

designsafe Report

Application: PneumoniaDiagnosticDevice

Analyst Name(s): Lauren Bedell, Sheun Aluko, Clark Ingram

Description:

Company:

Product Identifier:

Facility Location:

Assessment Type: Detailed

Limits:

Sources:

Risk Scoring System: ANSI B11.0 (TR3) Two 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 /Control System	Final Assessment		Status / Responsible /Comments /Reference
			Severity Probability	Risk Level		Severity Probability	Risk Level	
1-1-1	Patient and User contact with diagnostic testing equipment	biological / health : unsanitary conditions Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-1-2	Patient and User contact with diagnostic testing equipment	biological / health : bacterial Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-1-3	Patient and User contact with diagnostic testing equipment	biological / health : viral Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-1-4	Patient and User contact with diagnostic testing equipment	mechanical : cutting / severing Improper usage of diagnostic device.	Moderate Unlikely	Low	standard procedures for use	Moderate Remote	Negligible	On-going [Daily] User
1-1-5	Patient and User contact with diagnostic testing equipment	mechanical : pinch point Improper usage of diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-6	Patient and User contact with diagnostic testing equipment	mechanical : stabbing / puncture Improper usage of diagnostic device.	Moderate Remote	Negligible	N/A	Moderate Remote	Negligible	Complete [11/30/2014] Design Team

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment			Final Assessment		Status / Responsible /Comments /Reference
			Severity Probability	Risk Level	Risk Reduction Methods /Control System	Severity Probability	Risk Level	
1-1-7	Patient and User contact with diagnostic testing equipment	mechanical : machine instability Improper usage of diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-8	Patient and User contact with diagnostic testing equipment	electrical / electronic : lack of grounding (earthing or neutral) Improper/careless wiring of the diagnostic device.	Moderate Unlikely	Low	quality inspection before use	Moderate Remote	Negligible	In-process Manufacturer
1-1-9	Patient and User contact with diagnostic testing equipment	electrical / electronic : shorts / arcing / sparking Improper/careless wiring of the diagnostic device.	Moderate Unlikely	Low	quality inspection before use	Moderate Remote	Negligible	In-process Manufacturer
1-1-10	Patient and User contact with diagnostic testing equipment	electrical / electronic : improper wiring Improper/careless wiring of the diagnostic device.	Moderate Unlikely	Low	quality inspection before use	Moderate Remote	Negligible	In-process Manufacturer
1-1-11	Patient and User contact with diagnostic testing equipment	electrical / electronic : water / wet locations Improper sealing in production of the diagnostic device.	Moderate Likely	Medium	quality inspection before use, warning label	Moderate Unlikely	Low	In-process Manufacturer
1-1-12	Patient and User contact with diagnostic testing equipment	electrical / electronic : unexpected start up / motion Improper/careless wiring of the diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-13	Patient and User contact with diagnostic testing equipment	electrical / electronic : power supply interruption Improper/careless wiring of the diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-14	Patient and User contact with diagnostic testing equipment	ergonomics / human factors : excessive force / exertion Improper usage of diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-15	Patient and User contact with diagnostic testing equipment	ergonomics / human factors : posture Improper usage of diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment			Final Assessment		Status / Responsible /Comments /Reference
			Severity Probability	Risk Level	Risk Reduction Methods /Control System	Severity Probability	Risk Level	
1-1-16	Patient and User contact with diagnostic testing equipment	ergonomics / human factors : repetition Improper usage of diagnostic device.	Minor Unlikely	Negligible	N/A	Minor Unlikely	Negligible	Complete [11/30/2014] Design Team
1-1-17	Patient and User contact with diagnostic testing equipment	fire and explosions : static electricity Improper/careless wiring of the diagnostic device.	Minor Likely	Low	quality inspection before use	Minor Remote	Negligible	In-process Manufacturer
1-1-18	Patient and User contact with diagnostic testing equipment	heat / temperature : severe heat Improper/careless wiring of the diagnostic device.	Moderate Unlikely	Low	quality inspection before use	Moderate Remote	Negligible	In-process Manufacturer
1-1-19	Patient and User contact with diagnostic testing equipment	environmental / industrial hygiene : contamination Improper disposal of the diagnostic device.	Moderate Unlikely	Low	standard procedure	Moderate Remote	Negligible	In-process User
1-2-1	Patient and User clean / sterilize instruments / equipment	biological / health : unsanitary conditions Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-2-2	Patient and User clean / sterilize instruments / equipment	biological / health : bacterial Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-2-3	Patient and User clean / sterilize instruments / equipment	biological / health : viral Improper sanitation of the diagnostic device.	Serious Likely	High	warning and sanitation instruction labels, gloves and mask for user	Serious Unlikely	Medium	On-going [Daily] User
1-2-4	Patient and User clean / sterilize instruments / equipment	electrical / electronic : water / wet locations Improper sealing in production of the diagnostic device.	Moderate Likely	Medium	quality inspection before use, warning label	Moderate Unlikely	Low	In-process Manufacturer