Risk Analysis

Risk Analysis — A device risk analysis was performed according to ANSI/AMMI/ISO 9001-2001 and ISO 13485-2003. The purpose of this analysis is to identify potential harm that a user could encounter while Using the EVRF.

Table 8.1 Device Risk Analysis

Risk Category	Potential Hazard	Cause(s)	Probability Low, Moderate, or High	Severity Low, Moderate, or High	Risk Probability x Severity	Mitigation	Standard(s) Considered	Test Acceptance Criteria	Test Result
Energy	Unwanted power on output	Inconsistency between screen and program	Low	Moderate	Moderate	Patient safety is not at harm + effect is instantly visible for practitioner so he can stop the treatment		No harm is caused to user.	Pass
	Leakage current	Improper mounting of the device	Low	Low	Low	Final quality check	601-1-2	Measurement of leakage current	Pass
	Electrical discharge	Improper mounting of the device	Low	Moderate	Moderate	No metallic parts on the outside of the machine	601-1-2	Measurement of earth continuity	Pass
Biological	Allergenicity/ Bio-incompatibility	User Contacting Materials	Low	Low	Low	Material Specification	ANSI/AAMI/ISO 10993	Material non-irritating and non-sensitizing.	Pass

Risk Category	Potential Hazard	Cause(s)	Probability Low, Moderate, or High	Severity Low, Moderate, or High	Risk Probability x Severity	Mitigation	Standard(s) Considered	Test Acceptance Criteria	Test Result
	Infection of the patient	Usage of infected needles	Low	High	High	Only use sterile needles from which the package is not damage.	ISO 11135-1:2007	Sterilization validation by approved company	Pass
Environmental	EM Emissions	Cellular Modem	Low	Low	Low	Safety Testing	NF EN 60601-1-2(2007)	EM emissions comply with standard.	Pass
	ESD	Contact with High Voltage Source	Low	Moderate	Moderate	Design, Safety Testing	IEC 601-1:1988 +A1:1991 +A2:1995	ESD immunity complies with standard.	Pass
	Use During or Following Excessive Conditions	Excessive Temperature or Humidity	Low	Low	Low	Safety Testing, User Instruction	IEC 601-1:1988 +A1:1991 +A2:1995	Performance acceptable under conditions stated in standard.	Pass
Mechanical	Mechanical Failure	Drop (Shock), Vibration, Spillage	Low	Low	Moderate	No potential risk for the patient or operator.		No harm is caused to user. .	Pass
User Interface	Overheating off the device	Improper placement of the device	Low	Low	Low	Instruction on how to place the machine in user manual.		No harm is caused to user.	Pass
	Unwanted triggering of the output	Falling of the device	Low	Moderate	Low	Instruction on how to place the machine in user manual + usage of rubber feet		No harm is caused to user.	Pass
Software	Unresponsiveness of the screen	Internal EMC	Low	Low	Low	Usage of I2C protocol to reduce interference		No harm is caused to user.	Pass

Risk Category	Potential Hazard	Cause(s)	Probability Low, Moderate, or High	Severity Low, Moderate, or High	Risk Probability x Severity	Mitigation	Standard(s) Considered	Test Acceptance Criteria	Test Result
Software	Cut off application during operation	Electrical power drop	Low	Low	Low	Automatic restart of the device when power is back		No harm is caused to user.	Pass

The machine can only be used in monopolar mode but if the patient is grounded with a reference plate then it is possible that a current (that can exceed the normal value) will flow between the electrode and the reference plate. Resulting in an increased heating of the path between electrode and reference plate. This can also result in damaging the machine.