



Singapore Healthcare Management 2017

Pre-emptive intervention to increase patient safety via close monitoring and failure mode effects analysis (FMEA)

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INTRODUCTION

Pre-emptive intervention to prevent medical equipment potential failure causing disruption to patient care.

METHODOLOGY

Checked and monitored repair records

Feb to May 2016 : 3 incubators faulty
Jun to July 2016 : 3 more incubators faulty

Same model of incubators were faulty
Same cause : faulty power supply board

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Failure Mode Effects Analysis

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Function	Potential Failure Mode	Potential Effects of Failure	Severity (S)	Cause	Occurrence (O)	Detection Mode (D)	Detection	Risk Probability Number (RPN) = S x O x D	Recommended Action	Responsibility	Target Date	Action Taken
Infant Incubator Warmer keeps the baby warm and comfortable, provides resuscitation therapy for high-risk newborn	Unable to power-up	Incubator's total failure caused disruption to patient care	9	Faulty internal power supply board	7	Breakdown repair fault reporting	9	567	Replaces the internal power supply board before it fails	BME and Vendor	Sep 2016	Done in Sep 2016

Severity Scale for Failure Modes & Effects (scale of 1 [least severe] to 10 [most severe] for each effect)			Severity Scale for Failure Modes & Effects (scale of 1 [least severe] to 10 [most severe] for each effect)			Detection Scale for Failure Occurrence (scale of 1 [always detected] to 10 [never detected] for each occurrence)		
Rating	Description	Definition (Severity of Effect)	Rating	Description	Potential Failure Rate	Rating	Description	Definition
10	Dangerously high	Catastrophic. Failure may result in complete unsafe operation and possible death or injury to patient or user.	10	Very High	Unavoidable failure Two or more faults per week	10	Absolute Uncertainty	No known routine preventive maintenance available to detect the failure mode.
9	Extremely high	High degree of user dissatisfaction due to inoperable equipment. May result in serious disruption to subsequent processing. Failure does not breach safety or government regulation.	9	High	Almost certain failure One fault per week	9	Very Remote	Routine preventive maintenance will not detect the existence of failure mode
8	Very high	Failure renders the unit inoperable or unfit for use.	8	High	Repeated failures. Two faults per month	7 to 8	Low	Routine preventive maintenance has a poor chance of detecting the existence of failure mode
7	High	Failure causes a high degree of user dissatisfaction.	7	High	Regular failures One fault per month	5 to 6	Moderate	Routine preventive maintenance may or may not detect the existence of failure mode.
6	Moderate	Failure results in a partial malfunction/loss of performance of the equipment to cause the user to complain.	6	Moderately High	Frequent failures Four faults per year	3 to 4	High	Routine preventive maintenance has a good chance of detecting the failure mode
5	Low	Failure causes some user dissatisfaction which may include discomfort or annoyance.	5	Moderate	Occasional failures Two faults per year	1 to 2	Very High	Routine preventive maintenance will certainly detect the failure mode. Reliable detection controls are known with similar processes.
4	Very Low	Failure can be overcome with modifications to the user's process, but there is minor performance loss.	4	Moderately Low	Infrequent failures One fault per year			
3	Minor	Failure would create a minor nuisance to the user, but the user can overcome it without performance loss.	3	Low	Relatively few failures One fault every two to three years			
2	Very Minor	No relevant effect on reliability or safety. Failure may not be readily apparent but would have minor effects on the process.	2	Low	Failures are few and far between One fault every three to five years.			
1	None	No relevant effect on reliability or safety. Failure would not be noticeable by user and would not affect the process.	1	Remote	Failure is unlikely One fault every five years			

Met and shared FMEA finding with vendor

Vendor agreed to replace all the power supply boards before they fail

Vendor waived off all cost for the power supply board replacement

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RESULT

Till end Dec 2016, there is no fault reported related to the power supply board.

CONCLUSION

Reduced failure rate of the incubator due to faulty power supply board.
Improve the uptime of the incubator resulting in better and safer patient care.
Cost saving of \$2,970.

