



Initial Hazard Analysis

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Project: Incubator Designed for Emerging Areas (iDEA)

Risk Designation (in order of increasing severity)

Negligible < Minor < Considerable < Critical < Calamitous

Device Hazard and Risk Designation

1. Device falls over, due to material failure, with infant inside - Critical
2. Device catches fire due to electrical failure - Calamitous
3. Device heats 1° C over the target temperature - Considerable
4. Device warms to only 1° C under the target temperature - Considerable
5. Device infects infant occupant from infectious agents endogenous to the device – Considerable (Pending disease)
6. Device admits infectious microbes to enter from the surrounding environment – Considerable (pending disease)
7. Device loses power - Minor
8. Airflow inhibited, causing infant to suffer from lack of oxygen - Critical
9. Device rolls away, encountering potential hazards, (stairs, hills, etc.) - Calamitous
10. Device shocks infant occupant – Calamitous
11. Visibility impaired by fog or condensation – Negligible
12. Burnt out heating element – Considerable
13. Caretaker’s hands become lodged in access portals – Minor
14. Hinge failure restricts opening or closing of infant access hatch – Considerable
15. Device fails to bring in fresh (oxygen-rich) air from environment – Calamitous
16. Failure of regulation circuit – Critical

Cause of Above Hazards

1. Incubator supports break, due to repeated stressing over an extended period of time.
2. Flammable components of the device’s design reach their flash point, or are subjected to an electrical spark, resulting in flame.
3. Device control systems fail, causing heat in excess to be supplied to the infant chamber, and thereby the infant.
4. Device control systems fail, or are not properly calibrated, causing a dearth of heat to be supplied to the infant, not meeting the infant’s thermal needs. This could also be caused by a failing power supply (eg. battery nearing the end of its useful life).
5. Improper cleaning of device; infectious microbes transferred from one occupant to the next. Improper cleaning of the mesh cloth meant to wick water for humidity may result in mold spores being introduced to the infant chamber.

6. Air filter is punctured or otherwise faulty, thereby admitting infectious microbes into the infant's airspace.
7. Electrical failure of heating circuit.
8. Air vents somehow occluded, prohibiting the entrance of fresh air.
9. Wheels are not locked, or wheel locks fail; a force in a certain direction overcomes the static friction of the ball bearings, and device begins to translate horizontally.
10. Fluid introduced into the device (spill, vomitus, urine, etc.) connects infant into the device electronic loop, thereby causing electric shock.
11. Humidity from baby's respiration and/or perspiration causes condensation to gather on the inside surface.
12. Heating element reaches the end of its functional lifespan.
13. Access portal covers' springs fail, causing access covers to fall onto the caretaker's hands.
14. Hinge attaching infant access hatch to wooden body of device becomes somehow frozen and inoperable.
15. Device intake fan failure.
16. Circuit elements reach the end of their lifespan.

System Responses

1. Device falls over; injury to infant imminent.
2. Device bursts into flames; overheat alarm most likely sounds, unless its components or circuit have been melted by the flames; injury to infant imminent.
3. Overheat alarm sounds, alerting healthcare workers in the vicinity.
4. Alarm sounds indicating insufficient heat, alerting healthcare workers in the surrounding area. Device attempts to compensate by adding more heat.
5. Patient infected.
6. Patient infected.
7. Medical staff in the area alerted by the lack of the 'on' LED.
8. Patient asphyxiated, due to lack of oxygen.
9. Device rolls along until it meets an impediment to its movement.
10. Infant receives a shock; voltage depends on the portion of circuitry involved; short circuit alarm sounds, alerting healthcare workers in the area.
11. Device visibility occluded.
12. Device unable to produce sufficient heat, and the device alarm goes off.
13. Internal device temperature falls due to open portal access covers.
14. Infant access hatch will neither open nor close. If it is stuck open, the internal device temperature will drop to that of ambient temperature. If it is stuck closed, the infant cannot be put into or taken out of the device.
15. Patient asphyxiated, due to lack of oxygen.

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- Formatting. Editing alarm system response.