

Kravspesifikasjon - blod- og væskevarmere for Luftambulansetjenesten HF

Ref.	Oppdragsgivers kravspesifikasjon				Tilbyders svar		
	Beskrivelse av krav	Krav-type	Dok	TK	Oppfylles kravet?		Beskrivelse/henvisning til nærmere beskrivelse
					Ja	Nei	
1	General requirements						
1-1	The warmer shall be CE-marked and classified as MEDICAL ELECTRICAL EQUIPMENT, PORTABLE EQUIPMENT and comply with <ul style="list-style-type: none"> IEC 60601-1: <i>Medical electrical equipment – general requirements for safety</i>, IEC 60601-1-2:2014: <i>Medical electrical equipment – Electromagnetic compatibility - requirements and tests</i>. IEC 60601-1-12: <i>Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment</i> 	O	X				
1-2	The warmer shall be designed for emergency medical services. See appendix "Intended use - description of environment" for a description of the operating environment. A certificate/declaration of conformity shall be presented.	O	X				
1-4	There shall be provided a list of all relevant performed tests and standards, including class/category determination and methods/limits, proving conformity to these requirements.	O	X				
1-5	The expected lifecycle in normal use shall be minimum 5 years.	O					
1-6	The warmer shall be designed for the purpose of administrating Full blood, plasma and clear infusion fluids	O					
2	Physical design requirements						
2-1	Weight I. The total weight of the warmer including batteries and parts for normal use shall not exceed 1,8 kg when fulfilling all mandatory requirements in this document. Storage bag and accessories shall be excluded from this total weight.	O					
2-3	Size I The total size of the warmer and all necessary accessories for normal use, fluid lines and bag/storage solution excluded, shall not exceed 10 x 16 x 25 cm in total, when all components for normal use are stacked in most favourable orientation.	O					
3	Environmental conditions requirements						

3-1	EMS environment The warmer shall comply with IEC60601-1-12: Electromedical equipment in EMS services or equivalent.	O	X				
3-2	Fixation The manufacturer shall advise fixation points and/or methods to ensure safe use of the warmer during flight and transference	O					
3-3	Emission of radio frequency energy The warmer shall comply with RTCA DO-160G section 21 category M, or equivalent.	O	X				
3-4	Radio frequency susceptibility The warmer shall comply with RTCA DO-160G section 20 minimum category R, or equivalent.	O	X				
3-5	Ingress protection The warmer, without any storage solution, shall fulfill requirements to be classified as IPX3 or higher according to IEC 60529.	O					
3-7	Fireproofness The warmer shall comply with requirements in EN 13718-1:2014 clause 4.9 or equivalent.	O	X				
3-8	Wireless communication Wi-Fi, Bluetooth, GSM or any other wireless transmitting mode shall be possible to turn off/set to flight mode by the end user while in use.	O					
4	Electrical requirements						
4-1	Internal battery general The following requirements regarding internal batteries shall be fulfilled: <ul style="list-style-type: none"> The warmer shall display the state of charge and remaining capacity, when running on internal battery/batteries (not connected to external power supply) All cells and batteries (Lithium batteries excluded) shall fulfill specifications given by IATA (IATA Dangerous regulation) to be classified as non dangerous goods. A recommended replacement frequency of the batteries specified in months shall be stated. 	O	X				
4-2	Internal battery charging time Charging time from depleted to 80% charged shall be less than 3 hrs.	O					
4-3	Internal Lithium Ion Battery The following requirements regarding internal Lithium Ion batteries shall, if offered with the warmer, be fulfilled: <ul style="list-style-type: none"> Rechargeable Lithium Ion cells/batteries shall be tested in accordance with and proved to fulfill requirements of international transport regulations with regards to shipment and use on board aircraft as described in UN Manual of tests and criteria Part III subsection 38.3 (DGR 3.9.2.6) or equivalent. 	O	X				

4-4	Battery lithium content <ul style="list-style-type: none"> Any single battery, classified UN3480/3481, shall not exceed a total capacity of 160 Wh and shall not contain more than 8g of Lithium equivalent. Any single battery, classified UN3091, shall not contain more than 1g of Lithium metal equivalent 	O					
4-5	Battery capacity I The battery capacity shall provide warming of a minimum volume of 1,5 l fluid from 5 to 36 °C before charge or replacement.	O					
4-7	Exchanging battery/batteries It shall be possible for the end user to exchange battery or powersource during a procedure without the need of tools in less than 10 seconds.	O					
4-9	External charger The warmer shall have an external 230V charger for batteries/powerpack to be used on ground. These unit is exemptioned from requirements in this specification other than those necessary for CE marking.	O					
5	Funktional requirements						
5-1	Warming capacity I The warmer shall have the capacity to heat water from 5°C to 36°C	O					
5-3	Capacity III The warmer shall have the capacity to heat a flow of 120 ml/min	O					
5-6	Warming capacity V The minimum performance for warming vs flow vs input temperature shall be 34°C @ flow 120 ml/min @ 20 °C ambient temperature and inlet fluid temperature 10°C	O					
5-8	Warmer orientation The warmer shall be able to perform within all requirements in all orientations under use	O					
5-9	Pressurized reservoir The warmer shall be able to perform as intended with a pressurized fluid of 300mmHg	O					