

Data Sheet Mistral-Air® Premium Blankets

Description	Mistral-Air® Premium Blankets
Indication	The Mistral-Air® Warming System is a forced air warming system and comprises of a warming unit and a variety of blankets. It is intended to raise and/or maintain patient temperature by means of surface warming. Intended patient population: adults and paediatric patients. Intended to be used only by trained clinicians in clinical areas during the entire perioperative pathway.
Use	Single use Mistral-Air® Blankets should be used only with a Mistral-Air® Warming Unit (commingling use statement)
S4	
Composition	- Premium blankets: Non-woven materials Polypropylene and Polyethylene, Aluminium and Polyurethane coating - Adhesive tape: Pressure sensitive hot-melt on synthetic rubber base - Face shield: Polyethylene - Connector: Cardboard
Compliance	16 CFR 1610 in relation to: Flammability of Clothing Textiles, Class 1. EN 13795 in relation to: Resistance to microbial penetration Cleanliness Linting Bursting strength Tensile strength ISO 10993 series in relation to: Cytotoxicity Sensitization Irritation
Regulatory	Class I device and CE marked as per Regulation (EU) 2017/745 (EC Declaration of Conformity)
Disposability	According to hospital protocol or local regulation (Disposal Statement)
Packaging	Details indicated in the Packaging overview below Double corrugated cardboard box Inner bags: Polyethylene Individual blanket bags: Polyethylene One Instructions For Use (IFU) per box LOT number and REF number printed on single bag label and box label Time stamp printed on blanket and box label PVC free (PVC Free Statement)
Recommended storage conditions	Clean, dry, between + 16 °C and + 25 °C (preferably room temperature), keep away from sunlight
Manufacturing	The Netherlands
Note	Always consult the latest User and Technical Manual of the Mistral-Air Warming System

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Specifications

S4

Description	Reference number	GTIN 14 Barcode (1 piece)	Blanket size (mm x mm)	Warming surface (mm x mm)	Weight (grams)
Premium Adult	MA3320	18719867001103	2270 x 1330	1730 x 790	198
Premium Paediatric	MA3330	18719867001141	1660 x 1330	790 x 1010	144
Premium Neonatal	MA3340	18719867001189	1160 x 1330	1080 x 570	132
Premium Lower Body	MA3350	18719867001226	1320 x 1330	945 x 790	124
Premium Upper Body	MA3360	18719867001264	2010 x 760	1880 x 580	120
Premium Half Upper Body	MA3365	18719867001301	1600 x 760	1375 x 580	109
Premium Full Underbody	MA3400	18719867001349	2200 x 900	2160 x 840	219
Premium Half Underbody	MA3450	18719867001387	1680 x 900	1020 x 840	168
Premium Paediatric Underbody	MA3475	18719867001424	1680 x 900	1630 x 840	163
Premium Lithotomy	MA3455	18719867002653	1675 x 900	1200 x 840	140

Properties

Description	Reference Number	Hose inlet qty	Face shield	Adhesive Tape		Tie strips (integrated)	Arm slits
				on width	on length		
Premium Adult	MA3320	2	removable				
Premium Paediatric	MA3330	1					
Premium Neonatal	MA3340	2					
Premium Lower Body	MA3350	1		1			
Premium Upper Body	MA3360	2	Fixed	1		2 x 2	
Premium Half Upper Body	MA3365	2	Fixed	1 per side		1 x 2	
Premium Full Underbody	MA3400	4	removable		1 per side		1 per side
Premium Half Underbody	MA3450	2	removable		1 per side		1 per side
Premium Paediatric Underbody	MA3475	2	removable				
Premium Lithotomy	MA3455	2				2 x 1	1 per side