Product Service

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# Technical Report No. 713068233

**Revision: 1**
**dated 2015-09-11**

| | |
|---|---|
| Client: | Vendlet ApS<br>Egelund 33<br>6200 Aabenraa<br>DENMARK |
| Manufacturing place: | Vendlet ApS<br>Egelund 33<br>6200 Aabenraa<br>DENMARK |
| Test object: | Accessory for medical beds<br>Electronic device for handling/turning patients in medical beds,<br>type: VENDLET V5S / VENDLET V5S+ |
| Test specifications: | EN 60601-1-2-52:2010, clause 201.9.1.101<br>EN 60601-1-2-52:2010, clause 201.9.2.2 |
| Purpose of examination: | Testing according to the test specification(s). |
| Test result: | The test results show that the presented product is in compliance with the specified requirements. |





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## 1 Description of the test subject

Manufacturer's specification for intended use:
The VENDLET V5S and VENDLET V5S+ are used for handling bedridden patients, for example: Turning, moving from one side of the bed to the other, repositioning the patient up in the bed, mobilizing the patient in and out of the bed, transferring the patient from one bed to another

VENDLET V5S has a load capacity of 200 kg.
VENDLET V5S+ has a load capacity of 400 kg and is designed for bariatric patients


[HAN-184759-1]


[HAN-167623-1]



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## 2 Order

### 2.1 Date of Purchase Order

The testing of the test sample (VENDLET V5S) has been carried out per purchase order of Vendlet ApS dated 2015-08-17.

### 2.2 Date of Receipt of Test Subject

The testing has been performed at TÜV SÜD Product Service, Masurenweg 1-3, 30163 Hanover, GERMANY on 2015-08-19.

The test sample (VENDLET V5S) with the TÜV SÜD Product Service GmbH test sample ID HAN-184759-1 was delivered to the test laboratory on 2015-08-19.

The test sample (VENDLET V5S) with the TÜV SÜD Product Service GmbH test sample ID HAN-167623-1 was delivered to the test laboratory on 2015-04-21.

## 3 Test results

Possible test case verdicts:

| | |
|---|---|
| - test case does not apply to the test object | N(.A.) |
| - 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 client | C(omment) |
| - suffix for important information for factory inspection | M(anufacturing) |



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| Clause --- *Prüfpunkt* | Requirement + Test --- *Anforderung + Prüfung* | Result - Remark --- *Ergebnisse – Bemerkungen* | Verdict *Wertung* |
|---|---|---|---|
| **3.1** | **Protection against PATIENT entrapment in non-moving parts** [IEC 60601-2-52:2009, section 201.9.1.101]<br><br>Any openings or areas (A1, A2, A3, A4, A5, A6, B, C, and D) within the MEDICAL BED system and which are above the MATTRESS SUPPORT PLATFORM shall meet the dimensional and constructional requirements of Figures 201.107, 201.108 and Table 201.101.<br><br>Where a RISK of PATIENT entrapment exists and is addressed in another way this shall be justified by the MANUFACTURER in the RISK MANAGEMENT FILE. | **Area: A1**<br>Fully enclosed openings within the SIDE RAIL<br><br>Gap is specified to be less than 120 mm.<br><br>Result:<br>- 94 mm<br>- 80 mm<br>- 80 mm<br><br>**Area: A2**<br>Fully enclosed opening defined by the SIDE RAIL, its supports, and the MATTRESS SUPPORT PLATFORM<br><br>Gap is specified to be less than 120 mm<br><br>Result:<br>- 34 mm<br><br>**Area: C1**<br>Gap between the HEAD BOARD and adjacent SIDE RAIL.<br><br>*Gap between the HEAD BOARD and adjacent SIDE RAIL is required to be < 60 mm.*<br><br>Result:<br>The 60 mm cylinder tool did not slide into the Opening between HEAD BOARD and SIDE RAIL | P<br><br>P<br><br>P |



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| | | **Area: C2**<br>Gap between segmented or split SIDE RAILS with both SIDE RAILS raised.<br>*Gap between segmented or split SIDE RAILS with both SIDE RAILS raised is required to be*<br>*< 60 mm or > 318 mm.*<br><br>Result:<br>The 60 mm cylinder tool did not slide into the Opening between HEAD BOARD and SIDE RAIL<br><br>**NOTE: to meet the requirements of the test specification the height of side rail must be adjusted correctly as described in the user manual** | P |

Area: C1

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| **3.2** | **Gaps**<br>[IEC 60601-2-52:2009, section 201.9.2.2.2]<br><br>*Amendment:*<br>The locations identified in Figure 201.109 and 201.110 shall be considered as TRAPPING ZONES for fingers.<br>Distances between moving parts shall always be either less than 8 mm or more than 25 mm (as dimensioned in Figure 201.109).<br><br>The 200 mm cross-hatched area represents the areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM. The 200 mm distance can be measured taking into account any barrier preventing access to fingers (see Figure 201.110). The region within the APPLIED PART and above the MATTRESS SUPPORT PLATFORM shall be considered in the RISK ANALYSIS with regard to finger spacing between moving parts. | The area between the inner side of the side rail bar and the actuator is covered by a *cover plate*. | P |

Cover plate

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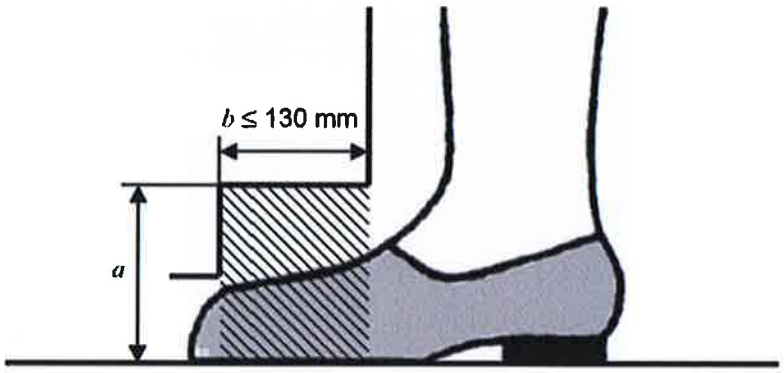
| **3.3** | The locations identified in Figures 201.111 a) and 201.111 b) shall be considered as TRAPPING ZONES for feet.<br>  <br><br>**Figure 201.111 a) Foot and toe clearance area between moving parts and the floor** | | |
| | **Foot and toe clearance area between moving parts and the floor**<br><br>For area where $b \leq 130$ mm;<br>shall always be $a \geq 120$ mm<br><br>NOTE The dimension "*a*" is only measured from the floor. The dimension "*b*" is measured from the outer edge of the MEDICAL BED. Including any permanently fixed ACCESSORIES (e.g. SIDE RAIL), if applicable. | Foot and toe clearance area between moving parts and the floor: 125 mm<br><br>Note: To adjust the height adjustment mechanism of the bed, the range of the actuator (LA31) can be set by a minimum height regulator. | P |

Minimum height regulator

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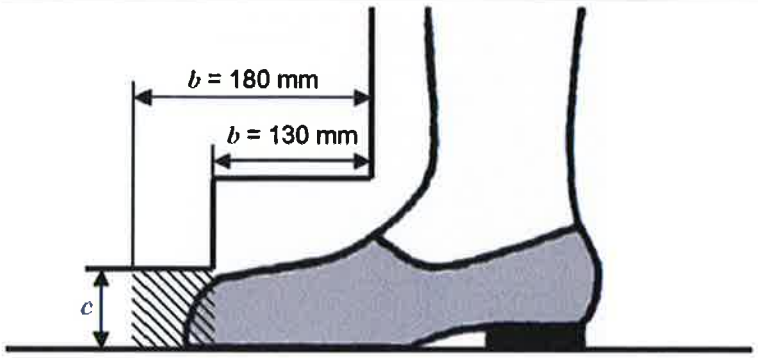
| 3.4 |  <br>**Figure 201.111 b) – Toe clearance area between moving parts and the floor** | | |
| | **Toe clearance area between moving parts and the floor**<br><br>For area where b is between 130 mm to 180 mm; shall always be c ≥ 50 mm.<br><br>NOTE The dimension "c" is only measured from the floor. The dimension "b" is measured from the outer edge of the MEDICAL BED. Including any permanently fixed ACCESSORIES (e.g. SIDE RAIL), if applicable. | Foot and toe clearance area between moving parts and the floor: 125 mm<br><br>Note: To adjust the height adjustment mechanism of the bed, the range of the actuator (LA31) can be set by a minimum height regulator. | P |

Foot and toe clearance area between moving parts and the floor

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## 4 Remarks

### 4.1 Remark to the test setup

The accessory for medical beds, type: VENDLET V5S was tested in combination with a medical bed. The testing of the medical bed was not part of the manufacturers order and not part of this testing.
In case of a full testing of the medical bed non-compliances can be located.

### 4.2 Remarks to user manual

The examination of the user manual was not part of the manufacturers order and not part of this testing.

## 5 Revision History

Rev.0: Initial Version
Rev.1: Test object: V5S / V5S+

test object was renamed,
- former product name: V5 / V5+
- new product name: V5S / V5S+

## 6 Summary

The test results show that the presented product is in compliance with the specified requirements.

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Technical report checked:

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