

**designsafe Report**

Application: Stroke Feedback System

Analyst Name(s): Andrew Acevedo, Ben Glassman, Brandon Maddy

Description:

Company: Group 16

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 /Comments	Final Assessment		Status / Responsible /Reference
			Severity Probability	Risk Level		Severity Probability	Risk Level	
1-1-1	Doctor monitor patients	biological / health : unsanitary conditions Lack of sanitation before use	Serious Likely	High	instruction manuals	Serious Remote	Low	Action Item
2-1-1	Therapist monitor patients	biological / health : unsanitary conditions Lack of sanitation before use	Serious Likely	High	instruction manuals	Serious Remote	Low	
2-2-1	Therapist monitor machines	biological / health : unsanitary conditions lack of sanitation after use	Serious Likely	High	instruction manuals	Serious Remote	Low	
2-2-2	Therapist monitor machines	electrical / electronic : shorts / arcing / sparking careless construction or system failure	Serious Unlikely	Medium	warning label(s)	Serious Remote	Low	
2-2-3	Therapist monitor machines	electrical / electronic : water / wet locations liquids in surrounding environment or due to patient perspiration	Moderate Likely	Medium	standard procedures /Can not do anything about patient perspiring	Moderate Unlikely	Low	
2-2-4	Therapist monitor machines	electrical / electronic : power supply interruption wiring becomes unconnected/system failure	Minor Unlikely	Negligible		Minor Unlikely	Negligible	
2-3-1	Therapist setup/breakdown system	biological / health : unsanitary conditions lack of sanitation before/after use	Serious Likely	High	instruction manuals	Serious Remote	Low	
2-3-2	Therapist setup/breakdown system	mechanical : crushing straps tightened too much	Moderate Likely	Medium	on-the-job training (OJT)	Moderate Unlikely	Low	

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2-3-3	Therapist setup/breakdown system	mechanical : cutting / severing device not setup properly	Moderate Likely	Medium	on-the-job training (OJT)	Moderate Unlikely	Low	
2-3-4	Therapist setup/breakdown system	mechanical : pinch point device not setup properly	Moderate Likely	Medium	on-the-job training (OJT)	Moderate Unlikely	Low	
2-3-5	Therapist setup/breakdown system	electrical / electronic : energized equipment / live parts careless construction/system ware leading to exposed parts	Serious Unlikely	Medium	warning label(s)	Serious Remote	Low	
2-3-6	Therapist setup/breakdown system	wastes (Lean) : waiting / delay therapist does not know how to setup device	Minor Likely	Low	on-the-job training (OJT)	Minor Remote	Negligible	
2-4-1	Therapist clean/sterilize system	electrical / electronic : water / wet locations improper cleaning	Serious Unlikely	Medium	instruction manuals	Serious Remote	Low	
2-5-1	Therapist transport system	mechanical : drawing-in / trapping / entanglement device is not transported properly	Minor Likely	Low	instruction manuals	Minor Remote	Negligible	
2-5-2	Therapist transport system	material handling : storing improper storing of device	Moderate Likely	Medium	instruction manuals	Moderate Remote	Negligible	
2-5-3	Therapist transport system	material handling : movement to / from storage device not handled carefully during movement	Minor Likely	Low	instruction manuals	Minor Remote	Negligible	
3-1-1	Patient therapy exercises	biological / health : unsanitary conditions Lack of sanitation before use	Serious Likely	High	instruction manuals	Serious Remote	Low	
3-1-2	Patient therapy exercises	mechanical : crushing straps tightened too much	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-3	Patient therapy exercises	mechanical : cutting / severing device setup improperly	Moderate Unlikely	Low		Moderate Unlikely	Low	

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3-1-4	Patient therapy exercises	mechanical : pinch point device setup improperly	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-5	Patient therapy exercises	ergonomics / human factors : excessive force / exertion pinch sensors require too much force/device is too heavy	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-6	Patient therapy exercises	ergonomics / human factors : posture device does not conform to patient's normal posture	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-7	Patient therapy exercises	ergonomics / human factors : lifting / bending / twisting device causes strain on patients hand	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-8	Patient therapy exercises	heat / temperature : radiant heat device overheats	Moderate Unlikely	Low		Moderate Unlikely	Low	
3-1-9	Patient therapy exercises	noise / vibration : noise / sound levels > 80 dBA speaker is set too loud	Moderate Unlikely	Low	use alternate materials	Moderate Remote	Negligible	
3-1-10	Patient therapy exercises	noise / vibration : equipment damage device is handled roughly	Moderate Likely	Medium	special procedures	Moderate Remote	Negligible	
3-1-11	Patient therapy exercises	noise / vibration : fatigue / material strength device is handled roughly	Moderate Likely	Medium	special procedures	Moderate Unlikely	Low	
3-1-12	Patient therapy exercises	radiation : bright visible light LEDs are too bright	Moderate Unlikely	Low	warning label(s)	Moderate Remote	Negligible	