Failure Mode and Effects Analysis (FMEA)

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Project: Incubator Designed for Emerging Areas (iDEA)

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Failure Mode Effects Analysis

Function or Component	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection Means	Applicable Controls
Regulation: Electrical Thermoregulation Unit	Incomplete/short circuit, microchip malfunction	Temperature of the system deviates from set value	Over or underheating of the infant, dehydration; shock from circuit itself	10	Monitoring of temperature shows system is not being moderated adequately; alarm sounds	Utilize circuit components with low voltage demands
Regulation: Electrical Thermosensitive Alarm Unit	Incomplete/short circuit, thermistor malfunction; battery runs out	Alarm fails in the event of large temperature deviation from set value	Infant remains in an over or under-heated state for an amount of time that is fatal; shock from circuit	10	Monitoring of system shows temperature reads too high or low and no alarm has sounded	Utilize circuit components with low voltage demands; provide detailed, clear schematics for repair
Regulation: Integrated Circuit Thermoregulator	IC burnout	Device will no longer draw a current/regulate	Hypothermia of infant due to heat requirements not being met	15	Display will lack visual output, heat will be off	Provide backup breadboard circuit with components in place
Regulation: Auditory Alarm	Burnout or loss of function	Alarm fails to sound in the event of large deviation from set value	Infant remains in an over or under-heated state for an amount of time that is fatal	15	Monitoring of system shows temperature reads too high or low and no alarm has sounded	Provide instructions for replacement; recommend regular tests; visual LED alarms
Support: Table & Legs	Failure to provide adequate support	Device falls unexpectedly	Trauma to infant	12	Visual observation.	Ensure that device platform is structurally sound, provide warnings for incubator placement
Incubator: Box/Insulation Component	Insufficient capacity to retain heat; puncture; material toxicity (wood lacquer)	Device is unable to reach set temperature value; vapor fills chamber	Infant temperature too low, hypothermia; infection via vapor	6	Alarm sounds.	Warnings and detailed instructions for leak repair; polyurethane used for lacquer.
Incubator: Doors and Hinges	Unable to easily open	Infant trapped inside of incubator	Asphyxiation, overheating, dehydration of infant	17	The door resists opening.	Enable hinges to be manually detached, provide warnings for proper handling of doors + hinges; recommend regular tests

Air Flow: Holes	occlusion	Air ceases to be able to pass through device	Oxygen depletion, asphyxiation of infant	12	Visual inspection of occlusion, unable to feel air flow placing hand over the hole	Ensure hole diameters are at a value that minimizes both occlusion occurrence and heat loss
Air Flow: Fan	Mechanical failure, circuit failure	Air ceases to be pushed through device	Overheating of infant, oxygen depletion, asphyxiation	14	Visual or auditory recognition of fan failure	Ensure fan component is easily replaceable, provide warnings for use
Humidity: Water Pan	Dry-out	Humidity ceases to be supplied to system	Dry-heat causes excessive water loss to infant, dehydration	13	Visual detection	Regular inspection and changing out of water by caretaker
Heating: Resistive Heating Coil	Burnout, improper connection	Air ceases to be heated	Hypothermia; shock, burns	9	Visual recognition or alarm sounds.	Have readily available back-up; use coil with a long predicted useful life.

Table 1. Probability/Severity Matrix

Probability of Occurrence	Severity I Catastrophic	Severity II Significant	Severity III Marginal	Severity IV Negligible
Frequent	1	3	7	13
Probable	2	5	9	16
Occasional	4	6	11	18
Remote	8	10	14	19
Improbable	12	15	17	20

Table 2. Risk Acceptance Criteria Matrix

Hazard Risk Index	Acceptance Criteria
1 to 5	Unacceptable
6 to 9	Undesirable; written and reviewed decision required to proceed
10 to 16	Acceptable upon completion of quality assurance review
17 to20	Acceptable without review

Revised 12/3/07 – BMR

Added risk of wood lacquer vapor. Increased severity/significance of the risk of box materials.

Revised 12/13/07 – BHM

Changed all aspects of design dealing with lighting, and added aspects of design dealing with a resistive heating coil.

Revised 2/14/08 – CEW

Changed to reflect IC thermoregulator issues, humidity pan

Revised 4/16/08 – BMR

Formatting. Changed thermoregulator failure mode to reflect usage of microchip rather than thermistor.