

**designsafe Report**

Application: Design Project Analyst Name(s): Olivia Sutton, Tony Wang, Charles Wu  
 Description: Company: Chartonia  
 Product Identifier: Facility Location: Washington University in St. Louis  
 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 /Control System	Final Assessment		Status / Responsible /Comments /Reference
			Severity Exposure Probability	Risk Level		Severity Exposure Probability	Risk Level	
1-1-1	Housekeeping disinfect / sterilize equipment / supplies	electrical / electronic : shorts / arcing / sparking During cleaning of facilities or device itself, if left exposed and water is spilled on the device, there is a chance of sparking or short circuiting	Slight Remote Unlikely	Low	Proper precautions should be taken. The device will be properly coated as to avoid any sparking or failures if the worst occurs. Battery compartment will be isolated from the rest of the electronics. /Waterproofing	Slight Remote Unlikely	Low	Complete [11/19/2014] Olivia
1-1-2	Housekeeping disinfect / sterilize equipment / supplies	chemical : skin exposed to toxic chemical During battery change, battery could leak and expose skin to toxic chemicals	Slight Remote Unlikely	Low	Include warning for proper handling of batteries /Warnings included with the device	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles  /University of Alberta, Department of Biological Sciences
1-1-3	Housekeeping disinfect / sterilize equipment / supplies	chemical : chemical emissions If the user chooses to put in an aftermarket rechargeable battery, overcharging the battery can result in production of toxic gas.	Slight Remote Negligible	Low	Include warning for proper handling of batteries /Warnings included with the device	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
2-1-1	Physician/PA/Nurse/Physical Therapist Conduct test	mechanical : pinch point Physician could improperly grip handle and pinch their hand between the patient and the device	Minimal Occasional Unlikely	Low	Train physician to correctly hold the device/conduct the test /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles

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2-1-2	Physician/PA/Nurse/Physical Therapist Conduct test	mechanical : stabbing / puncture Physician could sit improperly close to the patient while conducting the test and risk getting kicked by the patient or forceful contact with the device	Slight Remote Unlikely	Low	Train physician to properly conduct the test /Training for Device Usage	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
2-1-3	Physician/PA/Nurse/Physical Therapist Conduct test	mechanical : unexpected start Physician could be bumped if the patient's spasticity causes an unexpected start or stop to the test	Minimal Occasional Possible	Moderate	Include warnings in physician training directions and be sure they are aware of the proper position to sit so that they are not in the line of motion of the test at any point. /Training for Device Usage	Minimal Remote Possible	Low	On-going [Daily] Olivia, Tony, Charles
2-1-4	Physician/PA/Nurse/Physical Therapist Conduct test	electrical / electronic : shorts / arcing / sparking If the device electronics get wet or is improperly dismantled, there is a chance of sparking or fire	Serious Remote Negligible	Low	Proper precautions should be taken. The device will be properly coated as to avoid any sparking or failures if the worst occurs. Battery compartment will be isolated from the rest of the electronics. /Waterproofing	Serious None Negligible	Low	Complete [11/21/2014] Olivia
2-1-5	Physician/PA/Nurse/Physical Therapist Conduct test	ergonomics / human factors : excessive force / exertion If physician uses excessive force during the test, they risk straining their own muscles	Minimal None Unlikely	Low	Include physician safety warnings in training directions /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
3-1-1	General public / family walk near equipment / patients	mechanical : Bump if too close to test If standing too close to patient during the test, they risk being bumped.	Minimal Occasional Possible	Moderate	Include warnings in physician training directions to have family members stand an appropriate distance away /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles

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3-1-2	General public / family walk near equipment / patients	chemical : chemical / toxicity effects felt at distant time / place Batteries, if improperly disposed of, can release toxic and corrosive materials into landfills and cause negative effects for the general public	Slight Occasional Possible	Moderate	Include proper disposal warnings for batteries /Warnings included with the device	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles  /University of Alberta, Department of Biological Sciences
3-1-3	General public / family walk near equipment / patients	None / Other : Misuse If a child were to pick up the device sitting around, they could potentially harm themselves with it. For example, wrap the cuff around neck and accidentally strangle themselves.	Serious Occasional Possible	High	Include warnings to keep out of reach of children and those who aren't qualified to use it. Also include case that it can be placed in while not in use /Warnings included with the device	Serious None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-1	Patient Have test conducted	mechanical : pinch point Improper securing of device on patient limb could cause pinching skin during test	Minimal Occasional Possible	Moderate	Train physician to properly attach device /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-2	Patient Have test conducted	mechanical : stabbing / puncture If sharp edges or uncoated materials are left on the device, the patient could be cut during test conduction.	Slight Occasional Possible	Moderate	Round device edges, coat with comfortable material /Device Comfort Program	Minimal Remote Unlikely	Low	Complete [11/20/2014] Charles
4-1-3	Patient Have test conducted	electrical / electronic : shorts / arcing / sparking If water somehow seeps into the device during testing, or if the device is improperly handled and dismantled, there is a chance of sparking or fire	Serious Remote Negligible	Low	Proper precautions should be taken. The device will be properly coated as to avoid any sparking or failures if the worst occurs. Battery compartment will be isolated from the rest of the electronics. /Waterproofing	Serious None Negligible	Low	Complete [11/21/2014] Olivia

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4-1-4	Patient Have test conducted	ergonomics / human factors : excessive force / exertion Tester could potentially use excessive force on the limb during testing causing pain or damage to the patient	Slight Remote Unlikely	Low	Train customers of the device to understand that only physicians and those familiar with the patient's condition should be conducting the test. /Warnings included with the device	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-5	Patient Have test conducted	ergonomics / human factors : posture Tester could improperly conduct the test by improperly directing the patient's posture or having a patient unable to control his or her posture. This could lead to inaccurate data	Minimal Occasional Possible	Moderate	Train physician on how to use the device and how to get proper data. /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-6	Patient Have test conducted	ergonomics / human factors : repetition Tester could fail to repeat the measurement if data is questionable and patient could receive an incorrect diagnosis	Serious Remote Unlikely	Moderate	Train physician on how to properly conduct the test and recognize errors that may occur in test conduction /Training for Device Usage	Serious None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-7	Patient Have test conducted	ergonomics / human factors : lifting / bending / twisting Tester could improperly move the limb if untrained on how to conduct test, potentially causing discomfort to the patient or causing incorrect data	Minimal Occasional Unlikely	Low	Train physician on how to properly conduct test /Training for Device Usage	Minimal None Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-1-8	Patient Have test conducted	ergonomics / human factors : Excessive tightness of cuff If the cuff is excessively tightened when the physician puts it on the patient, it could cut off the patient's circulation	Slight Remote Unlikely	Low	Train physician to properly secure cuff to patient /Training for Device Usage	Slight None Negligible	Low	On-going [Daily] Olivia, Tony, Charles

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4-1-9	Patient Have test conducted	environmental / industrial hygiene : contamination Between patients, if not cleaned, germs could accumulate and infect either the physician/user or the next patient.	Minimal Frequent Probable	High	Include instructions for how to clean device between each usage /Training for Device Usage	Minimal Remote Negligible	Low	On-going [Daily] Olivia, Tony, Charles
4-2-1	Patient Receive prescribed medication/treatment	medication : improper prescription Physician could prescribe medication or treatment based on incorrect data	Serious Remote Possible	Moderate	Train physician to correctly administer test and respond properly if some aspect of the test fails, or if there is an abnormality. /Training for Device Usage	Serious None Negligible	Low	On-going [Daily] Olivia, Tony, Charles