

	749 Benedum Hall Pittsburgh, PA 15261	<b>Initial Hazard Analysis</b>	
		Doc. No. DHF-005	Rev. 0
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Title:	<b>Initial Hazard Analysis</b>		
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<b>Revision Approvals:</b>			Date
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Function or Component	Failure Mode	Effect on System	Possible Hazards	Risk Index	User Detection Means	Applicable Controls
Controller	Loss of Power	System shutdown (open coupling)	Loss of perfusion to patient	10	Patient alarms Visual inspection	Battery backup Manual backup
Controller	Electronic or mechanical failure	System shutdown (open coupling)	Loss of perfusion to patient	10	Device alarms Patient alarms Visual inspection	Manual backup
Pump	Mechanical failure	Loss of flow	Loss of perfusion to patient	8	Device alarms Patient alarms Visual inspection	Backup pump available for rapid replacement
Pump or cannulae	Leak	Pressure/flow drop	Decreased perfusion to patient. Blood loss.	6	Device alarms Visual inspection	Component replacement
Pump or cannulae	Air entering system	Pressure/flow change	Decreased perfusion to patient. Risk of embolism.	4	Device alarms Visual inspection	Bubble trap?
Pump or cannulae	Thrombus formation	Pressure/flow change. Possible occlusion or pump failure.	Decreased or lost perfusion to patient. Risk of embolism.	8	Device alarms. Visual inspection	Anti-coagulation. Circuit design.
Pump or cannulae	Pathogenic contamination	None	System infection	6	Patient monitoring.	Device handling controls.