Product Service

TEST REPORT

Standard DIN EN 1865-1:2010

TUV SUD Test report for Patient handling equipment used in road ambulances – Vacuum mattress

Report reference No. ..... :	713040024-1
Date of issue ..... :	2014-04-25
Project handler ..... :	Jens Meyer
Testing laboratory ..... :	TÜV SÜD Product Service GmbH
Address ..... :	Masurenweg 1-3, D-30163 Hanover
Testing location ..... :	as above
Client ..... :	B&W Schmidt GmbH
Client number ..... :	10169
Address ..... :	Porschestraße 29, D-30827 Garbsen
Contact person	Mrs. Gabriele Heydenreich
Standard ..... :	This TUV SUD test report form is based on the following requirements: DIN EN 1865-1:2010, section 4, 4.7 (5.6), 6
TRF originated by ..... :	TUV SUD Product Service GmbH, Mr. Jens Meyer (product specialist)
Copyright blank test report ..... :	This test report is based on the content of the standard (see above). The test report considered selected clauses of the a.m. standard(s) and experience gained with product testing. It was prepared by TUV SUD Product Service GmbH. TUV SUD Group takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.
Test procedure ..... :	☐ TÜV Mark ☒ without certification
Non-standard test method ..... :	----
National deviations ..... :	----
Number of pages (Report) ..... :	12
Number of pages (Attachments) ..... :	----

Compiled by ..... : Jens Meyer (+ signature)

Approved by .... : Torsten Zimmer (+ signature)

Digitally signed by Furculiță Andrei
Date: 2022.12.27 16:26:34 EET
Reason: MoldSign Signature
Location: Moldova

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Test sample.....:	HAN-139598-1
Type of test object .....:	Vacuum mattress
Trademark.....:	Schmidt
Model and/or type reference.....:	5986
Rating(s) .....:	----
Manufacturer.....:	B&W Schmidt GmbH
Manufacturer number... .....:	10183
Address.....:	Porschestraße 29, D-30827 Garbsen
Sub-contractors/ tests (clause) .....:	----
Name.....:	----

Order description... .....:		
	☒	Complete test according to TRF
	☐	Partial test according to manufacturer's specifications
	☐	Preliminary test
	☐	Spot check

Date of order.....:	2014-04-01
Date of receipt of test item .....:	2014-04-02 2014-04-14 (Technical documentation for re-test)
Date(s) of performance of test.....:	2014-04-03 to 2014-04-25

Test item particulars:

Attachments:

General remarks:

"(see remark #)" refers to a remark appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a comma is used as the decimal separator.
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 testing laboratory.

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Summary of testing:

☒ The test subject was found to be in compliance with the test specification.

☐ After removal of the points of non-compliance as listed in the report and appropriate re-testing the test subject is in compliance with the test specification.
Re-testing has to be performed within the following six months, otherwise a complete re-test may become necessary.

Copy of marking plate:

- print sample -

Picture of the product

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Characteristic data
(not shown on the marking plate)

Length:	2000 mm
Width:	940 mm
Weight: (Vacuum mattress with pump)	11,8 kg
loading capacity:	200 kg

Characteristic data Factory
(only if certification is provided)

Purpose of the product

The vacuum mattress is a device intended primarily to provide immobilization for the patient during transportation.

Possible test case verdicts:

- test case does not apply to the test object .....: N(.A.) / not included in the order
- test object does meet the requirement .....: P(ass)
- test object does not meet the requirement.....: F(ail)

Possible suffixes to the verdicts:

- suffix for detailed information for the - C(omment)
- suffix for important information for factory inspection...: - M(anufacturing)

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Clause	Requirement – Test	Measuring result – Remark	Verdict
4	**Requirements**		
4.1	**General**		
	When lifting and carrying devices are operated and maintained in accordance with manufacturer instructions they shall not present any high level of risk. Any identified risk shall be reduced to an acceptable level by using risk management principles in accordance with EN ISO 14971 taking account of normal and single fault condition.		P
	Carrying handles on devices for handling of patients shall permit fixation in extended positions.		N
	All equipment for the handling of patients shall be free of any sharp edges. The minimum radius should be0,5 mm.		P
	All patient restraint-systems shall have quick release systems.		N
	The lying-sitting part shall be made of a strong material which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean and disinfect, washable, waterproof and petrol-oil resistant.	Self declaration of the company HEYTex, dated 2014-04-04 was delivered.	P-C
4.7	**Vacuum mattress**		
4.7.1	**Construction**		
	The vacuum mattress consists of a mattress part and a vacuum pump.		P
	The mattress shall be made of strong material which is disinfectable, washable, putrid resistant, waterproof, petrol-oil resistant and allow preliminary x-ray diagnostics.	Self declaration of the company HEYTex, dated 2014-04-04 was delivered.	P-C
	The valve air inlets or outlets shall not disturb the patient.		P
	The pump shall be able to reduce the pressure by 500 hPa within 4 min.		P
	The vacuum mattress including the filling shall have the following minimum properties: - heat resistance: 70 °C; - heat resistance pre-loaded with 5 000 N/m²: 50 °C; - cold resistance: - 30°C; - melting point: approx. 100 °C.	Self declaration of the company B. u. W. Schmidt GmbH, dated 2014-04-11 was delivered.	P-C

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Clause	Requirement – Test	Measuring result – Remark	Verdict
4.7.2	**Dimensions**		
	The dimensions of the vacuum mattress shall be as follows:		
	- Length: minimum 2000 mm	2000 mm	P
	- Width: minimum 800 mm in flat position .	940 mm	P
4.7.3	**Mass**		
	The mass including the pump shall be not more than 15 kg. NOTE: The mass should be as low as possible.	11,8 kg	P
4.7.4	**Loading capacity**		
	The loading capacity shall be a minimum of 150 kg.		P
4.7.5	**Handles**		
	The vacuum mattress shall be equipped with at least four handles on each longitudinal side, in order to transport a patient in an immobilized position.	5 handles on each longitudinal side.	P-C
4.7.6	**Restraint system**		
	During transportation the mattress shall be in accordance with 4.5.9 of EN 1789:2007 +A1:2010.		N
	When a patient is being conveyed outside of the vehicle or craft, a system shall be available to ensure that the patient can be carried in a safe manner. NOTE: During transportation, it should be possible to secure the patient with the restraint system which is provided with the stretcher.	5 handles on each longitudinal side. No additional safeguards available.	P-C
4.7.7	**Flammability - Toxicity burning gases**		
	There shall be no progressive smouldering or flaming ignition when tested in accordance with EN 597-1.		P

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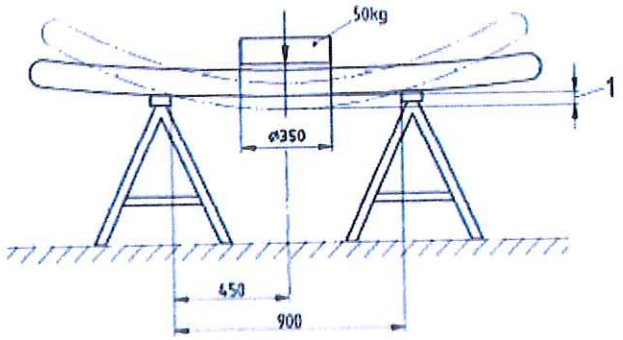
Clause	Requirement – Test	Measuring result – Remark	Verdict
4.7.8	**Deformation**		
	There shall be no permanent deformation when tested in accordance with DIN EN 1865-1, section 5.6.1.		P
	DIN EN 1865-1, section 5.6.1 For rigidity and density the mattress shall be placed on a stand: a) the pressure inside the vacuum mattress shall be reduced by 500 hPa; b) after 30 min, the remaining pressure difference shall be at least 300 hPa; c) the mattress (after opening the valve) shall be shaped to a human body by means of a test person of (75 ± 5) kg body weight, and a height of (175 ± 5) cm; d) the pressure inside the vacuum mattress shall be reduced again by 500 hPa; e) the test person shall be removed; f) the mattress is then placed according to Figure 8 with a load of 50 kg applied on a surface of 350 mm diameter centred in the middle of the mattress; g) after 2 h the remaining pressure difference shall be at least 300 hPa and the deflection shall not exceed 100 mm.		
	Dimensions in millimetres  **Key** 1 Deflection **Figure 8**		

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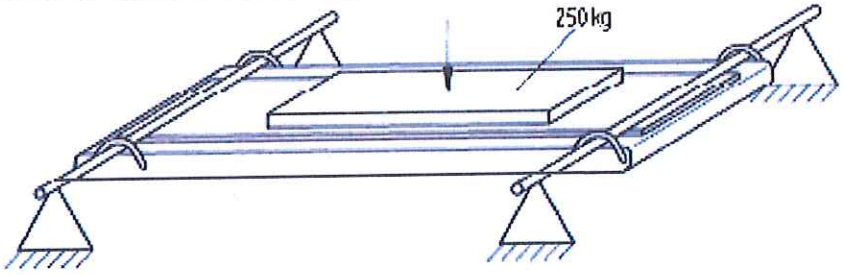
Clause	Requirement – Test	Measuring result – Remark	Verdict
4.7.9	**Fixation**		
	Not applicable.		N
4.7.10	**Shrinkage**		
	The immobilization of the patient is achieved by the suitable shrinkage of the vacuum mattress. In order to avoid additional injuries the shrinkage shall not exceed the following requirement. The shrinkage of the lying area of the mattress shall not be more than 1 % in length and 3 % in width when tested in accordance with DIN EN 1865-1, section 5.6.2	The shrinkage of the lying area in length is 0,7 % and in width 2%.	P-C
	DIN EN 1865-1, section 5.6.2 Place the mattress in flat position on a flat surface. Measure the mattress in the middle longitudinally and middle transversally. The pressure inside the mattress shall then be reduced by 500 hPa. Measure the size of the mattress, at same places as before, whilst under this vacuum pressure.		
4.7.11	**Deformation of the lying area**		
	There shall be no remaining deformation of the lying area when tested in accordance with DIN EN 1865-1, section 5.6.3.		P
	DIN EN 1865-1, section 5.6.3 a) The pressure inside the vacuum mattress shall be reduced by 500 hPa and then suspended by means of its external handles (instead of loops) and a load of 250 kg applied as shown in Figure 9; b) after 15 min there shall be no visible damage and/or failure; c) the same applies if the mattress is provided with a protective coating/cover and if the latter is intended to be used in combination with the patient.		
	 **Figure 9**		

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Clause	Requirement – Test	Measuring result – Remark	Verdict
6	**Marking / *Kennzeichnung***		
	The vacuum mattress covered by this European Standard shall be labelled in accordance with EN 980 and EN 1041.		
	EN 1041		
	General Product information and labelling shall be part of risk management procedures.		P
	Units, symbols and colours Units used shall be SI units as specified in ISO 1000 or any other legal units. Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonized standards, e.g. EN 980.		P
	Language and country identifiers If the manufacturer decides to identify the language used in the information provided, for example to indicate to users the appropriate language in a multilingual document. this shall be done using the language codes given in ISO 639-1 and/or the plain text of the language (e.g. "English"). If the manufacturer decides to identify the country in the information provided, for example to indicate to users the appropriate customer service contact details for their country, this shall be done using the country codes given in EN ISO 3166-1 and/or the plain name of the country (e .g. "France").		P
	Dates Any human-readable date shall be expressed in the format YYYY-MM-DD, YYYY-MM or YYYY, in accordance with ISO 8601.		P
	Device nomenclature		
	Identifiers of nomenclature When it is required to include the identification of the generic device group or the device category in the information supplied with the device, this may be done using a nomenclature that is in compliance with EN ISO 15225.		N

Clause	Requirement – Test	Measuring result – Remark	Verdict
	Device common terms When it is appropriate to identify collective terms for medical devices in the information supplied, for example common technology or common materials of construction, this shall be done using the terms and codes set out in CEN/TR 15133.		N
	Batch code; lot number; batch number; lot code These shall consist of alphanumeric characters but may also be presented by other means, for example by using machine-readable codes.		P
	Requirements for provision of information		
	General		
	Any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device. This shall apply regardless of whether the specific requirements listed below apply to the device.		P
	The appropriate way of providing information shall be based on a risk assessment and in line with the training, experience and education of the intended users.		P
	Specific requirements		
	Applicability These specific requirements shall be applicable to all devices to the extent that they are applicable to the specific device type concerned and to the means of provision of the relevant information. For example, the requirement to allow for a "use by" date is not applicable to devices that do not bear a "use by" date.		N
	Accessibility The information presented with a device shall be accessible to intended users taking into account their age, education, knowledge and training. When appropriate, a specific means of provision may be restricted to users to whom it is particularly applicable.		P

Clause	Requirement – Test	Measuring result – Remark	Verdict
	Legibility Information intended for visual recognition shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the particular device.		P
	Availability Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.	Users manual is a paper version.	N-C
	Security As far as practicably possible, the medium of information provision shall be protected from corruption, degradation and deliberate change by those other than the manufacturer, whether malicious or not. If the user can readily identify faulty information, for example by virtue of damaged labels, advice on the action to take shall be provided. Where the damage to information is not readily apparent and/or the consequences of damage are not obvious, guidance shall be provided on how to maintain the security of the information and limit any adverse consequences.	Users manual is a paper version.	N-C
	Changes to information provided Any changes to information provided for existing users shall be clearly communicated if they are important for patient safety.		N

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6	**Marking on the product**		
	- name and adress of manufacturer		P
	- Model Name and / or number of manufacturer		P
	- Year and Month of manufacture and / or serial number	Serial number is on the product.	P-C
	- maximum load capacity		P
	- Warnings / Application notes, e.g.: • Read the instructions • Other safety hints		P
	The durability of the inscription is to check through each 15 seconds rubbing with distilled water, denatured alcohol and isopropyl alcohol. The markings must be legible even after carrying out the tests.		P