Test Report issued under the responsibility of:

PARTIAL TEST REPORT
IEC 60601-2-52
Medical electrical equipment
Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

Report Number. ..... :	**R-105 MED 2019**
Main Report Number ..... :	**R-96 MED 2017**
Date of issue ..... :	**25/06/2019**
Total number of pages ..... :	**27**
Name of Testing Laboratory preparing the Report ..... :	Prolab service srl Via Ratti 82 – 20855 Lesmo (Monza & Brianza) Italy
Applicant's name ..... :	REHAB ITALIAN DESIGN Ltd
Address ..... :	Lo F9-F10-F11-F12, D3-N4-N5- Road, Nam Tan Uyen Industrial Park (Expansion), Uyen Hung Ward, Tan Uyen Town, Binh Duong Province, Vietnam
Test specification:	
Standard ..... :	IEC 60601-2-52:2009, AMD1:2015 for use with IEC 60601-1:2005
Test procedure ..... :	CE Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_2_52B
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	Dated 2017-08-31

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

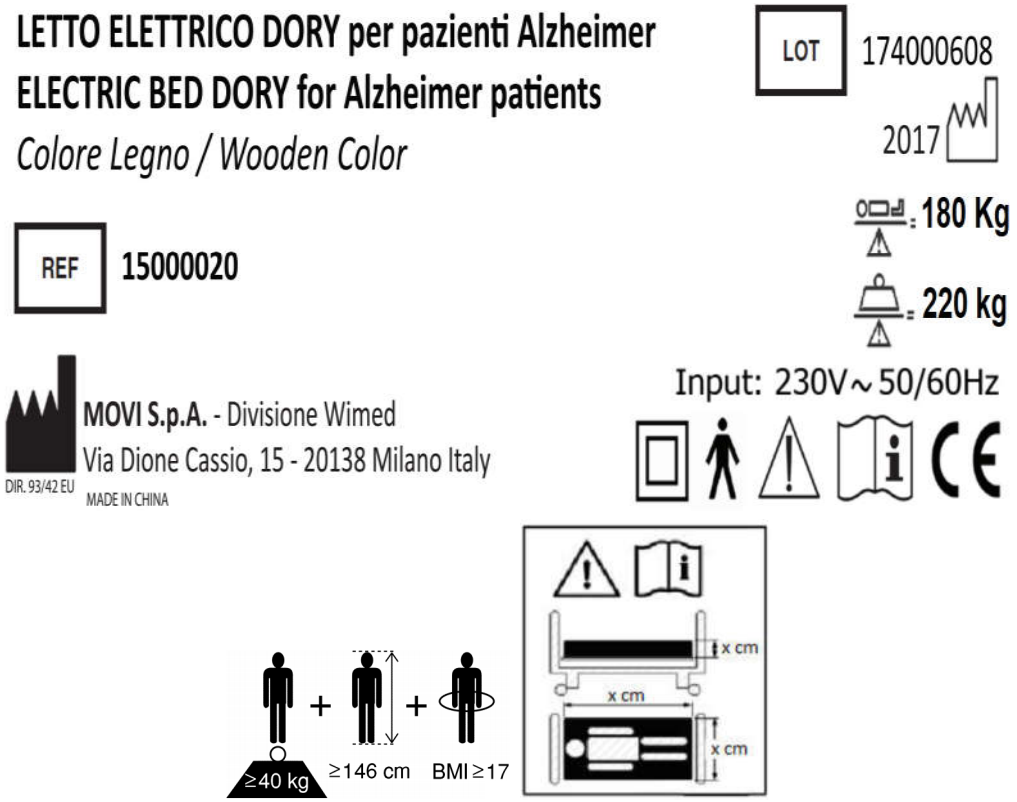
Test item description ..... :	Electric bed
Trade Mark ..... :	REHAB ITALIAN DESIGN Ltd
Manufacturer ..... :	REHAB ITALIAN DESIGN Ltd
Model/Type reference ..... :	Super low
Ratings ..... :	230 V ~, 50/60 Hz, class II

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☐	**CB Testing Laboratory:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name + signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments **Report EN 60601-1 and EN 60601-2-52**	
Summary of testing:	
Tests performed (name of test and test clause): **See report EN 60601-1**	**Testing location:** **Prolab service srl**
Summary of compliance with National Differences (List of countries addressed): ☒ **The product fulfils the requirements of EN 60601-2-52: 2010; A1 2015; EN 60601-1-11: 2010**	

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Example of label

Test item particulars.....:	
Classification of installation and use.....:	transportable / portable / stationary / **mobile** / fixed / permanently installed / hand-held
Supply Connection.....:	internally powered /permanently installed / appliance coupler / **non-detachable cord**
.....:	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item .....:	03/06/2019
Date (s) of performance of tests.....:	19/06/2019 up to 25/06/2019

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form is intended for the investigation of medical beds in accordance with IEC 60601-2-52. It can only be used together with IEC 60601-1 Test Report.

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard. However, IEC 60601-1-3, IEC 60601-1-8, and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

Sampling performed by the manufacturer.

Where declared, the measurement uncertainties stated in this document have been determined according to our PT01 procedure. Usually, they have been estimated as expanded uncertainty obtained multiplying the standard uncertainty by the coverage factor K=2 corresponding to a confidence level of about 95%; the conformity declared in this document, in the measurement carried out it also considers uncertanty.

This laboratory is accredited in accordance with the recognized International Standard ISO / IEC 17025:2005. This accreditation demonstrates technical competence for a defined purpose and activity management system for the laboratory's quality refers to the official release of June 18, 2005 ISO-ILAC-IAF meeting.

This test report is only for internal use and it is released to provide technical support to the manufacturer.

The test results presented in this report relate only to the object tested.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.
Name and address of factory (ies) ..... :
General product information and other remarks: The device is a bed with motorized movement. The motorized movement has certified (linak) This report has to read with report R-96 MED 2018. This report has been issued to change the max work load and safety load The new work load is 180 Kg The new safety load is 220 Kg In this report has been carried out only the test which have a regulatory impact on the change the load.

IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		
201.7.2.2	MEDICAL BED marked with the name or trademark and address of MANUFACTURER, MODEL, or TYPE REFERENCE, and means to allow traceability.....:	See Marking	P
	Detachable components marked with the name or trademark and address of the MANUFACTURER, MODEL, or TYPE REFERENCE and means to allow traceability, except when misidentification does not present an unacceptable RISK		N/A
201.7.2.2.101	MEDICAL BED marked with the corresponding max. PATIENT weight (see 201.9.8.3.1) and SAFE WORKING LOAD according to Figure 201.105 (Kg, Kg).....:	Max patient weight: 180 kg; Max safe working load: 220 kg	P
	Detachable parts of the MEDICAL BED weighing more than 20 kg marked with symbol ISO 7000-1321 (2004-01) symbol		N/A
201.7.9.2.1	Instructions for use include .....:	See attached instructions for details	P
	a) a description according to clause 201.3 of the intended APPLICATION ENVIRONMENT(S)	Application environment 3 and 4	P
	b) maximum PATIENT weight and SAFE WORKING LOAD (i.e., sum of patient & mattress in Kg)		P
	- PATIENT.....:	180 kg	—
	– mattress .....:	220 kg	—
	– ACCESSORIES of the MEDICAL BED (only when supported by the support system of the MEDICAL BED), and	Lifting pole	P
	– load supported by the ACCESSORIES (excluding PATIENT weight) (Kg).....:	Lifting pole: 40 kg	P
	c) an explanation of how to deactivate any MEDICAL BED function when movement caused by that function could cause injury to the PATIENT		
	d) result of the measurement of auditable acoustic energy according to ISO 3746 for APPLICATION ENVIRONMENT 4 intended MEDICAL BED .....:	48 dB	P
	e) a description of the intended PATIENT group(s)		P
201.7.9.2.5.104	Instructions for use specify the maximum mass (in kg) of the MEDICAL BED (Kg).....:	180 Kg	P
	Instructions for use specify the maximum mass (in kg) of all parts when the MEDICAL BED is intended to be disassembled into parts		P

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Clause	Requirement + Test	Result - Remark	Verdict

201.9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		
201.9.4.2	Instability – overbalance		
201.9.4.2.2	MEDICAL BED did not tip over with the height and length of the MATTRESS SUPPORT PLATFORM, castors, SIDE RAILS, and other ACCESSORIES with their SAFE WORKING LOAD in their most adverse position of NORMAL USE when the following tests were performed		P
	The MEDICAL BED equipped with the lightest mattress as specified by the MANUFACTURER or a load representing the weight of the specified mattress that is centred on the MATTRESS SUPPORT PLATFORM was tested		P
	The following tests conducted with the MATTRESS SUPPORT PLATFORM in the flat and horizontal positions		P
	Lateral stability test conducted by placing a load of 2 200 N at the side edge of the MATTRESS SUPPORT PLATFORM and evenly distributing over an area 250 mm × 950 mm (see Figure 201.112)		P
	The maximum PATIENT load evenly distributed over an area 950 mm long and 250 mm wide (see Fig. 201.112) when the maximum PATIENT load according to the MANUFACTURER exceeded 2 200 N		P
	Test performed at each corner of the MEDICAL BED		P
	Longitudinal stability tests were conducted as follows:		
	aa) For FOOT BOARD removable without the use of TOOLS, the FOOT BOARD removed, a load of 2200 N for APPLICATION ENVIRONMENTS 1, 2, 3 and 5, and 1850 N for APPLICATION ENVIRONMENT 4 evenly distributed over an area of 250 mm across the full width of the MEDICAL BED (see Fig 201.113) (N).....:		N/A
	Maximum PATIENT load used when specified by MANUFACTURER to be > 2200 N (or 1850 N for APPLICATION ENVIRONMENT 4) (N).....:		N/A
	bb) For HEAD/FOOT BOARDS permanently fixed or requiring the use of TOOLS to remove them, the two loads, each of 1100 N for APPLICATION ENVIRONMENTS 1, 2, 3 and 5, and two loads, each of 925 N for APPLICATION ENVIRONMENT 4 evenly & simultaneously distributed over an area of 250 mm × 475 mm (Fig. 201.114) (N).....:		P
	Test performed at both ends of the MEDICAL BED		P
201.9.4.2.3	Instability from horizontal and vertical forces		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) MEDICAL BED did not tip over due to sitting or stepping as verified by inspection and test		P
	MEDICAL BED placed on a horizontal plane and a downward force of 1100 N applied at the point of maximum moment to any working surface, excluding the MATTRESS SUPPORT PLATFORM, offering a foothold or sitting surface of a min. 20 cm by 20 cm area, and at a height max. 1 m from the floor		P
	MEDICAL BED prepared as described in 201.9.4.2.2 prior to the test		P
201.9.4.2.4 .2	- for MEDICAL BEDS intended for PATIENT transport, test conducted on the MEDICAL BED with SAFE WORKING LOAD in place		P
	- for MEDICAL BEDS not intended for PATIENT transport, test conducted on MEDICAL BED without SAFE WORKING LOAD in place		P
201.9.4.2.4 .3	MOBILE MEDICAL BED intended to transport PATIENTS withstood the stresses caused by rough handling as verified by the following threshold test:		P
	This requirement not applied to the MEDICAL BED specified by the MANUFACTURER only for movement within the PATIENT room for cleaning or PATIENT access		P
	SIDE RAILS raised and latched, with all other ACCESSORIES intended for NORMAL USE during transport attached to the MEDICAL BED and with the SAFE WORKING LOAD in place and the height in the worst case position		P
	MEDICAL BED moved at a speed of 0,8 m/s ± 0,1 m/s, and for motor-driven MEDICAL BEDS for transportation, the maximum speed used, while all castors impacted and passed over an obstruction fixed flat on the floor, with a rectangular cross-section, 20 mm high and 80 mm deep		P
	MEDICAL BED, with all castors, was pulled back over the obstruction and back to the starting position of the test		P
	Test repeated 10 times		P
	MEDICAL BED, its parts, and ACCESSORIES did not display loss of function, and the SIDE RAILS did not unlock/unlatch, and there was no physical deterioration which may result in degradation of the NORMAL USE or creation of a RISK such as collapsing, permanent deformation, modifying gap for entrapment or pinching, etc		P

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Clause	Requirement + Test	Result - Remark	Verdict
	MEDICAL BED went over the obstruction		P
	MEDICAL BED did not tip over		P
	MEDICAL BED or its parts did not present an unacceptable RISK		P
	Unacceptable RISK determined by inspection of the MEDICAL BED, its parts, and relevant information from the RISK MANAGEMENT FILE.....:	See RISK MANAGEMENT FILE	P
201.9.4.3.2	Instability excluding transport		P
	Item a) replaced by: See 201.9.4.3.1		P
201.9.4.4	This sub-clause not applied to APPLICATION ENVIRONMENTS 1, 2, 3 and 5		P
201.9.8	HAZARDS associated with support systems		P
201.9.8.1	First dashed item not applied		—
201.9.8.2	This sub-clause not applied (see 201.9.8.3.2)		—
201.9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		
201.9.8.3.1	MEDICAL BED parts serving for immobilization or support of the PATIENT minimize RISK of physical injuries and of accidental loosening of fixings		P
	For APPLICATION ENVIRONMENTS 1 and 2, the SAFE WORKING LOAD of MEDICAL BED is at least 2000 N.....:	___ N	N/A
	SAFE WORKING LOAD of MEDICAL BED is considered to be the sum of the following minimum loads		
	– 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT .....:		N/A
	– 200 N, corresponding approximately to a mass of 20 kg for the mattress .....:		N/A
	– 450 N, corresponding approximately to a mass of 45 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight .....:		N/A
	The SAFE WORKING LOAD of MEDICAL BED was at least 1700 N for APPLICATION ENVIRONMENTS 3, 4 and 5 ..:		N/A
	The SAFE WORKING LOAD of MEDICAL BED considered to be the sum of the following minimum loads		N/A
	– 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT (N).....:		N/A
	– 200 N, corresponding approximately to a mass of 20 kg for the mattress .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 150 N, corresponding approximately to a mass of 15 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight .....:		N/A
	The SAFE WORKING LOAD of a BED-LIFT was at least 2 200 N.....:		P
	It was considered to be the sum of the following minimum loads:		N/A
	– 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT .....:	180 N	N/A
	– 200 N, corresponding approximately to a mass of 20 kg for the mattress .....:	200 N	N/A
	– 150 N, corresponding approximately to a mass of 15 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight .....:	150 N	N/A
	– 500 N, corresponding approximately to a mass of 50 kg for those parts of the MEDICAL BED intended to be lifted by the BED-LIFT .....:	500 N	P
	When the SAFE WORKING LOAD as specified by the MANUFACTURER is greater than 2000 N for MEDICAL BEDS for APPLICATION ENVIRONMENTS 1 and 2, and 1700 N for MEDICAL BEDS FOR APPLICATION ENVIRONMENTS 3,4 and 5 or 2200 N for BED-LIFTS, then it was used as the basis for testing		P
	The SAFE WORKING LOAD placed at the worst-case position permitted by configuration or ACCESSORIES attachment on support/suspension parts .....:	2200 N	P
	The SAFE WORKING LOAD distributed as shown in Fig 201.115		P
	The part of the SAFE WORKING LOAD for a foot rest representing the mass of PATIENT distributed over an area of 0,1 m^2, or the available area		P
	The SAFE WORKING LOAD of the LIFTING POLE (including PATIENT handle) is at least 750 N .....:	750 N	P
201.9.8.3.2	Static forces due to loading from persons		
	The MEDICAL BED and BED-LIFT are capable of withstanding a uniformly distributed static load equal to the greater of the 2x the SAFE WORKING LOAD, or 4000 N, in the most disadvantageous position on the MATTRESS SUPPORT PLATFORM in a horizontal position (see Fig. 201.115) .....:	4400 N	P

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Clause	Requirement + Test	Result - Remark	Verdict
	When impairment by wear, corrosion, material fatigue or aging was expected, relevant supporting parts provided with a safety factor not less than 4x the SAFE WORKING LOAD (Safety Factor) .....:		N/A
	a) A static load applied to MEDICAL BED for at least 1 min, except when the material creep became an issue, in which case the time increased to at least 1 h (N) (min, h).....:		N/A
	Permanent deformation was acceptable only when the MEDICAL BED complied with its intended function		N/A
	b) A TEST BED BOARD mounted to a BED-LIFT not supplied with a bed board, and the mattress placed as specified by the MANUFACTURER, onto the bed board/TEST BED BOARD, in its flat position.		P
	A vertical load of two times the SAFE WORKING LOAD or 4000 N, the greater of the two, applied equally distributed over the mattress (excluding the mass of mattress placed onto the MEDICAL BED or mass of the TEST BED BOARD).....:	4400 N	P
	Permanent deformation was acceptable only when the BED-LIFT was in compliance with its intended function		P
	The static load applied for at least 1 min, except when material creep became an issue and time was increased to at least 1 h (N) (min, h) .....:	1 min	P
	All ACCESSORIES (including those not supporting PATIENT weight) supported a load of at least two times the SAFE WORKING LOAD specified for the accessory.....:	___ N	N/A
	This load applied to the ACCESSORY in the most disadvantageous direction and position		N/A
	A test conducted with the ACCESSORY (other than LIFTING POLES) in its worst case NORMAL USE position, and a static load equal to two times its SAFE WORKING LOAD ATTACHED for at least 1 min, except when the material creep became an issue and the time was increased to at least 1 h (N) (min, h) .....:		N/A
	There was no HAZARD or loss of function		N/A
	The fastenings of LIFTING POLES still functioned normally and presented no HAZARDS after the following tests		
	1) The LIFTING POLE positioned to the MEDICAL BED in its most adverse position intended in use		P
	For the LIFTING POLE, permanent deformation was acceptable in the first test		P

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Clause	Requirement + Test	Result - Remark	Verdict
	A sudden movement of the LIFTING POLE considered to be a HAZARD did not occur		P
	A downward load of 2 x the SAFE WORKING LOAD of LIFTING POLES (at least 1500 N) applied to the outermost suspension point of the handle for at least 1 min, except when material creep became an issue, time was increased to at least 1 h (N) (min, h).....:		P
	The LIFTING POLE and its fastenings examined during and after application of the load		P
	2) A test was conducted by positioning the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use, and when necessary, due to instability, the MEDICAL BED was secured during test		P
	A horizontal force of 350 N applied perpendicular to the MEDICAL BED side, and to the outermost suspension point of the handle		P
	The LIFTING POLE and its fastenings examined during and after application of the load		P
201.9.8.3.3	Dynamic forces due to loading from persons		
201.9.8.3.3 .1	Dynamic forces due to sitting down, standing up, PATIENT handling PROCESS, or the like, that could be exerted on equipment parts intended to support or suspend a PATIENT in NORMAL USE, did not result in an unacceptable RISK		P
	Durability relative to the most disadvantageous position of the MEDICAL BED parts intended to support or suspend a PATIENT in NORMAL USE was considered		P
	A test conducted by placing the worst-case mattress specified by MANUFACTURER onto the MEDICAL BED in its flat position		P
	The height adjusted to the worse case position		P
	Loading pad (Fig. 201.104) utilized at position A in Fig. 201.116, at the weaker side		P
	The loading pad (Fig. 201.104) applied 10 000 times at the position A shown in Fig. 201.116, with a load of 1 350 N or the maximum PATIENT load, the greater of the two .....:	1800 N	P
	When tested as described above, the MEDICAL BED still functioned normally and presented no HAZARDS after removal of the loading pad		P
	The mattress removed, and the following evaluations and tests conducted:		P
	– entrapment HAZARDS evaluated according to 201.9.1.101		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– TRAPPING ZONES evaluated according to 201.9.2.2		P
	– and test conducted according to 201.9.8.3.2		P
201.9.8.3.3.2	The height adjustment of MEDICAL BED or BED-LIFT functioned normally and presented no unacceptable RISK after 3 000 cycles of operation in NORMAL USE		P
	A test conducted by placing the MEDICAL BED in its flat position as follows:		P
	A TEST BED BOARD mounted to the BED-LIFT when the BED-LIFT was separate from a MATTRESS SUPPORT PLATFORM		P
	The SAFE WORKING LOAD, distributed as indicated in 201.9.8.3.1 (Figure 201.115), applied on the MATTRESS SUPPORT PLATFORM .....:	2200 N	P
	For BED-LIFTS, the SAFE WORKING LOAD applied minus the weight of the TEST BED BOARD distributed as indicated in 201.9.8.3.1 (Fig. 201.115) on the MATTRESS SUPPORT PLATFORM .....:		N/A
	The entire MEDICAL BED, or BED-LIFT lowered and raised 3000 times in accordance with the procedure in the instructions for use, and the SAFE WORKING LOAD removed after the test		P
201.9.8.3.3.4	The LIFTING POLE and its fastenings still functioned normally and presented no HAZARDS after the following test:		P
	A sudden movement of the LIFTING POLE or its handle which may result in a HAZARD did not occurred		P
	A test conducted by positioning the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use as follows:		P
	A vertical downward load of the SAFE WORKING LOAD applied to LIFTING POLE (at least 750 N) 1000 times onto the handle of LIFTING POLE.....:	2200 N	P
	The LIFTING POLE and its fastenings examined during and after application of the force and recorded deflection and deformation		P
	The deflection of the LIFTING POLE was not > 100 mm during application of the SAFE WORKING LOAD .....:	61 mm	P
	The permanent deformation was not more than 20 mm after the durability test, measured in relation to the MATTRESS SUPPORT PLATFORM .....:	12 mm	P