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			Version	0.1
Reviewed	Name	Role	Signature	Date
Approved	Name	Role	Signature	Date

Hazard Identification

Meeting Date(s)			
Meeting Participants			
Intended Use			
Background	<p>Bioservo Hazard Identification is a risk management activity in compliance with the harmonized standard EN ISO 14971. Terms and definitions from the standard are used or referred to whenever possible.</p> <p>In Hazard Identification a top-down risk assessment approach is used to identify harm (potential adverse effects) and hazards (product failure modes, i.e. causes for harm) that can be caused by the device, with the intended use in mind.</p>		
Severity Rankings	Harm is related to a severity. Each hazard shall be assigned a severity ranking, based on the harm it can cause.		
Catastrophic	CA	3	The he hazard can directly cause death or serious injury.
Critical	CR	2	<p>The hazard can indirectly cause death or serious injury.</p> <p>The hazard can directly cause moderate injury.</p>
Marginal	MA	1	<p>The hazard can indirectly cause moderate injury.</p> <p>The hazard can directly cause minor injury.</p>
Negligible	NE	0	<p>The hazard can indirectly cause minor injury.</p> <p>The hazard can cause no clinical effect.</p>

Hazard Identification Manual

Sabine Zange



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