Test report No.: PB - 16 - 227 - MP - PA 088 - 02 - E

Devices against decubitus ulcer – Test according to test method 11-2 03/2004 MDS-Hi (examination of the microclimatic characteristics) / English Version

BERLIN CERT AFNOR Group

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 Wave Type according to HMV: 11.29.04 Quantity / Identification: 1 / label Receipt / Condition: 2016-11-15 / new

Test standard:	Test method 11-2 03/2004 MDS-Hi (examination of the microclimatic characteristics)
Type of the test:	complete test
Test period:	2017-01-09 to 2017-02-09
Test site:	Rooms of the test institute
Test results (see page 3):	classification microclima: class G

established: 2017-03-16

B.Sc. L. Lehmann

released: 2017-03-16

Dipl.-Ing. M. Tettke

This test report may not be published in abstracts or duplicated without the written permission of the Berlin Cert GmbH. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the other products in regular production.

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:		
Room ambient temperature:	(23 ± 2) °C	Measured value: 21,6 °C
Relative humidity:	(40 ± 5) % rF	Measured value: 39,2 % rF
Air pressure:	(960 ± 100) hPa	Measured value: 1030 hPa

2 Preparatory operations:	
2.1 If the specimen is detachable it has to be assembled as described in the users instructions delivered by the manufacturer.	The detachable specimen was delivered in assembled condition by the manufacturer.
2.2 The specimen has to be unpacked and has to be conditioned for at least 12 hours at a temperature of (23 ± 2) °C and a relative humidity of (40 ± 5) %. Thereby it has to be placed on the patient's bed with flat bed-head / base part according to the manufacturer's specifications in the users instructions. If the specimen is an overlay-system the reference-mattress has to be placed on the patient's bed first and then the overlay-system.	The conditioning took place on 2017-01-05.
2.3 During conditioning and also during testing the cover delivered by the manufacturer has to be used.	The delivered cover was used.

3 Examination of the microclimatic characteristics:	
The test of the microclimatic characteristics are made according to index number 2.3 of the test method 11-2 03/2004 MDS-Hi.	Diagrams of the measured values are in the appendix.
Test duration:	60 minutes

4 Evaluation:	
The evaluation of the recorded values are made according to index number 2.4 of the test method 11-2 03/2004 MDS-Hi. The valuation and the classification of the device are based on the final values measured.	
Peak value of the temperature:	28,4 °C
Final value of the temperature:	28,4 °C
Peak value of the relative humidity:	79,3 % rF
Final value of the relative humidity:	79,3 % rF

5 Valuation of the device:
The final values of the temperature and the relative humidity in the area of contact between the microclimatic simulator and the sample after a test duration of one hour were 28,4 °C for the temperature and 79,3 % rF for the relative humidity. The device has a low transportation of humidity and is classified in class G.

Description of the device (manufacturer's specifications):	
Used materials:	Aggregat: Gehäuse aus Kunststoff Zellen: Nylon / PVC Bezug: Nylon / PU
Structure of the device:	Aggregat und Luftkammerauflage
Cover of the device:	wasserabweisend, atmungsaktiv, feuerfest
Maximal patient's weight [kg]:	140
Minimal patient's weight [kg]:	30
Required base mattress (overlay-system):	Mindestens 4 cm hohe Schaumstoffunterlage
Applications (indication):	Dekubitusprophylaxe bei niedrigem bis mittlerem Dekubitusrisiko Druckverteilung und Druckentlastung bei immobilen und teilimmobilen Patienten Dekubitustherapie bis einschl. Grad 2 nach EPUAP
Criterion of exclusion (contraindication):	bei einem Körpergewicht unter 30 kg und über 140 kg bei Instabile Frakturen (insbesondere im Rückenbereich, Hals- und Lendenwirbelsäule) bei neurologischen Erkrankungen, bei denen dynamischer Wechseldruck nicht angewandt werden darf Schmerzpatienten 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

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

Accessories and submitted documentation:
Users manual (revision level 2016-11 / German)
Air pump (REF 820000100)

Appendices:	
Appendix I:	Description of the test structure
Appendix II:	Diagrams of the measured values of the temperature and the relative humidity
Appendix III:	Photo-documentation of the sample including accessories

Test equipment:	
PM 3087	combo-pickup, Type HygroClip HS 28 of the company rotronic
PM 3037	Microclimatic module
PM 3036	Loading test device
PM 3042	Patient's bed
PM 3046	Model of the body

Appendix I: Description of the test structure

To simulate transpiration and heat supply, a transpiration model is used, where an evaporating chamber is coupled to the test piece via a porous plate (see Fig. 1). Distilled water is vaporised in the evaporating chamber so that the test piece is subjected to a defined amount of water vapour through the membrane. The heat supply to the chamber is set so that a temperature of (33 ± 1)°C is reached on the outer surface of the membrane. The complete simulation module is loaded with a total weight of 35 kg so that the compression corresponds to an average patient load. Additionally the aid is loaded with a body model. The measurement of the humidity and the temperature are made with a combined temperature-humidity sensor type HygroClip HS 28 of the company rotronic. The sensors are inside a sword pick-up with a length of 280 mm. The cross-section in the area of the sensors is 18 mm x 4 mm. The temperature sensor is a PT100 pick-up, the humidity determination is made with a capacitive sensor. For signal processing respectively as Data logger and display unit an instrument of the type HygroLog D is used. The determined values are passed to a computer by a serial interface and are analysed there. The maximum measuring inaccuracy is, according to the calibration certificate of the company rotronic, for the relative humidity ± 1 % rF and for the temperature ± 0,3 °K within the climate relevant for the measurement.

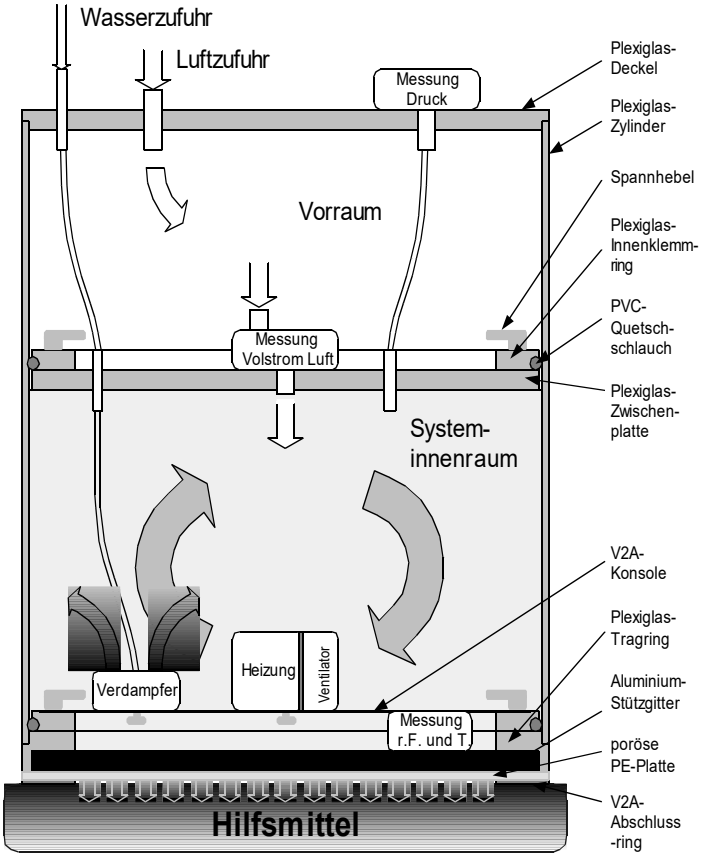


Figure 1: Microclimate module

Wasserzufuhr – Water supply
Luftzufuhr - Air supply
Messung – Measurement
Druck – Pressure
Vorraum - Front chamber
Volstrom Luft - Full air stream
Innenraum - Inner chamber
Verdampfer – Evaporating apparatus
Heizung – Heating
Ventilator – Ventilator
Hilfsmittel – Aid

Plexiglas Deckel – Plexiglas cover
Zylinder – Cylinder
Spannhebel - Tension lever
Innenklemmring – Inner clamp ring
Quetschschlauch - Collapsible tube
Zwischenplatte – Spacer plate
Konsole – Console (bracket)
Tragring - Supporting ring
Stützgitter - Support mesh
poröse Platte – Porous plate
Abschlussring - End ring

Appendix II: Diagrams of the measured values of the temperature and the relative humidity

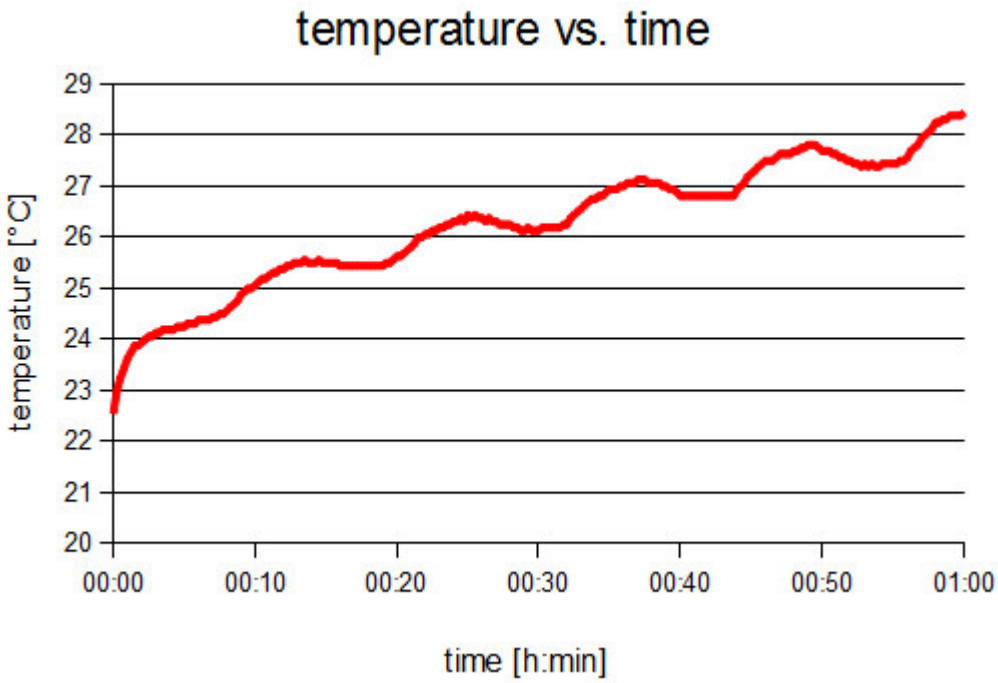


Diagram 1: temperature vs. time

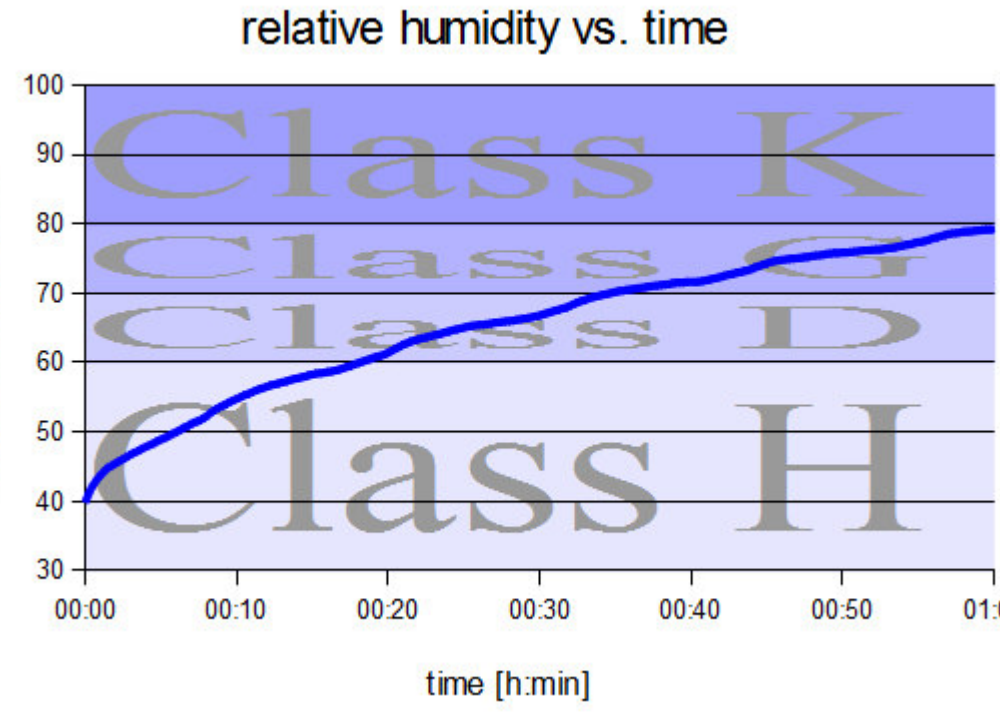
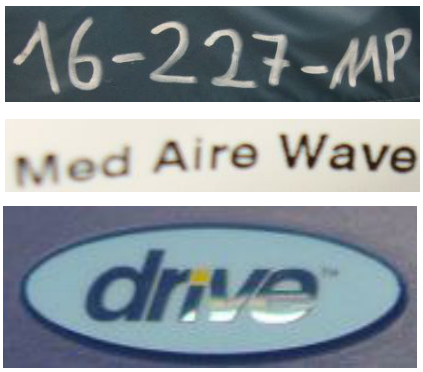


Diagram 2: relative humidity vs. time

BERLIN CERT AFNOR Group

Appendix III: Photo-documentation

Sample:



Accessories: