Test report No.: PB - 16 - 229 - MP - PA 088 - 04 - E

Devices against decubitus ulcer – Test according to test method 11-4 03/2004 MDS-Hi (examination of the shear force and the pressure relief capability) / 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 11-4 03/2004 MDS-Hi (examination of the shear force and the pressure relief capability)
Type of the test:	complete test
Test period:	2017-01-09 to 2017-02-23
Test site:	Rooms of the test institute
Test results (see page 8):	pressure relief capability classification for 80 kg: H pressure relief capability classification for 200 kg: G

established: 2017-03-16

B.Sc. L. Lehmann

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:		
Room ambient temperature:	(23 ± 2) °C	Measured value: 21,4 °C
Relative humidity:	(40 ± 5) % rF	Measured value: 40,1 % rF
Air pressure:	(960 ± 100) hPa	Measured value: 1024 hPa

2 Examination of the pressure relief capability	
Static support surfaces have to be tested according to index number 2.4 of the test method 11-4 03/2004 MDS-Hi.	Applicable: ☐ Yes ☒ No
Dynamic support surfaces have to be tested according to index number 2.5 of the test method 11-4 03/2004 MDS-Hi.	Applicable: ☐ Yes ☒ No
A dynamic system that can also be used statically analogous to a continuous pressure relief (according to the manufacturer's specifications) has to be tested according to index numbers 2.4 and 2.5.	Applicable: ☒ Yes ☐ No
2.1 Preparatory operations:	
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.
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 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 bed first and then the overlay-system.	The conditioning took place on 2017-01-05.
If the manufacturer prescribes an adjustment of the device before usage it has to be done according to the users instructions.	The adjustment was made according to the manufacturer's specifications.
During conditioning and also during testing the cover delivered by the manufacturer has to be used.	The delivered cover was used.
The support surface has to be heated up to a temperature of (33 ± 1) °C in the loaded area.	The heating took place.

2.2 Execution of the tests	
2.2.1 Test of static antidecubitus-systems	
Test with a patient weight of 80 kg:	
Loaded with:	80 kg (24 kg from the model of the sacrum and 56 kg from the body-model)
Number of effected measurements:	3
Test with a maximum patient weight of 200 kg (according to manufacturer's specifications):	
Loaded with:	200 kg (60 kg from the model of the sacrum and 140 kg from the body-model)
Number of effected measurements:	3
Reference measurement (80 kg):	
Loaded with:	80 kg (24 kg from the model of the sacrum and 56 kg from the body-model)
Number of effected measurements:	3
Reference measurement (200 kg):	
Loaded with:	200 kg (60 kg from the model of the sacrum and 140 kg from the body-model)
Number of effected measurements:	3
2.2.2 Test of dynamic antidecubitus-systems	
Test with a patient weight of 80 kg:	
Loaded with:	80 kg (24 kg from the model of the sacrum and 56 kg from the body-model)
Measurement over a period of at least 3 pressure-cycles.	
Number of effected measurements: (Positioning of the ischial tuberosities at the vertice of the air cell, at the seam between two air cells and between these positions – see picture 5 in appendix I.)	3
Test with a maximum patient weight of 200 kg (according to manufacturer's specifications):	
Loaded with:	200 kg (60 kg from the model of the sacrum and 140 kg from the body-model)
Measurement over a period of at least 3 pressure-cycles.	
Number of effected measurements: (Positioning of the ischial tuberosities at the vertice of the air cell, at the seam between two air cells and between these positions – see picture 5 in appendix I.)	3

2.3 Evaluation	
2.3.1 Evaluation for static antidecubitus-systems	
Results of the test with a patient weight of 80 kg:	
Peak pressure p_{max}:	30,1 mmHg
Average pressure p_{mittel}:	9,3 mmHg
Loaded area A:	474 cm²
Pressure Area Index:	10 mmHg: 0,64
	20 mmHg: 0,90
	30 mmHg: 0,97
	40 mmHg: 0,98
Values of the reference measurement (80 kg):	
Peak pressure p_{max}:	39,4 mmHg
Average pressure p_{mittel}:	10,0 mmHg
Loaded area A:	567 cm²
relative pressure relief D_{rel}: $D_{rel} = \frac{p_{ref} - p_{prüf}}{p_{ref}}$ The calculation is effected by the measured peak pressures.	D_{rel} = 0,24 (corresponds to 24%)
Results of the test with a maximum patient weight of 200 kg (according to manufacturer's specifications):	
Peak pressure p_{max}:	63,2 mmHg
Average pressure p_{mittel}:	27,5 mmHg
Loaded area A:	1146 cm²
Pressure Area Index:	10 mmHg: 0,23
	20 mmHg: 0,33
	30 mmHg: 0,53
	40 mmHg: 0,80
Values of the reference measurement (200 kg):	
Peak pressure p_{max}:	66,2 mmHg
Average pressure p_{mittel}:	23,6 mmHg
Loaded area A:	1137 cm²
relative pressure relief D_{rel}: $D_{rel} = \frac{p_{ref} - p_{prüf}}{p_{ref}}$ The calculation is effected by the measured peak pressures.	D_{rel} = 0,05 (corresponds to 5%)

2.3.2 Evaluation for dynamic antidecubitus-systems	
Results of the test with a patient weight of 80 kg:	
Peak pressure p_{max}:	54,2 mmHg
Minimum pressure p_{min}:	23,1 mmHg
Average pressure p_{mittel}:	40,5 mmHg
Time of a cycle t_Z:	640 s
Pressure Relief Index (PRI): $PRI = \frac{t_1 + t_2}{t_Z}$ (see figure 4 in appendix I)	10 mmHg: 0,00
	20 mmHg: 0,06
	30 mmHg: 0,14
	40 mmHg: 0,43
Results of the test with a maximum patient weight of 200 kg (according to manufacturer's specifications):	
Peak pressure p_{max}:	83,3 mmHg
Minimum pressure p_{min}:	43,0 mmHg
Average pressure p_{mittel}:	65,5 mmHg
Time of a cycle t_Z:	643 s
Pressure Relief Index (PRI): $PRI = \frac{t_1 + t_2}{t_Z}$ (see figure 4 in appendix I)	10 mmHg: 0,00
	20 mmHg: 0,00
	30 mmHg: 0,00
	40 mmHg: 0,04

3 Examination of the characteristics causing shear forces	
3.1 Preparatory operations:	
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.
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 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 bed first and then the overlay-system.	The conditioning took place on 2017-01-05.
If the manufacturer prescribes an adjustment of the device before usage it has to be done according to the users instructions.	The adjustment was made according to the manufacturer's specifications.
During conditioning and also during testing the cover delivered by the manufacturer has to be used.	The delivered cover was used.
The support surface has to be heated up to a temperature of (33 ± 1) °C in the loaded area.	The heating took place.
3.2 Execution of the tests	
Loaded with:	80 kg (25 kg from the model of the sacrum and 55 kg from the body-model)
Velocity of pulling:	5 mm/s
Number of effected measurements:	3
Values obtained in static use:	
Maximum pulling force F_{Max}	188 N
Normal force W	245 N
Mean pulling force during slip-phase F_{Quer}	185 N
Values obtained in dynamic use:	
Maximum pulling force F_{Max}	197 N
Normal force W	245 N
Mean pulling force during slip-phase F_{Quer}	191 N

3.3 Evaluation	
3.3.1 shear force measurement in static mode	
Coefficient of cohesive friction μ_H between patient and interface	
The static coefficient of friction is calculated by the maximum pulling force (F_{max}) divided by the normal force (W). $\mu_H = \frac{F_{Max}}{W}$	μ_H = 0,77 ± 0,04
Coefficient of sliding friction μ_G between patient and interface	
The dynamic coefficient of friction is calculated by the average pulling force during sliding (F_{Quer}) divided by the normal force (W). $\mu_G = \frac{F_{Quer}}{W}$	μ_G = 0,75 ± 0,05
Horizontal Stiffness Φ_H of the device	
The horizontal stiffness is calculated as follows: $\Phi_H = \frac{F_2 - F_1}{(t_1 - t_2)\, v}$	Φ_H = (4,71 ± 0,19) N/mm

3.3.2 Evaluation of the shear force measurement in dynamic mode	
Coefficient of cohesive friction μ_H between patient and interface	
The static coefficient of friction is calculated by the maximum pulling force (F_{max}) divided by the normal force (W). $\mu_H = \frac{F_{Max}}{W}$	μ_H = 0,81 ± 0,01
Coefficient of sliding friction μ_G between patient and interface	
The dynamic coefficient of friction is calculated by the average pulling force during sliding (F_{Quer}) divided by the normal force (W). $\mu_G = \frac{F_{Quer}}{W}$	μ_G = 0,78 ± 0,01
Horizontal Stiffness Φ_H of the device	
The horizontal stiffness is calculated as follows: $\Phi_H = \frac{F_2 - F_1}{(t_1 - t_2)\, v}$	Φ_H = (4,85 ± 0,40) N/mm

4 Valuation of the device:

Loading of the device with 80 kg:
According to test method 11-4 03/2004 MDS-Hi paragraph 2.4 the tested device has a pressure relief of $D_{rel} \geq 20$ % (determined: 24%) relating to the reference mattress and has to be classed in class H.

According to test method 11-4 03/2004 MDS-Hi paragraph 2.5 the tested device has the following specific values:
- peak pressure: 54,2 mmHg
- minimum pressure: 23,1 mmHg
- average pressure: 40,5 mmHg

Loading of the device with 200 kg:
According to test method 11-4 03/2004 MDS-Hi paragraph 2.4 the tested device has a pressure relief of $0\ \% < D_{rel} < 10\ \%$ (determined: 5%) relating to the reference mattress and has to be classed in class G.

According to test method 11-4 03/2004 MDS-Hi paragraph 2.5 the tested device has the following specific values:
- peak pressure: 83,3 mmHg
- minimum pressure: 43,0 mmHg
- average pressure: 65,5 mmHg

Examination of the shear forces in static mode:
According to the test defined in the test method 11-4 03/2004 MDS-Hi the tested device has the following specific values:
- Maximum pulling force F_{max}: 188 N
- Mean pulling force during slip-phase F_{quer}: 185 N
- Coefficient of sliding friction μ_G: 0,75 ± 0,05
- Horizontal Stiffness Φ_H: (4,71 ± 0,19) N/mm

Examination of the shear forces in dynamic mode:
According to the test defined in the test method 11-4 03/2004 MDS-Hi the tested device has the following specific values:
- Maximum pulling force F_{max}: 197 N
- Mean pulling force during slip-phase F_{quer}: 191 N
- Coefficient of sliding friction μ_G: 0,78 ± 0,01
- Horizontal Stiffness Φ_H: (4,85 ± 0,40) N/mm

Transferability:

The results of this test report are transferable to the following products:
No transferability

Pressure relief capability		
article number	*product designation*	*remarks*
N/A	N/A	N/A
N/A	N/A	N/A
Shear force		
article number	*product designation*	*remarks*
N/A	N/A	N/A
N/A	N/A	N/A

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 kg
Minimal patient's weight [kg]:	20 kg
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

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

Appendices:	
Appendix I:	Description of the test structure for the examination of the pressure relief capability
Appendix II:	Description of the test structure for the examination of shear forces
Appendix III:	Graphs of the isobars of the static pressure distribution
Appendix IV:	Graphs „Pressure vs. Time“ of the dynamic pressure distribution
Appendix V:	Diagram “pulling force vs. time”
Appendix VI:	Photo-documentation of the sample including accessories

Test equipment:	
PM 3038	sacral area model (pressure relief)
PM 3036	Loading device
PM 3042	patient's bed
PM 3046	Model of the body
PM 3040	Measurement system for distribution of pressure
PM 3047 #1	Reference mattress
PM 3039	Sacrum model (shear forces)

Appendix I: Description of the test structure for the examination of the pressure relief capability

To determine the pressure-relieving characteristics, a sacral area model is used, which simulates the bony structures of the ischial protuberances and the coccyx. The bone models are covered by a 4 cm thick mat of interlaced polymerised gel which is fastened to a frame (see Figure 1). The settings and dimensions are orientated to physiological features. The surface in contact with the test item is heated to (33 ± 1) ºC. The loading device applies a controlled force (predetermined test weight) on to the sacral area model.

To measure pressure distribution, a measuring system of the company NOVEL GmbH is used. It consists of a sensor field with 32 x 32 (altogether 1024) capacitive single sensors. The resolution is 1,875 mmHg.

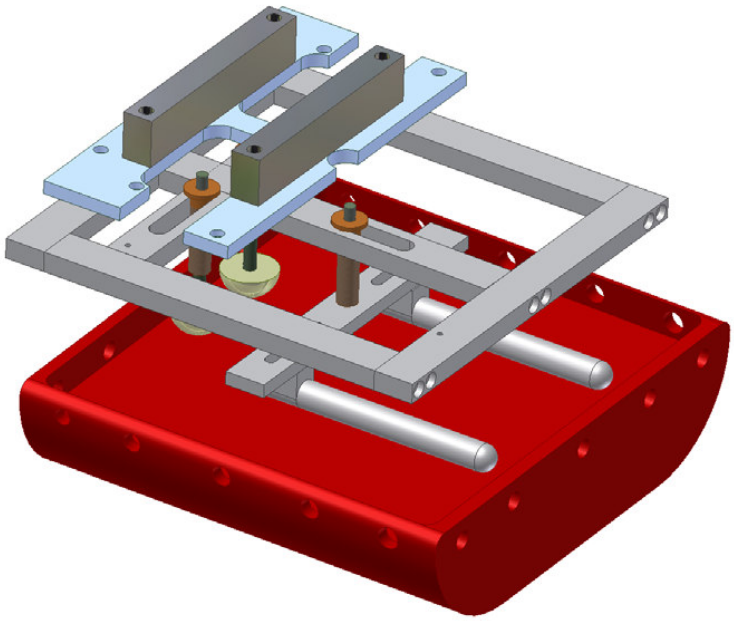

Figure 1: set-up of sacral area model

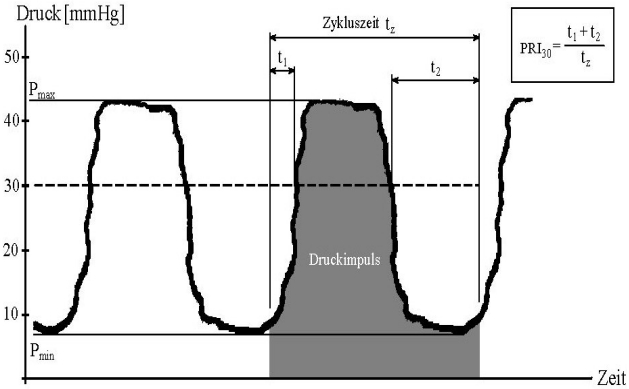

Figure 2: pressure vs. time

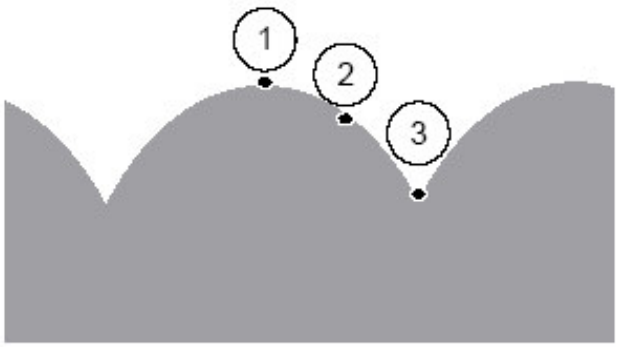

Figure 3: Position of the ischial tuberosities

Appendix II: Description of the test structure for the examination of shear forces

To determine the characteristics causing shear stress, a simulation model is used which applies a load to the cushion with a defined crosswise movement and thus measures the lateral forces which occur. The test method is based on a method from a draft of 16840 for to detect the frictional properties of a cushion. The test will be performed for a patient weight of 80 kg, whereas the sacrum model will have a total weight of 35 kg. When testing special care products according to Technical Aid Directory PG 11, a different typical load must be employed when necessary. Measurements for this range are to carried out in an analogue manner.

The moving velocity of the sacrum model is 5 mm/s. The measured force is sampled with a frequency of 500Hz. The set-up is shown in Figure 4.

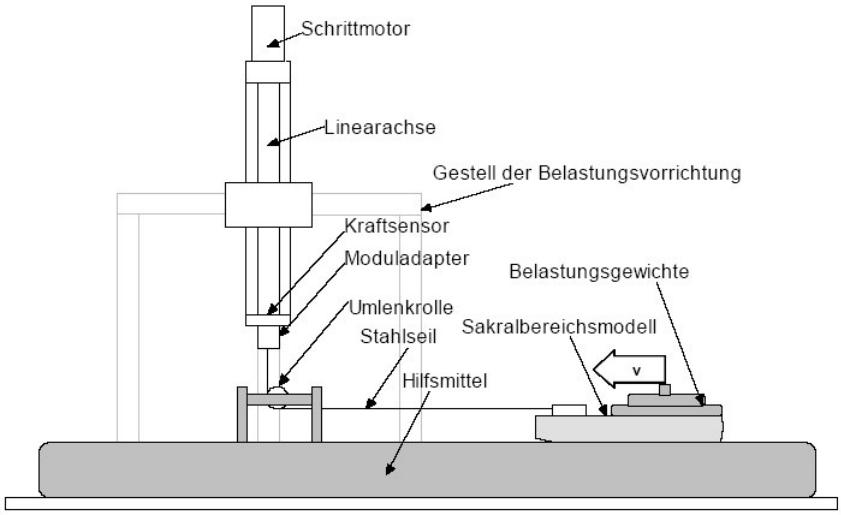

Figure 4: set-up for shear force measurement

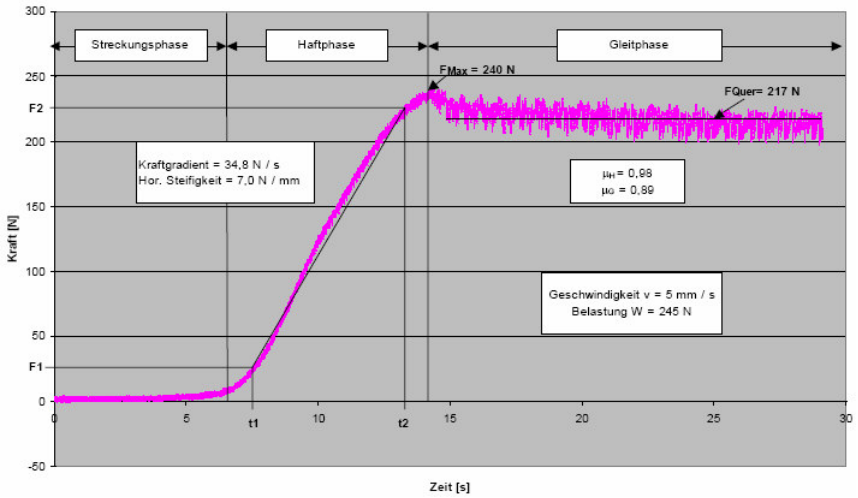

Figure 5: diagram pulling force vs. time

Appendix III: Static pressure distribution

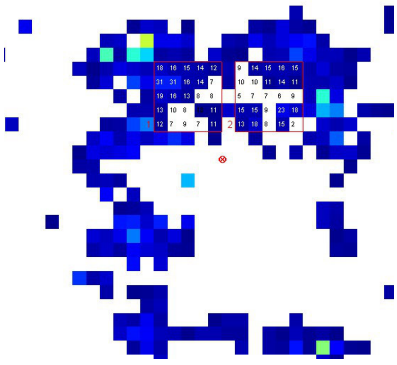

Figure 6: static pressure distribution – 80 kg load - 1

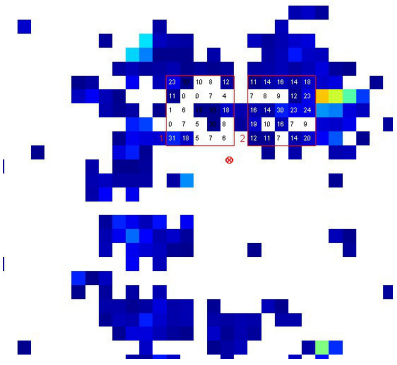

Figure 7: static pressure distribution – 80 kg load - 2

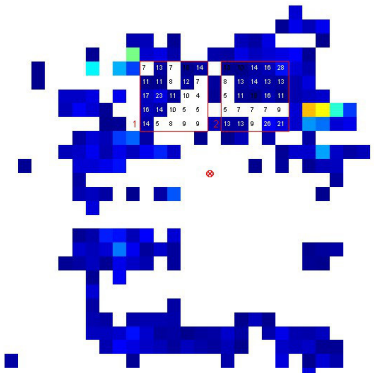

Figure 8: static pressure distribution – 80 kg load - 3

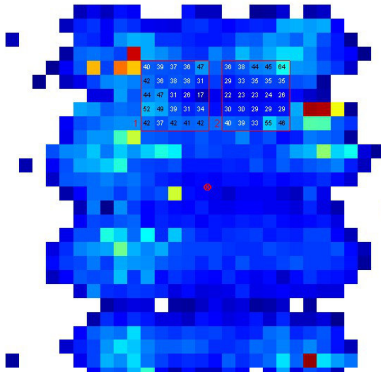

Figure 9: static pressure distribution – 200 kg load - 1

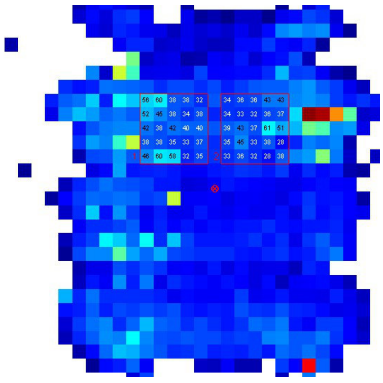

Figure 10: static pressure distribution – 200 kg load - 2

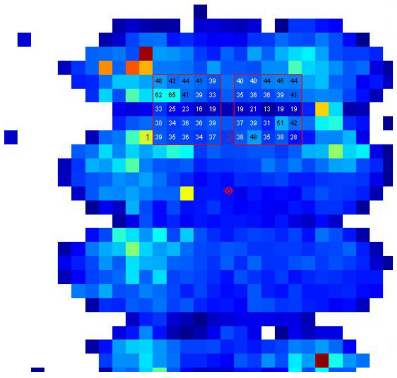

Figure 11: static pressure distribution – 200 kg load - 3

Appendix IV: „Pressure vs. Time“ of the dynamic pressure distribution

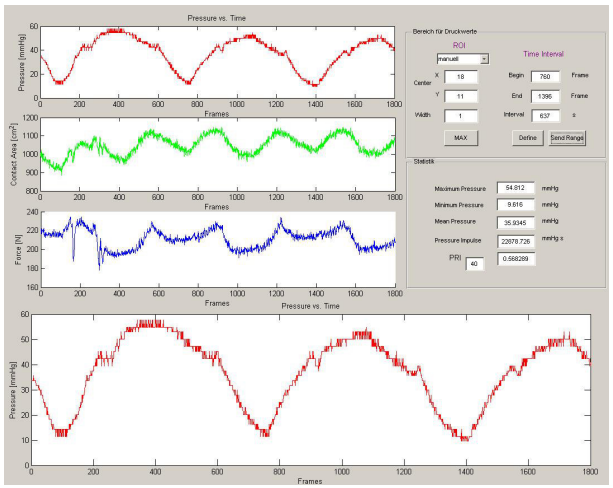

Figure 12: dynamic pressure distribution – 80 kg load - 1

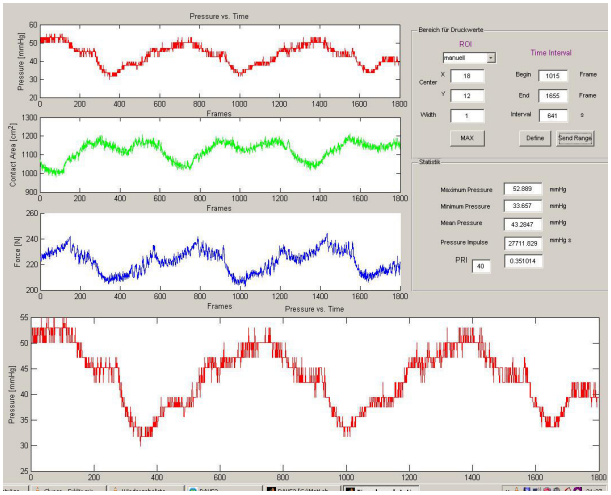

Figure 13: dynamic pressure distribution – 80 kg load - 2

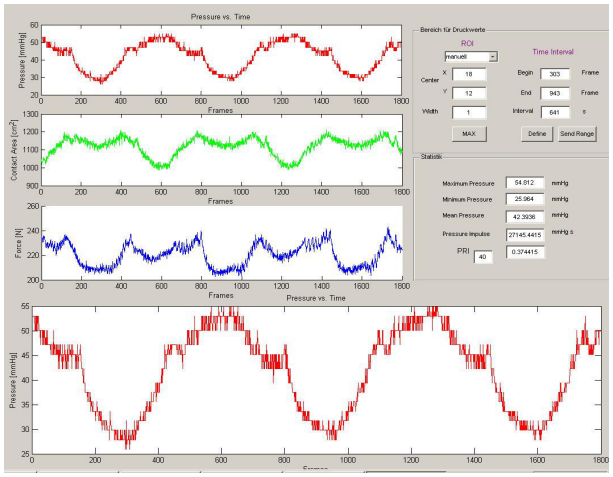

Figure 14: dynamic pressure distribution – 80 kg load - 3

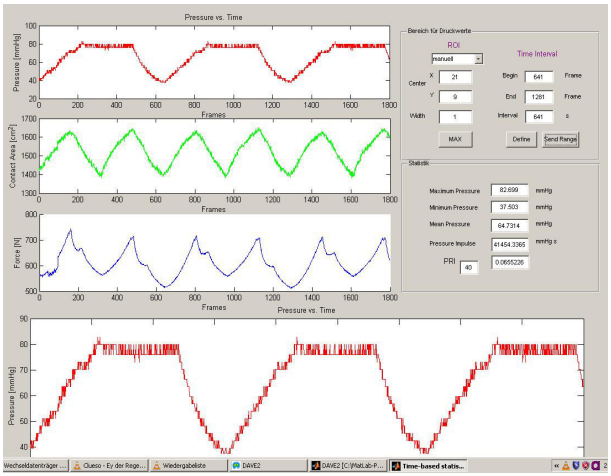

Figure 15: dynamic pressure distribution – 200 kg load - 1

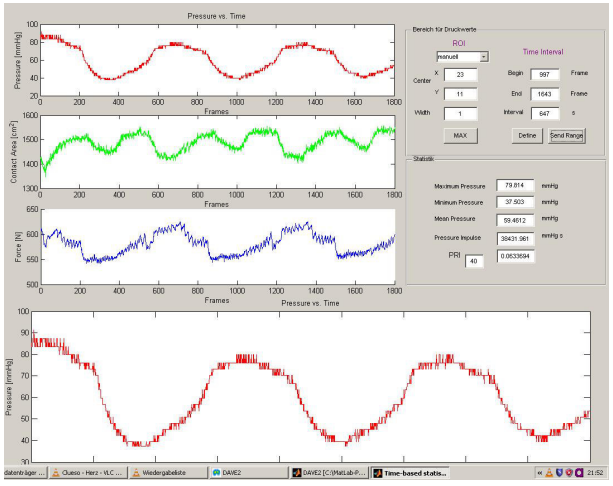

Figure 16: dynamic pressure distribution – 200 kg load - 2

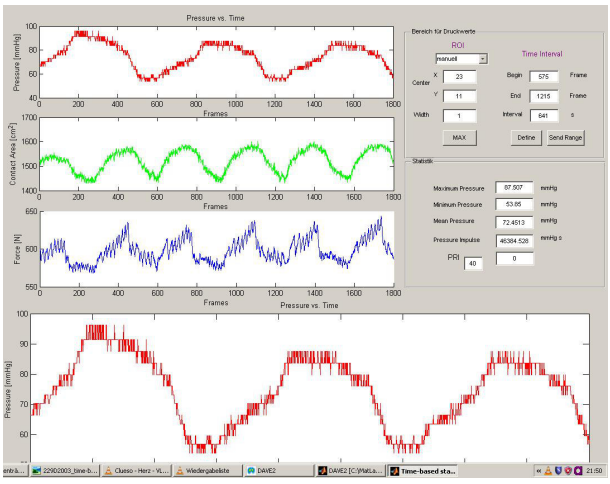

Figure 17: dynamic pressure distribution – 200 kg load - 3

Appendix V: Diagram “pulling force vs. time”

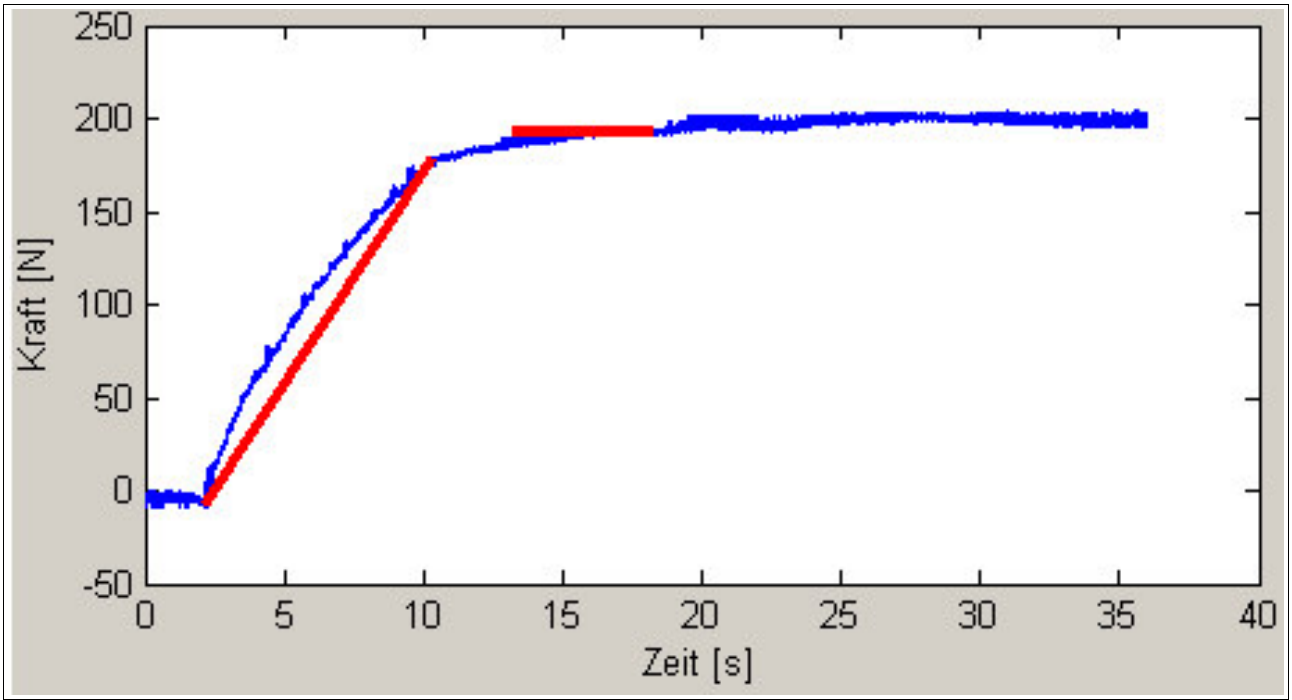

Figure 18: measurement of the shear force in static mode

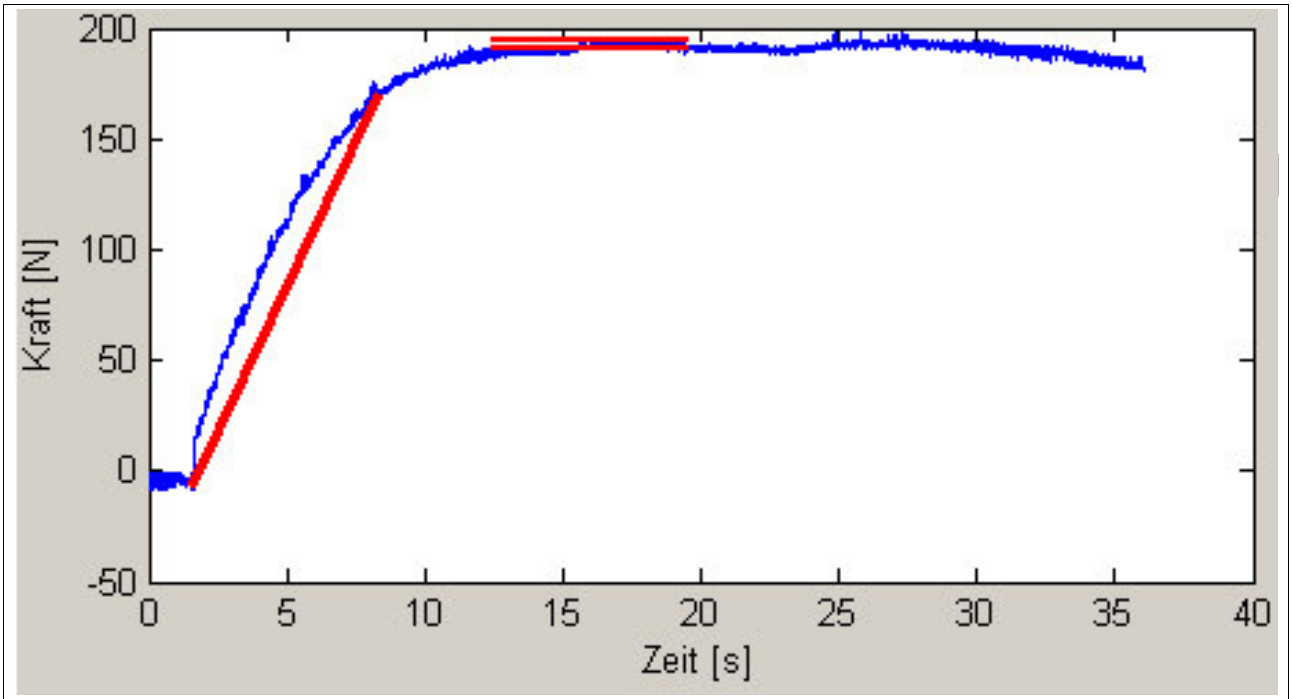

Figure 19: measurement of the shear force in dynamic mode

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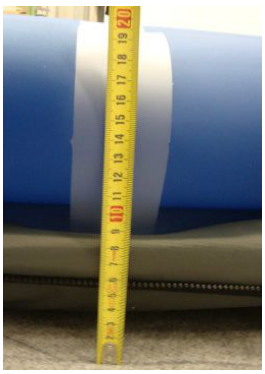
Appendix VI: Photo-documentation

Sample:



Accessories: