

designsafe Report

Application: Infant Respiratory Rate Monitor

Analyst Name(s):

Description:

Company:

Product Identifier:

Facility Location:

Assessment Type: Detailed

Limits:

Sources:

Risk Scoring System: designsafe Three Factor

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment		Risk Reduction Methods /Comments	Final Assessment		Status / Responsible /Reference
			Severity Exposure Probability	Risk Level		Severity Exposure Probability	Risk Level	
1-1-1	Doctor apply / remove medical monitoring equipment	electrical / electronic : improper wiring Monitor is smashed or physically broken	Serious Remote Negligible	Low	Strong and durable plastic casing and electrical cords	Slight Remote Negligible	Low	
1-1-2	Doctor apply / remove medical monitoring equipment	electrical / electronic : overloading Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
1-1-3	Doctor apply / remove medical monitoring equipment	electrical / electronic : overvoltage /overcurrent Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
1-1-4	Doctor apply / remove medical monitoring equipment	electrical / electronic : power supply interruption Smashed monitor, dead battery or battery malfunction	Minimal Remote Unlikely	Low	Reliable power regulator, LED signalling for low battery	Minimal Remote Negligible	Low	
1-1-5	Doctor apply / remove medical monitoring equipment	noise / vibration : noise / sound levels > 80 dBA Alarm triggered	Slight Remote Unlikely	Low	On/off switch limits sound duration	Minimal Remote Unlikely	Low	
2-1-1	Nurse lift / reposition patients	mechanical : drawing-in / trapping / entanglement Elastic strap and/or cords causes entanglement	Minimal Occasional Unlikely	Low	Disconnectable cords	Minimal Occasional Negligible	Low	
2-2-1	Nurse monitor patients	electrical / electronic : improper wiring Monitor is smashed or physically broken	Serious Remote Negligible	Low	Strong and durable plastic casing and electrical cords	Slight Remote Negligible	Low	

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2-2-2	Nurse monitor patients	electrical / electronic : overloading Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
2-2-3	Nurse monitor patients	electrical / electronic : overvoltage /overcurrent Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
2-2-4	Nurse monitor patients	electrical / electronic : power supply interruption Smashed monitor, dead battery or battery malfunction	Minimal Occasional Probable	Moderate	Reliable power regulator, LED signalling for low battery	Minimal Occasional Negligible	Low	
2-2-5	Nurse monitor patients	noise / vibration : noise / sound levels > 80 dBA Alarm triggered	Slight Occasional Possible	Moderate	On/off switch limits sound duration	Minimal Remote Possible	Low	
3-1-1	Nurse Aide / Orderly help patients in / out of bed	mechanical : drawing-in / trapping / entanglement Chest strap and/or cords causes entanglement	Minimal Occasional Unlikely	Low	Disconnectable cords	Minimal Occasional Negligible	Low	
3-2-1	Nurse Aide / Orderly monitor patients	electrical / electronic : improper wiring Monitor is smashed or physically broken	Serious Remote Negligible	Low	Strong and durable plastic casing and electrical cords	Slight Remote Negligible	Low	
3-2-2	Nurse Aide / Orderly monitor patients	electrical / electronic : overloading Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
3-2-3	Nurse Aide / Orderly monitor patients	electrical / electronic : overvoltage /overcurrent Monitor is smashed or physically broken	Serious Remote Negligible	Low	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Remote Negligible	Low	
3-2-4	Nurse Aide / Orderly monitor patients	electrical / electronic : power supply interruption Smashed monitor, dead battery or battery malfunction	Minimal Occasional Probable	Moderate	Reliable power regulator, LED signalling for low battery	Minimal Occasional Negligible	Low	
3-2-5	Nurse Aide / Orderly monitor patients	noise / vibration : noise / sound levels > 80 dBA Alarm triggered	Slight Occasional Possible	Moderate	On/off switch limits sound duration	Minimal Remote Possible	Low	

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4-1-1	Patient rest	mechanical : crushing Chest strap too tight; restricts breathing	Serious Frequent Negligible	Moderate	Highly elastic strap; monitor detects breathing cessation	Minimal Occasional Negligible	Low	
4-1-2	Patient rest	mechanical : drawing-in / trapping / entanglement Chest strap and/or cords causes entanglement	Slight Frequent Unlikely	Moderate	Highly elastic strap and simple wiring design with only 2 cords limits entanglement	Minimal Occasional Negligible	Low	
4-1-3	Patient rest	electrical / electronic : improper wiring Monitor is smashed or physically broken	Serious Frequent Negligible	Moderate	Strong and durable plastic casing and electrical cords	Slight Occasional Negligible	Low	
4-1-4	Patient rest	electrical / electronic : overloading Monitor is smashed or physically broken	Serious Frequent Negligible	Moderate	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Occasional Negligible	Low	
4-1-5	Patient rest	electrical / electronic : overvoltage /overcurrent Monitor is smashed or physically broken	Serious Frequent Negligible	Moderate	Reliable power regulator, DC/DC converter with built-in safety responses	Slight Occasional Negligible	Low	
4-1-6	Patient rest	electrical / electronic : power supply interruption Smashed monitor, dead battery or battery malfunction	Serious Frequent Probable	High	Reliable power regulator, LED signalling to nurses for low battery	Slight Occasional Negligible	Low	
4-1-7	Patient rest	noise / vibration : noise / sound levels > 80 dBA Alarm triggered	Slight Frequent Possible	High	Nurse use of on/off switch limits sound duration	Minimal Occasional Unlikely	Low	