

designsafe Report

Application: Steth-Oximeter Analyst Name(s): Megan Stevenson, Stefanie Shahan, John Bacon
 Description: Company: Washington University in St. Louis
 Product Identifier: Facility Location: St. Louis, MO
 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	All Users Common Tasks	biological / health : blood borne diseases Transfer of blood borne diseases between patients if product is not properly sanitized between uses	Serious Remote	Low	Ensure users have proper sanitation training	Serious Remote	Low	On-going [Monthly]
1-1-2	All Users Common Tasks	biological / health : unsanitary conditions Product may harbor or transfer pathogens if used in unsanitary conditions	Serious Remote	Low	Ensure users have proper sanitation training	Serious Remote	Low	On-going [Monthly]
1-1-3	All Users Common Tasks	biological / health : bacterial Product may harbor or transfer bacteria if not properly sanitized between uses	Serious Remote	Low	Ensure users have proper sanitation training	Serious Remote	Low	On-going [Monthly]
1-1-4	All Users Common Tasks	biological / health : viral Product may harbor or transfer viruses if not properly sanitized between uses	Serious Remote	Low	Ensure users have proper sanitation training	Serious Remote	Low	On-going [Monthly]
1-1-5	All Users Common Tasks	biological / health : mold Product may harbor or transfer mold spores if not properly sanitized between uses	Serious Remote	Low	Ensure users have proper sanitation training	Serious Remote	Low	On-going [Monthly]

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1-1-6	All Users Common Tasks	electrical / electronic : energized equipment / live parts Extensive use could cause the product to develop wear and tear, exposing wires	Serious Unlikely	Medium	Regularly inspect electrical components and connections, make wire protection robust	Moderate Unlikely	Low	On-going [Weekly]
1-1-7	All Users Common Tasks	electrical / electronic : shorts / arcing / sparking Extensive use could cause the product to develop wear and tear, exposing wires	Serious Unlikely	Medium	Regularly inspect electrical components and connections, make wire protection robust	Moderate Unlikely	Low	On-going [Weekly]
1-1-8	All Users Common Tasks	electrical / electronic : improper wiring Circuit not setup optimally so the oxygen saturation readings are full or noise or incorrect	Serious Likely	High	Rigorous product testing to ensure that circuit elements are functional and that results are accurate	Serious Remote	Low	Complete [11/21/2015]
1-1-9	All Users Common Tasks	electrical / electronic : water / wet locations Liquids including water, saline, and blood could come in contact with circuitry and wiring	Serious Unlikely	Medium	Ensure product design has multiple barriers preventing liquid from reaching the circuitry	Moderate Remote	Negligible	Complete [11/27/2015]
1-1-10	All Users Common Tasks	electrical / electronic : overvoltage /overcurrent Wrong power source used for device, defibrillators used on patient while product is still on patient	Moderate Unlikely	Low	Ensure users have proper training about power source and defibrillator risk, include proper warning label	Moderate Remote	Negligible	On-going [Monthly]
1-1-11	All Users Common Tasks	electrical / electronic : power supply interruption Wiring disconnected during use or transportation	Serious Unlikely	Medium	Ensure product has robust wiring protection, evaluate the robustness of wire protection	Serious Remote	Low	Complete [11/27/2015]
1-1-12	All Users Common Tasks	slips / trips / falls : falling material / object Stethoscope could be knocked to the ground	Moderate Very Likely	High	Ensure product materials are robust enough to survive most falls	Minor Very Likely	Medium	Complete [11/27/2015]

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1-1-13	All Users Common Tasks	ergonomics / human factors : excessive force / exertion Clinician could press stethoscope or oximeter against patient with excessive force. This could injure the patient and will affect the accuracy of the measurements.	Moderate Remote	Negligible	Ensure that users are properly trained in the use of stethoscopes and oximeters.	Moderate Remote	Negligible	On-going [Monthly]
1-1-14	All Users Common Tasks	ergonomics / human factors : lifting / bending / twisting Clinicians may need to bend or twist into an uncomfortable position to perform auscultation or attach the oximeter clip.	Minor Remote	Negligible	Adjust patient position when possible	Minor Remote	Negligible	On-going [Daily]
1-1-15	All Users Common Tasks	fire and explosions : spontaneous combustion The battery may spontaneously combust	Catastrophic Remote	Low	Avoid using lithium ion batteries which have a higher risk of this.	Catastrophic Remote	Low	Complete [11/20/2015]
1-1-16	All Users Common Tasks	heat / temperature : burns / scalds If exposed, circuit elements that have built up heat could come in contact with skin and cause burns.	Serious Unlikely	Medium	Keep circuitry insulated. Make sure users know to replace product if damaged to avoid exposing circuitry	Serious Remote	Low	On-going [Daily]
1-1-17	All Users Common Tasks	heat / temperature : radiant heat Circuit elements could build up heat if used for extended periods of time	Minor Likely	Low	Keep circuitry insulated and set autoshutoff function to avoid overheating	Minor Unlikely	Negligible	Complete [11/27/2015]

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1-1-18	All Users Common Tasks	material handling : movement to / from storage Material will be carried around clinician in a potentially crowded clinical setting, may bump into things which would damage tubing or other parts of the stethoscope	Moderate Likely	Medium	Use materials that are robust enough to maintain functionality through bumps or drops	Minor Unlikely	Negligible	Complete [11/27/2015]
1-1-19	All Users Common Tasks	radiation : infrared radiation The 880 nm LED produces infrared rays which could be damaging to either the clinician's or patient's eyes	Minor Likely	Low	Keep LED's guarded to avoid accidental exposure, keep LEDs default as off	Minor Unlikely	Negligible	Complete [11/20/2015]
1-1-20	All Users Common Tasks	radiation : bright visible light The 730 nm LED produces red light which may be damaging to the clinician's or patients eyes	Minor Likely	Low	Keep LED's guarded to avoid accidental exposure, keep LEDs default as off	Minor Unlikely	Negligible	Complete [11/20/2015]