designsafe Report

Application:	Spirometer Software	Analyst Name(s):	
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 Severity Probability	Risk Level	Risk Reduction Methods /Comments	Final Assessment Severity Probability	Risk Level	Status / Responsible /Reference
1-1-1	All Users Common Tasks	mechanical : cutting sharp mouthpiece	Minor Likely	Low	making the mouthpiece with smooth edges	Minor Unlikely	Negligible	
1-1-2	All Users Common Tasks	mechanical : impaired movement tangling in cord	Minor Likely	Low	warning label(s)	Minor Likely	Low	
1-1-3	All Users Common Tasks	mechanical : swallowing foreign object swallowing microphone, swallowing foreign object in microphone cavity	Moderate Unlikely	Low	strong connection between components, warning label(s), clean between users	Moderate Unlikely	Low	
1-1-4	All Users Common Tasks	mechanical : stangulation tangling in cord	Catastrophic Unlikely	Medium	warning label(s)	Catastrophic Unlikely	Medium	
1-1-5	All Users Common Tasks	mechanical : chocking hazard inhaling microphone, inhaling foreign object in microphone cavity	Minor Unlikely	Negligible	strong connection between components, warning label(s), clean between users	Minor Unlikely	Negligible	
1-1-6	All Users Common Tasks	electrical / electronic : electrocution exposed wires	Catastrophic Unlikely	Medium	fixed enclosures / barriers	Catastrophic Remote	Low	
1-1-7	All Users Common Tasks	slips / trips / falls : tripping loose cord	Minor Very Likely	Medium	warning label(s)	Minor Likely	Low	
1-1-8	All Users Common Tasks	slips / trips / falls : falling spirometer dropping spirometer	Minor Very Likely	Medium	substitute less hazardous material / methods	Minor Very Likely	Medium	

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1-1-9	All Users Common Tasks	slips / trips / falls : falling computer dropping computer, pulling computer off surface through cord	Minor Likely	Low	make connection cord that has adjustable length	Minor Likely	Low	
1-1-10	All Users Common Tasks	ergonomics / human factors : excessive force / exertion too many tests	Minor Likely	Low	limit the number of tests in a certain time period to be performed by a single user	Minor Unlikely	Negligible	
1-1-11	All Users Common Tasks	ergonomics / human factors : repetition too many tests	Minor Likely	Low	limit the number of tests in a certain time period to be performed by a single user	Minor Unlikely	Negligible	
1-1-12	All Users Common Tasks	environmental / industrial hygiene : irritants foreign objects in spirometer cavity	Minor Likely	Low	clean between users	Minor Unlikely	Negligible	
1-1-13	All Users Common Tasks	environmental / industrial hygiene : cross-contamination sanitation failure	Moderate Likely	Medium	instruct to wash hardware between users, place disposable filter on microphone	Moderate Remote	Negligible	
1-1-14	All Users Common Tasks	Other : emotional stress false positives, false negatives	Moderate Likely	Medium	add in accuracy and precision measures, ensure that only doctors are using to diagnose, instruction manuals	Moderate Unlikely	Low	
1-1-15	All Users Common Tasks	Other : security of patient information security breach	Serious Unlikely	Medium	compliane with HIPAA regulations	Serious Unlikely	Medium	
1-1-16	All Users Common Tasks	Other : software error overburdened computer, faulty sound file	Minor Unlikely	Negligible	visible alarm or signal	Serious Unlikely	Medium	
1-1-17	All Users Common Tasks	Other : overburdened user computer too large of a downloadable component	Minor Unlikely	Negligible	visible alarm or signal	Minor Remote	Negligible	

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1-1-18	All Users Common Tasks	Other : incorrect test execution misunderstanding of device operation, lack of proper guidance	Moderate Likely	Medium	instruction manuals	Moderate Unlikely	Low	
1-1-19	All Users Common Tasks	Other : wrong diagnosis misunderstanding of results	Moderate Likely	Medium	instruction manuals	Moderate Unlikely	Low	