FAILURE MODES & EFFECTS ANALYSIS AS A QUALITY IMPROVEMENT PROCESS

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FMEA Project - Background

The Health Centers' Respiratory Compressed Air (RCA) system which consists of three parallel compressors completely shut down when the main 100A fuse feeding the RCA system blew. Investigations revealed that the BeaconMedaes Triflex RCA system, compressor #1 had short-circuited and failed to trip the dedicated circuit breaker for compressor #1 and had instead blown the 100A supply fuse to the entire RCA Beacon Triflex system, shutting down both back up compressors. An analysis of the incident showed that the cause of failure was due to a mismatch between circuit breaker and fuse technologies with these devices having different tolerances to short circuit current.

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FMEA Taskforce

The taskforce included the following stakeholders:

Director of Clinical Engineering

- Assoc. VP Facilities Management and Operations
- Director of Mechanical Engineering
- Electrical Engineering
- Plumbing Department Supervisor
- BeaconMedaes Sales and Service
- Quantum Engineering
- Director of Respiratory Therapy
- Director of Patient Safety

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FMEA Project Overview

A Failure Modes and Effects Analysis (FMEA) was undertaken to evaluate all steps and potential failure points for the entire RCA delivery process including electrical feeds, performance of the Beacon Triflex system, alarm systems and emergency back up response procedures. Each of the failure points was scored for Severity, Frequency and Detectability using the Sheff & Marder FMEA Process, and the ten highest priority risk of failures were addressed in an Action Plan. Several action steps were completed immediately, and the remaining steps were completed during subsequent weeks, including electrical feed changes by UCHC, an upgrade to the RCA by BeaconMedaes, changes to RCA monitoring protocols, and review of available back up systems and RCA loss response protocols.

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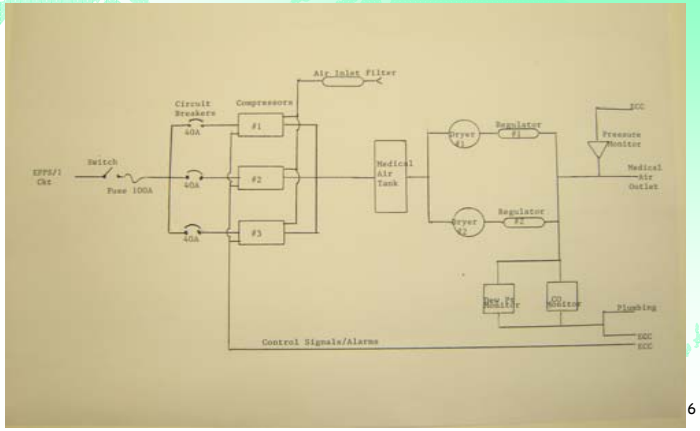
Medical Air Compressor System Schematic (Flow Diagram)



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FMEA Process Guide

"The Step-by-Step Guide to Failure Modes and Effects Analysis" by Sheff & Marder was applied to the schematic (flow chart) of the power supply to the air compressors and for the Respiratory Compressed Air delivery to the hospital which resulted in a completed FMEA Failure Mode Prioritization Chart. This chart included a score from 1-10 for each step on the schematic for the following categories: Severity, Frequency and Detectability. The scores were multiplied, with the highest resulting Risk Prioritization Numbers (RPN's) serving to focus attention on the highest risk of failure steps on the flow chart.

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SEVERITY SCORE
Sheff & Marder

1	No significant impact on clinical outcome
3	Mild impact
5	Moderate impact
7	Significant impact
10	Entire process will fail

FREQUENCY SCORE
Sheff & Marder

1	May occur once in 100 years
3	May occur once every 5 years
5	May occur once each year
7	May occur once a month
10	May occur one or more times per day

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Detectability Score

Sheff & Marder

1 Very easy to detect; highly visible; multiple steps

3 Fairly easy to detect; several steps

5 Moderately detectable; fair visibility; 2 or more steps in process

7 Moderately difficult to detect; low visibility; only one step prior to failure

10 Extremely difficult to detect; invisible

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	FAILURE	MODE	PRIORITIZATION			
Process Step	**Failure Modes**	**Severity Score**	**Frequency Score**	**Discoverability Score**	**RPN**	**Priority Rating**
UCHC power source to compressor	Normal power failure	3	3	1	9	
	Emergency power failure	10	2	1	20	
	Transfer switch failure	10	5	1	50	
UCHC wiring	Wire disconnects or opens	10	2	6	120	7
UCHC EPPS/1 Fuse	Blows prematurely	10	3	7	210	2
	Improper fuse for load conditions; replacement fuses not readily available	10	3	8	240	1

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Beacon Circuit Breaker #1,2,3	Trips early	3	3	1	9	
	Fails to trip	10	2	8	160	5
Beacon Starter/Controller	Compressor fails to start	3	2	7	42	
	Control logic failure	9	2	7	126	6
Beacon Compressor #1,2,3	Fails to start	3	5	7	105	10
	Low pressure	3	3	7	63	
	High pressure	3	3	7	63	
Air Intake	Blocked	10	2	3	60	
	Contaminated	8	3	5	120	8
Air Reservoir	Leaks, bursts	8	2	3	48	
	Air flow blocked	10	2	2	40	

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Med Gas Pressure Alarm	Fail to detect hi/lo pressure	5	3	5	75	
	Inaccurate	5	3	8	120	9
Back Up RCA System	Power Supply Fails	10	2	2	40	
	Fails to start when needed	10	2	2	40	
Response Protocol –Back up cylinder/regs/hoses	Cylinders not available/empty/regulators missing/hoses missing/inadequate emergency supply	10	3	7	210	3
Response Protocol-staff knowledge	Emergency responders are not knowledgeable of backup systems and response protocols –ECC, facilities, plumbing,respiratory therapy, clinical engineering.	10	3	7	210	4

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Action Plans – Top 10 Scores

- Install holder for replacement 100A fuses for emergency situations
- Install three separate fused feeds to Beacon Air Compressors
- Beacon to annunciate compressor power failure at Environmental Control Center (ECC)
- Beacon to annunciate control logic failure at ECC
- Beacon to annunciate lag alarm in ECC to ensure quick response
- On rounds, Plumbers to verify that all three compressors are cycling
- Verify pressure monitoring systems for early detection of problems
- Correct medical air intake piping – protect from pigeons; remove extraneous filter
- Verify secondary Quincy compressor system will remain on Normal Power vs. Emergency Power in case emergency switchgear fails
- Review backup and response strategies for Medical Air Compressor system failure
- Train clinical personnel on contingency plans for loss of Medical Air
- Verify that the wiring and power distribution system to the Medical Air compressors are adequate.

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		ACTION	PLAN			
Process Step	**Failure Modes**	**Risk Reduction Action Steps**	**Error Detection Action Steps**	**Person Responsible**	**Implementation Date**	**Follow-Up Measurements**
UCHC EPPS/1 Fuse	Improper fuse for load conditions	Review Beacon Triflex installation guide; Beacon does not advocate using a fuse in line with circuit breakers.	Electrical Engr will design a plan to install three separate fused feeds to each Beacon Compressor; BeaconMedaes will review design	Elec Engr UCHC; Service-BeaconMedaes.	March 15, 2006	Tested and verified on 4/26/06.
	Replacement fuses not readily available	Install replacement fuses on site	Label replacement fuses for EPPS/1; check that fuses are in place on routine basis	Elec Engr,Electrical Shop-UCHC	Nov. 15, 2005	Completed
	Blows prematurely	BeaconMedaes to analyze compressor #1 failure and suggest ways to minimize risk of EPPS/1 fuse blowing before compressor circuit breakers open.	BeaconMedaes recommends that circuit breakers not be used in line with fuses. Beacon does not advocate using a fuse in line with circuit breakers. Separate fuses to be installed.	Elec Engr-UCHC; Service-BeaconMedaes	March 15, 2006	Tested and verified on 4/26/06

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Beacon Circuit Breaker #1,2,3	Fails to trip	Evaluate relationship between circuit breakers for each compressor and fuse rating for EPPS/1 fuse	Beacon to annunciate power failure at ECC.	Service-BeaconMedaes	March 15, 2006	Tested and verified on 4/26/06
Beacon Starter/Controller	Control logic failure	BeaconMedaes confirmed that design of control logic failure will not cause entire system to fail	Beacon to provide logic failure to be annunciated in ECC	BeaconMedaes	March 15, 2006	Tested and verified on 5/3/06
Beacon Compressor #1,2,3	Fails to start	Review with Beacon standard protocol for compressor failure. Determined that compressor failure to start is not alarmed via the Lag Alarm ckt.	Lag Alarm can be annunciated in ECC for early action response. Plumbers to verify that each compressor is cycling on/off properly during normal rounds.	FM&O; Plumbing; Service-BeaconMedaes	Lag Alarm annunciated in ECC: March 15, 2006 Plumbers to continue normal rounds procedures - on going.	Tested and verified on 5/3/06 Verify performance by observing that three compressors cycle on/off.

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Air Intake	Contaminated	Review location of RCA intake duct for possible sources of contamination; off Penthouse; no possible contamination.	10 ppm CO alarm should provide early detection….already in place and checked routinely; each compressor has dedicated inlet filter.	Elect Engr-UCHC; Plumbing to check intake pipe; remove filter if present, add screen, and turn intake housing down.	January 6, 2006 March 15, 2006	Check for cleaning of intake; check air intake filter Verify on plumbing rounds log book.
Med Gas Pressure Alarm	Inaccurate	Review calibration of RCA Med Gas alarm switches and pressure gauges.	Review location of med gas pressure alarms with BeaconMedaes to ensure that correct point in the RCA system is being monitored to provide earliest sign of hi/lo pressure problems	Elect Eng-UCHC; Plumbing; Clinical Engr; Service-Beacon	January 6, 2006	Determined that Quincy RCA compressors will continue to serve a secondary backup RCA system. Determined that Quincy RCA will remain on normal power as alternative to emergency power supply.

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Response Protocol –Back up cylinders, regulators, hoses	Cylinders not available/empty/regulators missing/hoses missing/inadequate emergency supply	Review RCA backup strategies and check existing systems to respond to potential RCA system failure	Plumbing Shop to check availability of back up systems as part of routine surveillance.	FM&O, Clinical Engr; Plumbing Shop; Resp Therapy	Nov. 10, 2005	On-going monitoring
Response Protocol- staff knowledge	Emergency responders are not knowledgeable of backup systems and response protocols –ECC, facilities, plumbing,respiratory therapy, clinical engineering.	Train new UCHC personnel on RCA backup systems, locations, and plans.	Re-examine use of air compressors on adult ventilators; and ensure Resp Therapy staff are aware of back up systems for RCA	FM&O, Clinical Engr, Plumbing; Resp Therapy	Nov. 10, 2005	On-going
UCHC wiring	Wire disconnects or opens	Verify wiring and distribution system to RCA is properly sized.	Perform annual thermal survey of wiring, circuits, and distribution system from power source to RCA system to look for hot spots	Elec Engr-UCHC; Electricians	Elec Engr-UCHC verified that thermal survey is completed annually.	Routine scheduled thermal surveys

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Summary

1 Install three separate fused feeds to Beacon Air Compressors

2 Beacon to annunciate compressor power failure/lab alarm/control logic failure at Environmental Control Center (ECC)

3 Correct medical air intake piping – protect from pigeons; remove extraneous filter

4 Review backup and response strategies for Medical Air Compressor system failure

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Example: FMEA-MRI Safe NICU Ventilator Project

Clinical Engineering coordinated a Failure Modes and Effects Analysis of a new Biomed Devices MRI-Safe infant ventilator. A team analyzed the flow of installing the special ventilator in the MRI procedure room; connecting and monitoring the infant during scanning; following MRI-safe procedures; and analyzing the contingency plans for emergency situations.

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Summary

As a result of the Failure Modes and Effects Analysis…

1 Modify regulators to have 2” pressure gauges for better visibility;

2 Replace clear med gas tubing with color-coded tubing (green for O2 and yellow for Air);

3 Non-ferrous code kit;

4 Physicians to research impact of tissue heating (SAR) and gradient noise levels on neonates.

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Questions?
Discussion
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