Test report No.: PB - 16 - 229 - MP - PA 088 - 05 - E

Devices against decubitus ulcer – Test according to test method 11-5 03/2004 MDS-Hi (examination of the operating loudness of motorized AD-systems) / English Version

Test institute:	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH Dovestr. 6, D-10587 Berlin Tel.: +49(0)30-314-25111, Fax: -23719
Client:	Drive Medical GmbH & Co. KG, Leutkircher Straße 44, D-88316 Isny/Allgäu
Manufacturer:	Drive Medical GmbH & Co. KG, Leutkircher Straße 44, D-88316 Isny/Allgäu
Test sample:	Product designation: MED AIRE FlexWave Type according to HMV: 11.29.08 Quantity / Identification: 1 / label Receipt / Condition: 2016-11-15 / new

Med Aire FlexWave

drive

Test standard:	test method 11-5 03/2004 MDS-Hi (examination of the operating loudness of motorized AD-systems)
Type of the test:	complete test
Test period:	2016-11-28 to 2016-12-05
Test site:	Rooms of the test institute
Test results (see page 3):	max. sound pressure level: 29 dB(A)

established: 2017-03-16

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released: 2017-03-16

Dipl.-Ing. M. Tettke

Note:
If a test method is not applicable it has to be indicated with “N/A” in the column “results / remarks”.
If a test method is not ordered it has to be indicated with “N/O” in the column “results / remarks”.
If it is not possible to make any definitions it has to be indicated with “N/D” in the correspondent column.

Test method:	**Results / remarks:**
1 Environmental conditions during testing:	
The measurements were made under standardized laboratory conditions.	

2.0 Preparatory operations / test setup for lying aids:	
The specimen has to be placed centricly and has to be fixed on a patient bed according to DIN EN 60601-2-38:2001-07 with a surface area of 190 cm x 90 cm according to the users instructions delivered by the manufacturer.	The specimen has been placed and fixed on a patient bed according to the manufacturer's specifications.
If the tested products are designated for special care according to PG 11, the bed's dimensions can differ.	N/A
The pump unit of the specimen has to be fixed on the patient bed respectively put on the floor according to the manufacturer's specifications in the users instructions. The specimen has to be put into operation according to the manufacturer's specifications in the users instructions.	The pump unit has been fixed on the patient bed and the specimen was put into operation according to the manufacturer's specifications. Positioning of the pump unit see Appendix I.
The specimen has to be loaded with the trunk and limbs model. The test has to be effected with a maximal loading as specified by the manufacturer in the users instructions.	Loading of the specimen with 200 kg. Adjustment of the pump unit: 200 kg.
If the specimen is an overlay-system the reference-mattress has to be placed on the patient bed first and then the overlay-system.	N/A
If the tested products are designated for special care according to PG 11, the dimensions of the reference-mattress can differ.	N/A

2.1 Preparatory operations / test setup for sitting aids:	
The specimen has to be placed on a plane board (at least 600 mm x 600 mm x 22 mm) according to the manufacturer's specifications in the users instructions. The maximum flexing with a loading of 300 N on an area of 400 mm x 400 mm is 5 mm.	N/A
For cushions which shall explicitly be used on convex surfaces only a support according to Figure 2 in the test method 11-5 is used.	N/A
The pump unit of the specimen has to be fixed according to the manufacturer's specifications in the users instructions. The specimen has to be put into operation according to the manufacturer's specifications in the users instructions. The cushion has to be loaded with the maximum loading specified by the manufacturer in the users instructions.	N/A

2.2 Preparatory operations / test setup for back systems:	
The specimen has to be fixed according to the manufacturer's specifications in the users instructions on a seating facility released by the manufacturer in the users instructions.	N/A
The pump unit of the specimen has to be fixed according to the manufacturer's specifications in the users instructions. The specimen has to be put into operation according to the manufacturer's specifications in the users instructions.	N/A

2.3 Execution of the sound pressure level measurement:		
The A-weighted sound pressure level which is caused by the device and to which the patient is exposed has to be measured under the following conditions:		
The device has to be set up according to paragraph 2.0 (lying aids) respectively 2.1 (sitting aids) respectively 2.2 (back systems).	setup according to paragraph 2.0 for lying aids	
Using a microphone, a sound test instrument fulfilling the requirements of type I according to IEC 60651, the sound pressure level is measured at the head position of the loading model (lying aids) respectively 1 m vertical above the center of the seating cushion (seating aids) respectively 1 m vertical above the seating of the seating facility according to paragraph 2.2 (back systems). The microphone has to be placed centric.	Positioning of the sound test instrument centric above the head of the loading model, see appendix I.	
It has to be ensured that the A-weighted external sound is at least 10 dB lower than the determined result during testing.	External sound during testing: 13 dB(A)	
Using a sound level measure instrument the measurement has to be made by using the frequency-weighted characteristic A and the time-weighted characteristic F in a free acoustic field above a reflecting plane according to ISO 3744.	2 measurements were effected:	
	measurement 1:	29 dB(A)
	measurement 2:	29 dB(A)
If several positions are designated for the pump unit according to the manufacturer's specifications in the users instructions the above-mentioned measurement has to be repeated for every position.	Altogether provided for 2 positions , positioning see appendix I.	

3 Valuation of the test results:
By determining the operating loudness of the specimen a maximum value of 29 dB(A) was measured centric above the head of the loading model, thereby the specimen was placed hanging centric at the foot end / centric on the floor at the foot end.

Description of the device (manufacturer's specifications):	
Used materials:	Aggregat: Gehäuse aus Kunststoff Zellen: Nylon / PU Bezug: Nylon / PU
Structure of the device:	Aggregat und CellonCell Luftkammerauflage
Cover of the device:	abgesteppt, wasserabweisend, atmungsaktiv, feuerfest
Maximal patient's weight [kg]:	200
Minimal patient's weight [kg]:	20
Required base mattress (overlay-system):	nicht notwendig
Applications (indication):	Dekubitusprophylaxe bei hohem bis sehr hohem Risiko; Druckverteilung und Druckentlastung bei immobilen und teilimmobilen Patienten; Dekubitustherapie bis einschl. Grad 4 nach EPUAP; Die statische Weichlagerung eignet sich für: Patienten, die dynamischen Wechseldruck nur zeitweise oder gar nicht tolerieren; Schmerzpatienten
Criterion of exclusion (contraindication):	bei einem Körpergewicht unter 20 kg und über 200 kg; bei instabile Frakturen (insbesondere im Rückenbereich, Hals- und Lendenwirbelsäule) bei neurologischen Erkrankungen, bei denen dynamischer Wechseldruck nicht angewandt werden soll, darf nur die statische Weichlagerung angewandt werden; Um Unsicherheiten in Bezug auf Indikation und Kontraindikation zu vermeiden, empfehlen wir, den behandelnden Arzt zu konsultieren.
Boundary conditions (cover etc.) / other limitations (patient's bed):	Bettmaß 90x200cm
Sort of the microclima-regulation (active / passive):	aktiv
For alternating systems: adjustments for the pressure-cycle-times (if variable, additionally the recommended adjustments)	10/15/20/25 Minuten Empfehlung 10/15 Minuten

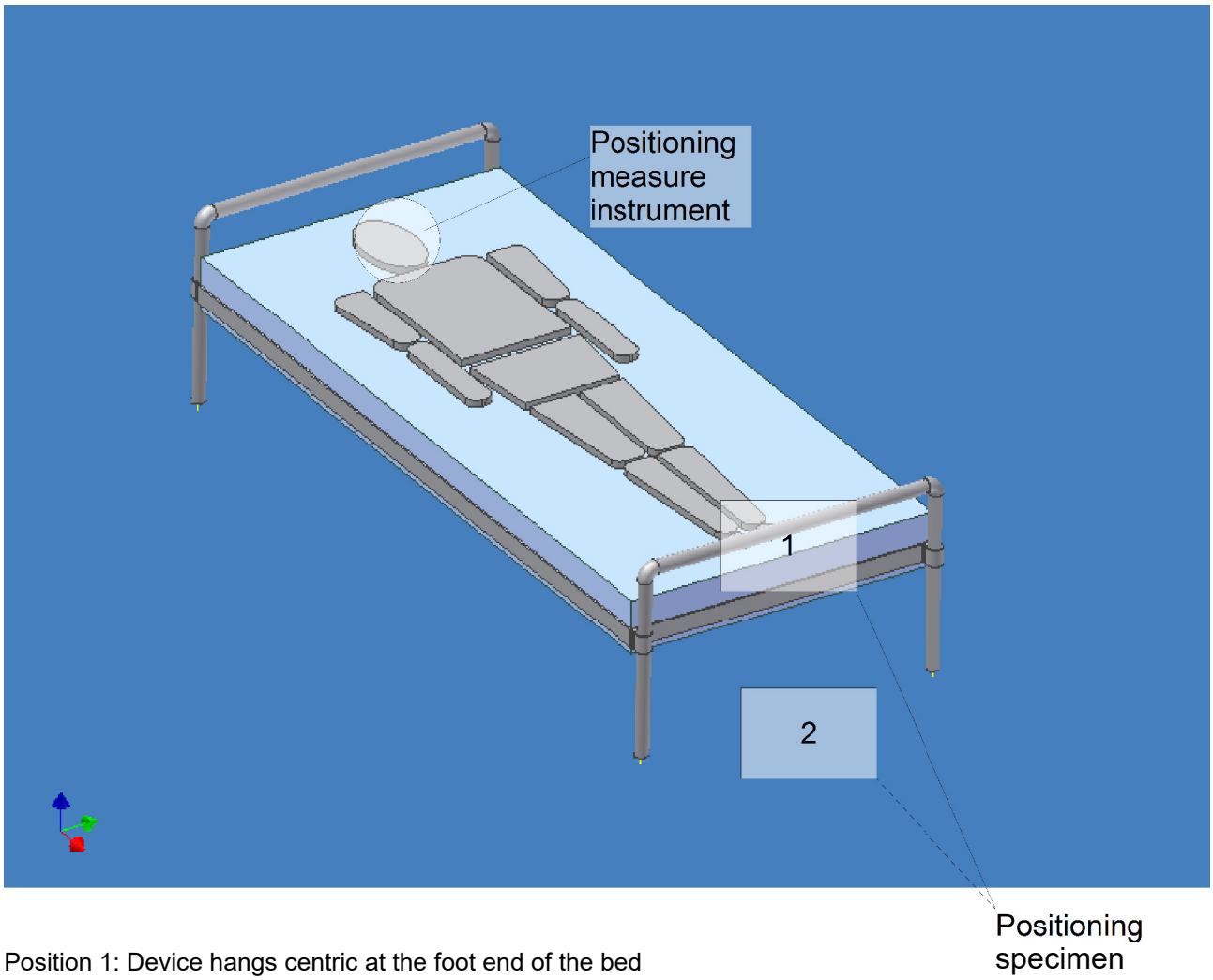
Transferability:		
The results of this test report are transferable to the following products: No transferability		
article number	*product designation*	*remarks*
N/A	N/A	N/A
N/A	N/A	N/A

Appendices:	
Appendix I:	Positioning(s) of the specimen
Appendix II:	Photo-documentation of the specimen

Accessories and submitted documentation:
Users manual (revision level 2016-11 / German)
Air pump (REF 820000300)

Test equipment:	
PM 1031	Impulse Precision Level Sound Meter

Appendix I: Positioning(s) of the specimen



Position 1: Device hangs centric at the foot end of the bed

Position 2: Device stands centric on the floor at the foot end

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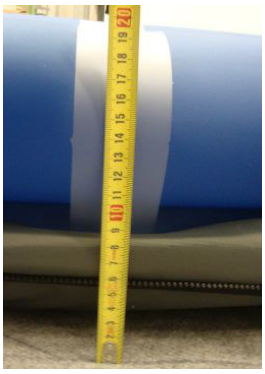
Appendix II: Photo-documentation

Sample:



Accessories: