Technical Data Sheet

Repose® Babytherm

General Description

Repose pressure relieving inflatable Babytherm overlay for the prevention and treatment of pressure ulcers.



Product Details			
Intended Use	Intended for use in both acute and community healthcare facilities by medically trained and untrained users. There are no special skills required to operate or use Repose. The Repose Babytherm overlay is a pressure relieving mattress for neonatal units and is suitable for use with the majority of standard incubators, cots, and warmers. The product is sized to fit the majority of paediatric bed frames and mattresses. More information can be found online at www.frontier-group.co.uk		
Product Codes	Repose Babytherm – 6401100	GS1 Codes	5056279301961
Inflated Dimensions Tolerance: +/- 10 (mm)	Length (mm): 760 Width (mm): 530 Height (mm): 43 Weight (kg): 0.06		
Classification	Class 1 Medical Device. MDR 2017/745.		
Warranty	Repose comes with a three-year warranty		
Packaging	Height (mm): 110 Width (mm): 375 Depth (mm): 110 Weight (kg): 0.7		
Cleaning and Decontamination	If visible signs of dirt and contamination are present the Repose Babytherm should be mechanically cleaned using detergent and water. In the absence of visible contamination, it should be mechanically cleaned using detergent and water on a weekly basis. Do not use abrasive cloths. Rinse with clean water and wipe down with single-use, nonabrasive cloth and thoroughly dry. End tapes can be cleaned and decontaminated in the same way. Do not machine wash the Repose Babytherm. Once cleaned and decontaminated, store the Repose Babytherm inside the inflation pump.		

Materials Used	Inner: TPU and TPU coated nylon. Valve: Acetyl and stainless steel. Cords: Polyproylene.
Flammability	Tested to: BS7175:1989 – The Ignitability of Bedcovers and Pillows by Smouldering and Flaming Ignition Sources, BS 597 parts 1&2 – Furniture – Assessment of the Ignitability of Mattresses and Upholstered Bed Bases, 16 CFR part 1632 - Standards for the Flammability of Mattresses and Mattress Pads.
Biocompatibility	Tested to: BS EN ISO 10993-5:2009 Biological Evaluation of Medical Devices. Tests for In Vitro Cytotoxicity. BS EN 10993-10:2013 Biological Evaluation of Medical Devices. Tests for Irritation and Skin Sensitization
Latex / Phthalate Free	Yes At the time of publication the Repose range does not contain any substances, over 0.1% by weight, that are described on the Candidate List of substances of very high concern for Authorisation - EC Regulation 1907/2006 – REACH.
Max User Weight	No weight limit for its intended use.
Storage	Store and keep in a cool, dry space and away from direct sunlight. Do not store next to radiators or other heating devices.
Disposal	At the end of its life, clean and disinfect according to the instructions within the cleaning and decontamination section and dispose of with non-hazardous clinical waste.
Expected life	Product life will vary depending on care, maintenance and levels of usage.
Logistics Information	
Unit of issue	Please refer to www.frontier-group.co.uk

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