## designsafe Report

Application: Balance Boot

Description:

Analyst Name(s): Ashley Williams, Jill Greenfield, Catie Reynolds

Company:

Facility Location: Product Identifier:

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 Asses Severity Probability	ssment Risk Level	Risk Reduction /Comments	Final Assess Severity Probability	sment Risk Leve	Status / Responsible / /Reference
1-1-1	All Users Common Tasks	mechanical : drawing-in / trapping / entanglement	Moderate Unlikely	Low	standard procedures, fixed enclosures / barriers	Minor Unlikely	Negligible	On-going [Daily]
1-1-2	All Users Common Tasks	mechanical : pinch point	Minor Unlikely	Negligible	fixed enclosures / barriers, standard procedures	Minor Remote	Negligible	On-going [Daily]
1-1-3	All Users Common Tasks	electrical / electronic : improper wiring	Moderate Unlikely	Low	standard procedures	Moderate Unlikely	Low	In-process
1-1-4	All Users Common Tasks	electrical / electronic : water / wet locations	Serious Likely	High	fixed enclosures / barriers	Serious Unlikely	Medium	Action Item
1-1-5	All Users Common Tasks	electrical / electronic : unexpected start up / motion	Moderate Unlikely	Low	prevent energy release	Minor Unlikely	Negligible	In-process
1-1-6	All Users Common Tasks	slips / trips / falls : slip User may slip while walking in shoe	Serious Likely	High	safety mats / contact strip, warning label(s), standard procedures	Serious Unlikely	Medium	In-process
1-1-7	All Users Common Tasks	slips / trips / falls : trip User may trip over shoe	Serious Likely	High	safety mats / contact strip, warning label(s), standard procedures	Serious Unlikely	Medium	In-process
1-1-8	All Users Common Tasks	ergonomics / human factors : posture Shoe arch may affect patient posture	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	TBD
1-1-9	All Users Common Tasks	noise / vibration : desensitization Constant stimulus may desensitize somatosensory receptors	Moderate Likely	Medium	warning label(s)	Moderate Likely	Medium	TBD

	User /	Hazard /	Initial Assessment Severity		Risk Reduction	Final Assessment Severity		Status / Responsible /
tem Id	Task	Failure Mode	Probability	Risk Level	/Comments	Probability	Risk Leve	/Reference
1-1-10	All Users Common Tasks	noise / vibration : low amplitude noise/sound levels Constant noise over long period of time may impair hearing	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	TBD
1-1-11	All Users Common Tasks	environmental / industrial hygiene : hazardous waste battery disposal may contain hazardous waste	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	In-process
I-2-1	All Users normal operation	Other : Refer to other user / task All Users/Common Tasks						
1-3-1	All Users trouble-shooting / problem solving	Other : Refer to other user / task All Users/Common Tasks						
1-4-1	All Users clean up	Other : Refer to other user / task All Users/Common Tasks						
2-1-1	operator normal operation	mechanical : unexpected start	Minor Remote	Negligible	prevent energy release	Minor Remote	Negligible	In-process
2-1-2	operator normal operation	electrical / electronic : improper wiring	Moderate Unlikely	Low	standard procedures	Moderate Unlikely	Low	In-process
2-1-3	operator normal operation	electrical / electronic : water / wet locations	Serious Likely	High	fixed enclosures / barriers, warning label(s)	Serious Unlikely	Medium	In-process
2-1-4	operator normal operation	slips / trips / falls : slip User may slip while walking in shoes	Serious Likely	High	safety mats / contact strip, warning label(s)	Serious Unlikely	Medium	In-process
2-1-5	operator normal operation	slips / trips / falls : trip User may trip over shoes	Serious Likely	High	safety mats / contact strip, warning label(s)	Serious Unlikely	Medium	In-process
2-1-6	operator normal operation	noise / vibration : desensitization Constant stimulus may desensitize somatosensory receptors	Moderate Likely	Medium	warning label(s)	Moderate Likely	Medium	TBD
2-1-7	operator normal operation	noise / vibration : low amplitude noise/sound levels Constant noise over long period of time may impair hearing	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	TBD
3-1-1	maintenance technician Common Tasks	mechanical : cutting / severing	Minor Remote	Negligible	standard procedures	Minor Remote	Negligible	On-going [Daily]

Item Id	User / Task	Hazard / Failure Mode	Initial Asses Severity Probability	ssment Risk Level	Risk Reduction /Comments	Final Assess Severity Probability	sment Risk Leve	Status / Responsible / /Reference
3-1-2	maintenance technician Common Tasks	mechanical : pinch point	Minor Unlikely	Negligible	fixed enclosures / barriers, standard procedures	Minor Remote	Negligible	On-going [Daily]
3-1-3	maintenance technician Common Tasks	mechanical : unexpected start	Minor Remote	Negligible	prevent energy release	Minor Remote	Negligible	In-process
3-1-4	maintenance technician Common Tasks	electrical / electronic : energized equipment / live parts	Moderate Unlikely	Low	prevent energy buildup, standard procedures	Moderate Unlikely	Low	In-process
3-1-5	maintenance technician Common Tasks	electrical / electronic : lack of grounding (earthing or neutral)	Moderate Unlikely	Low	other design change, standard procedures	Moderate Unlikely	Low	On-going [Daily]
3-1-6	maintenance technician Common Tasks	electrical / electronic : shorts / arcing / sparking	Moderate Unlikely	Low	prevent energy release, standard procedures	Moderate Unlikely	Low	On-going [Daily]
3-1-7	maintenance technician Common Tasks	electrical / electronic : improper wiring	Moderate Unlikely	Low	standard procedures	Moderate Unlikely	Low	On-going [Daily]
3-1-8	maintenance technician Common Tasks	electrical / electronic : water / wet locations	Serious Unlikely	Medium	warning label(s), standard procedures, fixed enclosures / barriers	Serious Unlikely	Medium	On-going [Daily]
3-1-9	maintenance technician Common Tasks	noise / vibration : low amplitude noise/sound levels Constant noise over long period of time may impair hearing	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	On-going [Daily]
3-1-10	maintenance technician Common Tasks	environmental / industrial hygiene : hazardous waste Battery disposal may contain hazardous wastery	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	On-going [Daily]
3-2-1	maintenance technician set-up or changeover	Other: Refer to other user / task Maintenance technician/Common Tasks						
3-3-1	maintenance technician parts replacement	Other: Refer to other user / task Maintenance technician/Common Tasks						
3-4-1	maintenance technician adjust controls / settings / alignment	Other: Refer to other user / task Maintenance technician/Common Tasks						

I I	User /	Hazard /	Initial Asses		Risk Reduction	Final Assess Severity		Status / Responsible /
3-5-1	maintenance technician trouble-shooting / problem solving	Other: Refer to other user / task Maintenance technician/Common Tasks	Probability	Risk Level	/Comments	Probability	Risk Leve	/Reference
4-1-1	passer by / non-user walk near machinery	slips / trips / falls : trip Person may trip over shoes	Minor Remote	Negligible		Minor Remote	Negligible	On-going [Daily]
4-1-2	passer by / non-user walk near machinery	noise / vibration : low amplitude noise/sound levels Constant noise over long period of time may impair hearing	Minor Remote	Negligible	warning label(s)	Minor Remote	Negligible	On-going [Daily]