



**HAL**  
open science

## Characterization of a pressure measuring system for the evaluation of medical devices

Rébecca Bonnaire, Marion Verhaeghe, Jérôme Molimard, Paul Calmels,  
Reynald Convert

► **To cite this version:**

Rébecca Bonnaire, Marion Verhaeghe, Jérôme Molimard, Paul Calmels, Reynald Convert. Characterization of a pressure measuring system for the evaluation of medical devices. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine, 2014, 228 (12), pp.1264-1274. 10.1177/0954411914562871 . hal-01137411

**HAL Id: hal-01137411**

**<https://hal.science/hal-01137411>**

Submitted on 30 Mar 2015

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

1 *Original article*

2

3 **Characterization of a pressure measuring system for the evaluation of**  
4 **medical devices**

5 Rébecca Bonnaire<sup>1,2\*</sup>, Marion Verhaeghe<sup>3</sup>, Jérôme Molimard<sup>1</sup>, Paul Calmels<sup>4</sup> and Reynald  
6 Convert<sup>2</sup>

7 <sup>1</sup> LGF, UMR 5307, École Nationale Supérieure des Mines, CIS-EMSE, CNRS, Saint-Etienne, France

8 <sup>2</sup> Thuasne, Levallois-Perret, France

9 <sup>3</sup> Université de Technologie de Compiègne, Compiègne, France

10 <sup>4</sup> Université de Lyon, Laboratoire de Physiologie de l'Exercice, F-42023, Saint-Etienne, France

11

12 \* **Corresponding author :**

13 Rébecca Bonnaire, LGF, UMR 5307, Ecole Nationale Supérieure des Mines de Saint-Etienne, CS 62362,

14 F-42023 Saint-Etienne cedex 2, France

15 Email : [bonnaire@emse.fr](mailto:bonnaire@emse.fr)

16

17 **Abstract**

18 The purpose of this study is to evaluate the possible use of four “FSA” thin and flexible resistive pressure  
19 mapping systems, designed by Vista Medical (Winnipeg, Manitoba, Canada), for the measurement of  
20 interface pressure exerted by lumbar belts onto the trunk. These sensors were originally designed for the  
21 measurement of low pressure applied by medical devices on the skin.

22 Two types of tests were performed: standard metrology tests such as linearity, hysteresis, repeatability,  
23 reproducibility and drift, and specific tests for this application such as curvature, surface condition and  
24 mapping system superposition.

25 The linear regression coefficient is between 0.86 and 0.98; hysteresis is between 6.29% and 9.41%.  
26 Measurements are repeatable. The location, time and operator, measurement surface condition and  
27 mapping system superposition have a statistically significant influence on the results. A stable measure is  
28 verified over the period defined in the calibration procedure, but unacceptable drift is observed afterward.  
29 The measurement stays suitable on a curved surface for an applied pressure above 50mmHg.

30 To conclude, the sensor has acceptable linearity, hysteresis and repeatability. Calibration must be adapted  
31 to avoid drift. Moreover, when comparing different measurements with this sensor the location, the time,  
32 the operator and the measurement surface condition should not change; the mapping system must not be  
33 superimposed.

34

35 **Keywords**

36 Pressure measurement, pressure mapping system, medical device, mechanical characterization, metrology

37

## 38 **Introduction**

39 Low back pain is a major public health problem in developed countries. In France, prevalence of low  
40 back pain is higher than 50% [1]. Because of health care costs and sick leave [1-2], low back pain has  
41 adverse consequences on both the social and economic level. Many treatments have been proposed.  
42 However, no guidelines are proposed to practitioners, particularly for chronicle evolution. Treatment  
43 propositions and success depend on the patient comportment, on the aetiology and/or mechanical causes  
44 of low back pain, on the evolution along the time and also on the physician's opinions. Lumbar belts are  
45 frequently proposed to treat low back pain. Several clinical trials have shown their clinical effectiveness  
46 [3-4]. Nevertheless, both the mechanical and the physiological effects of lumbar belts remain unclear.

47 It is assumed that the main mechanical effect of lumbar belts is the pressure applied on the trunk;  
48 therefore it has been decided to investigate experimentally this pressure. In the medical field, pressure  
49 measurement is already used to evaluate devices employed to prevent bedsores [5-11], to measure the  
50 interface pressure of compression stockings, compression bandages [12-18] and rigid orthosis [19-20].  
51 Using pressure measurement to mechanically characterize lumbar belts can be considered as new  
52 approach.

53 Four types of interface pressure sensors exist: pneumatic (Example: PicoPress<sup>®</sup>, St Neots  
54 Cambridgeshire, United Kingdom), electro-pneumatic (Example: Salzmänn<sup>®</sup>, St. Gallen, Switzerland),  
55 resistive (Example: Tekscan<sup>®</sup>, Boston MA, USA) or capacitive (Example: X-Sensor<sup>®</sup>, Calgary Alberta,  
56 Canada or Novel<sup>®</sup>, Munich Germany) sensors. Resistive or capacitive sensors may be assembled into a  
57 structure that enables the pressure to be measured at several points simultaneously; this structure is often  
58 called a pressure mapping system.

59 In this study, four identical FSA<sup>®</sup> pressure mapping systems were chosen and purchased (Vista Medical<sup>®</sup>,  
60 Winnipeg Manitoba, Canada). They are composed of resistive sensors, based on the piezoresistive

61 properties of some materials. The resistivity of piezoresistive materials varies according to the forces  
62 exerted on this material. Resistivity is proportional to the electrical resistance which is converted into  
63 voltage. After calibration, measurement of voltage enables the interface pressure to be measured [21].  
64 These pressure mapping systems were chosen because they are thin and compliant, free from error of  
65 measurement on curved surfaces, sensitive in detecting a range of pressure as low as 0-100mmHg (0-  
66 13.3kPa), in accordance to in-vivo studies (free from temperature or moisture effects, dynamic range  $\geq 10$   
67 Hz ) and give indications of pressure gradients in a context of spatial variations of support stiffness and  
68 shape [22-24]. Compared to the capacitive sensors, resistive sensors have a lower drift and are less  
69 expensive [25-26].

70

71 Aim of this study is to evaluate these four identical pressure mapping systems, particularly in challenging  
72 applications such as lumbar belts. This evaluation is performed by two types of tests:

- 73 - classical tests of metrology such as linearity, hysteresis, repeatability, reproducibility and  
74 drift,
- 75 - specific test for the application developed in this study, such as curvature, surface condition  
76 and mapping system superposition.

77 The goal of classical tests is to determine the proper functioning of sensors in their general use. The goal  
78 of specific tests is to characterize the pressure sensors in case of interface pressure measurement between  
79 the trunk and the lumbar belt. Actually, in this specific type of measurement, surfaces are soft and curved.  
80 Moreover, the four pressure mapping systems may be partially superimposed during the measurement.

81

82

## 83 **Methods**

### 84 *The FSA pressure mapping systems*

85 Four mapping systems are needed to measure the interface pressure all around the trunk. In this study, the  
86 mapping systems will be tested all together and no comparison between them will be done. Pressure  
87 mapping systems are composed of 12 by 32 piezoresistive sensors. Each sensor is a square with sides  
88 measuring 7.9mm, separated by 4.2mm. The active area is 382 by 142mm. The total size of the mapping  
89 system is 482 by 242mm. Sensor calibration is performed with the pressure range from 0 to 100mmHg.  
90 During calibration, 50mmHg is measured for 60 seconds to compensate the drift effect. The FSA pressure  
91 mapping system is illustrated in Figure 1. The pressure mapping systems are denoted below A, B, C and  
92 D.

93

### 94 *Classical tests of metrology [27]*

95 *Linearity test.* For the linearity test, seven cylindrical steel weights were designed to apply pressure  
96 between 6 and 96mmHg on one sensor. Weights were randomly applied in sensors 1, 2 and 3 (see Figure  
97 1). Thirty measurements were carried out for each sensor. The linear regression coefficient  $R^2$  between  
98 applied and measured pressures, the dispersion and the standard deviation  $s_p$  were calculated. The linear  
99 regression coefficient  $R^2$  is defined by the following formula:

$$100 \quad R^2 = \frac{cov(P,P_i)^2}{var(P)var(P_i)} \quad (1)$$

101 with P, the measured pressure value in mmHg and  $P_i$ , the applied pressure value in mmHg.

102 The dispersion is defined as the difference between the maximum and the minimum pressure measured  
103 for each applied pressure. The standard deviation  $s_p$  of the measured pressure is defined by the following  
104 formula:

$$s_p = \sqrt{\frac{1}{(n-1)} \sum_{i=1}^n (P_i - \bar{P})^2} \quad (2)$$

with n, the size of the measured sample and P, the measured pressure value for each applied pressure in mmHg.

*Hysteresis test.* Two types of hysteresis tests were performed: an hysteresis test in only one sensor and an hysteresis test in all sensors at the same time of the mapping system.

For the first test, the same weights as for the linearity test, were increasingly and decreasingly applied on eight sensors. The position of these sensors is represented in Figure 1. For the second test, pressure mapping was placed on an air pocket and introduced between two wooden planks. Figure 2 illustrates this experimental device. The air pocket was inflated to apply increasing then decreasing pressure between 10 and 100mmHg to the mapping system.

Hysteresis is defined by the following formula:

$$E_h(\%) = \frac{|y_d(x_i) - y_m(x_i)|}{x_i} * 100 \quad (3)$$

with  $x_i$ , the discrete values of applied pressure in mmHg,  $y_m$  the measured pressure value during the increasing phase corresponding to a given  $x_i$  in mmHg, and  $y_d$  the measured pressure value during the decreasing phase corresponding to a given  $x_i$  in mmHg.

*Repeatability test.* The repeatability of experiments was assessed by performing the first hysteresis test three times. Repetitions were compared by statistical analysis as explained in paragraph 2.4.

*Reproducibility test.* The reproducibility of time, location and operators was tested. The first hysteresis test was performed in two different rooms, by two different operators and at two different times separated by two months.

125 A specific design of experiments was used to evaluation reproducibility (Table 1). In this design of  
126 experiments, there are four independent factors: location, time, operators and weight applied to the  
127 mapping system. The interactions between each factor are considered. The selected design of experiments  
128 is factorial and follows this polynomial model:

$$129 \quad P = \sum_i \beta_i x_i + \sum_{ij} \beta_{ij} x_i x_j \quad (4)$$

130 with P, the measured pressure (mmHg),  $\beta_i$  or  $\beta_{ij}$ , the polynomial coefficients and  $x_i$  or  $x_j$ , the input factor  
131 of the design of experiments.

132 *Drift test.* To determine if the pressure recorded changes over time, four weights corresponding to 26, 40,  
133 52 and 80mmHg applied pressure were left on 1, 2, 3, 4, 5 and 6 sensors (see Figure 1) for a duration  
134 higher than that of the calibration to drift (30 minutes).

135 For each case, the range of stored drift, as defined by the minimum and maximum pressures measured  
136 during the testing, was determined. The relative pressure variation was expressed by the following  
137 formula:

$$138 \quad \Delta P_r = \frac{|P_m - P_a|}{P_a} \quad (5)$$

139 with  $\Delta P_r$  the relative pressure variation,  $P_m$  the measured pressure and  $P_a$  the applied pressure.

140 *Tests specific to the application*

141 *Curvature test.* An experimental setup was developed to characterize the impact of measurement on  
142 curved surfaces. This experimental setup consists in a support on which it is possible to place cylinders of  
143 different radii. Radii used in this study were 60, 80, 100 and 125mm. Pressure mapping systems were  
144 placed on the cylinder. Pressure was applied on one single line of sensors using a 15mm band, at the end  
145 of which weights were hung on. This experimental setup is illustrated in Figure 3. Three lines were tested

146 for one mapping system. As results were similar for these three lines, just one line was tested for the other  
147 three pressure mapping systems. Six or seven different pressures were applied per cylinder, per line and  
148 per pressure mapping system.

149 For each applied pressure, cylinder and pressure mapping system, normalized pressure was calculated  
150 according to the following formula:

$$151 \quad P_n = \frac{P_m}{P_a} \quad (6)$$

152 with  $P_n$  the normalized pressure,  $P_m$  the measured pressure and  $P_a$  the applied pressure.

153 *Surface condition test.* The possible application of this system is to measure the interface pressure applied  
154 by lumbar belts. Usually these belts are worn over garments (tee shirt, shirts, etc.). The surface condition  
155 of the measured zone is important. Two different surface conditions have been tested. Evaluation of the  
156 effect of the surface condition was done in two stages.

157 Firstly, a hysteresis test was performed with only one sensor and seven different medical fabrics placed  
158 between the table and the mapping system. For two of the tested fabrics, the pressure decrease was more  
159 than 50%. Therefore, these two fabrics were not considered for the statistical analysis. For the other five  
160 fabrics, two statistical analyses were performed. The first one was used to compare results with and  
161 without fabric between the pressure mapping system and the table. The second one was used to determine  
162 if results are different depending on fabrics inserted between the table and the pressure mapping system.

163 Secondly, the hysteresis test was conducted with only one sensor with weights surrounded by silicone and  
164 with froth positioned between the table and the mapping system. Statistical analysis was done to  
165 determine if there are statistical significant differences between results for this test and for the first test of  
166 hysteresis (test in one sensor). The linear regression coefficient was calculated thanks to equation 1.

167 *Mapping system superposition test.* To determine the impact of two superimposed pressure mapping  
168 systems on the results, the first hysteresis test (test in one sensor) was performed in three sensors stacking  
169 two mapping systems.

170 Statistical analysis was performed to determine if there are statistical significant differences between  
171 results for the pressure mapping system “from above” and the pressure mapping system “from the  
172 bottom”. Absolute differences between measured pressures with or without superposition were calculated  
173 for each pressure mapping system.

174 *Statistical analysis*

175 Statistical analysis was used to determine differences between two or more than two distributions.  
176 Depending on the number of data sets to compare, two types of statistical approach were used. A Jarque-  
177 Bera test was used to check whether or not data matched normal distribution.

178 To compare two sets of data, a Student t-test was used if they were distributed following a normal  
179 distribution, and a Wilcoxon signed ranks if not. The statistical analysis of two distributions was used for  
180 mapping system superposition and surface condition tests. Student t-test was also used for the linearity  
181 test to determine if the linear regression curve’s slope is zero.

182 To compare more than two sets of data, an ANOVA was used if they were all distributed following a  
183 normal distribution, and a Kruskal-Wallis test if not. If needed, the post-hoc test of Tukey was used to  
184 find which of the data sets were different. The statistical analysis of more than two distributions was used  
185 for repeatability and surface condition tests.

186 All the statistical tests were performed with a risk  $\alpha$  to be equal or smaller than 5%.

## 187 **Results**

188 *Classical tests of metrology*

189 *Linearity.* Linear regression coefficients and p-value of the Student's test on slope=0 are given in Table 2.  
190 The results are illustrated for one sensor of one mapping system in Figure 4. The linear regression  
191 coefficient  $R^2$  is between 0.86 and 0.98 depending on the sensor and the mapping system. The maximum  
192 dispersion and the maximum standard deviation to the measured pressure are 18.9 and 9.60mmHg  
193 respectively. Table 3 shows the results of maximum dispersion and maximum standard deviation for  
194 sensors with the best and the worst linearity.

195 *Hysteresis.* All results are given in Table 4. For the first test of hysteresis (test in only one sensor),  
196 hysteresis is between 0.228% and 27.9%. An example of results for the second hysteresis test (test in all  
197 sensors of a pressure mapping system) is given in Figure 5. For this test of hysteresis, the hysteresis is  
198 between 6.29% and 9.41%. All results are given in Table 5.

199 *Repeatability.* The Kruskal-Wallis test shows no difference (p-value = 0.88). Measurements are  
200 repeatable.

201 *Reproducibility.* Table 6 indicates the polynomial coefficient of the experimental design model and  
202 probability that the factor  $x_i$  has at least a 95% chance of not significantly affecting the response to  
203 pressure of the sensors.  $x_i$  can be time, space, operators, weight or interactions factors. The biggest  
204 polynomial coefficient corresponds to the weight influence and the smaller corresponds to the time  
205 influence. Location, weight, time coupling with operators and time coupling with location have statistical  
206 influence to the measured pressure.

207 *Drift.* No significant drift was observable during the first 60 seconds, i.e. the calibration time for drift.  
208 After that period, three types of drift are obtained: measured pressure increases during the first few  
209 minutes and becomes stable, measured pressure decreases during the first few minutes and becomes  
210 stable and measured pressure is stable over time. Figure 6 represents these three typical results. For all  
211 sensors, measured pressure becomes stable and reaches its nominal value after 800 seconds.

212

213 *Tests specific to the application*

214 *Curvature.* Figure 7 shows results for the mapping pressure system A. The results depend on the applied  
215 pressure. When the applied pressure is less than 50mmHg, the measured pressure is lower than the  
216 applied pressure. Nevertheless, when the applied pressure is more than 50mmHg, the difference between  
217 the applied pressure and the measured pressure is minor.

218 *Surface condition.* The probabilities of there being at least a 95% chance that results with and without  
219 fabric between the pressure mapping system and the table are different for the five tested fabrics are given  
220 in Table 7. All fabrics have a statistically significant influence on the results.

221 The Kruskal-Wallis test is significant ( $p$ -value  $< 0.001$ ). The five fabrics are statistically significantly  
222 different. Only measured pressure for fabrics 1 and 2, 3 and 4, and 3 and 5 do not have a statistically  
223 significant difference.

224 For the second surface condition test, the linear regression coefficient  $R^2$  is between 0.95 and 0.99,  
225 depending on the sensor and the mapping system. Hysteresis is between 4.2% and 15%. For the third  
226 surface condition test, the linear regression coefficient  $R^2$  is between 0.92 and 0.98. Detailed results for  
227 the second and third tests are presented in Table 8.

228 *Mapping system superposition.* Mapping system superposition results consist of two distributions:  
229 measured pressure for the mapping systems “from above” and for the mapping systems “from the  
230 bottom”.

231 Results for the test of Wilcoxon signed rank, to compare results for the mapping systems “from above”  
232 and “from the bottom”, are given in Table 9. Table 10 indicates absolute differences between measured  
233 pressures with or without superposition for each pressure mapping system.

234

235

236 **Discussion**

237 In this study, four identical pressure mapping systems were evaluated in term of linearity, hysteresis,  
238 reproducibility and drift. Some other evaluations demonstrated the efficacy of the pressure mapping  
239 systems in the specific application of lumbar belts characterization. According to the results, pressure  
240 mapping systems are suitable for this application.

241 We found that linearity is acceptable according to the linear regression coefficient  $R^2$  which is always  
242 greater than 0.85. Pressure measured with sensors is always underestimated. The maximum deviation is  
243 15.4mmHg. The hysteresis of the pressure mapping system depends on sensors. On the whole, hysteresis  
244 is low between 6.29% and 9.41%. Measurements are repeatable. The reproducibility test shows the  
245 influence of experimental location, time and operator; the most influencing parameter is the location.  
246 According to the drift test, the value remains stable if the measuring time remains lower than the drift  
247 calibration time, but dramatically changes afterward.

248 Thanks to our tests specific to the application, it is possible to conclude that curvature test results depend  
249 on the applied pressure. For applied pressure higher than 50mmHg, measurement is the same as on a flat  
250 surface. Nevertheless, for applied pressure less than 50mmHg, the measured pressure is lower than the  
251 applied pressure. This can be explained by the experimental device. It is supposed that the band sticks on  
252 the cylinder when the applied pressure is too low and the pressure estimation from Laplace's law is not  
253 valid any more. Thus, no conclusions to the impact of curvature for low measured pressure can be drawn  
254 from these results.

255 We also proved that the surface measurement has a significant influence on the measured pressure.  
256 However, there is no change in hysteresis and linearity when pressure is measured between two soft  
257 surfaces. In this case, hysteresis is between 4.2% and 15% and the linear regression coefficient is between

258 0.92 and 0.98. Last, the superposition of two pressure mapping systems can have a significant influence  
259 on the measurement.

260

#### 261 *Comparison of the FSA pressure mapping system to the other resistive pressure mapping systems*

262 Metrological results of other sensors have been collected from the literature: Flexiforce<sup>®</sup> [22], F-Socket<sup>®</sup>  
263 [25] and F-Scan<sup>®</sup> [21] sensors from Tekscan<sup>®</sup>, Rincoe's sensor [25] and Lück sensor [29]. Measurement  
264 error and hysteresis are summarized in Table 11. For accuracy, FSA sensor is identical (Flexiforce<sup>®</sup>, F-  
265 Socket<sup>®</sup>) or even better (Rincoe, Lück, F-Scan<sup>®</sup>) than other pressure mapping systems. For hysteresis,  
266 performances of other resistive sensors are identical (Flexiforce<sup>®</sup>) or lower (F-Socket<sup>®</sup>, Rincoe) than the  
267 FSA<sup>®</sup> sensor. Measurement is repeatable for all resistive sensors [22-23]. Other resistive sensors drift as  
268 well: Flexiforce sensors' measurements increase or decrease with time [22] [26]; Rincoe SFS and F-  
269 Socket<sup>®</sup> from Tekscan<sup>®</sup> sensors' measurements increase with time [21] [25]. The increase or decrease of  
270 the measurement varies from 7.4% to 11.9% in twenty minutes [25]. According to the literature, the  
271 curvature of the measurement surface has an influence, for other resistive sensors than FSA<sup>®</sup> sensor on  
272 the measurement regardless of the pressure range. The sensitivity of the Tekscan<sup>®</sup>'s Flexiforce<sup>®</sup> sensor is  
273 modified with radius of curvature [22]. For Rincoe SFS and F-Socket<sup>®</sup> sensors from Tekscan<sup>®</sup>, accuracy  
274 decreases, drift error increases and hysteresis can increase or decrease with radius of curvature [25]. No  
275 data was found to compare the FSA<sup>®</sup> sensor with other resistive sensors in term of reproducibility, surface  
276 condition and superposition of two pressure mapping system.

277

#### 278 *Comparison of the FSA pressure mapping system to the capacitive pressure mapping system*

279 It is also possible, according to data from the literature, to compare the FSA<sup>®</sup> sensors with other types of  
280 pressure mapping systems for measuring interface pressure: the X-Sensor<sup>®</sup> capacitive pressure mapping

281 system [21, 28, 29] and Novel<sup>®</sup> distributed sensors [23]. For linearity, the X-Sensor<sup>®</sup> is linear [28] and  
282 measures 75.1% of the applied pressure [21]. The capacitive sensor may demonstrate a worse  
283 performance than FSA<sup>®</sup>. The maximum measurement error for X-Sensor<sup>®</sup> is 65% of applied pressure or  
284 27mmHg [29]. Novel<sup>®</sup>'s sensor demonstrates a superior performance: its linear coefficient is 0.997 and  
285 the measurement error is less than 1mmHg [23]. But capacitive sensors have a greater hysteresis than  
286 resistive sensors. For example, the X-Sensor<sup>®</sup> hysteresis is 14% [28]. Measurement with capacitive  
287 sensors is repeatable [23-24]. According to the drift test, measured pressure with capacitive sensors  
288 increases with time [21] [26]. Concerning the surface condition, capacitive sensors, X-Sensor<sup>®</sup> and  
289 Novel<sup>®</sup>, allow better or worse measurement on soft surfaces depending on the thickness of these surfaces  
290 [28]. No data was found to compare the FSA<sup>®</sup> sensor with capacitive sensors in terms of reproducibility,  
291 curvature and superposition of two pressure mapping systems.

292

### 293 *Considerations on the use of FSA<sup>®</sup> pressure mapping system for the clinical study of lumbar belt*

294 Based on these results, it is necessary to take into account some points to develop the experimental  
295 protocol. First, to be accurate, measurement must be done in the same place and preferably by the same  
296 operator and in short time frame. It's easy to perform measurement in the same place, but it's more  
297 difficult, in a clinical field, to respect the two other points, because measurements is often done by more  
298 than one experimenter and it's difficult to find enough subjects in a short time frame. However, these two  
299 parameters have influence on the results with coupled parameters. Secondly, drift result shows the  
300 importance in the choice of the drift calibration period, drift being uncontrolled if the measuring time is  
301 higher. Actually, during calibration, the central value of the calibration interval is measured for a flexible  
302 period. Pressure mapping system was calibrated in this study with a flexible period of 60 seconds, but the  
303 period can be increased to more than 800 seconds to avoid drift. This solution permits to perform  
304 dynamic measurements. Third, improving the curvature test is necessary before beginning the clinical

305 study to ensure that the measurement of low pressure will be accurate on curved surfaces. Fourthly,  
306 surface condition having an influence on the results, pressure measurements will be done between lumbar  
307 belts and a tee-shirt of the same composition for all experiments and all subjects. Whatever the surface  
308 condition, pressure measurement remains accurate in term of linearity and hysteresis. Finally, the pressure  
309 mapping systems will be used to never overlap while covering the whole trunk. To overcome the  
310 difficulty of this condition, measures will be taken side by side. All these conditions allow a suitable  
311 measurement of pressure and to compare pressure applied by lumbar belt in term of lumbar belt's types  
312 and patient's morphology.

313

314 To conclude, the FSA<sup>®</sup> sensor performance can be considered as better than other resistive sensors and  
315 demonstrates an identical performance to the capacitive sensor X-Sensor<sup>®</sup> with lower hysteresis.  
316 Nevertheless, the capacitive sensor Novel demonstrates a better performance than the FSA<sup>®</sup> sensor, but  
317 has a higher drift effect. FSA<sup>®</sup> sensors can be a good choice for the future clinical study developed to  
318 measure the static pressure applied by the lumbar belt on the trunk, because this study will be done in the  
319 same place, in a short time frame, with the same operator, with no overlapped mapping system and  
320 between same types of surface. Indeed, the procedure described earlier with FSA<sup>®</sup> pressure mapping  
321 system still lacks of robustness for a routine clinical practice to evaluate pressure applied by lumbar belts  
322 prescribed to the low back pain patients.

### 323 **Conclusion**

324 In this study, four FSA<sup>®</sup> pressure mapping systems were characterized in term of linearity, hysteresis,  
325 repeatability, reproducibility, drift, curvature, surface condition and mapping system superposition. It was  
326 found that these pressure mapping systems are suitable for our application: pressure measurement  
327 between two soft surfaces, lumbar belt and the human trunk. Linearity, accuracy and hysteresis are

328 adequate. Measurement is repeatable and suitable on a flat surface. The curvature of the surface  
329 measurement has no significant impact on the measured pressure.

330 However, it is necessary to take into account some recommendations before performing measurements  
331 with this FSA<sup>®</sup> sensor. To compare the results of different experiments, measurement must be performed  
332 in the same place, over a short timeframe, with the same operator. Calibration must be adapted to prevent  
333 sensor drift. The measurements shall concern the same type of surface. Moreover, it is important to avoid  
334 overlap of pressure mapping systems.

335 Further study is needed to evaluate the performance of the sensor on a curved surface when applied  
336 pressure is lower than 50mmHg and also how the sensor behaves when temperature and humidity change.

337

#### 338 **Acknowledgements**

339 The authors would like to thank Mr. Poirier for his assistance with this work.

340

#### 341 **Conflict of interest**

342 There is no conflict of interest in this study.

343

#### 344 **Funding:**

345 This research received no specific grant from any funding agency in the public, commercial, or not-for-  
346 profit sectors.

347

#### 348 **References**

349 1. Fassier JB. [Prevalence, costs and societal issues of low back pain]. *Rev Rhum* 2011; 78(sup.2): S38-  
350 S41. French

- 351 2. Leclerc A, Gourmelen J, Chastang JF, Plouvier S, Niedhammer I, Lanoë JL. Level of education and  
352 back pain in France: the role of demographic, lifestyle and physical work factors. *Int Arch Occup Environ*  
353 *Health* 2009; 82(5): 643-652.
- 354 3. Calmels P, Galtier B, Carzon JG, Poinsignon JP, Vautravers P, Delarque A. Etude de l'effet antalgique  
355 et fonctionnel du port d'une orthèse lombaire souple dans la lombalgie aiguë. *Annales de Réadaptation et*  
356 *de Médecine Physique* 1999; 42(6): 333-340.
- 357 4. Calmels P, Queneau P, Hamonet C, Le Pen C, Maurel F, Lerouvreur C, Thoumie P. Effectiveness of a  
358 lumbar belt in subacute low back pain: an open, multicentric and randomized clinical study. *Spine* 2009;  
359 34(3): 215-220.
- 360 5. Vaisbuch N, Meyer S, Weiss PL. Effect of seated posture on interface pressure in children who are  
361 able-bodied and who have myelomeningocele. *Disabil Rehabil* 2000; 22(17): 749-755.
- 362 6. Fenety PA, Putnam C, Walker JM. In-chair movement: validity, reliability and implications for  
363 measuring sitting discomfort. *Appl Ergon* 2000; 31(4): 383-393.
- 364 7. Shelton F, Lott JW. Conducting and interpreting interface pressure evaluations of clinical support  
365 surfaces. *Ger Nursing* 2003; 24(4): 222-227.
- 366 8. Tam EW, Mak AF, Lam WN, Evans JH, Chow YY. Pelvic movement and interface pressure  
367 distribution during manual wheelchair propulsion. *Arch Phys Med Rehabil* 2003; 84(10): 1466-1472.
- 368 9. Reenalda J, van Geffen P, Nederhand M, Jannink M, IJzerman M, Rietman H. Analysis of healthy  
369 sitting behavior: interface pressure distribution and subcutaneous tissue oxygenation. *J Rehabil Res Dev*  
370 2009; 46(5): 577-586.

- 371 10. Rithalia SV, Heath GH, Gonsalkorale M. Assessment of alternating-pressure air mattresses using a  
372 time-based pressure threshold technique and continuous measurements of transcutaneous gases. *J Tissue*  
373 *Viability* 2000; 10(1): 13-20.
- 374 11. Hamanami K, Tokuhira A, Inoue H. Finding the optimal setting of inflated air pressure for a multi-  
375 cell air cushion for wheelchair patients with spinal cord injury. *Acta Med. Okayama* 2004; 58(1): 37-44.
- 376 12. Partsch H, Partsch B, Braun W. Interface pressure and stiffness of ready made compression stockings:  
377 comparison of in vivo and in vitro measurements. *J Vasc Surg* 2006; 44(4): 809-814.
- 378 13. Hafner J, Lüthi W, Hänssle H, Kammerlander G, Burg G. Instruction of compression therapy by  
379 means of interface pressure measurement. *Dermatol Surg* 2000; 26(5): 481-486.
- 380 14. Damstra RJ, Brouwer ER, Partsch H. Controlled, comparative study of relation between volume  
381 changes and interface pressure under short-stretch bandages in leg lymphedema patients. *Dermatol Surg*  
382 2008; 34(6): 773-778.
- 383 15. Damstra RJ, Partsch H. Compression therapy in breast cancer-related lymphedema: A randomized,  
384 controlled comparative study of relation between volume and interface pressure changes. *J Vasc Surg*  
385 2009; 49(5): 1256-1263.
- 386 16. Dumbleton T, Buis AWP, McFadyen A, McHugh BF, McKay G, Murray KD, Sexton S. Dynamic  
387 interface pressure distributions of two transtibial prosthetic socket concepts. *J Rehabil Res Dev* 2009;  
388 46(3): 405-415.
- 389 17. Candy LHY, Cecilia LTWP, Ping ZY. Effect of different pressure magnitudes on hypertrophic scar in  
390 a Chinese population. *Burns* 2010; 36(8): 1234-1241.

- 391 18. Reich-Schupke S, Gahr M, Altmeyer P, Stücker M. Resting pressure exerted by round knitted  
392 moderate-compression stockings on the lower leg in clinical practice--results of an experimental study.  
393 *Dermatol Surg* 2009; 35(12): 1989-1997.
- 394 19. van den Hout JAAM, van Rhijn LW, van den Munckhof RJH, van Ooy A. Interface corrective force  
395 measurements in Boston brace treatment. *Eur Spine J* 2002; 11(4): 332-335.
- 396 20. Aubin CE, Labelle H, Cheriet F, Villemure I, Mathieu PA, Dansereau J. Évaluation tridimensionnelle  
397 et optimisation du traitement orthopédique de la scoliose idiopathique adolescente. *MS. Médecine*  
398 *Sciences* 2007; 23(11): 904-909.
- 399 21. Fergenbaum MA, Hadcock L, Stevenson JM, Bryant JT, Morin E, Reid SA. Development of a  
400 dynamic biomechanical model for load carriage: Phase 4, Part C2: Assessment of Pressure Measurement  
401 Systems on Flat Surfaces for the Dynamic Biomechanical Model of Human Load Carriage. *Contract*  
402 *Report*, Queen's University, Kingston, Ontario, Canada. 2005; 33p.
- 403 22. Ferguson-Pell M, Hagiwara S, Bain D. Evaluation of a sensor for low interface pressure applications.  
404 *Med Eng Phys* 2000; 22(9): 657-663.
- 405 23. Lai CHY, Li-Tsang CWP. Validation of the Pliance X System in measuring interface pressure  
406 generated by pressure garment. *Burns* 2009; 35(6): 845-851.
- 407 24. Chiang CC, Lin CCK, Ju MS. An implantable capacitive pressure sensor for biomedical applications.  
408 *Sens Actuators A Phys* 2007; 134(2): 382-388.
- 409 25. Polliack AA, Sieh RC, Craig DD, Landsberger S, McNeil DR, Ayyappa E. Scientific validation of  
410 two commercial pressure sensor systems for prosthetic socket fit. *Prosthet Orthot Int* 2000; 24(1): 63-73.

- 411 26. Wheeler JW, Dabling JG, Chinn D, Turner T, Filatov A, Anderson L, Rohrer B. MEMS-based bubble  
412 pressure sensor for prosthetic socket interface pressure measurement. *Conf Proc IEEE Eng Med Biol Soc*  
413 2011; 2925-2928.
- 414 27. BIPM, IEC, IFCC, ILAC, IUPAC, IUPAP, ISO, OIML. The international vocabulary of metrology—  
415 basic and general concepts and associated terms (VIM), 3rd edn. *JCGM 200:2012*.
- 416 28. Hochmann D, Diesing P, Boenick U. Evaluierung der Messmethoden zur Bewertung des  
417 Therapeutischen nutzens von Antidekubitus-Systemen. *Biomed Tech* 2002;47(suppl 1 pt 2):816-819.
- 418 29. Völker HU, Rölker N, Willy C. Auflagedruckmessung in der Dekubitusbehandlung. *Anaesthesist*  
419 2006; 55(2): 142-147.
- 420

421 **Table captions**

422 Table 1. Design of experiments to test the reproducibility of time, place and operators

423 Table 2. Results of linearity: linear regression coefficient

424 Table 3. Results of linearity: dispersion and standard deviation for sensor 1 and mapping system C

425 Table 4: Results of hysteresis: test in only one sensor per mapping system

426 Table 5. Results of hysteresis: test in all sensors per mapping system

427 Table 6. Results of the design of experiments for reproducibility. t: time, o: operators, l: location, w:

428 weight

429 Table 7. Results of surface condition: 95% probability of a significant difference between measured

430 pressure with and without fabric between the pressure mapping system and the table are different for the

431 five tested fabrics

432 Table 8. Results of surface condition: linear regression coefficient for the second and third surface

433 condition tests

434 Table 9. Results of mapping system superposition: 95% probability of a significant difference between

435 the mapping system “from above” and “from the bottom”

436 Table 10. Results of mapping system superposition: absolute differences between measured pressures

437 with or without superposition for each pressure mapping system

438

439 **Figure captions**

440 Figure 1. FSA Pressure mapping system

441 Figure 2. Experimental device for the second hysteresis test

442 Figure 3. Experimental device for curvature test

443 Figure 4. Results of linearity: measured pressure depending on applied pressure for the sensor 1 of the  
444 pressure mapping system A

445 Figure 5: Results of the second hysteresis test (test in all sensors of a pressure mapping system): mean  
446 measured pressure depending on applied pressure for mapping system A

447 Figure 6. Results of drift: a. drift for 26mmHg applied pressure for mapping system A in the sensor 1, b.  
448 drift for 40mmHg applied pressure for mapping system C in the sensor 1, c. drift for 26mmHg applied  
449 pressure for mapping system D in the sensor 3

450 Figure 7. Results of curvature: normalized measured pressure depending on applied pressure and radius of  
451 cylinders  $R_c$  for mapping system A

452 Table 1. Design of experiments to test the reproducibility of time, place and operators

Experiments	Time	Operators	Location	Weight
	-1: t0 +1: t0 + 2 months	-1: operator A +1: operator B	-1: place A +1: place B	-1: 53mmHg +1: 79mmHg
1	-1	-1	-1	-1
2	+1	-1	-1	-1
3	-1	+1	-1	-1
4	+1	+1	-1	-1
5	-1	-1	+1	-1
6	+1	-1	+1	-1
7	-1	+1	+1	-1
8	+1	+1	+1	-1
9	-1	-1	-1	+1
10	+1	-1	-1	+1
11	-1	+1	-1	+1
12	+1	+1	-1	+1
13	-1	-1	+1	+1
14	+1	-1	+1	+1
15	-1	+1	+1	+1
16	+1	+1	+1	+1

453  
454

455 Table 2. Results of linearity: linear regression coefficient and p-value of the Student's t-test on slope=0

Mapping system Sensor	A	B	C	D
1	$R^2 = 0.978$ $p = 4.7e-6$	$R^2 = 0.962$ $p = 8.8e-6$	$R^2 = 0.982$ $p = 2.6e-8$	$R^2 = 0.967$ $p = 2.1e-5$
2	$R^2 = 0.961$ $p = 8.1e-5$	$R^2 = 0.954$ $p = 1.0e-4$	$R^2 = 0.936$ $p = 2.3e-4$	$R^2 = 0.967$ $p = 2.5e-5$
3	$R^2 = 0.972$ $p = 4.3e-7$	$R^2 = 0.951$ $p = 3.9e-5$	$R^2 = 0.964$ $p = 3.5e-7$	$R^2 = 0.862$ $p = 9.0e-4$

456

457 Table 3. Results of linearity: Dispersion and standard deviation for sensors with the best and the worst  
 458 linearity.

Sensors	Applied pressure (mmHg)	Dispersion (mmHg)	Standard deviation
With the best linearity: sensor 1, mapping system C	6.4	0	0
	13	1.74	0.641
	26	3.32	2.35
	39	2.97	1.54
	53	3.99	1.97
	79	9.05	3.22
	96	15.6	6.30
With the worst linearity: sensor 3, mapping system C	6.4	0	0
	13	0.103	0.0201
	26	0.120	0.0320
	39	1.01	0.376
	53	1.74	0.775
	79	4.35	1.97
	96	5.52	3.08

459  
 460

461 Table 4: Results of hysteresis: test in only one sensor per mapping system

Mapping system	A								B							
Sensor	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8
Hysteresis Eh (%)	15.2	16.9	7.63	4.58	11.9	7.84	16.1	10.1	3.51	6.38	11.7	0.228	18.3	15.7	27.9	9.20
Mapping system	C								D							
Sensor	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8
Hysteresis Eh (%)	3.99	4.53	7.13	2.80	5.26	3.15	9.93	2.70	6.52	3.15	3.66	3.63	2.27	3.99	10.5	7.20

462

463

464 Table 5. Results of hysteresis: test in all sensors per mapping system

Mapping system	A	B	C	D
Hysteresis Eh (%)	9.41	7.87	7.58	6.29

465

466

467 Table 6. Results of the design of experiments for reproducibility. t: time, o: operators, l: location, w:  
 468 weight

Polynomial coefficient	Value	Probability
$\beta_0$	67.76	0
$\beta_t$	0.28	0.70
$\beta_o$	1.47	0.054
$\beta_l$	2.08	0.0080
$\beta_w$	19.19	0
$\beta_{to}$	1.94	0.0013
$\beta_{tl}$	-3.84	0
$\beta_{tw}$	-0.17	0.82
$\beta_{ol}$	0.66	0.38
$\beta_{ow}$	1.24	0.10
$\beta_{tw}$	-0.73	0.33

469  
 470

471 Table 7. Results of surface condition: p\_value of the statistical test to determine the statistically  
472 significant differences between measured pressure with and without fabric between the pressure mapping  
473 system and the table.

Fabric	1	2	3	4	5
	$2.97e^{-21}$	$3.36e^{-18}$	$3.77e^{-47}$	$2.48e^{-31}$	$8.17e^{-57}$

474

475 Table 8. Results of surface condition: linear regression coefficient for the second and third surface  
476 condition tests

Sensors	1	2	5	7
Second surface condition test	0.97	0.95	0.97	0.99
Third surface condition test	0.92	0.93	0.98	0.95

477

478 Table 9. Results of mapping system superposition: p\_value of the statistical test to determine the  
479 statistically significant differences between mapping system “from above” and “from the bottom”

Sensors	1	2	3
Between mapping system A: “from above” and mapping system B: “from the bottom”	0.010	0.43	0.038
Between mapping system C: “from above” and mapping system D: “from the bottom”	0.0041	0.015	0.0058

480

481 Table 10. Results of mapping system superposition: absolute differences between measured pressures  
482 with or without superposition for each pressure mapping system in mmHg

Mapping system	A	B	C	D
Sensor 1	10.3	14.6	3.94	4.16
Sensor 2	14.0	12.5	2.97	2.48
Sensor 3	9.32	23.0	9.64	2.75

483

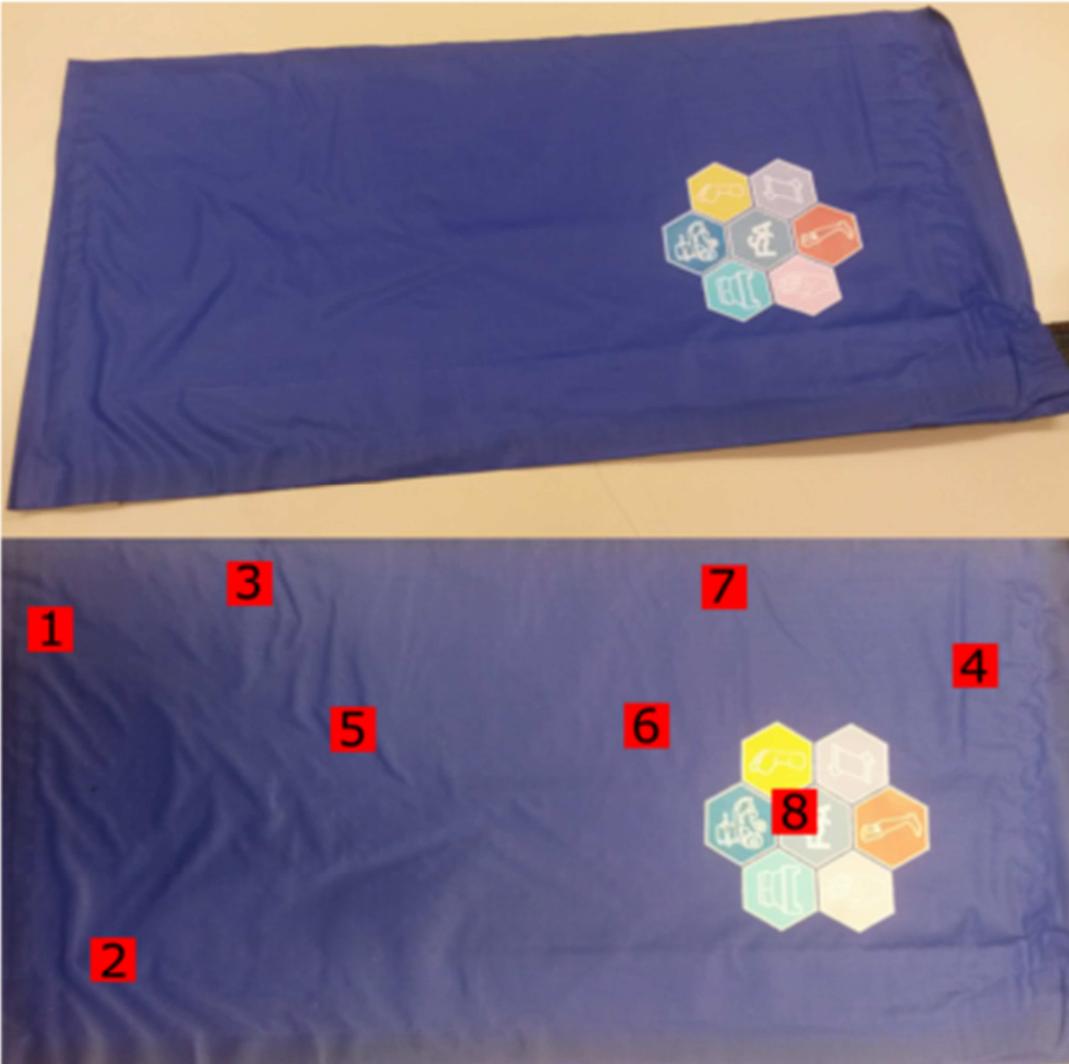
484

485 Table 11. Comparison between the studied pressure mapping system and other commercial systems based  
 486 on literature survey: resistive pressure mapping systems.

Mapping system reference	FSA	Tekscan's Flexiforce [22]	Tekscan's F-Socket [25]	Tekscan's F-Scan [21]	Rincoe [25]	Lück [29]
Measurement error	12.6 %	[5.62%, 26.3%]	8.5±7.2%	247%	24.7±19.02%	-33%
Hysteresis	[6.29%, 9.41%]	5.4±2.5%	41.9±15%	-	15.1±8%	-

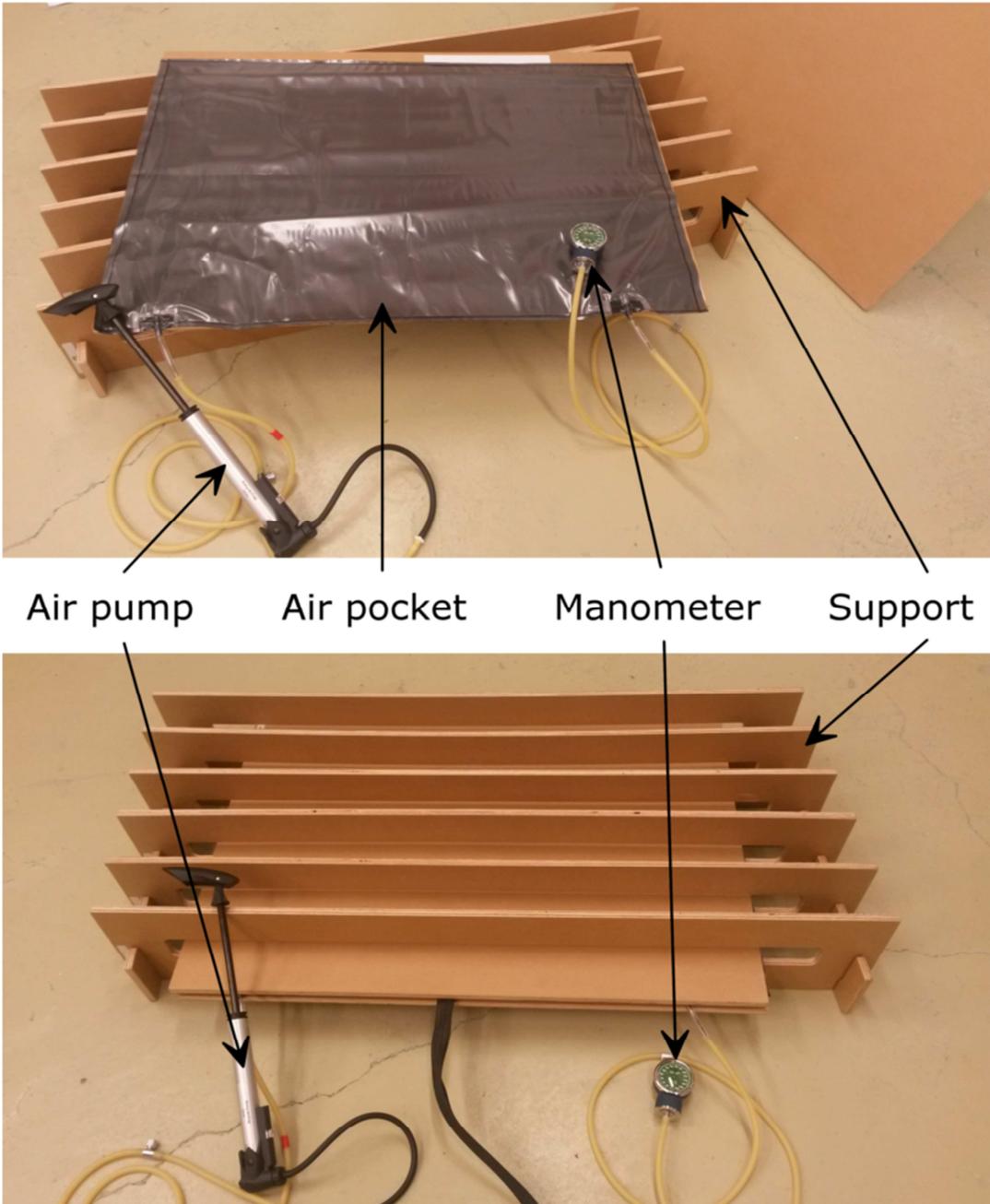
487

488 Figure 1. FSA Pressure mapping system



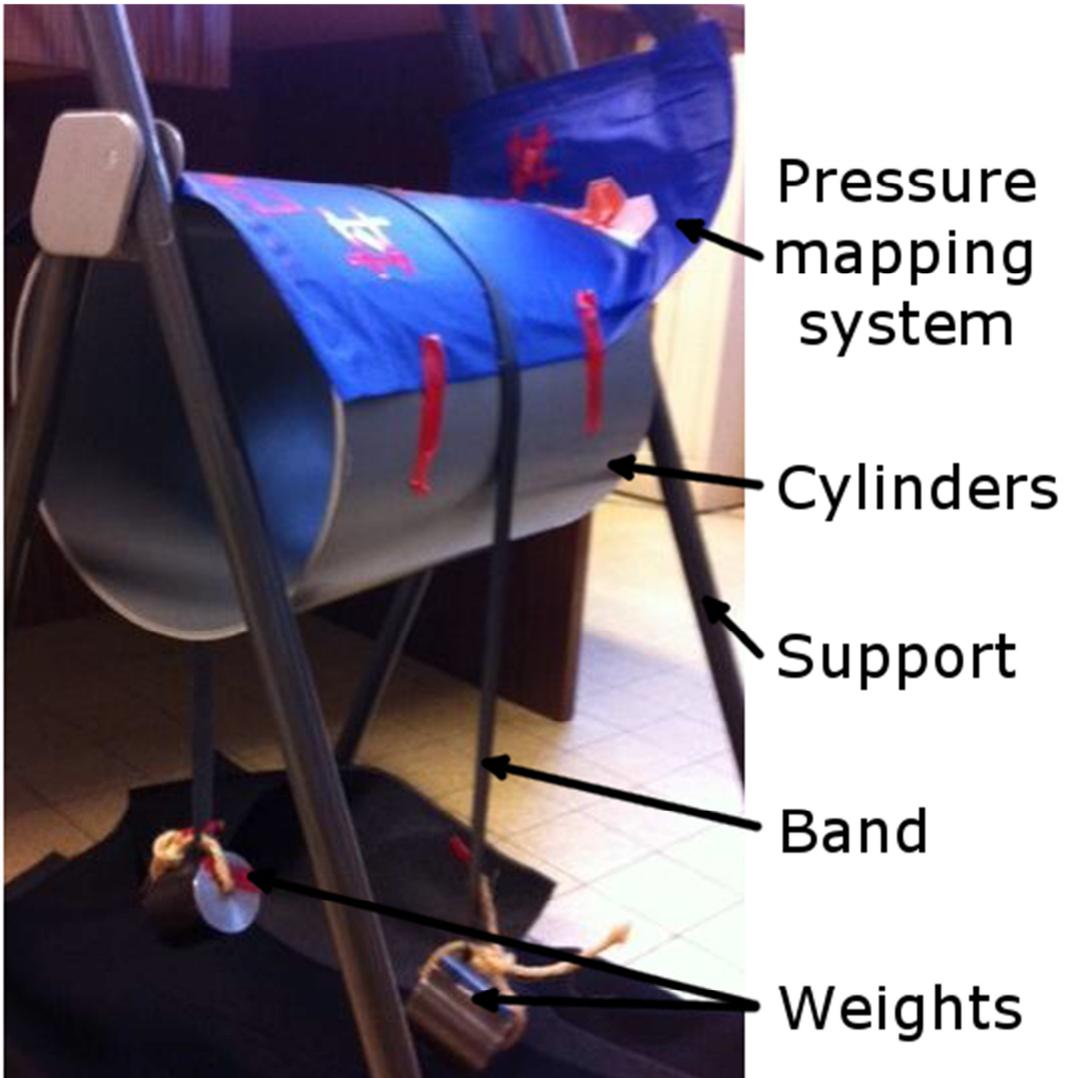
489

490 Figure 2. Experimental device for the second hysteresis test: (a) All elements of the experimental device,  
491 (b) Device in used, with one pressure mapping system inside



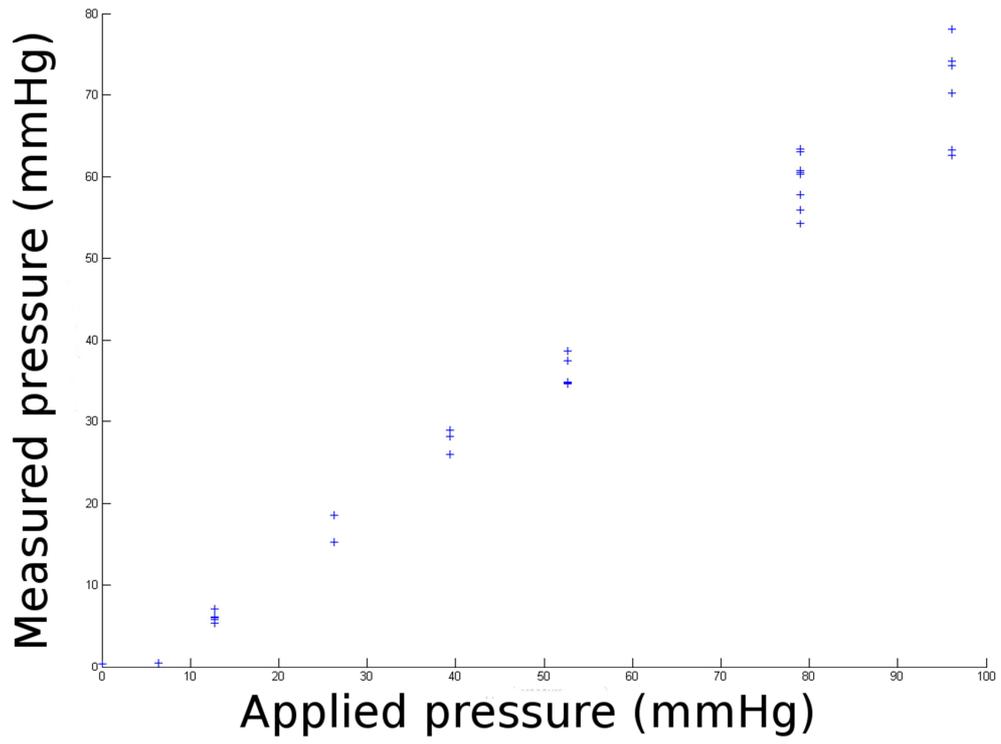
492

493 Figure 3. Experimental device for curvature test



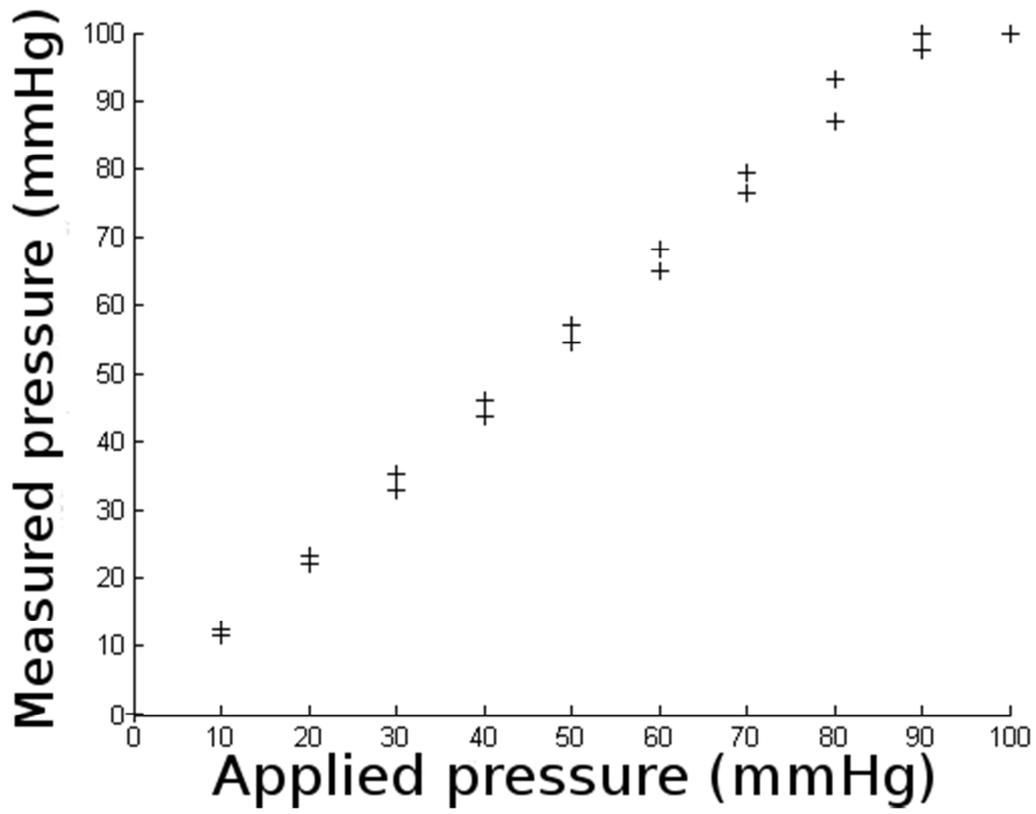
494

495 Figure 4. Results of linearity: measured pressure depending on applied pressure for the sensor 1 of the  
496 pressure mapping system C



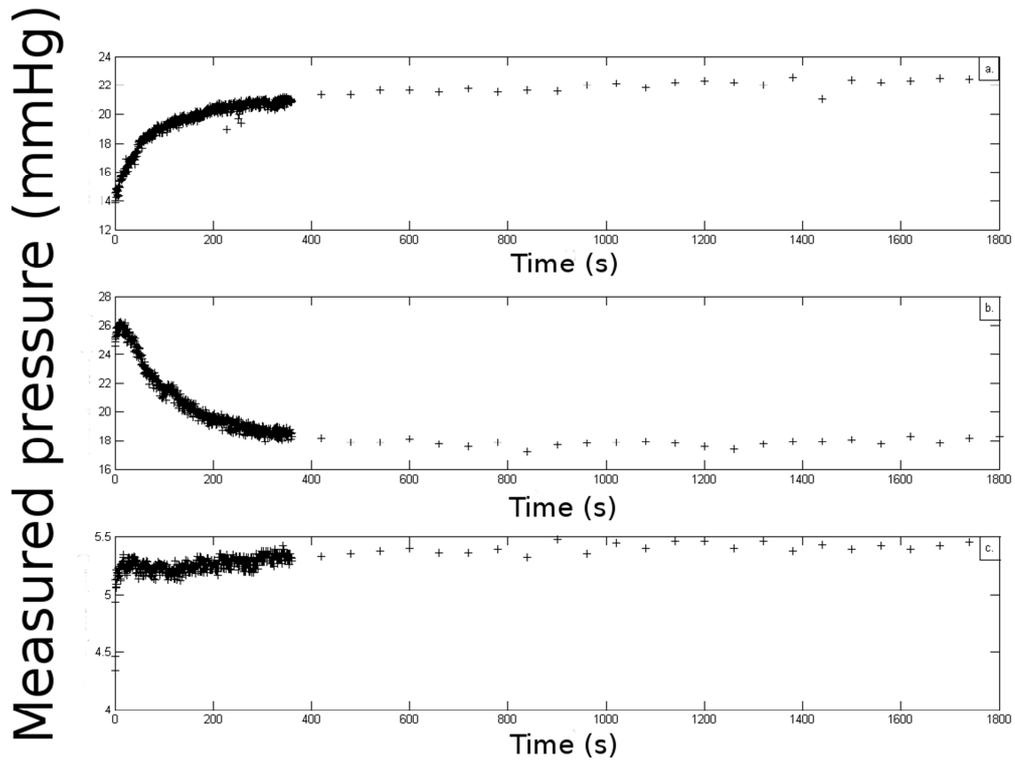
497

498 Figure 5: Results of the second hysteresis test (test in all sensors of a pressure mapping system): mean  
499 measured pressure depending on applied pressure for mapping system A



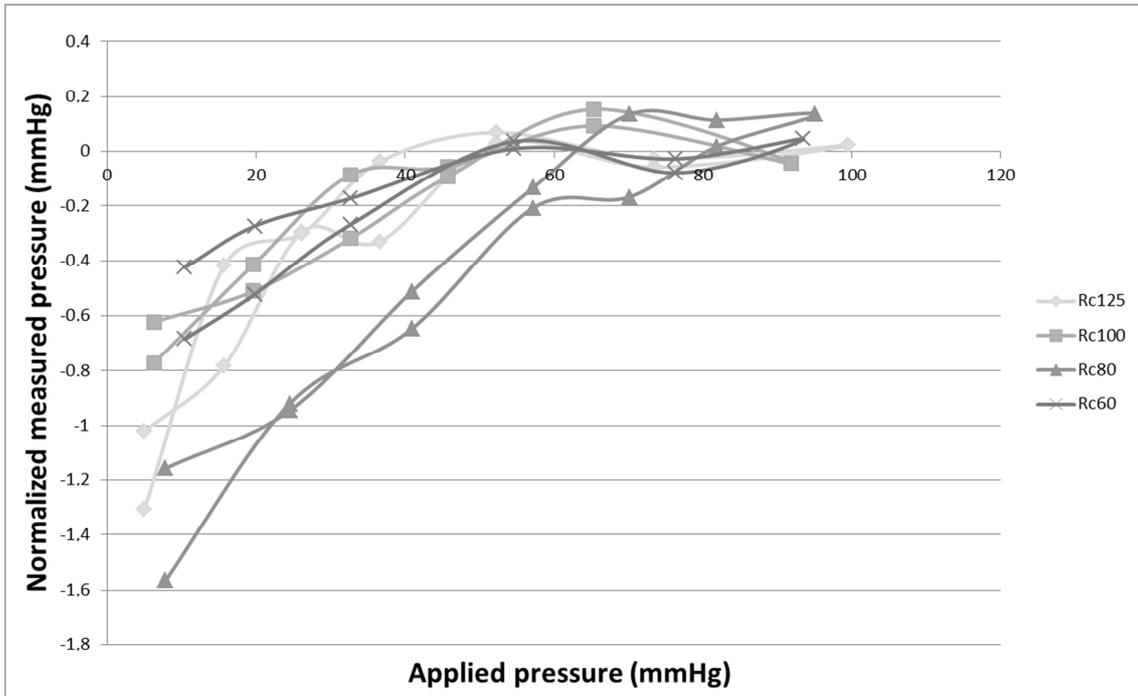
500

501 Figure 6. Results of drift: (a) drift for 26mmHg applied pressure for mapping system A in the sensor 1,  
502 (b) drift for 40mmHg applied pressure for mapping system C in the sensor 1, (c) drift for 26mmHg  
503 applied pressure for mapping system D in the sensor 3



504

505 Figure 7. Results of curvature: normalized measured pressure depending on applied pressure and radius of  
506 cylinders Rc for mapping system A



507