Product Requirements and Specifications for MSF Conductive Warmer

Saige Sunier, Design that Matters

Design Principle: Is Effective							
	Quality	**Metric**	**MSF Target**	**MSF Worst Acceptable Performance**	**International Standard**	**Domain Expert or MSF Authority**	**Stakeholders**
1	Prevents hypothermia	device temperature	36C-38C	36C	IEC80601-2-35 Performance requirements of heating devices using blankets, pads or mattresses and intended for heating in medical use	Manufacturer QA/QC standards certification	design volunteers and domain experts, MSF Biomed (medical devices)
2	Treats mild hypothermia	device temperature	36C-40C	36C	IEC80601-2-35 Performance requirements of heating devices using blankets, pads or mattresses and intended for heating in medical use	Design volunteers and domain experts	Manufacturer QA/QC standards certification, MSF Biomed (medical device)
3	Meets IEC specifications (and/or UNICEF Target Product Profiles aka TPP)	IEC Test Report (supports CE certification)	Meets all relevant IEC specifications	Meets UNICEF TPP requirements and specifications	IEC80601-2-35; IEC60601-1	Manufacturer QA/QC standards certification	MSF Biomed, EU/HCN medical device regulator, MSF Procurement & Logistics, MSF ESCS, Device Manufacturer
4	Has CE Mark certification (or regional regulatory approval)	CE certification mark	Has CE certification	Has national or regional "certificate of free sale"		MSF Biomed	MSF Procurement & Logistics, MSF European Supply Center
5	Fast warm-up from cold/off state	time from power up to ready to treat patients	instant on (ie radiant warmer)	twenty minutes to warm up from room-termperature start		MSF Pediatric Working Group	HCN nurse/clinician, MSF expat clinician, device manufacturer, design volunteers &domain experts
6	Provides warming during hand-held carry	protective measures to prevent falling hazard	Non-enclosed: side height >/= 191mm	Enclosed device (ie sleeping bag, wrap)	ASTM F2194-13 Standard Consumer Safety Specification for Bassinets and Cradles	EU Medical device regulator	HCN medicald device regulator, design volunteers & domain experts
Design Principle: Looks Effective							
	Quality	**Metric**	**MSF Target**	**MSF Worst Acceptable Performance**	**International Standard**	**Domain Expert or MSF Authority**	**Stakeholders**
7	Feels warm	device surface temperature	>37C (warmer than body temperature)	>34C (warmer than skin temp)	IEC 80601-2-35	HCN Nurse	MSF pediatric working group, MSF expat clinician, HCN clinician
8	Looks intuitive	subjective: determined by stakeholders			IEC 62366: Usability/Human Factors Engineering	MSF pediatric working group	HCN clinicians/nurses, MSF expat clinician
9	Looks clean and resists stains	stain test	pink stain test: <10% of surface area discoloration	pink stain test: <25% of surface area discoloration	ATME 1428/ ASTM C1378 Standard Test Method for Determination of Resistance to Staining	MSF IPC	MSF project IPS & cleaning staff, Manufacturer QA/QC standards certification, EU/HCN medical device regulator, MSF pediatric working group
10	Looks modern and high tech	subjective: determined by stakeholders				MSF pediatric working group	HCN clinicians/nurses, MSF expat clinician, Newborn Patient & Family
11	Looks familiar (matches expecations for a medical device	subjective: determined by stakeholders				MSF pediatric working group	HCN clinicians/nurses, MSF expat clinician, Newborn Patient & Family
12	Device state is obvious (on, off, broken)	Industrial design requirements	visual indication of device state and temperature display on UI	visual indication of device state	IEC 62366: Usability/Human Factors Engineering	MSF pediatric working group	HCN clinicians/nurses, MSF expat clinician, Design volunteers & domain experts
Design Principle: User Friendly							
	Quality	**Metric**	**MSF Target**	**MSF Worst Acceptable Performance**	**International Standard**	**Domain Expert or MSF Authority**	**Stakeholders**
13	Hard to use wrong	Usability Testing Compliance	Reduces opportunity for latent error or intentional but mistaken ac; Minimal user interface with few adjustable settings; settings adjustments intuitive	Reduced opportunity for latent error or intentional but mistaken ac	IEC 62366: Usability & Human Factors Engineerins/ ISO 9241-210 HCD for Interactive Systems	HCN nurse	HCN clinician, MSF expat clinician, MSF pediatric working group
14	Does not inhibit or discourage KMC	subjective: determined by stakeholders				MSF pediatric working group	HCN clinicians/nurses, MSF expat clinician, Newborn Patient & Family
15	Discourages bed-sharing among potentially infectious newborns	device dimensions (can only fit one baby)	L: 44.9cm (3%)-54.9(97%); W:10cm(3%)-12.4cm(97%)		CDC/WHO Newborn Length and Head Circumference Charts (Percentiles)	MSF IPC	MSF pediatric working group, HCN nurse/clinician, MSF expat clinician, MSF project IPC & cleaning staff
16	Requires minimal user training	time to train and skill level of user	Can train an unskilled user in <20 min	Can train a skilled user in <1hr	IEC 62366 (Specify User/Context for design)	MSF project clinical trainer	MSF Biomed (medical device), MSF pediatric working group, HCN nurse/clinician, MSF expat clinician

17	Does not obstruct patient access	actions to access patient	no actions required for access	<3 actions required for access		MSF pediatric working group	HCN nurse/clinician, MSF expat clinician
18	Does not obsruct patient visibility	nuisance distance	can visually scan 3 patients from 3-4ft away	1 action required for visual acess		MSF pediatric working group	HCN nurse/clinician, MSF expat clinician
19	Limited risk of scalding or hyperthermia (over-heating)	max surface temperature	40C, can be operated at any temperature	42C, can be operated at any temperature	IEC 80601-2-35: 201.11.1.2.1.101.1	Manufacturer QA/QC standards certification	Design volunteers & domain experts
20	Device requries minimal supervision (set and forget)	operations manual use description	user supervision not required in device manual		ISO 9241-210 Human Centered Design for interactive systems		MSF project clinical trainer, MSF Biomed (medical device), HCN nurse/clinician, MSF expat clinician
21	Is portable (by as small adult)	ergonomic handles for carrying	1.9-3.8cm diameter; >/=11.5cm length; 5cm clearance; cylindrical shape; smooth non-slip surface		NIOSH/CDC Applications Manual for Lifting Equation	Design volunteers & domain experts	MSF pediatric working group, HCN nurse/clinician, MSF expat clinician
22	Is portable (by as small adult)	device dimensions	<40cm L; <30cm H		NIOSH/CDC Applications Manual for Lifting Equation	Design volunteers & domain experts	MSF pediatric working group, HCN nurse/clinician, MSF expat clinician
23	Is portable (by as small adult)	device weights	8.5kg (13kg at chest height; w/out baby:13-4.5=8.5kg)	8.5kg (13kg at knuckle height; w/out baby:13-4.5=8.5kg)	NIOSH/CDC carrying weight limits for a small female ; CDC/WHO newborn 97% weight	Design volunteers & domain experts	MSF pediatric working group, HCN nurse/clinician, MSF expat clinician
Design Principle: Context Appropriate							
	Quality	**Metric**	**MSF Target**	**MSF Worst Acceptable Performance**	**International Standard**	**Domain Expert or MSF Authority**	**Stakeholders**
24	Easy to clean between patients (IPC)	Industrial Design Requirements	minimalistic surfaces with no crevices, seams or corners that might collect dirt; can be wiped clean between patients	can be wiped clean between patients; does not require submerging in water and drying over several hours		MSF project IPC & cleaning staff	MSF IPC
25	Compatible with common MSF cleaning products	sterilization process	compatible with Surfanios (non water-based cleaner) and chlorine/bleach based cleaning products	compatible with Surfanios (non water-based cleaner)	ISO 1137-2: Sterilization of health care products; IEC 60601: 11.6.6	MSF IPC	MSF project IPC & cleaning staff
26	Stable in long-term storage and shipping	shelf life	5 years	1 year		MSF procurement & logistics	MSF project pharmacy (local storage), MSF project lead who places device orders, MSF European Supply Center, LogCo
27	Easy to maintain by HCN biomed staff with limited tools, training	maintenance/operations manual	can be repaired using tools commonly found in a toolkit; does not specificy specialized personnel needed for repairs (warranty not broken by biomed repairs)	can be repaired using tools commonly found in a tool kit and standard electrical repair kit		MSF project biomedical engineer	
28	Durable and rugged	Drop Test; Impact Test	No damage when dropped from avg carry height (5ft/ 153cm)	No damage when dropped from counter height (3ft/ 92cm)	IEC 60601-1: 15.3.3 and 15.3.4.2	MSF project logistics coordinator (LogCo)	MSF project medical coordinator (MedCo), MSF project pharmacy (local storage)
29	Resistant to and functions in dusty environments	IP Code Classification	IP64W	IP53	IEC 60529: 4.2 IP rating	Manufacturer QA/QC standards certification	Design volunteers & domain experts
30	Limited infrastructure requirements (low installation cost)	installation requirements	installation cost <?; does not require expanding electrical system to support single device, does not require controlled climate for safe funtionality	installation cost <?, does not require controlled climate		MSF Biomed (electrical systems)	MSF LogCo, MSF Biomed (medical devices)
31	Lower current than a radiant warmer (given limited MSF power supply)	device wattage	40W	100W		MSF Biomed (electrical systems)	MSF Biomed (medical devices), domain experts, device manufacturer
32	Less expensive than a radiant warmer (low purchase price)	purchase price	<$1500	<$3000		MSF project lead who places device orders	MSF procurement & logistics
33	Easy to deliver and install	installation prodecure	minimally trained staff can set up in <30 min	trained staff can set up in <1hr		MSF Biomed (electrical systems and medical devices)	MSF LogCo, MSF project pharmacy
34	Compatible with dirty power: surges; brownouts, blackouts, no ground	IEC+ (modified for context) compliance	Class 1 (ground required) AND surge protection that functions without opereational ground (MOV protection); input voltage: 80-275V	Class 1 surge protection to ground; input voltage: 80-275V	IEC 60601; MTTS electrical engineer domain expert	Design volunteers & domain experts	MSF Biomed (electrical systems)
35	Internal backup battery	transition to battery powered	Automatic switch to battery backup	manual switch to battery backup		MSF pediatric working group	MSF Biomed (medical devices), Device Manufacture, Design volunteers and domain experts

36	Internal backup battery	durtation of battery power	2 hours of power	30 min of power		MSF pediatric working group	MSF Biomed (medical devices), Device Manufacture, Design volunteers and domain experts
37	Limited consumables, maintenance (low operating cost)	consumable requirements	no consumables	consumable required every 5 year		MSF procurement & logistics	MSF Biomed (medical devices), MSF project pharmacy (local storage), MSF project biomedical engineer
38	Limited consumables, maintenance (low operating cost)	maintenence requirements	maintenence every 5+ years	maintenance every year		MSF project biomedical engineer	MSF Biomed (medical devices), MSF procurement & logistics
40	Easy to relocate within the hospital	device portability and ease of set-up; possibly also compatibility with standard cradle/bassinet	device fits inside standard bassinet; device can be carried between wards and set up again within 10 min without Biomed assistance	device fits inside standard bassinet		MSF project biomedical engineer	MSF Biomed (medical devices); MSF pediatric working group
41	Compatible with a wide range of ambient temperatures	beyond IEC assumption of "room temperature" at 20C (68F)	10C (50F) - 15C (60F)	35C (98F) - 40C (105F)		MSF Biomed (medical devices)	MSF LogCo; MSF procurement & logistics