



ROTHBAND

PATIENT POSITIONING

INSTRUCTIONS FOR USE

IMAGING MATTRESSES

VERSION 6.0

**UK
CAE**

Table of Contents

INTRODUCTION	3
INTENDED USE.....	4
REGULATORY COMPLIANCE.....	4
CAUTIONS AND WARNINGS.....	5
COVERING MATERIALS	6
CLEANING INSTRUCTIONS.....	6
1.1 DARTEX	6
1.2 GRIPLOCK	6
1.3 PVC.....	6
1.4 HEAVY DUTY NYLON.....	6
ATTENUATION PROPERTIES.....	7
PRESSURE DATA	8
CONTACT DETAILS	8

INTRODUCTION

Thank you for purchasing a Rothband Imaging mattress. In doing so, you have chosen a quality mattress which has been designed to provide excellent functionality.

To ensure the Mattress is always used in a safe manner, please read this document thoroughly and strictly follow all the operating, cleaning and maintenance instructions.

These Instructions cover the following models:

Angiographic Mattress	X Ray Mattress	Covered Foam	Transfer Mattress
ANGMAT-2-2150600-50	FP47	FP68GY	All FPXXZ
ANGMAT-2-2150600-75	FP48	FPL47BE	FP58-50
ATAMAT40	FP67	FPL47KB	FP58-75
ANGMAT-2-2950700-50	FP68	FPL47GY	
ANGMAT-2-2950700-75	ST1F	FPL48BE	
ANGMAT03-2950700-50	FPL47	FPL48KB	
ANGMAT-3-2950700-75	FPL48	FPL48GY	
ANGMAT-3-2950600-50	FPL67	FPL67BE	
ANGMAT-3-2950600-75	FPL68	FPL67KB	
ANGMAT-ARM-500150-50	FPL1033	FPL67GY	
ANGMAT-ARM-500150-75	FPL148	FPL68BE	
ATAMATCUST75	FPL168	FPL68KB	
ATAMATCUST50	FPL198	FPL68GY	
MATT CUST	FP97	FPL97	
MATT CUSTBE	FP98	FPL98	
MATT CUSTKB	FP42		
MATT CUSTGY	SIE-MAT125WSC		
SIE-MATVEL25WSCV	FP47BE		
SIE-MATFVEL25WWCFV	FP47KB		
SIE-MATWHITEFL25WWCWF	FP47GY		
SIE-MATGREYFL2GWCF	FP48BE		
SIE-MATGR25GWC	FP48KB		
SIE-MATGR40GWC	FP48GY		
SIE-MATGR40GWCV	FP67BE		
	FP67KB		
	FP67GY		
	FP68BE		
	FP68KB		

INTENDED USE

The Rothband Mattress range has been designed for use with medical imaging equipment.

The mattress does not make any claims on maximum weight limit as it will conform to the maximum limit of the table on which it is placed.

The design of the mattress provides a radiolucent, homogenous area that focuses on minimising the x-ray attenuation properties in order to minimise dose to the patient.

FP58 Mattresses are designed for transferring patients onto medical imaging tables.

REGULATORY COMPLIANCE

The Rothband mattress range complies with MDR (EU) 2017/745 (EU) and MDD 93/42/EEC (UKCA) concerning medical devices (class I) and has been designed and manufactured to comply with the following standards:

Standard	Description
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. Grade 1 (ISO10993-10) Skin Irritation – classed as non-irritant; Skin Sensitisation – considered to be non-sensitiser
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.

CAUTIONS AND WARNINGS



- The mattress/positioning aid must be x-rayed prior to use, to ensure there are no artefacts.
- There are no special skills required to use this mattress/positioning aid.
- A medical professional should stabilise the mattress when patients are mounting the mattress.
- The medical professional is responsible for applying his/her best medical judgment when positioning a patient on this mattress and using the positioning aids.
- The mattress/positioning aids is suitable for continuous use.
- Not suitable for sterilisation.
- Do not place device on or near a heat source.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Do not allow sharp objects to penetrate the mattress material.
- Intended for professional healthcare facility environments where operators with medical training are continually available when patients are present.
- Do not use abrasive cleaners, please see page 5 for the correct cleaning instructions.
- Do not place heavy objects on the surface of foam mattresses when not in use.
- Be aware when using contrast media, as staining may cause radiographic artefact.
- Be aware of fluid ingress on stitched mattress designs
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.
- Patient with a high risk of pressure sore formation should not lie on a mattress for more than 10 minutes. Pressure points such as Elbows, Heels, Neck and Sacrum should be supported appropriately.

COVERING MATERIALS

MATERIAL	USE
DARTEX	ALL X RAY MATTRESSES (EITHER IN FULL OR PARTIAL)
GRIPLOCK	BOTTOM SURFACE OF ANGIOGRPHIC MATTRESSES
PVC	BUDGET MATTRESSES
HEAVY DUTY NYLON	BUDGET MATTRESSES

CLEANING INSTRUCTIONS

Whilst cleaning the Mattress, it is always good practice to look for signs that the mattress may have been damaged. Such indicators include (but are not limited to) rips or tears and signs of fluid ingress into the interior of the Mattress.

1.1 DARTEX

Wipe with mild detergent. Wash or dry-clean using detergent up to 95oC. (remove foam element first) For disinfection use sodium hypochlorite up to concentrations of 10,000 parts per million of active chlorine. Do not use biological or phenolic-based cleaners. Wash and dry completely before storage. Some surface wrinkling may occur.

1.2 GRIPLOCK

Wipe with mild detergent. Wash or dry-clean using detergent up to 75oC. (remove foam element first) For disinfection use sodium hypochlorite at no more than 1000 parts per million of active chlorine. Do not use biological or phenolic-based cleaners. Wash and dry completely before storage. Some surface wrinkling may occur.

1.3 PVC

Wipe with mild detergent. Avoid chlorinated cleaners and it attacks the plasticisers and can result in a hardened coating. For disinfection use Rothband apron cleaner. Do not use biological or phenolic-based cleaners. Wash and dry completely before reuse. Some surface wrinkling may occur.

1.4 HEAVY DUTY NYLON

Wipe with mild detergent. For disinfection use sodium hypochlorite at no more than 1000 parts per million of active chlorine. Do not use biological or phenolic-based cleaners. Wash and dry completely before storage. Some surface wrinkling may occur.



Cross contamination is a major hazard to patients. The Mattress Cover should therefore be cleaned in between patients. Always check for fluid ingress.

ATTENUATION PROPERTIES

kV	mAs	Standard foam 25 mm	Standard foam 50 mm	Levitex 25 mm	Levitex 50 mm	Levitex 75 mm	Transfer Mattress
65	40	-0.44	0.26	0.01	1.56	2.09	1.54
70	25	-0.43	0.02	-0.14	0.85	1.16	0.80
75	20	-0.32	-0.01	-0.12	0.60	0.85	0.59
80	14	-0.28	-0.10	-0.13	0.38	0.55	0.37
85	10	-0.20	-0.04	-0.10	0.23	0.37	0.24
90	8	-0.14	-0.05	-0.07	0.14	0.27	0.19
95	6.3	-0.11	-0.03	-0.03	0.15	0.24	0.20
100	5.6	-0.07	-0.02	-0.05	0.16	0.24	0.17
105	4.5	-0.10	-0.03	-0.02	0.15	0.15	0.12
110	4	-0.06	0.02	-0.03	0.15	0.14	0.14

PRESSURE DATA

Head - Peak Pressure Values (mmHg)

	WEIGHT GROUP					
	1	2	3	4	5	6
25mm Levitex Foam	39.75014	53.92011	69.86116	91.00771	111.7463	131.3843
25mm Standard Foam	47.91901	54.66033	61.3686	67.98512	74.08072	83.4573
50mm Levitex Foam	32.2551	37.93223	49.56391	54.49146	60.73058	74.27989
50mm Standard Foam	55.78347	64.90744	69.98871	82.08264	83.49284	94.96997
75mm Levitex Foam	33.96529	41.16198	44.67658	52.63223	56.17466	62.43581

Sacrum - Peak Pressure Values (mmHg)

	WEIGHT GROUP					
	5	10	15	20	25	30
25mm Levitex Foam	21.68072	28.53361	37.03994	45.33857	56.14242	77.21212
25mm Standard Foam	31.99862	32.07163	33.60303	35.44656	39.00744	39.76997
50mm Levitex Foam	18.40386	22.90579	32.31625	32.45096	38.00771	45.15482
50mm Standard Foam	33.67576	33.26887	35.40303	38.74738	39.84435	42.5416
75mm Levitex Foam	19.94105	22.92066	27.2708	30.63857	33.13361	36.23361

Heels - Peak Pressure Values (mmHg)

	WEIGHT GROUP					
	1.5	2.5	3.5	4.5	5.5	6.5
25mm Levitex Foam	29.06226	35.12066	41.01625	45.80992	51.80716	59.34518
25mm Standard Foam	33.00386	37.72287	42.43526	48.82369	56.45758	63.09697
50mm Levitex Foam	29.17548	34.80964	43.14931	42.42121	46.63912	49.86061
50mm Standard Foam	34.22342	37.72176	42.09008	49.03333	56.82424	64.35978
75mm Levitex Foam	29.42397	34.18788	40.25041	46.22342	49.26942	50.27218

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