

User	Task	Hazard	Cause/Failure Mode	Severity	Exposure	Probability	Risk Level	Method of Risk Reduction/Mitigation	Severity	Exposure	Probability	Risk Level
Doctor	Implantation	Biological/Heath	Surgical Contamination	Serious	Remote	Possible	Low	Surgeon follows procedure	Serious	Remote	Unlikely	Low
		Biological/Health	Restriction of nerve	Serious	Remote	Possible	Low	Surgeon follows procedure	Serious	Remote	Unlikely	Low
		Biological/Health	Surgeon careless with knife	Serious	Remote	Possible	Low	Surgeon follows procedure	Serious	Remote	Unlikely	Low
		Biological/Health	Improper implantation	Serious	Remote	Possible	Medium	Surgeon follows procedure	Serious	Remote	Unlikely	Medium
All Users	Operation of Device	Electrical	Improper electrode application	Slight	Frequent	Possible	Medium	Improve training given to patients and families	Minimal	Occasional	Unlikely	Low
		Mechanical	Improper user handling	Serious	Frequent	Unlikely	Low	Improve training given to patients and families	Minimal	Occasional	Unlikely	Low
		Electrical	Battery failure	Slight	Occasional	Unlikely	Low	Monitor battery health	Minimal	Occasional	Unlikely	Low
Patient	Use of electrodes	Biological/Health	Allergic reaction to electrode	Slight	Remote	Unlikely	Low	Use TENS electrodes, proper TENS care	Minimal	Remote	Negligible	Low
	Operation of Device	Mechanical	LED burns out	Minimal	None	Unlikely	Low	Device uses brand-new LED	Minimal	None	Unlikely	Low
	Operation of Device	Biological/Health	Cuff comes loose	Slight	Frequent	Unlikely	Low	Teach surgeon how to use properly	Slight	Frequent	Negligible	Low
	Operation of Device	Biological/Health	Improper placement of electrode	Slight	Occasional	Possible	Low	Teach patient where to put the electrode post-op	Slight	Remote	Unlikely	Low
	Operation of Device	Electrical	Leakage current	Slight	Remote	Unlikely	Low	Proper circuit design, soder circuit	Minimal	Remote	Unlikely	Low
	Use of electrodes	Mechanical	Electrodes have been overused	Slight	Occasional	Possible	Low	Teach patient when to replace electrodes	Slight	Remote	Unlikely	Low
	Operation of Device	Electrical	Loose connection of wires	Slight	Remote	Unlikely	Low	Soder circuit	Slight	Remote	Unlikely	Low
	Operation of Device	Electrical	LCD screen burns out	Slight	Remote	Unlikely	Low	Use new LCD screen	Slight	Remote	Negligible	Low
	Operation of Device	Mechanical	Potentiometers break	Serious	Remote	Unlikely	Medium	Using quality parts	Serious	Remote	Negligible	Low
	Operation of Device	Mechanical	Switch breaks	Serious	Remote	Unlikely	Medium	Using quality parts	Serious	Remote	Negligible	Low
Operation of Device	Electrical	Function generator burns out	Serious	Remote	Unlikely	Medium	Only use 9V battery	Serious	Remote	Negligible	Low	
Operation of Device	Electrical	Operation amplifier burns out	Serious	Remote	Unlikely	Medium	Using quality parts	Serious	Remote	Negligible	Low	