Test Report issued under the responsibility of:

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 Reference No.....:	*Attachment #1 of Test Report Nº 2116 / 0524*
Date of issue.....:	*See main part of present Test Report*
Total number of pages	32
CB Testing Laboratory.....:	**SGS Tecnos, S.A. (Electric Test Laboratory)**
Address .....:	C/ Trespaderne, 29 - Edificio Barajas 1 28042 – MADRID (Spain)
Applicant's name.....:	*See main part of present Test Report*
Address .....:	*See main part of present Test Report*
Test specification:	
Standard.....:	IEC 60601-2-52:2009 (First Edition) + A1:2015 for use with IEC 60601-1:2005 (Third Edition)
Test procedure .....:	CE Examination
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_2_52A-SGS
Test Report Form(s) Originator .....:	SGS Tecnos S.A.
Master TRF .....:	Dated 2010-03

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.

Test item description .....:	*See main part of present Test Report*
Trade Mark.....:	*See main part of present Test Report*
Manufacturer .....:	*See main part of present Test Report*
Model/Type reference.....:	*See main part of present Test Report*
Ratings .....:	*See main part of present Test Report*

Testing procedure and testing location:		
☒	**CB Testing Laboratory**:	**SGS Tecnos, S.A. (Electric Test Laboratory)**
Testing location/ address ..... :		C/ Trespaderne, 29 - Edificio Barajas 1 28042 – MADRID (Spain)
⊟	~~**Associated CB Laboratory:**~~	
~~Testing location/ address ..... :~~		
	Tested by (name + signature) ..... :	*For signature see main part of present Test Report*
	Approved by (+ signature) ..... :	*For signature see main part of present Test Report*
☐	~~Testing procedure: TMP~~	
☐	~~Testing procedure: WMT~~	
☐	~~Testing procedure: SMT~~	
☐	~~Testing procedure: RMT~~	

Summary of testing:	
Tests performed (name of test and test clause): ***See main part of present Test Report***	**Testing location:** **SGS Tecnos, S.A.U. (Electric Test Laboratory)** **C/ Trespaderne, 29 - Edificio Barajas 1** **28042 – MADRID (Spain)**
Summary of compliance with National Differences: ***See main part of present Test Report***	
Copy of marking plate ***See main part of present Test Report***	

Test item particulars ..... :	
Classification of installation and use: See IEC 60601-1, General Information..... :	transportable / mobile
Supply connection: See IEC 60601-1, General Information..... :	internally powered / non-detachable cord
Accessories and detachable parts included in the evaluation ..... :	SIDE RAILS, HEAD/FOOT BOARD ASSEMBLY, MATTRESS SUPPORT PLATFORM, TRENDELENBURG
Options included..... :	*None*
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 ..... :	*See main part of present Test Report*
Date (s) of performance of tests ..... :	*See main part of present Test Report*

General remarks:

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 testing laboratory.
"(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 point (coma) is used as the decimal separator.

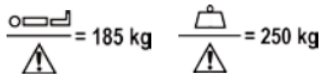
List of test equipment must be kept on file and available for review.

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.

General product information:

See main part of present Test Report

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.4	**GENERAL REQUIREMENTS**		P
201.4.2.2	HAZARD related to PATIENTS taller than 185 cm have been evaluated in the RISK MANAGEMENT PROCESS (IEC 60601-2-52/A1)		P
201.5	**GENERAL REQUIREMENTS FOR TESTING OF ME EQUIPMENT**		P
201.5.101	Entrapment test tools used (a cone tool and a cylinder tool respectively) are in accordance with Figures 201.103a and 201.103b	*Replaced by IEC 60601-2-52/A1*	P
201.5.102	The loading pad used for tests is in accordance with Fig 201.104		P
201.6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		N/A
201.6.2	MEDICAL BED is CLASS II for APPLICATION ENVIRONMENT 4		N/A
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		P
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	*Marked with trademark, misidentification does not present an unacceptable risk*	P
201.7.2.2.101	MEDICAL BED marked with the corresponding maximum PATIENT weight (see 201.9.8.3.1) and SAFE WORKING LOAD according to Figure 201.105 (Kg, Kg) ..... :		P
	Detachable parts of the MEDICAL BED weighing more than 20 kg marked with symbol ISO 7000-1321 (2004-01) symbol	*Weighing less than 20 kg*	N/A
201.7.2.2.102	MEDICAL BED for use with an automatic washing system marked “Caution, for cleaning purposes this bed can be used with automatic washing systems” ..... :	~~See Marking~~	N/A
201.7.2.2.103	MEDICAL BED for use with jet stream washing marked “Caution, for cleaning purposes, this bed can be used with jet stream washing” ..... :	~~See Marking~~	N/A
201.7.2.2.104	The range of an adjustable width carriage BED-LIFT is marked (e.g., by linear measurement indicator fixed to the adjustable parts)		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.2.105	MEDICAL BED with replacement mattress marked with the warning “Incompatible mattresses can create hazards. Read instructions for use”, or an appropriate symbol on a prominent place on the MATTRESS SUPPORT PLATFORM indicating the compatible mattresses ..... :	See Marking	P
201.7.2.2.106	MEDICAL BED with detachable SIDE RAILS marked with the warning “Incompatible SIDE RAILS can create HAZARDS. Read instructions for use”, or an appropriate symbol on a prominent place near the attachment point of the SIDE RAIL, indicating the compatible SIDE RAILS	*No detachable side rail*	N/A
201.7.2.2.107	MEDICAL BED marked on a prominent place with the symbol according to Figure 201.120 (IEC 60601-2-52/A1)		P
201.7.2.4	The corresponding SAFE WORKING LOAD is marked on the ACCESSORY where an overload on the ACCESSORY intended to support loads can create an unacceptable RISK		N/A
201.7.4.2	Markings or appropriate symbols on the outside of the MEDICAL BED, visible from a position of NORMAL USE, indicate reliance to prevent unintended movement of the MATTRESS SUPPORT PLATFORM is based on the MOTION LOCKOUT CONTROL requiring activation by the OPERATOR (Fig 201.106)		P
201.7.6.3	Controls and/or indicators, when possible, marked using symbols that convey the intended function of those controls or indicators without the need for additional text		P
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)		P
	b) maximum PATIENT weight and SAFE WORKING LOAD (i.e., sum of patient & mattress in Kg)		P
	- PATEINT..... :	*185 – 215 kg*	—
	– mattress ..... :	*20 kg*	—
	– ACCESSORIES of the MEDICAL BED (only when supported by the support system of the MEDICAL BED), and		P
	– load supported by the ACCESSORIES (excluding PATIENT weight) (Kg)..... :	*45 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		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	d) result of the measurement of auditable acoustic energy according to ISO 3746 for APPLICATION ENVIRONMENT 4 intended MEDICAL BED .....:		N/A
	e) a description of the intended PATIENT group(s) (IEC 60601-2-52/A1)		P
201.7.9.2.2	Warning and safety notices .....:	See attached copies of warnings	P
	a) Instructions for use provide a warning indicating MEDICAL BED should be left in its lowest position when the PATIENT is unattended to reduce RISK of injury due to falls		P
	b) Instructions for use provide a warning on HAZARDS caused by inappropriate handling of the POWER SUPPLY CORD		P
	c) Instructions for use provide a warning, stating that when routing cables from other equipment in the MEDICAL BED, precautions shall be taken to avoid squeezing those between parts of the MEDICAL BED		P
	d) Instructions for use provide a warning when the MEDICAL BED used only with certain hoists, because of the limited space underneath MEDICAL BED		P
	e) Instructions for use provide a warning when the MEDICAL BED is limited to a specific group of PATIENTS (IEC 60601-2-52/A1)		P
	f) Instructions for use provide a warning when an incompatible SIDE RAILS and mattresses can cause an entrapment hazard (IEC 60601-2-52/A1)		P
201.7.9.2.5	ME EQUIPMENT description.....:	See attached instructions for details	P
201.7.9.2.5 .101	Instructions for use contain information on the selection of mattresses, including mattress dimensions and mattress characteristics (e.g., to reduce RISK of entrapment and falls)		P
201.7.9.2.5 .102	Instructions for use contain information on the selection of SIDE RAILS, including SIDE RAIL dimensions and SIDE RAIL characteristics (e.g., to reduce RISK of entrapment and falls)		P
201.7.9.2.5 .103	Instructions for use identify the maximum angles that can be achieved in NORMAL USE by each part of the MATTRESS SUPPORT PLATFORM with reference to horizontal		P
	Instructions for use also identify the maximum and minimum heights from the floor which can be achieved by the MATTRESS SUPPORT PLATFORM in NORMAL USE (H_{max} Cm, H_{min} Cm).....:	*76,5 cm, 45 cm*	P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	Instructions for use also identify any emergency position(s) and the controls by which such position(s) are obtained		P
201.7.9.2.5 .104	Instructions for use specify the maximum mass (in kg) of the MEDICAL BED (Kg)..... :	*250 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		N/A
201.7.9.2.1 3	Instruction for use direct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance, and calibration to be performed including the frequency of such maintenance		P
	Instruction for use provide information for the safe performance of routine maintenance necessary to ensure the continued safe use of the MEDICAL BED		P
	Instructions for use, additionally, identify the parts requiring preventive inspection and maintenance by SERVICE PERSONNEL, including the periods to be applied and details about the actual performance of such maintenance		P
	Instruction for use contain directions to ensure adequate maintenance for MEDICAL BEDS with rechargeable batteries intended to be maintained by anyone other than SERVICE PERSONNEL		P
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
201.8.11.3. 2	POWER SUPPLY CORDS are 2,5 m long, minimum, measured from the plug to the outside perimeter of the MEDICAL BED (m) ..... :	2,6 m	P
	POWER SUPPLY CORD and other external flexible mains cables and cords on MEDICAL BEDS are type HD22.10 H05-BQ-F [1]3) or equivalent quality for mechanical robustness (type designation)..... :	*See table 8.10 of main part of present test report*	P
	POWER SUPPLY CORDS are equipped with appropriate strain relief and bend protection		P
	POWER SUPPLY CORD sets provided with molded-on plug or other means to withstand the ingress of water during the cleaning PROCESS for which the MEDICAL BED is intended		P
	MEDICAL BED equipped with a means to keep the POWER SUPPLY CORD clear of any moving MEDICAL BED part or mechanism, when the MEDICAL BED is in use, transport or not in use to prevent damage to the POWER SUPPLY CORD		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	POWER SUPPLY CORDS are adequately protected against damages from contact with moving part(s) or from friction at sharp corners and edges within the MEDICAL BED		P
201.9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		P
201.9.1	MECHANICAL HAZARDS of ME EQUIPMENT		P
201.9.1.101	All openings or areas (A1, A2, A3, A4, A5, A6, B, C, and D) within the MEDICAL BED system which are above the MATTRESS SUPPORT PLATFORM meet the dimensional and constructional requirements of Figs. 201.107, 201.108, and Table 201.101	See appended Table 201.9.1.101 *Figures 201.107 and 201.108 replaced by IEC 60601-2-52/A1*	P
	RISK of PATIENT entrapment addressed in another way is justified by the MANUFACTURER in the RISK MANAGEMENT FILE.....:	See RISK MANAGEMENT FILE	P
	MEDICAL BED complied with the requirement before and after application of the SIDE RAIL strength and latch reliability tests (see 201.9.8.3.3.3)		P
	Test conducted with the MATTRESS SUPPORT PLATFORM in the flat position, except as indicated in Table 201.101		P
	Test performed with the SIDE RAIL in all raised and locked positions		P
	All the tests performed without the mattress except the test for Dimension D		P
	Requirements involving the mattress verified with the mattresses type as specified by the MANUFACTURER .....:	*Mattress provided by applicant*	P
	Requirements of Figures 201.107, 201.108, and Table 201.101 involving the mattress excluded for SPECIALTY MATTRESSES		P
	A RISK ASSESSMENT performed to evaluate:	See RISK MANAGEMENT FILE	—
	– SPECIALTY MATTRESSES		P
	– MATTRESS OVERLAYS		P
	– ACCESSORIES		P
	– articulated MATTRESS SUPPORT PLATFORM positions		P
	The following tests conducted, and the RISK MANAGEMENT FILE inspected	See Table 201.9.1.101, and RISK MANAGEMENT FILE	P
201.9.2.2	TRAPPING ZONE		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.9.2.2.1	The entire region in the UNDERCARRIAGE considered in the RISK ANALYSIS with regard to trapping HAZARDS due to high/low motion		P
	RISK MANAGEMENT FILE inspected for verification	See RISK MANAGEMENT FILE	P
201.9.2.2.2	The locations identified in Figs 201.109 and 201.110 considered as TRAPPING ZONES for fingers		P
	Distances between moving parts are always < 8 mm or > 25 mm (as in Fig 201.109)(mm) .....:	*< 8 mm*	P
	The 200 mm cross-hatched area considered the area of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM		P
	The 200 mm distance measured taking into account any barrier preventing access to fingers (see Figure 201.110)		P
	The region within the APPLIED PART and above the MATTRESS SUPPORT PLATFORM considered in the RISK ANALYSIS with regard to finger spacing between moving parts		P
	The locations identified in Figs 201.111 a) and 201.111 b) considered as TRAPPING ZONES for feet		P
	Measurements taken under the most disadvantageous conditions for Figures 201.109, 201.110, 201.111a), and Fig 201.111b)		P
201.9.2.2.3	For the reach of a hand, the safe distance is 200 mm (see Figs 201.109 and 201.110) (mm).....:	*200 mm*	P
201.9.2.2.5	b) all movement of MEDICAL BED and its parts is possible only by activation of control device(s) which initiate and maintain operation of MEDICAL BED elements only as long as manual control is actuated and where manual control automatically returns to 'Stop' or 'Off' position when released		P
	When mass and velocity allowed adequate control of positioning without causing an unacceptable RISK, manually and foot-operated movements considered to comply with this clause		P
	MEDICAL BED inspected and functional tests conducted		P
201.9.2.3.1	The means to deactivate MEDICAL BED movement prevents re-activation by the PATIENT when the PATIENT is in the MEDICAL BED, except for emergency MEDICAL BED movements specified by MANUFACTURER		P
	Foot operated controls prevent accidental activation	*No foot operated controls*	N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	Means provided to deactivate the foot-operated controls used for MEDICAL BED movement not manually operated when the MEDICAL BED cannot exclude trapping or crushing		N/A
	The control deactivates without OPERATOR action after use		N/A
	Consideration is given to unintended activation by the PATIENT or other persons crawling under the MEDICAL BED or by objects used in close proximity		N/A
	Means to deactivate foot-operated MEDICAL BED movement is located or designed so that the PATIENT cannot accidentally re-activate the functions, taking into account PATIENT mobility and medical supervision, when means for the foot-operated MEDICAL BED movement are provided		N/A
201.9.4.2	Instability – overbalance		P
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 centered 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		N/A
	Test performed at each corner of the MEDICAL BED		P
	Longitudinal stability tests were conducted as follows:		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	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) ....:	*2200 N*	P
	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).....:		N/A
	Test performed at both ends of the MEDICAL BED		P
201.9.4.2.3	Instability from horizontal and vertical forces		P
	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 max. 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	*2500 N*	P
	- for MEDICAL BEDS not intended for PATIENT transport, test conducted on MEDICAL BED without SAFE WORKING LOAD in place		N/A
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		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	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~~	N/A
201.9.4.3.1	Instability in transport		P
	c) MOBILE MEDICAL BED did not result in an unacceptable RISK due to unwanted horizontal movement		P
	MEDICAL BED prepared with the following in the most disadvantageous position of NORMAL USE and subjected to the following test:		P
	– the height, articulation, and length of the MATTRESS SUPPORT PLATFORM		P
	– castors		P
	– SIDE RAILS		P
	– ACCESSORIES with their SAFE WORKING LOAD in place, including in combination with other accessories		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	– mattress (e.g., height and weight) as specified by the MANUFACTURER or a load representing the weight of the specified mattress uniformly distributed and centered on the MATTRESS SUPPORT PLATFORM		P
	MOBILE MEDICAL BED placed with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a plane covered with 2 mm to 4 mm thick vinyl flooring material and inclined at 6° from the horizontal plane on a concrete floor		P
	Following initial elastic movement, initial creepage, and initial pivoting of castors, there was no movement of the MOBILE MEDICAL BED greater than 50 mm (in relation to the inclined plane)		P
	The initial movements did not result in an unacceptable RISK, taking into account the NORMAL USE of the MEDICAL BED		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	*Application environments 2 and/or 3*	N/A
201.9.6.2.1	The results of the measurement provided in the instruction for use		—
	Maximum A-weighted sound pressure level measured at the minimum distances of PATIENT, OPERATOR, and other persons from the source of acoustic energy (noise) in NORMAL USE (db).....:	*38,7 dBA*	P
	Calculated the A-weighted sound pressure level produced by the ME EQUIPMENT in accordance with ISO 3746, when necessary, applying the following conditions .....:		N/A
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		P
201.9.8.3.1	MEDICAL BED parts serving for support or immobilization 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 the MEDICAL BED is at least 2 000 N (N).....:	*2500 N*	P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	SAFE WORKING LOAD of the MEDICAL BED is considered to be the sum of the following minimum loads		P
	– 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT (N)..... :	*1850 N*	P
	– 200 N, corresponding approximately to a mass of 20 kg for the mattress (N) ..... :	*200 N*	P
	– 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)..... :	*450 N*	P
	The SAFE WORKING LOAD of the MEDICAL BED was at least 1 700 N for APPLICATION ENVIRONMENTS 3, 4 and 5 (N) ..... :	*Application environment 2 more restrictive*	N/A
	The SAFE WORKING LOAD of the 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) ..... :		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 (N)..... :		N/A
	The SAFE WORKING LOAD of a BED-LIFT was at least 2 200 N (N)..... :		N/A
	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 (N) ..... :		N/A
	– 200 N, corresponding approximately to a mass of 20 kg for the mattress (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 (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 (N) ..... :		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	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 the configuration or ACCESSORIES attachment on support/suspension parts (N) .....:	*Attachment on support parts 500 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		N/A
	The SAFE WORKING LOAD of the LIFTING POLE (including PATIENT handle) is at least 750 N (N) ....:		N/A
201.9.8.3.2	Static forces due to loading from persons		P
	The MEDICAL BED and BED-LIFT are capable of withstanding a uniformly distributed static load equal to 2x the SAFE WORKING LOAD, or 4000 N, the greater of the two, in the most disadvantageous position on the MATTRESS SUPPORT PLATFORM in a horizontal position (see Fig. 201.115) (N) .....:	*4600 N*	P
	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) .....:	*4600 N 1 min*	P
	Permanent deformation was acceptable only when the MEDICAL BED complied with its intended function	*No deformation*	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.		N/A
	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) (N).....:		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	Permanent deformation was acceptable only when the BED-LIFT was in compliance with its intended function		N/A
	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) .....:		N/A
	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		N/A
	1) The LIFTING POLE positioned to the MEDICAL BED in its most adverse position intended in use		N/A
	For the LIFTING POLE, permanent deformation was acceptable in the first test		N/A
	A sudden movement of the LIFTING POLE considered to be a HAZARD did not occur		N/A
	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 and time was increased to at least 1 h (N) (min, h) .....:		N/A
	The LIFTING POLE and its fastenings examined during and after application of the load		N/A
	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 the test		N/A
	A horizontal force of 350 N applied perpendicular to the MEDICAL BED side, and to the outermost suspension point of the handle		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	The LIFTING POLE and its fastenings examined during and after application of the load		N/A
201.9.8.3.3	Dynamic forces due to loading from persons		N/E
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		N/E
	Durability considered relative to the most disadvantageous position of the MEDICAL BED parts intended to support or suspend a PATIENT in NORMAL USE		N/E
	A test conducted by placing the worst-case mattress specified by MANUFACTURER onto the MEDICAL BED in its flat position		N/E
	The height adjusted to the worse case position		N/E
	Loading pad (Fig. 201.104) utilized at position A in Fig. 201.116, at the weaker side		N/E
	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 (N) .....:		N/E
	When tested as described above, the MEDICAL BED still functioned normally and presented no HAZARDS after removal of the loading pad		N/E
	The mattress removed, and the following evaluations and tests conducted:		N/E
	– entrapment HAZARDS evaluated according to 201.9.1.101		N/E
	– TRAPPING ZONES evaluated according to 201.9.2.2		N/E
	– and test conducted according to 201.9.8.3.2		N/E
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		N/E
	A test conducted by placing the MEDICAL BED in its flat position as follows:		N/E
	A TEST BED BOARD mounted to the BED-LIFT when the BED-LIFT was separate from a MATTRESS SUPPORT PLATFORM		N/E

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	The SAFE WORKING LOAD, distributed as indicated in 201.9.8.3.1 (Figure 201.115), applied on the MATTRESS SUPPORT PLATFORM (N) .....:		N/E
	For BEDLIFTS, 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) .....:		N/E
	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		N/E
201.9.8.3.3.3	SIDE RAIL latches/locks remained secure when subjected to the forces in NORMAL USE		N/E
	A test conducted by applying forces at the worst-case accessible location for latching/locking		N/E
	- The SIDE RAIL mechanism subjected to 30 000 cycles of operation from the latched, upper position, to the unlatched, lowered position, and back to the latched, upper position		N/E
	- A force A, B, C, D, E, or F (as specified in Fig. 201.117) applied to the worst-case position for locking/latching of the SIDE RAIL in the direction of unlatching/unlocking (Force A, B, etc) .....:		N/E
	SIDE RAIL did not become unlatched/unlocked, and did not result in any other unacceptable RISK		N/E
	SIDE RAILS withstood the forces applied during reasonably foreseeable misuse over the product life cycle without creating an unacceptable RISK		N/E
	A lateral force cycling test conducted with the SIDE RAIL in the upper position as follows:		N/E
	a) A force of 100 N perpendicular to the SIDE RAIL exerted at the top middle section of the SIDE RAIL in the direction indicated by E or F in Fig. 201.117 & the direction reversed, repeating the test for 3 000 cycles		N/E
	b) A longitudinal force cycling test conducted by exerting a force of 100 N on the SIDE RAIL in the lengthwise direction of the SIDE RAIL as indicated by C or D in Fig. 201.117, and the direction reversed, repeating the test for 3 000 cycles		N/E
	c) A vertical force cycling test conducted by exerting a force of 100 N on the uppermost part of the SIDE RAIL in the vertical direction of the SIDE RAIL as indicated by B in Fig. 201.117, and the test repeated for 3 000 cycles		N/E

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	No test required in direction A		N/E
	d) Upon completion of a), b) and c) above, a static load applied in the directions of Fig. 201.117 in worst case positions		N/E
	The SIDE RAIL did not become unlatched/unlocked and did not result in any other unacceptable RISK		N/E
201.9.8.3.3.4	The LIFTING POLE and its fastenings still functioned normally and presented no HAZARDS after the following test:		N/A
	A sudden movement of the LIFTING POLE or its handle which may result in a HAZARD did not occurred		N/A
	A test conducted by positioning the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use as follows:		N/A
	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 (N) .....:		N/A
	The LIFTING POLE and its fastenings examined during and after application of the force and recorded deflection and deformation		N/A
	The deflection of the LIFTING POLE was not > 100 mm during application of the SAFE WORKING LOAD (mm).....:		N/A
	The permanent deformation was not more than 20 mm after the durability test, measured in relation to the MATTRESS SUPPORT PLATFORM (mm).....:		N/A
201.9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		P
201.9.8.4.1	This sub-clause not applied		—
201.9.8.5	This sub-clause not applied		—
201.9.101	SIDE RAILS designed with minimum height requirements as indicated by G in Fig. 201.118 and Table 201.102		P
	A RISK ASSESSMENT performed on the SPECIALTY MATTRESS or MATTRESS OVERLAY where the SIDE RAIL did not meet G as indicated in Table 201.102, to assure equivalent safety	See RISK MANAGEMENT FILE	P
	G measured and the RISK MANAGEMENT FILE inspected (mm) .....:	*275 mm*	P
201.11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		P
201.11.1.1	Maximum temperature during NORMAL USE	See Table 11.1.1 in Part 1	P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

	Table 24 replaced		—
201.11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P
201.11.6.5.101	ENCLOSURES OF MEDICAL BED provide a minimum protection degree of IPX4 in accordance with the classification of IEC 60529.....:	*IP X4*	P
	Tests of IEC 60529 conducted with the MEDICAL BED placed in the least favorable position of NORMAL USE (as defined in the instructions for use) and by inspection.....:	*All electrical components certified at least as IP X6, see table 8.10 of main part of present test report*	N/A
	All parts removable without a TOOL removed (detached/opened) before the test, and test executed without a mattress		P
	After the tests, MEDICAL BED displayed no signs of bridging of insulation (or electrical components) that could result in a HAZARD in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION followed by the appropriate dielectric strength and LEAKAGE CURRENT tests		P
	MEDICAL BED complied with its INTENDED USE		P
201.11.6.6	MANUFACTURER has specified the cleaning and/or disinfection PROCESS for the MEDICAL BED intended for cleaning and disinfection .....:	*Specified in the IFU*	P
201.11.6.6.101	MEDICAL BED or BED-LIFT specified by the MANUFACTURER to be machine washable by an automatic washing system functioned normally after the test		N/A
	Variations to the test procedure relative to test-cycle, temperature, time and cleaning fluids covered in the RISK MANAGEMENT FILE	~~See RISK MANAGEMENT FILE~~	N/A
	The present test method represents a basic procedure for disinfection of a MEDICAL BED in a washing machine		N/A
	a) Parts and access covers which can be detached/opened without the use of a TOOL were detached/opened		N/A
	– a 10 day temperature preconditioning treatment conducted at 65 °C ± 2 °C, or at maximum value of rated storage temperature, when higher (°C).....:		N/A
	– MEDICAL BED maintained at room temperature for not less than 16 h (°C).....:		N/A
	b) 50 test cycles of operation conducted according to the MANUFACTURER'S procedure described in the instructions for use		N/A
	Alternatively, the wash consisted of the following:		N/A

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	– 2 min wash with 70 °C water at a ph-value 5-8, 0,5 % cleaning and disinfectant solution as specified by the MANUFACTURER		N/A
	– 20 s rinse with 85 °C water at a ph-value 5-8, and 0,2 % clear rinsing solution according to the data of the MANUFACTURER		N/A
	– 10 min cooling at 20° C ambient temperature		N/A
	– MEDICAL BED complied with the following:		N/A
	1) Immediately after the test cycles, MEDICAL BED connected to mains		N/A
	No unintentional movements occurred		N/A
	2) MEDICAL BED functioned as specified by the INTENDED USE at the following intervals:		N/A
	– immediately after the test cycles		N/A
	– 5 min (± 1 min) after the test cycles		N/A
	– 60 min (± 5 min) after the test cycles		N/A
	– 24 h (± 30 min) after the test cycles		N/A
	3) Dielectric strength and LEAKAGE CURRENT tests were conducted in accordance with 8.8.3 and 8.7 of Part 1 at the following intervals:	~~See Tables 8.7A, 8.7B, 8.7C, & 8.7.4.7, 8.8.3A, & 8.8.3B in Part 1~~	N/A
	– immediately after the test cycles		N/A
	– 24 h (± 30 min) after the test cycles		N/A
	4) A visual inspection for ingress of water that may result in an unacceptable RISK performed (i.e., shorting of isolation barriers and violation of creepage distances)		N/A
201.11.8	Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT		P
	In an emergency situation when MAINS VOLTAGE was interrupted, ESSENTIAL PERFORMANCE functions defined by the MANUFACTURER operated by other means and back section lowering, or other emergency position as specified by the MANUFACTURER, achieved within 30 s	*Equipment provided with a battery.*	P
	Functional tests were conducted under the most adverse conditions		P
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.12.2	USABILITY analysis has taken into account MEDICAL BED design aspects such as the MATTRESS SUPPORT PLATFORM height, relative to the OPERATOR and PATIENT, as relevant to the APPLICATION ENVIRONMENT .....:	See attached information for USABILITY analysis	P
201.13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		P
201.13.1.4	Protection provided in the motion controls of electrical MEDICAL BEDS such that a SINGLE FAULT CONDITION does not cause a movement without human intervention		P
	A MOTION LOCKOUT CONTROL, optionally, used as a means of compliance		P
	A MOTION LOCKOUT CONTROL is activated automatically or as an OPERATOR option. (See also 201.7.4.2.)	*Operator option*	P
	The auxiliary subsystem that deactivates motion controls (MOTION LOCKOUT CONTROL), when provided, remained functional under SINGLE FAULT CONDITION		P
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are used for switches and other components that control motion in electrical MEDICAL BEDS when failure of such components could cause a HAZARD .....:	~~See Table 8.10, Critical Components, in Part 1~~	N/A
	Hydraulic, pneumatic, and mechanical subsystems of MEDICAL BED did not cause unintended movement of the MATTRESS SUPPORT PLATFORM in SINGLE FAULT CONDITION, where such movement could cause a HAZARD		P
	Protection of SINGLE FAULT CONDITION for pneumatic, hydraulic, or mechanical MEDICAL BEDS, and/or subsystems of electrical MEDICAL BEDS, is met by compliance with 9.7.2 of Part 1, and other applicable clauses of Part 1 and this standard pertaining to safety factors		P
201.13.2.2	Electrical SINGLE FAULT CONDITION		N/A
201.13.2.2.101	Power-driven MEDICAL BED for transportation provided with a means to allow transport by the OPERATOR under SINGLE FAULT CONDITION of the transport system	~~See Attachment #~~	N/A
201.15	**CONSTRUCTION OF ME EQUIPMENT**		P
201.15.3	Mechanical strength		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.15.3.4.1	PENDANT CONTROL did not result in an unacceptable RISK as a result of a free fall	*Component certified, see appended table 8.10*	N/A
	The PENDANT CONTROL subjected to 1000 time free fall tests as specified in IEC 60068-2-31:2008		N/A
	After the test the PENDANT CONTROL checked by inspection, functional test, and relevant electrical safety tests		N/A
201.15.3.5	Rough handling test		P
	c) The MEDICAL BED subjected to the “door frame shock test” by moving it three times in its normal direction of travel		P
	The speed was 0,4 m/s ± 0,1 m/s with the MATTRESS SUPPORT PLATFORM in the worst case position (except when transport position was specified by the MANUFACTURER) against a hardwood vertical obstacle 40 mm wide and 40 mm thick secured to a vertical rigid support		P
	The height of the vertical obstacle was at the same level as the MEDICAL BED contact point(s)		P
	The direction of movement was perpendicular to the face of the obstacle		P
	This requirement not applied to MEDICAL BED specified by the MANUFACTURER only to be moved within the PATIENT room for cleaning or PATIENT access		N/A
201.15.4	ME EQUIPMENT components and general assembly		P
201.15.4.4	The first two paragraphs of 15.4.4 in Part 1 not applied		P
201.15.4.6.2	The angle (“γ” in Fig. 201.119) between the back section and leg/upper leg section for various configurations of the MATTRESS SUPPORT PLATFORM is always > 90° under NORMAL CONDITIONS		P
	In APPLICATION ENVIRONMENT 4, the angle α of the back section in relation to the horizontal is always be greater than or equal to 0°		N/A
	The entire MATTRESS SUPPORT PLATFORM of the MEDICAL BED in APPLICATION ENVIRONMENTS 1, 2, 3, or 5 provided with Trendelenburg position, is capable of achieving a minimum of 12° so that the PATIENT’S head is lower than the circulatory centre point of the body (Angle achieved °) .....:	14º	P
	The controls operated to achieve the maximum angle γ and measuring this angle (γ°).....:	100º	P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
201.15.4.7.1	Amendment to item b):This requirement not applied when the foot-operated control device was so located that the operator's entire weight could not be placed on it	*No foot-operated control*	N/A
	An actuating force of 1350 N applied to the foot-operated control device, in its position of NORMAL USE, for 1 min		N/A
	The force applied over an area of 30 mm diameter		N/A
	There was no damage to the device resulting in an unacceptable RISK		N/A
	Addition to item b): The RISK MANAGEMENT FILE specifies the compliance criteria when the entire weight cannot be placed on the foot-operated control device		N/A
	The RISK MANAGEMENT FILE inspected	~~See RISK MANAGEMENT FILE~~	N/A
201.15.4.7.3	Foot-operated controls are rated IPX4 or better (IP Code).....:		N/A
201.15.4.101	In emergency situations, MEDICAL BED for APPLICATION ENVIRONMENTS 1 and 2 only allows immediate and unimpeded access to the PATIENT from the head end of the MEDICAL BED		P
	A trained OPERATOR was able to remove the HEAD BOARD within 15 s		P
201.15.4.102	MEDICAL BED retains the mattress in position during NORMAL USE to prevent the MATTRESS SUPPORT PLATFORM from sliding off		P
	A RISK ASSESSMENT performed to evaluate the maximum movement of the retained mattress according to Area "D" of Table 201.101		P
	The RISK MANAGEMENT FILE inspected	See RISK MANAGEMENT FILE	P
BB	**ANNEX BB (NORMATIVE) - DESIGN REQUIREMENTS AND RECOMMENDATIONS FOR MEDICAL BEDS**		P
BB.2	Strength and durability		P
BB.2.1	Adequate levels of protection from HAZARDS are provided on the MEDICAL BED throughout its EXPECTED SERVICE LIFE		P
	The MANUFACTURER used the following tests as methods to help determine if appropriate levels of protection are maintained during that period		P
	Tests performed in the sequence listed		P
BB.2.2	**THE EFFECT OF IMPACTS TO THE MATTRESS SUPPORT PLATFORM**		N/E

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	MEDICAL BED withstood the effects of impacts to the MATTRESS SUPPORT PLATFORM during NORMAL USE		N/E
	Mattress placed, as specified by the MANUFACTURER, onto the MATTRESS SUPPORT PLATFORM in a position in which moving elements were free of supporting elements and their incline was less than 7° in relation to horizontal		N/E
	MATTRESS SUPPORT PLATFORM with adjustable height placed in the middle of the possible range of adjustments		N/E
	The impactor (see Fig. BB.2) dropped onto the MEDICAL BED 20 times from a height of 180 mm above the mattress onto each of the locations marked “B” in Figure BB.1		N/E
	The impactor allowed to fall freely, except guides were, optionally, used to help insure that the impacts occurred as close as possible to the recommended locations		N/E
	After application of the load, no elements of the MEDICAL BED became loose, fractured, or presented any HAZARD		N/E
	Impactor body was approximately 200 mm in diameter and separated from the striking surface by helical compression springs		N/E
	Body was free to move on a line perpendicular to the plane of the central area of the striking surface		N/E
	Total mass of the assembly was 25 kg ± 0,1 kg and the body and its associated parts (minus the springs) was 17 kg ± 0,1 kg		N/E
	The combined spring rate (for the system) was 6,9 N/mm ± 1 N/mm and the total friction resistance of the moving parts between 0,25 to 0,45 N (N) .....:		N/E
	When the spring system was compressed to a load of 1040 N ± 5 N, the remaining compression distance was 60 mm minimum (mm) .....:		N/E
	The striking surface was a rigid circular object, (200 ± 5) mm in diameter with a convex spherical face having a curvature of 300 mm in radius and a 12 mm front edge radius		N/E
BB.2.3	**THE EFFECT OF LOADING ON THE EDGE OF THE MATTRESS SUPPORT PLATFORM**		P
	MEDICAL BED withstood the effect of loading on the edge of the MATTRESS SUPPORT PLATFORM as applied during NORMAL USE		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict
	MEDICAL BED placed in its flat position		P
	A TEST BED BOARD mounted to the BED-LIFT when the BED-LIFT was separate from a MATTRESS SUPPORT PLATFORM		N/A
	Height adjusted to the most adverse position		P
	Three loading pads weighted down with a load of 750 N each to the MATTRESS SUPPORT PLATFORM to the locations marked “C” in Fig. BB.1		P
	Specimen examined during and after application of the loads to determine if the deflections presented any HAZARD		P
	No elements of the BED became loose, fractured or presented any HAZARD after application of loads		P
	Deflection was not > 40 mm during application of the loads and not > 10 mm measured in relation to the floor after removal of the loads (mm, mm).....:	*9 mm during application of loads and no deflection after removal loads*	P
BB.2.4	**DURABILITY OF THE MOVEABLE SECTIONS (IF PROVIDED) OF THE MATTRESS SUPPORT PLATFORM**		N/A
	The moveable sections of the MATTRESS SUPPORT PLATFORM complied with the following test:	*No movable sections*	N/A
	The SAFE WORKING LOAD applied on the MATTRESS SUPPORT PLATFORM, distributed as in Fig 201.115		N/A
	Each of the moveable sections of the MATTRESS SUPPORT PLATFORM operated through its full range of travel as in NORMAL USE		N/A
	Test performed for 1 000 cycles of operation		N/A
	MEDICAL BED inspected 5 min after cycling was completed		N/A
	No elements of the MEDICAL BED became loose, fractured, or presented any HAZARD after application of the load		N/A
	Deformation of less than 10 mm (after removal of the load) from the corresponding measurements taken before the application of the load was acceptable		N/A
BB.3.3	**DIMENSIONS FOR HANDLES AND PEDALS**		P
BB.3.3.1	All handles and pedals are reachable from normal working positions and located so that they allow operations to be carried out in a safe and ergonomic manner		P
BB.3.3.2	Location and configuration of all buttons/switches/ actuators minimize RISK of unintentional activation		P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

BB.4	**FUNCTIONALITY**		P
BB.4.1	Characteristics of MEDICAL BED that could affect the safe operation of the system (MEDICAL BED with ME EQUIPMENT) as well as characteristics of MEDICAL BED which facilitate use of the system evaluated by MANUFACTURER as encouraged by this Sub-clause	See attached information	P
BB.4.3	**COMBINATION OF MEDICAL BED AND MATTRESS**		P
	The height of the mattress used is at least 20 mm higher than any construction part (e.g., MEDICAL BED frame, side structure or the lowered SIDE RAILS of MATTRESS SUPPORT PLATFORM) for all MEDICAL BEDS at the area of the MATTRESS SUPPORT PLATFORM intended for the ingress/egress of the BED (mm).....:	*120 mm*	P
	A RISK ASSESSMENT performed when the requirement could not be fulfilled for SPECIALITY MATTRESS used	~~See RISK MANAGEMENT FILE~~	N/A
BB.4.4	**RANGE OF ADJUSTMENT OF MOVEABLE SECTIONS OF THE MATTRESS SUPPORT PLATFORM**		P
	The range of adjustment (when applicable) for back, upper leg, and lower leg sections of the MATTRESS SUPPORT PLATFORM is as follows:		P
	– Angle C between the back rest section and a line draw between the turning point of the back rest section/seat section and turning point of upper/lower leg section (see Fig BB.4) is greater than 90° for all MEDICAL BEDS (as in 201.15.4.6.2) (Angle C°):	100º	P
	– The angle E between the upper side of the upper leg section and the upper side of the lower leg section (see Figure BB.4) is at least 180° for all MEDICAL BEDS (Angle E °) .....:	220º	P

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

201.9.1.101	**TABLE A: Protection against PATIENT entrapment**		P
Area	Description	Requirement/ Compliance method*	Complied? Yes/No (Remark)
A1	Fully enclosed openings within a SIDE RAIL, HEAD or FOOT BOARD	1), 2), 3), 4) and 5)	Yes, < 120 mm
A2	Fully enclosed opening defined by the SIDE RAIL, its supports, and the MATTRESS SUPPORT PLATFORM	1), 2), 3), 4) and 5)	Yes, fully enclosed
A3	Partially enclosed opening defined by the HEAD BOARD, MATTRESS SUPPORT PLATFORM, and SIDE RAIL	1), 2), 3), 4) and 5)	Yes, < 120 mm
A4	Partially enclosed opening defined by the FOOT BOARD, MATTRESS SUPPORT PLATFORM, and SIDE RAIL, except where the gap between the SIDE RAIL and the FOOT BOARD > 318 mm	1), 2), 3), 4) and 5)	Yes, < 120 mm
A5	Partially enclosed opening between segmented or split SIDE RAILS and the MATTRESS SUPPORT PLATFORM, except where the gap between the SIDE RAILS is > 318 mm)	1), 2), 3), 4) and 5)	Yes, < 120 mm
A6	Partially enclosed opening defined by the lowest point of a SIDE RAIL, the adjacent SIDE RAIL support, and MATTRESS SUPPORT PLATFORM, to the outside of the SIDE RAIL supports.	1), 2), 3), 4) and 5)	Yes, < 120 mm
A	Other opening(s) defined by ACCESSORIES (e.g., IV poles, fracture frames) and SIDE RAILS, HEAD/FOOT BOARDS, and/or MATTRESS SUPPORT PLATFORM (depending on the position of ACCESSORIES and construction of the MEDICAL BED)	1), 2), 3), 4) and 5)	N/A, no additional openings

Supplementary information:

*Where Requirement/Compliance method are:

1). Gap specified to be < 120 mm as defined by the following test:

2). Except for A3, articulated the MEDICAL BED and found the largest opening, and inserted 60 mm diameter part of cone tool through opening from inside of the MEDICAL BED system

3). Brought cone tool to bear on opening of interest

4). Exerted 250 N force applied to 60 mm cylindrical end of cone tool in most disadvantageous direction

5). Opening did not allow 120 mm diameter part of cone tool to enter and pass through

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

201.9.1.101	**TABLE B: Protection against PATIENT entrapment**		P
Area	Description	Requirement/ Compliance method*	Complied? Yes/No (Remark)
B	Distance between the MATTRESS SUPPORT PLATFORM and the lowest point of the SIDE RAIL outside of the SIDE RAIL support; and The angle between SIDE RAIL and the MATTRESS SUPPORT PLATFORM at the range of the mattress height defined by the MANUFACTURER ± 2 cm (takes into account mattress compression and height of the neck above the mattress)	Gap < 60 mm and 1) and 2) below	Yes, < 60 mm

Supplementary information:

*Where Requirement/Compliance method are:

1). Angle between MATTRESS SUPPORT PLATFORM and SIDE RAIL interface >60° over the entire range of mattress heights from the minimum recommended mattress height, minus 2 cm to the maximum recommended mattress height, plus 2 cm. RISK MANAGEMENT addresses the possibility of the use of a mattress not specified by the MANUFACTURER

2). RISK MANAGEMENT addresses the entrapment condition of area B (of Fig. AA.13) considering the following:

i) The SIDE RAIL shape and geometry

ii) The distance between the lowest point of the SIDE RAIL and the MATTRESS SUPPORT PLATFORM

iii) The mattress material properties

iv) The mattress dimensions

v) The fit relationship between the SIDE RAIL, mattress and MATTRESS SUPPORT PLATFORM

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

201.9.1.101	**TABLE C: Protection against PATIENT entrapment**		P
Area	Description	Requirement/ Compliance method*	Complied? Yes/No (Remark)
C_1	Gap between the HEAD BOARD and adjacent SIDE RAIL	Gap between the HEAD BOARD and adjacent SIDE RAIL is < 60 mm and test 1). The 60 mm cylinder tool did not slide into the opening	Yes, < 60 mm
C_2	Gap between segmented or split SIDE RAILS with both SIDE RAILS raised.	Gap between segmented or split SIDE RAILS with both SIDE RAILS raised is< 60 mm or > 318 mm verified by tests 2) and 3) below	Yes, < 60 mm
C_3	Gap between SIDE RAIL and FOOTBOARD. Other openings(s) defined by ACCESSORIES (e.g. IV poles, fractures frames, …..) and SIDE RAILS, HEAD BOARD, FOOT BOARD, and / or MATTRESS SUPPORT PLATFORM	Gap between SIDE RAIL and FOOTBOARD is < 60 mm or > 318 mm verified by tests 2) and 3) below	Yes, < 60 mm

Supplementary information:

*Where Requirement/Compliance method are:

1). The cylinder tool (Fig. 201.103b) oriented parallel to floor, in the most disadvantageous angle in the horizontal plane above the gap. The 60 mm cylinder tool rested with the full weight on the gap where the cylinder tool intersects. Extra vertical force not used, and the cylinder not to pry apart parts of MEDICAL BED

2). The gap < 60 mm verified by applying the cylinder tool (Fig. 201.103b) oriented parallel to floor, in the most disadvantageous angle in the horizontal plane above the gap. The 60 mm cylinder tool rested with the full weight on the gap where the cylinder intersects. Extra vertical force not used, and the cylinder tool not used to pry apart parts of the MEDICAL BED. FOR MEDICAL BED with split SIDE RAILS, test performed with MATTRESS SUPPORT PLATFORM articulated to identify the worst case opening between the SIDE RAILS. The 60 mm cylinder tool did not slide into the opening

3). For a gap > 318 mm: The gap is > 318 mm for the entire vertical distance

Attachment #1: Test Report IEC 60601-2-52			
Clause	Requirement + Test	Result - Remark	Verdict

201.9.1.101	**TABLE D: Protection against PATIENT entrapment**		P
Area	Description	Requirement/ Compliance method*	Complied? Yes/No (Remark)
D	Region defined between the SIDE RAIL and mattress.	After test 1) the large end of the cone tool did not sink below the mattress surface by 50 % or more of its 120 mm diameter	Yes, cone tool did not sink below the mattress surface

Supplementary information:

*Where Requirement/Compliance method are:

1) Mattress pushed away from the SIDE RAIL under measurement until the mattress retention system, or the opposing SIDE RAIL stopped the mattress

SIDE RAIL pulled outward to remove any lateral play and during application of the force the cone tool (see Figure 201.103a) placed with its longitudinal axis parallel to the SIDE RAIL, resting on the mattress in the horizontal gap between the SIDE RAIL and mattress

Cone tool turned until the line on the face of the 120 mm diameter became horizontal. Cone tool allowed to sink into the space by its own weight

When a mattress retention system, SIDE RAIL support or other structure kept the cone tool from sinking in the gap, the cone tool placed at a different location along the SIDE RAIL where there was no interference