

TESTING REPORT

TURNING SHEET - ISO classification 12.33.06
in accordance with the European standards EN 1970 and EN 12182

Testing No.

06.42A

This page is page 1 of a total of 10 pages

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This report is not an approval of the product tested, but is merely a record of testing results for a specific sample product

The recorded testing results are organised in conformity with the standard EN 1970, i.e. section numbers in the records are similar to the corresponding sections in the standard.

Product tested: **VENDLET HC - 2**

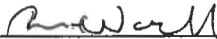
Product received: **22.06.2006**

Testing ordered by: **H. C. Equipment Aps.
Kaolinvej 5
DK - 9220 Aalborg Øst
Tel.: +45 59 44 49 30**

Person to contact: **Heine Buus (?)**

Product delivered by: **The orderer**

20.09.2006
DATE


Testing executive

SUMMARY OF THE TESTING

The sample product tested is an electrically operated turning sheet. The manufacturer identifies the product as follows:

- product name VENDLET HC – 2
- serial no. Test 5
- date of manufacture 2006

As agreed upon with the manufacturer, the testing was carried out in accordance with relevant requirements in the European standards EN 1970 "Adjustable beds for disabled persons – Requirements and test methods" and EN 12182 "Technical aids for disabled persons – Requirements and test methods".

The testing did not include electrical safety (ref. EN 60601-1), EMC (ref. EN 60601-1-2) and acoustic noise (ref. EN ISO 3746).

The product was tested in conjunction with an OPUS 1 – K. R. 3000 bed manufactured by K. R. Hospitalsudstyr A/S.

During the testing, the manufacturer introduced certain modifications on the product. The testing results apply for the final version of the product which, according to the manufacturer, is the one that will be marketed.

With the corrections carried out by the manufacturer, the VENDLET HC-2 fulfils the appropriate requirements tested for.

However, the fulfilment of certain requirements may be related to the specific bed on which the VENDLET HC – 2 is mounted. Since not every combination of bed and VENDLET HC – 2 is foreseeable, such problems are described in the instructions for use and warned against by marking.

The testing took place in the period from 22.06.2006 to 18.09.2006.

The testing was carried out under normal indoor conditions.

The testing laboratory upon request can inform tolerances of measurements.

DESCRIPTION OF THE PRODUCT

The product tested as shown on the photography below is a turning sheet with electrical turning function and manual folding down to be mounted on a number of different types of beds. The product may be useful as a side rail as well.

According to the manufacturer the product may be used by persons up to 200 kg.



VENDLET HC-2 turning sheet.

The basic part of the product is a pair of motor drums around which a sheet is wrapped. The motor drums are controlled by a handset with which the carer may move the sheet sideways over the mattress in both directions. A built in timing function switch of the electrical system within 1.5 minutes after it has been reset. Hence, to operate the system for more than 1.5 minutes will require multiple resetting.

To obtain fulfilment of the standards requirements for side rails, a system of Plexiglas shielding to be mounted on the drums as shown has been provided. The use of the shielding is described in the instructions for use and is of decisive importance for the safety of the product.

TESTING RESULTS

TESTING ACCORDING TO EN 1970

		Requirements fulfilled
<p>4 General safety requirements</p> <p>To be checked by measurements:</p> <ul style="list-style-type: none"> • distances between moving parts within normal reach for fingers of the disabled person, the attendant or other persons shall always be either maximum 8 mm or more than 25 mm, • distances between moving parts and the floor within normal reach for feet of the disabled person, the attendant or other persons, shall always be either maximum 20 mm or fulfil the dimensional requirements given in figure 6, • distances between elements in end panels shall comply with the requirements for distances between elements in side rails (see 5.5.5), <p>Comments:</p> <ol style="list-style-type: none"> 1. There are a number of squeezing points in the folding system which are described and warned in the instructions for use. Using the Plexiglas shielding will eliminate the risks for the disabled person. 2. Will depend on the type of bed in use and the mounting of the sheet. Described in the instructions for use and marked. 3. Will obviously depend on the type of bed in use. There were no openings in the end panels of the bed used for the testing. 	<p>Ref. comment 1.</p> <p>Ref. comment 2.</p> <p>Ref. comment 3.</p>	<p>/</p> <p>/</p> <p>OK</p>
<p>To be checked by visual inspection:</p> <ul style="list-style-type: none"> • open ends of tubular components shall be capped or otherwise closed • all edges and corners shall be smooth and shall have no burrs or sharp edges and protruding parts shall be avoided • single use components, e.g. wood screws or self tapping screws, shall not be used for the assembly of any components that are intended to be removed when disassembling for the purposes of transportation and storage, • a control unit shall be reachable by the disabled person and the attendant, • a control unit shall have a hold-to-run function, <p>Comments:</p> <ol style="list-style-type: none"> 4. The control unit is not intended to be reachable for the user. 	<p>Ref. comment 4.</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>/</p> <p>OK</p>

5.4.11/12 Test of the strength and rigidity of side rails and grab handles

Position the side rail in the highest, upright position. The side rail shall be positively latched.

Apply a horizontal outward force of 500 N ten times for 30 seconds onto the side rail/grab handle in the most adverse point of its total length at a point that is not more than 50 mm under the highest point of the side rail/grab handle.

If the side rail has a locking mechanism, those of the forces as given above which will result in shear forces in the locking mechanism, shall also be applied to the element closest to the locking mechanism in any fixed height position.

Apply a force of 350 N ten times for 30 seconds onto the weakest point/element (in relation to deflection during application of loads and in relation to permanent deformation) of the side rail in the most adverse direction.

	Before loading	During loading	After loading	Deflection	Permanent deformation
500 N	102	105	102	3	0 mm
750 N	108	104	107	4	1 mm
500 N	162	158	162	4	0 mm
500 N	163	167	164	3	1 mm
500 N	61	43	60	18	1 mm
500 N	26	52	35	26	9 mm
					mm

- Loading direction
- A vertically upwards
 - B vertically downwards
 - C longitudinal towards foot end
 - D longitudinal towards head end
 - E horizontally inwards
 - F horizontally outwards
 - G locking mechanism
 - H weakest point

- When tested in accordance with 5.4.12 the side rail and grab handle shall**
- still function normally
 - present no hazards.
 - any locking mechanism of the side rail shall still be locked

Note: The deflection of the side rail/grab handle should not be greater than 50 mm during application of the loads and not greater than 10 mm at any point in relation to the bed board after removal of the loads

Comments:

OK
OK
OK

OK

5.5.5/6 Test of dimensions of side rails and grab handles				
<p>Press the relevant cone as specified in 5.2.6 between any elements of the side rail/grab handle and/or between any elements of the side rail/grab handle and their supporting structure with 30 N</p>				
<p>Side rails</p>				
A	Dimension between elements	120 mm	Ref. comment 5.	
B	Thickness of mattress	120 mm		
C	Distance from side rail top to mattress top	230 mm		
D	Distance to end panels / accessories	app. 30 mm	Ref. comment 6.	
E	Distance between segmented side rails	mm	Not applicable.	
F	Opening below side rail	120 mm	Ref. comment 5.	
G	Length	1890 mm	Ref. comment 7.	
H	Distance between end panels	2.100 mm		
<p>Distances (see figures 20 and 21) between elements of side rails/grab handles and between side rails/grab handles and elements of the bed/accessories shall fulfil the requirements given in table 1.</p>				OK
<p>Comments:</p>				
<p>5. Distance is app. 120 mm – a 120 Ø cone goes easily through. Using the Plexiglas shielding, however, will eliminate the problem.</p>				
<p>6. Provided that the Plexiglas shielding is in proper position as described in the instructions for use.</p>				
<p>7. This dimension does not include the Plexiglas shielding.</p>				

<p>5.5.8 Dimensions of the control unit</p> <p>Button covers a circle of: = 14 mm Minimum distance between buttons: = 10.5 mm</p> <p>The surface of buttons shall at least cover a circle of 15 mm in diameter. Any distance between buttons shall be more than 10 mm.</p> <p>Note: The buttons may have any shape, e.g. they need not to be circular</p> <p>Comments:</p> <p>8. The dimension is of little relevance since the control unit is not foreseen to be used by the disabled person. For a normally functioning person there is no difficulty in using the handset.</p>	<p>Ref. comment 8.</p>	<p>/ OK</p>
<p>5.6 Operating forces</p> <p>Control unit buttons: operating force = 1.8 N</p> <p>In the case of electrically operated functions, the force to operate the control unit buttons shall be less than 5 N.</p> <p>The force required to lift any part of the bed board shall be no more than 200 N, when loads are fixed to the bed board as shown in figure 22, with their centre of gravity in the middle of the sections.</p> <p>Comments:</p> <p>9. The force referred to here is the force required to fold down / up the motor drum. The force amounts to app. 100 N.</p>	<p>Ref. comment 9.</p>	<p>OK OK</p>

<p>6 Instructions for use</p> <p>The bed shall be accompanied by instructions for use which shall include the following information as a minimum:</p> <p>a Name of the manufacturer; NOTE: A trademark or logo is not sufficient to specify the manufacturer</p> <p>b The address and telephone number of the manufacturer</p> <p>c The intended use, e.g. that the bed is intended for adults from 12 years of age;</p> <p>d Full operating instructions, e.g. how to immobilize a bed supplied with wheels ,installation, e.g. that care should be taken, so that an electrically operated bed is placed with a distance to the power supply plug, and assembly instructions;</p> <p>e Requirements on inspection and servicing;</p> <p>f Cleaning and maintenance instructions;</p> <p>g Overall dimensions and mass, including the mass of main parts;</p> <p>h Safe working load (see 4.1)</p> <p>i Safety precautions and any warnings, e.g.: a warning that precautions shall be taken if accessories not listed are used; warning, if only to be used with certain identified hoists</p> <p>j Description of all symbols used for marking;</p> <p>k The weighted sound power level (see 5.13) if not included in the marking;</p> <p>l Identification of those accessories that are intended to be used with the bed.</p> <p>If electrically driven, the bed shall also be followed by instructions for use in accordance with the requirements of EN 60601-1.</p> <p>NOTE: Further guidance on instructions for use can be obtained from EN 1041</p>	<p>Not applicable.</p>	<p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p> <p>OK</p>
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7 Marking		
The bed/bed lift shall be clearly and permanently marked with the following information:		
A Name, address and telephone number of the manufacturer;	H. C. Equipment etc.	OK
B Product identification (model number or reference);	VENDLET HC - 2	OK
C Lot and individual production number;	Test 5	OK
D Year and month of production;	09 - 2006	OK
E If the bed is of knock-down type, the mass of any main part with a mass of more than 50 kg (see 4.2);	Not applicable.	
F Safe working load (as specified in 4.1 and 4.2);	200 kg	OK
G Electrical protection class (class I, II or III in accordance with EN 60601-1);		OK
H The range of width of the carriage in the case of adjustable carriage of the bed lift;	Not applicable.	
I The functions of controls;	Pictograms.	OK
J The weighted sound power level (see 5.13) if not included in the instructions for use;	Ref. Instructions for use	/
K The class of IPX.		OK
If electrically driven, the bed shall also be marked in accordance with the requirements of EN 60601-1.		OK

ADDITIONAL REMARKS AND TESTING RESULTS

Notice: Remarks and testing results on this page is not included in the accredited testing system

The timing system.

The built in timing system specified to switch off the system after 1.5 minutes after resetting as described on page 3 was tested functionally. It was found that the system switches of 1 minute and 29 seconds after resetting. The system is reset by pressing a button on the electronics box.

Fastening the sheet.

The sheet is fastened to the motor drum by means of Velcro tape and partly kept in place due to the sheet itself which is wrapped some turns around the motor drum. It was found that due to the motor gear type, one motor drum is able to pull the sheet and rotate the other motor drum and eventually to pull of the sheet from its drum.

Main switch.

The main switch on the electronics box may be used as an emergency switch as well since it have in its design the mechanical properties of an emergency switch. In the instructions for use the manufacturer recommends to switch of the system every time the carer leaves the system.