Liver Assist Device 12/6/2011

Washington University in St. Louis

designsafe Report

Application: Liver Assist Device Analyst Name(s): Arjun Bahl, Cameron Hinkel, Ben Jiang

Description: Company: Hoganson Lab
Product Identifier: Facility Location: Whitaker Hall

Assessment Type: Detailed

Limits: Partial to Complete Assesment based on proposed design

Sources: BME 562 Term Papers

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].

	User / Task	Hazard / Failure Mode	Initial Assessm	nent	Risk Reduction Methods /Comments	Final Assessment		Status /
Item Id			Severity Probability	Risk Level		Severity Probability	Risk Level	Responsible /Reference
1-1	Doctor take vitals	<none></none>						
1-2	Doctor conduct tests	<none></none>						
1-3	Doctor diagnose patients	<none></none>						
1-4	Doctor trouble shooting / problem solving	<none></none>						
1-5	Doctor operate on patients	<none></none>						
1-6-1	Doctor pre-op patients	biological / health : bacterial Unsanitary surgical procedure	Serious Remote	Low		Serious		
1-6-2	Doctor pre-op patients	biological / health : viral Unsanitary surgical procedure	Serious Remote	Low		Serious		
1-7	Doctor apply / remove medical monitoring equipment	<none></none>						
1-8	Doctor calibrate / test / troubleshoot medical monitoring equipment	<none></none>						

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User /	Hazard /	Severity	Initial Assessment			nent	Status / Responsible
Task	Failure Mode	Probability	Risk Level	Risk Reduction Methods /Comments	Severity Probability	Risk Level	/Reference
Doctor monitor patients	<none></none>						
Doctor monitor machines	<none></none>						
Nurse lift / reposition patients	<none></none>						
Nurse take vital statistics on patients	<none></none>						
Nurse draw blood samples	<none></none>						
Nurse test machine functionality	<none></none>						
Nurse clean / sterilize instruments / equipment	<none></none>						
Nurse prepare / administer IV injections	<none></none>						
Nurse monitor patients	<none></none>						
Nurse monitor machines	<none></none>						
Surgical Technician setup supplies / equipment / instruments for operation	<none></none>						
Surgical Technician prepare patient for surgery	<none></none>						
	Task Doctor monitor patients Doctor monitor machines Nurse lift / reposition patients Nurse take vital statistics on patients Nurse draw blood samples Nurse test machine functionality Nurse clean / sterilize instruments / equipment Nurse prepare / administer IV injections Nurse monitor patients Nurse monitor patients Surgical Technician setup supplies / equipment / instruments for operation Surgical Technician	Task Failure Mode Doctor	Task Failure Mode Probability Doctor	Task Failure Mode Probability Risk Level Doctor	Task Failure Mode Probability Risk Level Comments Doctor	Task Failure Mode Probability Risk Level /Comments Probability Doctor	Task Failure Mode Probability Risk Level Comments Risk Level Comments Risk Level Comments Risk Level Risk Level Comments Risk Level Risk

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ltom lal	User / Task	Hazard / Failure Mode	Initial Assessr Severity		Risk Reduction Methods	Final Assessn Severity		Status / Responsible /Reference
3-3	Surgical Technician assist doctor with surgery	<none></none>	Probability	Risk Level	/Comments	Probability	Risk Level	Reference
3-4	Surgical Technician monitor patients	<none></none>						
4-1-1	Patient rest	biological / health : hazardous biological waste Unsanitary/Dead cells	Serious Unlikely	Medium	warning label(s)	Serious		
4-1-2	Patient rest	biological / health : bacterial Infected cells	Catastrophic Unlikely	Medium	warning label(s)	Catastrophic		
4-1-3	Patient rest	biological / health : viral Infected cells	Catastrophic Unlikely	Medium	warning label(s)	Catastrophic		
4-2	Patient moving	<none></none>						
4-3	Patient eating	<none></none>						
4-4	Patient waiting / delay	<none></none>						