. Even so, this incident still occasionally occurred primarily due to less experienced ECMO Specialists who failed to anticipate this problem.

#### EFFECTS, CAUSES and MANAGEMENT OVERVIEW:

The lack of adequate pressure alarms may cause the ECMO specialist to assume that the circuit is performing properly when it is not. There are three common causes: #1: Incorrect pressure alarm limit settings. The alarm limits are set outside the useful range for detecting danger. #2: Pressure transducer not connected, stopcock turned off, or clots in tubing or connections. And #3: Pressure transducer malfunction. Listed are three management actions. First is to check and reset pressure limits on pre-pump and post-pump. I left out perhaps the most important management action associated with this action. That is to perform a hand-off check list that includes a monitor test with every change of personnel and also an hourly check for proper function. This should dovetail into catching defective pressure transducer lines or stopcocks and finally to flush, zero, and replace pressure transducers as needed. It is probably better to keep a saline loaded syringe attached to the transducer and pressure line for intermittent use rather than to open the system and attach a fresh flush syringe each time flushing is performed. How often should the transducers and pressure lines be flushed and tested? I am not sure. But whatever time interval is chosen, it should be consistent. If there are three pressure lines on a system and each is flushed with 1 ml each hour; that adds 72 mls/day to the patient. This should be included in the maintenance fluid calculations. Not much in an adult, but possibly critical in a neonate. If flushing is very infrequent there is a risk of actually pushing a clot from the pressure line into the circuit. The method of aspirating on a line to assess and remove clots followed by the attachment of a new flush syringe can increase the chances of infection by repeatedly opening and closing the circuit.

RISK PRIOROTIES: This kind of risk is very low. But on the rare occasion when the alarm needs to sound (and stop the pump if so designed) and it doesn't sound, there can be critical problems such as air aspiration into the system or disruption of the circuit. Both require that ECMO be immediately terminated.

#### REVIEWER COMMENTS:

REVIEWER CN: Before using the XXXXXXXXX\* (which, if you don't know are unable to flush or zero transducers once up and running), we would flush and zero transducers Q 12 hours, which seemed adequate. One thing I would mention somewhere is that one way to recognize a non-functioning (whether b/c of clot or malfunctioning transducer) is that the pressure will have no variation in it and remains the same number. On any pump I've ever used you will see some fluctuations in the pressure numbers, if not it is a concern they are not functioning properly. I do want to clarify what I said about the transducers on the XXXXXXXXX. You can't flush the transducers, it is all internal. You can re-zero, BUT the zero will be very far off from true zero once any fluid is in the system. \*(Note from GG: I marked out the identity of this pump to protect myself and the author from legal action by the manufacturers if they should consider the comments libelous. You can never be too cautious on the internet! If you want to know the manufacturer's name, contact me directly.)

REVIEWER ML: Pressure monitoring in the ECMO circuit provides a measure of safety to determine access or return line occlusion, actuate servo controls for pumps, provide audible alarms outside of set ranges and to establish an upper limit to help prevent cellular damage. Additionally, isolated pre-oxygenator or trans-oxygenator pressures can alert to accumulating clot burden and rising internal oxygenator resistance. As part of patient care records for use, the following is recommended:

1. Pressures should be observed and recorded hourly to show trends and verify function.
2. Transducers and lines should be flushed each 12 hours to help prevent clotting.
3. Transducers, stopcocks and lines should be changed each 96 hours or in accordance with unit policies for all vascular access lines.

REVIEWER DB: I think it is important if we will be advocating for flushing a pressure line to address the inherent risks in that alone as well as how imperative it is to always follow hospital central line access standards and draw back on the line first. The majority of programs I have worked with either via referrals or start up or collaborative research use the XXXXXXXXX\*, or do not monitor continuous ECMO pressures. There is also little evidence to advocate pressure servoregulation of a centrifugal pump as it is quite self regulating and such can cause unnecessary interruptions in support. There are many other signs of trouble, particularly with a centrifugal pump. Alarm parameters, if monitoring, should be set to clinical scenario and for trending purposes. A failure to accurately display the pressures being monitored or accurately read the system pressures should then be addressed. This does in fact happen on occasion with the XXXXXXXXX\*. It is usually from one of the following:

- 1) dust/dirt/dried fluids in the pressure module connection (either hardware side or disposable side)- I'd say to blow in it like an old Nintendo cartridge, but your ID team would likely prefer you use a hospital gas source or pressurized air canister
- 2) bent pin in the pressure module connection, usually from brute force during connection- this is an expensive mistake and requires replacement of the module cable
- 3) failure to properly zero pressures (while not recommended by manufacturer, with many programs using pre-primed circuits you must either trust your software default zero or make sure team understands how to "trick" the zero with a fluid primed circuit at time of use. I find many errors in the "tricking process")
- 4) internal disposable pressure monitoring defects, drifts, malfunction (cannot be corrected but can sometimes be tricked by quickly decreasing RPMs to zero, achieving OLPM and re-zeroing just the offending parameter while making sure open to atmosphere, not a novice move- especially on a pt).
- 5) when transitioning disposable from one hardware unit to another there is often a discrepancy in device zero, particularly across service regions (different humans performing service on device which includes recalibration of the device native zero). Usually this is minor and should not cause alarm.

I advocate to my team and those I teach that a pressure itself is meaningless. In context it can give clues. A system pressure should never be acted upon in isolation. There is also evidence that, in the absence of an acute event or catalyst (novo7, RA clot sucked into pump) transmembrane pressure is a poor, very late indicator of compromised oxygenator function. \*(Note from GG: I marked out the identity of this pump to protect myself and the author from legal action by the manufacturers. If you want to know the name, contact me directly.)

REVIEWER TP: Gary, how would you feel with regards to adding a few other potential causes for error?

- 1) A change in patient position relative to the pump (specifically the transducer).
- 2) Shunting into a monitored line such as in the neonatal/pediatric component type systems, where shunts from high to low pressure may go into stopcocks on these monitored pressure lines in an effort to limit circuit connectors and access for hemofilters or (blood parameter monitoring system\*) sensors.
- 3) Clamping off a circuit (while pressurized or depressurized) which may violate the set alarms preventing the ECMO specialist from getting the pump RPM's up to reinitiate. \*(Note from GG: I marked out the identity of this monitor to protect myself and the author from legal action for libel by the manufacturers. If you want to know the name, contact me directly.)

REVIEWER DF: I have a possible fourth cause for a B1 failure: Incorrect transducer height / transducer too high, which can produce a false low measurement.

-management #4: check level periodically ( start of each shift), position transducer at level of membrane oxygenator, re-zero, set/check alarm limits.

I think this qualifies as a case in which the Specialist may assume that the circuit is performing properly, with pressures within an acceptable range at a certain flow.

REVIEWER DZ: This is a good discussion. I don't really have anything more to add at this point.