# Test report No.: PB - 16 - 227 - 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<br>Prüf- und Zertifizierstelle für Medizinprodukte GmbH<br>Dovestr. 6, D-10587 Berlin<br>Tel.: +49(0)30-314-25111, Fax: -23719 |
| **Client:** | Drive Medical GmbH & Co. KG, Leutkircher Straße 44,<br>D-88316 Isny/Allgäu |
| **Manufacturer:** | Drive Medical GmbH & Co. KG, Leutkircher Straße 44,<br>D-88316 Isny/Allgäu |
| **Test sample:** | Product designation: MED AIRE Wave<br>Type according to HMV: 11.29.04<br>Quantity / Identification: 1 / label<br>Receipt / Condition: 2016-11-15 / new |

| | |
|---|---|
| **Test standard:** | Test method 11-4 03/2004 MDS-Hi<br>(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):** | |

established: 2017-03-16

B.Sc. L. Lehmann

released: 2017-03-16

Dipl.-Ing. M. Tettke

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**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: 22,3 °C |
| Relative humidity: | (40 ± 5) % rF | Measured value: 40,1 % rF |
| Air pressure: | (960 ± 100) hPa | Measured value: 1020 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) %.<br>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.<br>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 140 kg (according to manufacturer's specifications):** | |
| Loaded with: | 140 kg (42 kg from the model of the sacrum and 98 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 (140 kg):** | |
| Loaded with: | 140 kg (42 kg from the model of the sacrum and 98 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:<br>(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 140 kg (according to manufacturer's specifications):** | |
| Loaded with: | 140 kg (42 kg from the model of the sacrum and 98 kg from the body-model) |
| Measurement over a period of at least 3 pressure-cycles. | |
| Number of effected measurements:<br>(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 $p_{max}$: | N/A |
| Average pressure $p_{mittel}$: | N/A |
| Loaded area A: | N/A |
| Pressure Area Index: | N/A |
| | N/A |
| | N/A |
| | N/A |
| **Values of the reference measurement (80 kg):** | |
| Peak pressure $p_{max}$: | N/A |
| Average pressure $p_{mittel}$: | N/A |
| Loaded area A: | N/A |
| relative pressure relief $D_{rel}$: $D_{rel} = \frac{p_{ref} - p_{prüf}}{p_{ref}}$ The calculation is effected by the measured peak pressures. | N/A |
| **Results of the test with a maximum patient weight of 140 kg (according to manufacturer's specifications):** | |
| Peak pressure $p_{max}$: | N/A |
| Average pressure $p_{mittel}$: | N/A |
| Loaded area A: | N/A |
| Pressure Area Index: | N/A |
| | N/A |
| | N/A |
| | N/A |
| **Values of the reference measurement (140 kg):** | |
| Peak pressure $p_{max}$: | N/A |
| Average pressure $p_{mittel}$: | N/A |
| Loaded area A: | N/A |
| relative pressure relief $D_{rel}$: $D_{rel} = \frac{p_{ref} - p_{prüf}}{p_{ref}}$ The calculation is effected by the measured peak pressures. | N/A |

| **2.3.2 Evaluation for dynamic antidecubitus-systems** | |
|---|---|
| **Results of the test with a patient weight of 80 kg:** | |
| Peak pressure $p_{max}$: | 64,4 mmHg |
| Minimum pressure $p_{min}$: | 15,7 mmHg |
| Average pressure $p_{mittel}$: | 41,5 mmHg |
| Time of a cycle $t_Z$: | 711 s |
| Pressure Relief Index (PRI): $PRI = \frac{t_1 + t_2}{t_Z}$ (see figure 4 in appendix I) | 10 mmHg: 0,04 |
| | 20 mmHg: 0,17 |
| | 30 mmHg: 0,32 |
| | 40 mmHg: 0,46 |
| **Results of the test with a maximum patient weight of 140 kg (according to manufacturer's specifications):** | |
| Peak pressure $p_{max}$: | 84,3 mmHg |
| Minimum pressure $p_{min}$: | 24,0 mmHg |
| Average pressure $p_{mittel}$: | 54,2 mmHg |
| Time of a cycle $t_Z$: | 715 s |
| Pressure Relief Index (PRI): $PRI = \frac{t_1 + t_2}{t_Z}$ (see figure 4 in appendix I) | 10 mmHg: 0,01 |
| | 20 mmHg: 0,09 |
| | 30 mmHg: 0,22 |
| | 40 mmHg: 0,35 |

| | |
|---|---|
| **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) %.<br>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.<br>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 $F_{Max}$ | N/A |
| Normal force W | N/A |
| Mean pulling force during slip-phase $F_{Quer}$ | N/A |
| **Values obtained in dynamic use:** | |
| Maximum pulling force $F_{Max}$ | 189 N |
| Normal force W | 245 N |
| Mean pulling force during slip-phase $F_{Quer}$ | 184 N |

| **3.3 Evaluation** | |
|---|---|
| **3.3.1 shear force measurement in static mode** | |
| **Coefficient of cohesive friction $\mu_H$ between patient and interface** | |
| The static coefficient of friction is calculated by the maximum pulling force ($F_{max}$) divided by the normal force (W). $\mu_H = \frac{F_{Max}}{W}$ | N/A |
| **Coefficient of sliding friction $\mu_G$ 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). $\mu_G = \frac{F_{Quer}}{W}$ | N/A |
| **Horizontal Stiffness $\Phi_H$ of the device** | |
| The horizontal stiffness is calculated as follows: $\Phi_H = \frac{F_2 - F_1}{(t_1 - t_2)\, v}$ | N/A |

| **3.3.2 Evaluation of the shear force measurement in dynamic mode** | |
|---|---|
| **Coefficient of cohesive friction $\mu_H$ between patient and interface** | |
| The static coefficient of friction is calculated by the maximum pulling force ($F_{max}$) divided by the normal force (W). $\mu_H = \frac{F_{Max}}{W}$ | $\mu_H$ = 0,77 ± 0,03 |
| **Coefficient of sliding friction $\mu_G$ 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). $\mu_G = \frac{F_{Quer}}{W}$ | $\mu_G$ = 0,75 ± 0,03 |
| **Horizontal Stiffness $\Phi_H$ of the device** | |
| The horizontal stiffness is calculated as follows: $\Phi_H = \frac{F_2 - F_1}{(t_1 - t_2)\, v}$ | $\Phi_H$ = (3,99 ± 0,72) 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 2.5 the tested device has the following specific values:

- peak pressure: 64,4 mmHg
- minimum pressure: 15,7 mmHg
- average pressure: 41,5 mmHg

Loading of the device with 140 kg:
According to test method 11-4 03/2004 MDS-Hi paragraph 2.5 the tested device has the following specific values:

- peak pressure: 84,3 mmHg
- minimum pressure: 24,0 mmHg
- average pressure: 54,2 mmHg

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 $F_{max}$: 189 N
- Mean pulling force during slip-phase $F_{quer}$: 184 N
- Coefficient of sliding friction $\mu_G$: 0,75 ± 0,03
- Horizontal Stiffness $\Phi_H$: (3,99 ± 0,72) 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<br>Zellen: Nylon / PVC<br>Bezug: Nylon / PU |
| Structure of the device: | Aggregat und Luftkammerauflage |
| Cover of the device: | wasserabweisend, atmungsaktiv, feuerfest |
| Maximal patient's weight [kg]: | 140 kg |
| Minimal patient's weight [kg]: | 30 kg |
| Required base mattress (overlay-system): | Mindestens 4 cm hohe Schaumstoffunterlage |
| Applications (indication): | Dekubitusprophylaxe bei niedrigem bis mittlerem Dekubitusrisiko<br>Druckverteilung und Druckentlastung bei immobilen und teilimmobilen Patienten<br>Dekubitustherapie bis einschl. Grad 2 nach EPUAP |
| Criterion of exclusion (contraindication): | bei einem Körpergewicht unter 30 kg und über 140 kg<br>bei Instabile Frakturen (insbesondere im Rückenbereich, Hals- und Lendenwirbelsäule)<br>bei neurologischen Erkrankungen, bei denen dynamischer Wechseldruck nicht angewandt werden darf<br>Schmerzpatienten<br>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 820000100) |

| **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.

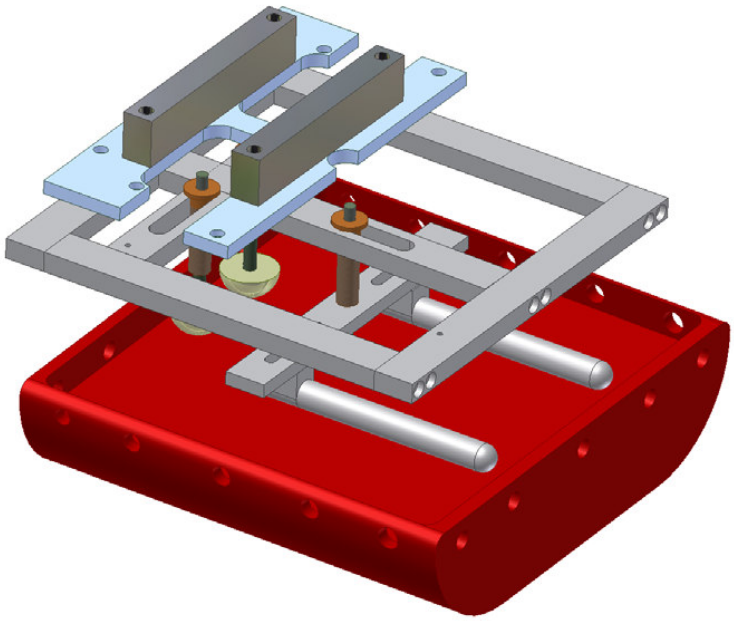

Figure 1: set-up of sacral area model

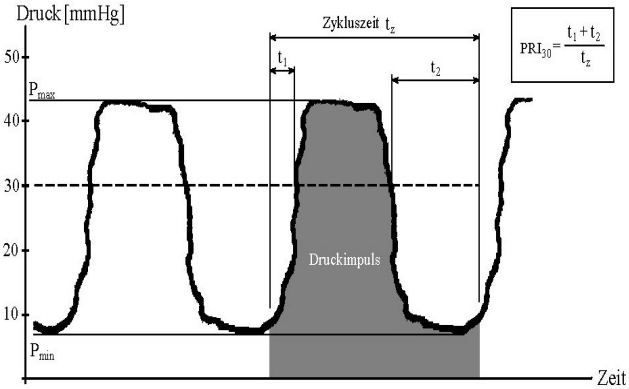


Figure 2: pressure vs. time

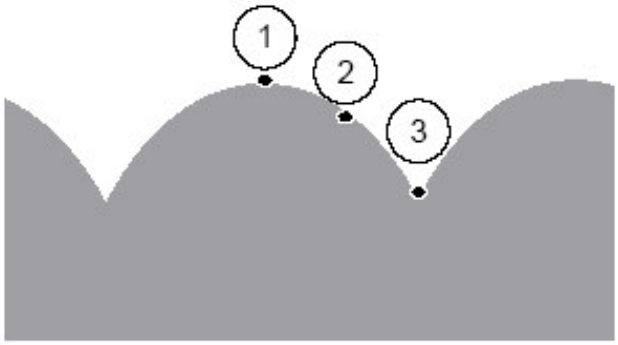


Figure 3: Position of the ischial tuberosities

**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.

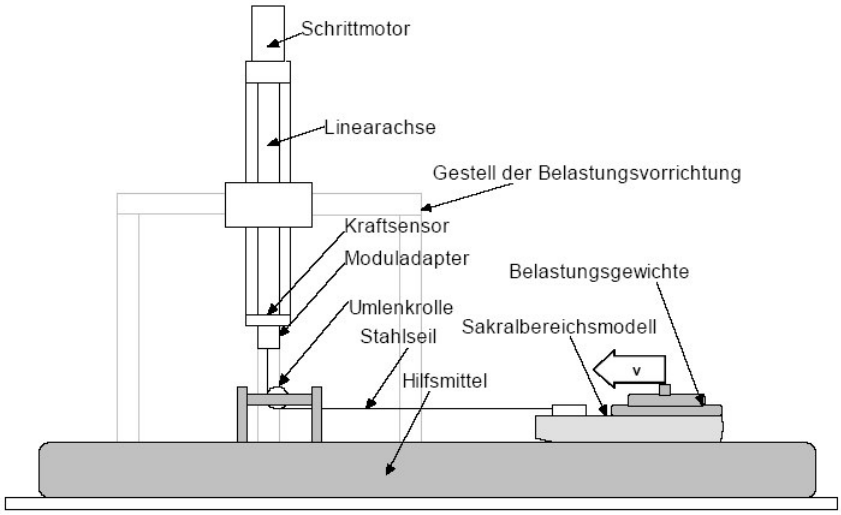


Figure 4: set-up for shear force measurement

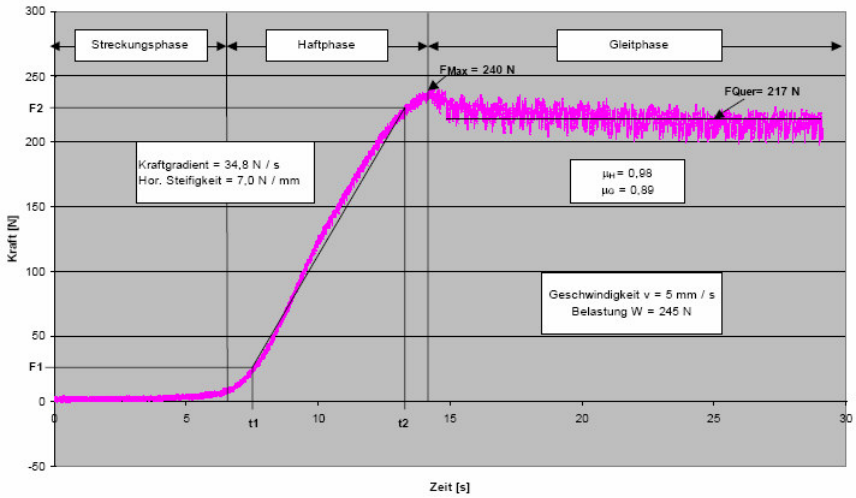


Figure 5: diagram pulling force vs. time

**Appendix III: Static pressure distribution**

N/A

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

N/A

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

N/A

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

N/A

Figure 9: static pressure distribution – 140 kg load - 1

N/A

Figure 10: static pressure distribution – 140 kg load - 2

N/A

Figure 11: static pressure distribution – 140 kg load - 3

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

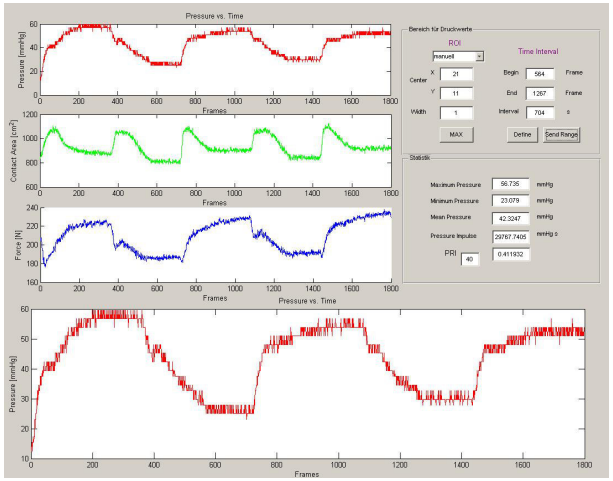


Figure 12: dynamic pressure distribution – 80 kg load - 1

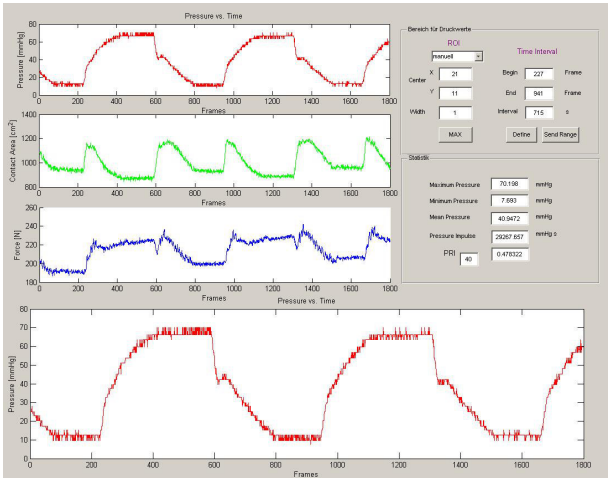


Figure 13: dynamic pressure distribution – 80 kg load - 2

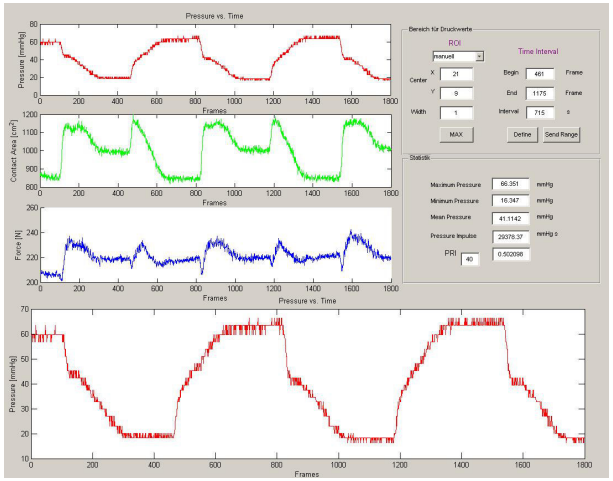


Figure 14: dynamic pressure distribution – 80 kg load - 3

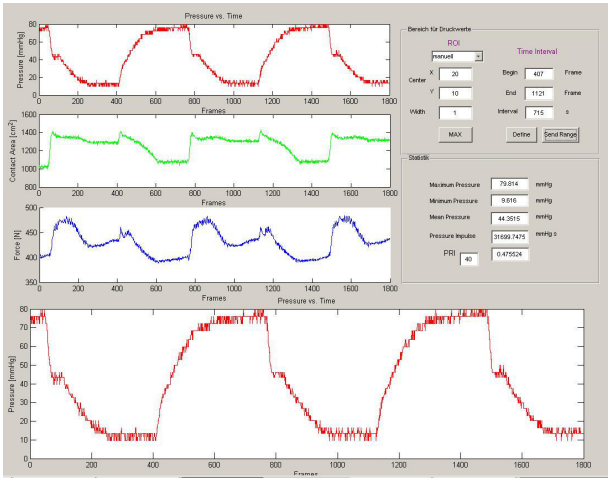


Figure 15: dynamic pressure distribution – 140 kg load - 1

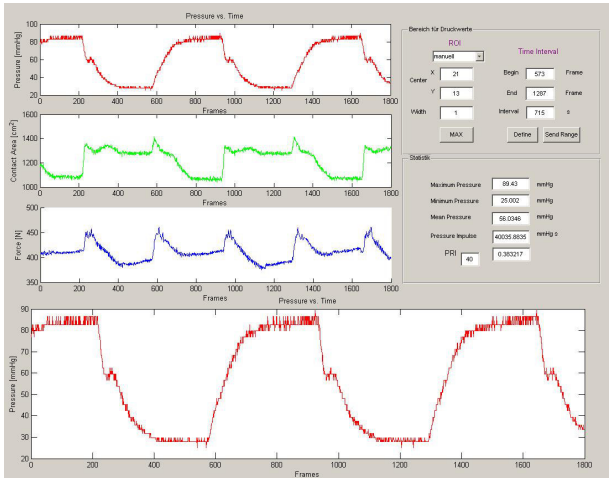


Figure 16: dynamic pressure distribution – 140 kg load - 2

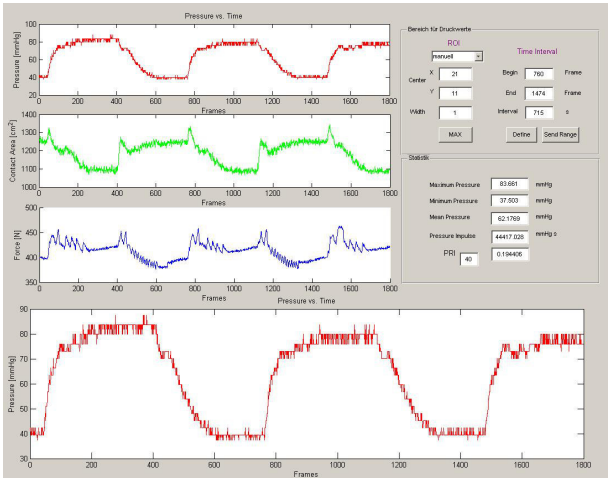


Figure 17: dynamic pressure distribution – 140 kg load - 3

**Appendix V: Diagram “pulling force vs. time”**

N/A

Figure 18: measurement of the shear force in static mode

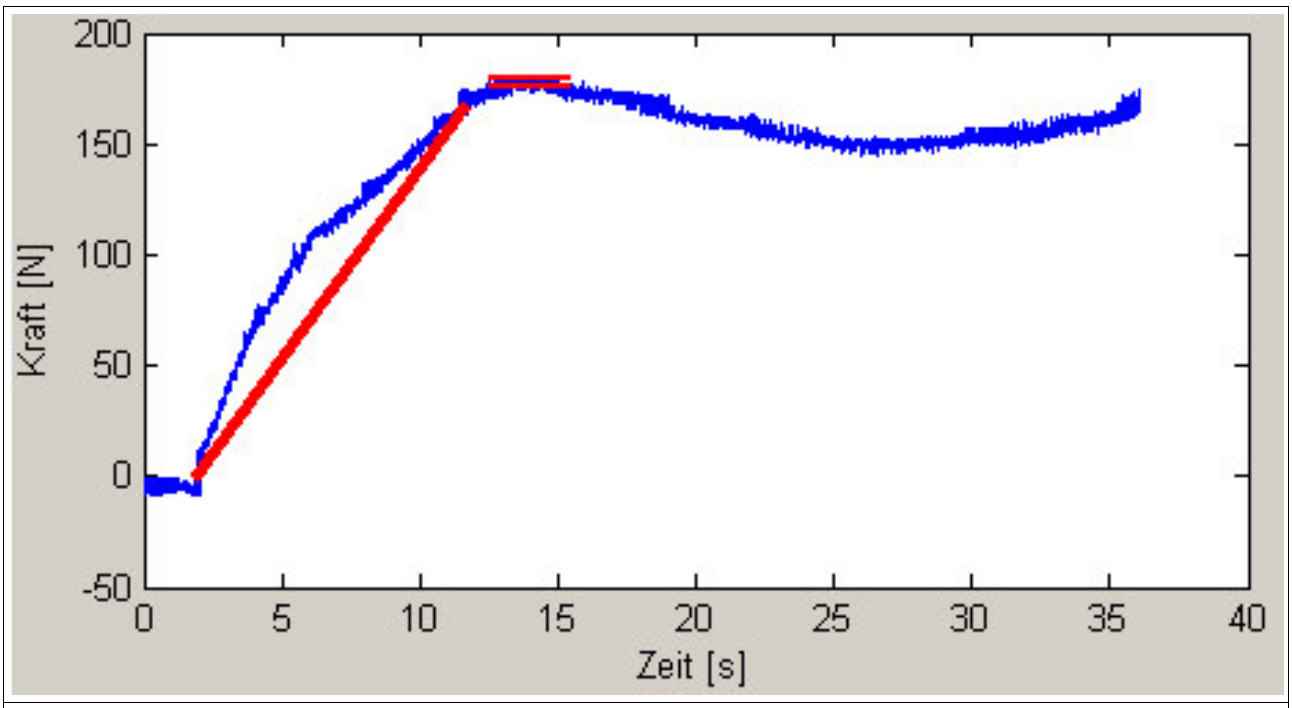


Figure 19: measurement of the shear force in dynamic mode

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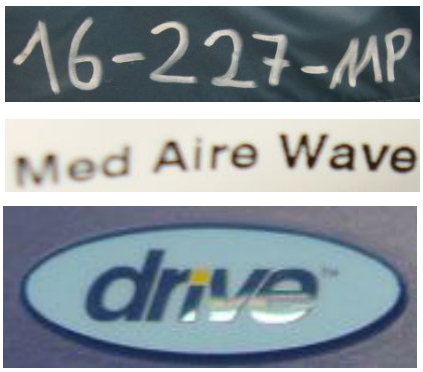
**Appendix VI: Photo-documentation**

**Sample:**




**Accessories:**