Proceedings of the 28th IEEE
EMBS Annual International Conference
New York City, USA, Aug 30-Sept 3, 2006

THE "PAROTEC" FOOT PRESSURE MEASUREMENT SYSTEM AND ITS CALIBRATION PROCEDURES (2005)

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I. INTRODUCTION

The Parotec is an electronic system used for measuring the pressure distribution on the plantar surface of the foot within the shoe while a subject is standing or walking. It has 8-instrumented insoles of various sizes. Each insole contains 24 sensors, which are connected to a micro-controller. The system is being used to obtain the pressure distribution within the shoe on a number of diabetic patients under various conditions.

The evaluation of the PAROTEC system was carried out in the first instance to determine errors due to non-linearity, hysteresis and zero offset. The system was evaluated in static and dynamic stages.

Key Words: Calibration Procedures, Foot Pressure Measurement System, Biomechanics, Diabetes.

This project was developed with a collaboration of the Electronics Department, the Orthopaedics and Trauma Department of the Javeriana University and the San Ignacio Teaching Hospital in Bogotá, under the supervision and cooperation of the Bioengineering Unit of Strathclyde University. The interdisciplinary team from Javeriana˝s Bioengineering resarch group was supported by COLCIENCIAS, a government sponsored research institution of Colombia; and the clinical orthopaedic centre Ortesica specialized in diabetic foot care.

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II.MATERIAL AND METHODS

The Parotec in–shoe system is effective because it consists of a minimum number of components such as:

A. A controller that receives signals from the measuring insoles
B. Four pairs of measuring insoles of different sizes with the advantage that they allowed for a good fit of the insole within the shoe during the in-shoe pressure measurement study. The four different sizes of insoles also served as a means of grouping patients during data analysis. These size groupings were: 35 to 36 (US men 3 to 41/2 or women 4 to 5), 37 to 38 (US men 5 to 6 or women 51/2 to 7), 39 to 40 (US men 61/2 to 71/2), finally 41 and 42 (US men 8 to 9 or women 91/2 to 10)
C. Software for analysis of data, see figure 1

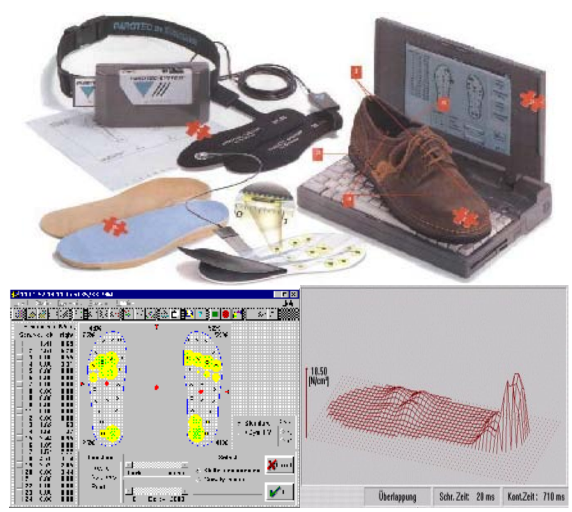

Figure 1 Parotec system, Taken from Paromed commercial catalogue (Kremer 1995)

The pressure vessel has been designed and built for the tests see figure 2. Linearity, hysteresis and accuracy were tested by fitting the insole inside a pressure vessel, which will then be pressurised to simulate the pressure loading within the shoe.
The manufactured pressure vessel underwent testing to evaluate the integrity of the sealing membrane and the fitness of purpose with regard to Parotec system evaluation.

The strength of the pressure vessel was checked by calculation for a pressure of 10000 Kpa within a water bath and these conditions maintained for approximately 10 minutes see figure 3. All other components fitted to the system are rated by the manufacturers to be capable of withstanding 10 000 Kpa

Operation and Applications of the System

The sensors measure the vertical forces under the plantar surface of the feet. Peak pressure (PP), pressure-time integral (PTI), and foot-to-sensor contact time (CoT) measurements can be made for five steps from 24 discrete sensors of predetermined positions in the foot.

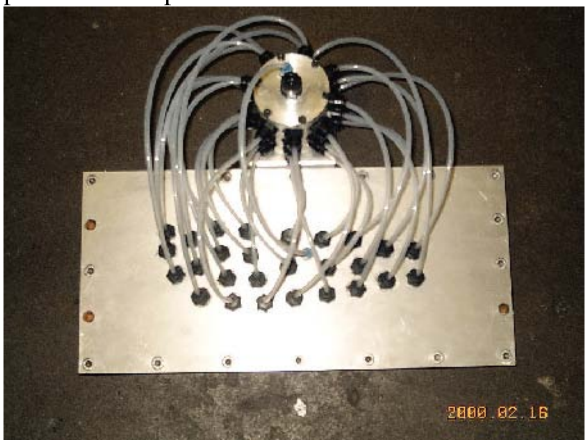

Figure 2: The pressure vessel was designed with 28 airlines for uniform redistribution of compressure air inside the vessel.

Figure 3: The pressure vessel was placed into water bath prior to testing and the strength of the pressure vessel was checked by calculation for a pressure of 10000 Kpa

The system is operated in Offline mode only and uses PCMCIA memory cards as a central storage device. Wire connections to the PC are not used. This means that the patient is not bound to the computer by a cable, allowing free and unrestricted movement within the clinical environment. The insoles have 24 measuring areas making it possible to measure 47% of the real surface of the foot and by selection of the models of measuring insoles it is possible to find exactly the places under the foot where variance in pressure has been found. This is a very simple way to accurately localise the pressure.

The Parotec-System opens all the measuring data via an ASCII file so it is possible for the end-user to have their own evaluation of all the measuring data because it is possible to import measuring data via an ASCII file into other statistical software and thus evaluate exactly those data, which are interesting for unique research applications. With the Parotec-System is possible to have real measurement frequency of 100 Hz in the basic equipment, and up to 250 Hz in the sports equipment. Every sensor is calibrated once in the factory and the calibrating data of every sensor is included in the software. Thus when installing the software the system provides calibrated measuring insole data for a lifetime. Also the system is able to give audio coded signals that sound at different events, such as the beginning of gait, state of the card, etc.

According to the manufacturer the patient must not walk more than 15 double steps. Previous research has shown that to walk more than 15 double steps does not improve the data accuracy. Sampling speed can be modified approximately according to the gait speed, as shown below:

1 m/s	3 m/s	5 m/s
100 Hz	180 Hz	250 Hz

- The software includes routines to prove the sensors performance and determine their functionality.
- The data charge station of the card is connected to the PC through a serial port.
- It allows individual sensor calibration.
- The direct temporary relationship between pressure and time is only realised in the first six double steps. The following steps will generate data to give average measurements [1],[2],[3],[5].

The measuring sequence of the Parotec system allows for an initialisation (+ zero adjustment) before each measurement. Then the 48 sensors are scanned during a period of 3 seconds and the appropriate chronological mean values are stored as offsets for the following measurements. After an adjustable pause, the static measurements follow at 10HZ over a time period of 5 seconds. All the 50 measuring cycles are recorded by the system. After this step, the dynamic measurements are carried out. At this stage the system requires at least two double steps before it accepts the measurement that the measurement is valid. [4],[6].

Static and Dynamic tests of the Equipment used for the validation of the Parotec system

Festo sensor (calibration procedure)

The Festo sensor was used to register the pressure inside the vessel and its output in different loads was compared with the Parotec sensors readings. Festo sensor is actuated via pneumatic pressure. The commercial specifications are FESTO SDE – 10 – 10 V/20 mA. No. 19562. (Pressure, from 0 to 10 bars) and the sensor output supplies an analogue signal.

Technical characteristics:

- Piezo Pressure range gauge pressure Converter
- Operating pressure max. 10 bar Minimum
- Maximum ambient temperature 85 °C
- Material of housing Aluminium
- Voltage type DC Operating voltage min. (DC) 12 V
- Operating voltage max. (DC) 30 V

The Festo pressure sensor was tested statically and dynamically at the following values of loads. (From 100, 150, 200, 250, 300, 350 and 400 kPa) at 1/4 Hz, before the insoles were positioned in the pressure vessel and all the equipment were connected for the validation of the
Parotec. See appendix B.4.c. calibration graph from the manufactures is shown in (figure 4).

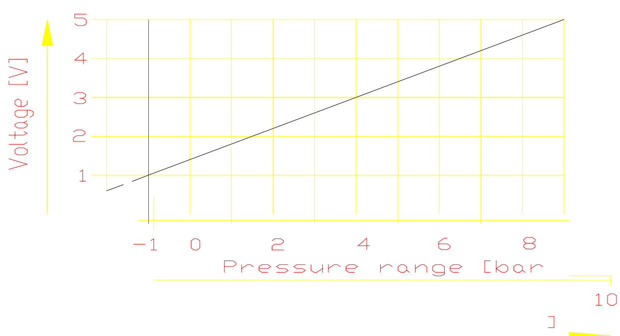

Figure 4. Calibration graph from the manufacturer a feature of this particular transducing element is an operating parameter in partial vacuum conditions and a positive output for zero pressure.

A Proportional pressure regulator FESTO valve type MPPES-3-B – ¼ - 6- 010 No.187337. (Pressure, from 0 to 10 bars) was used to allow the dynamic evaluation of the Parotec. This proportional valve was connected to a power supplied manufactured in the Bioengineering Unit of Strathclyde University and to a pulse generator UNAOHM, serial No. B10- 0010 at different sample of frequencies. The valve was accuracy for the propose of this study (figure 5).

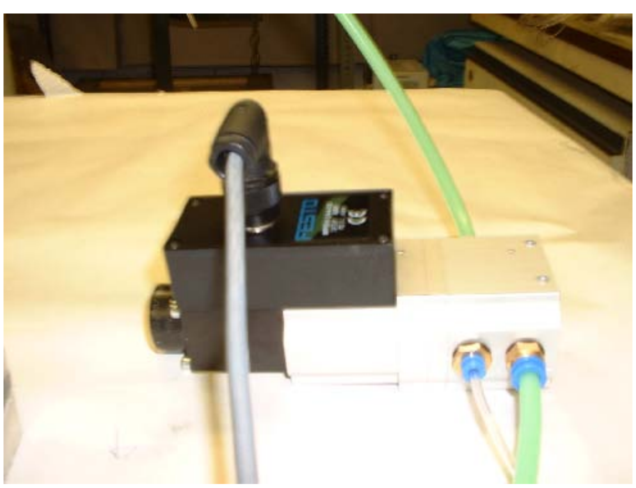

Figure 5 Proportional Festo Valve for the dynamic test

Static and Dynamic procedures:

A. Testing procedure

The Parotec insoles were positioned in the pressure vessel and all the equipment were connected. The insoles were tested statically and dynamically at the following values of loads. (From 100, 150, 200, 250, 300, 350 and 400 kPa) at 1/4 Hz, increasing for static test and increasing and decreasing for the dynamic pressure). Each test was repeated three times per insole.

Procedure for Static test

Two insoles with 24 pressure sensors for different sizes (35/36 and 39/40, the most common sizes used by the group of patients of this study) were tested in statically and dynamic conditions in the range from 100 kPa to 400 kPa used a pressure vessel and the data was recorded by the memory card of the microcontroller system and transmitted to the P.C. for analysis. See (figure 6).

The whole process was repeated three times with the same conditions for accuracy.

B. Test protocol for static test

- The air supply was connected to the test apparatus.
- The line pressure was set at the airflow regulator FAIRCHILD
- Model 16 No.16153
- The internal pressure of the vessel insole was checked by Bourdon pressure gauge (from 0 to 10 bar) and by the Pressure sensor FESTO SDE – 10 – 10 V/20 mA. No. 19562.
- The Parotec microcontroller was programmed for static conditions.
- The Parotec was initiated and the pressure to the vessel was applied via an on/off switch.
- The row data was recorded (10 second phase) and the applied pressure was removed from the pressure vessel.
- The microcontroller now goes into standby in readiness for the dynamic mode.

The proportional control valve is now placed in series with the applied pressure to simulate a dynamic response and connected to a power supply and to the pulse Generator UNAOHM, serial No. B10- 0010.

Data (Dynamic) is recorded (10 seconds) and the Parotec cycle is completed.

Data is transmitted to the P.C. for analysis. In this case only static data was analyzed.

From this data linearity and accuracy were found for the all-24 sensors in both insoles.

The results of the main sensors corresponding to the metatarsal heads, Hallux and heel of the foot were reported in this study.

The dynamic test was very similar to the static with the differences that Festo regulator valve was used for dynamic conditions and only the dynamic row data was recorded and the sensor output supplies an analogue signal. And the row data from Parotec sensors and Festo sensor were analyzed graphically and a comparison was made between them.
The apparatus was set up for the static and dynamic tests validation of the Parotec system.

- The input of pressure was set up at the Airflow regulator from 0 to 400 kPa.
- The electrical signals to energise the Festo pressure sensor, Festo proportional regulator valve, and the pulse generator were supplied at a frequency of 0.25 Hz.
- The input pressure was verified by means of a Bourdon gauge on the pressure vessel.

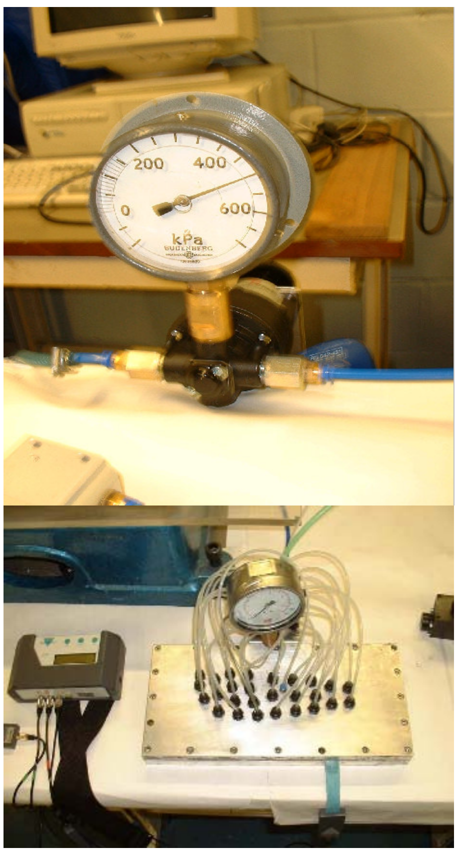

Figure 6 Instrumentation required for static test

- The Parotec microcontroller is programmed - start of test.
- For the static phase the Festo proportional valve was bypassed and the following dynamic phase was instigated by means of an on – off switch to facilitate the inclusion of the dynamic pulse.
- The Parotec them completed the static and dynamic cycle.
- The Festo pressure sensor by means of acquisition card and specially written in Lab View program 5.3 record the signal from Festo pressure sensor which was synchronize in time with the microcontroller of Parotec during static and dynamic cycle.
- Both sets of data (Parotec sensors and Festo pressure sensor) are processed and recorded for later analysis.

This procedure is repeated under varying condition, frequency, and pressure and size insoles. Of the Parotec system with relation to hysteresis, linearity, accuracy and system response.

The dynamic test was very similar to the static with the differences that Festo regulator valve was used for dynamic conditions and only the dynamic row data was recorded and the sensor output supplies an analogue signal. And the row data from Parotec sensors and Festo sensor were analyzed graphically and a comparison was made between them

Data Analysis

The average peak pressures values from the trials (maximal pressure measured by sensor) were found for each sensor (24 sensors) in static load inputs of 100, 150, 200, 250, 300, 350 and 400 at ¼ Hz. were tested in the two most commonly used sizes of insoles (No. 35/36 and 39/40).

IV. RESULTS

Errors for non-linearity, hysteresis and accuracy were reported from the data obtained in the satatic test for the sensors No 1,2,3,4 (heel area),17,18,19 and 20 (forefoot area) and for sensors 21,22,23 and 24 corresponding to the toe area. See tables 4.1 and 4.2 and examples of non-linearity and hysteresys results in table 4.3 and figures 4.10 and 4.11.

Area of Foot	Sensor No.	Hysteresis (%)	S.D. (%)	Accuracy (%)
Toes	24	6	2.00	8.00
	23	6	1.00	7.00
	22	8	2.00	10.00
	21	10	4.00	-8.00
Metatarsal Heads	20	9	4.00	-16.00
	19	8	3.00	0.00
	18	11	2.00	-2.00
	17	5	2.00	6.00
Heel	4	8	4.00	-12.00
	3	7	2.00	0.00
	2	6	2.00	2.00
	1	7	2.00	1.00

Table 9.1 Hysteresis and Accuracy found in insole size 35/36 (sensor located at heel, forefoot and toes areas)

In the static test for hysteresis, the incremental load started at zero and increased in value up to 400 kPa, then decreased back to 0 pressure. This resulted in 17 distinct sets of data for each sensor. The same procedure for processing data was carried out and hysteresis was calculated for each sensor for the two different sizes of insoles. See samples of the sensors, which represent the main area of the foot, which are heel (sensor 4), forefoot (sensor 19) and toe region (sensor 23) figures. From the previous test, this study will only report data from those sensors located in high-risk areas for high pressure according to the literature review.

Area of Foot	Sensor No.	Hysteresis (%)	Linearity (%)	Accuracy (%)
	24	5	1.00	10.00
Toes	23	4	1.00	10.00
	22	4	2.00	4.00
	21	10	3.00	12.00
	20	10	4.00	4.00
Metatarsal	19	5	3.00	-4.00
Heads	18	4	2.00	2.00
	17	4	2.00	5.00
	4	2	3.00	5.00
Heel	3	4	2.00	7.00
	2	5	2.00	0.00
	1	5	3.00	-6.00

Table 9.2 Hysteresis and Accuracy error found in insole size 39/40 (sensor located at heel, forefoot and toes areas)

In the dynamic test a similar procedure was carried out as for the static test for hysteresis, and with the data obtained from comparison of the average pressure values were made in order to established the variability of the sensor behaviour. This comparison was also made in order to determine if the pressure static and dynamic tests recorded in similar conditions, a

Sensor Input (kPa)	Sensor output (kPa)					%			
	Sa	Sb	Sc	Average	Accuracy	Accuracy 2	S.D.	Ave.S.D.	Linearity
0	2.2	1	1.3	1.5			0.62	0.47	
100	93.5	107	108.7	103.07	-3.1%	- 3.07	8.33	6.38	
150	135.4	132.3	151.6	139.77	6.8%	10.23	10.36	7.89	
200	188	174.9	202	188.3	5.9%	11.70	13.55	9.13	
250	237.7	245.1	249.8	244.2	2.3%	5.80	6.10	4.33	
300	293.7	290.4	294.3	292.8	2.4%	7.20	2.10	1.60	
350	337.4	359.6	347.7	348.23	0.5%	1.77	11.11	7.58	
400	391.1	412.3	397.7	400.37	-0.1%	- 0.37	10.85	7.96	
450	447.1	440.2	448.6	445.3	1.0%	4.70	4.48	3.40	
Average					**2%**	**4.75**	**8.36**		**2%**

Table 4.3 data from the static test from sensor No. 4 (Located in the heel area) in kPa

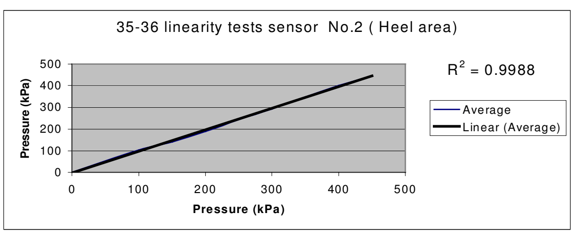

Figure 4.10 Static test of the Parotec insole at 400 kPa input at ¼ Hz.

vessel designed affected the output of the sensors of the Parotec system. The last test carried out was a comparison between the outputs of the Parotec sensors in the dynamic test with the output of Festo pressure sensors in order to determine accuracy by overlapping the output signals from both systems at $^1/_4$Hz.

V.CONCLUSIONS

The errors established for the Parotec sensors in non-linearity and hysteresis were found to be acceptable in the range of 0 – 400 kPa in the sizes of insoles evaluated (35/36, 39/40). The accuracy of the system is estimated after 4 years of use to be 10 % (Max) and non-linearity 4% and the accuracy and non-linearity of the system were 2 % and 0.42 % .

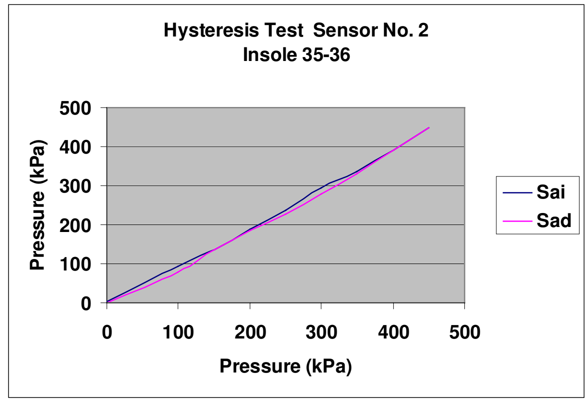

Figure 4.11 Hysteresis test of the Parotec insole for 400 kPa input at ¼ Hz

It is believe that the design of the pressure vessel for applying static and dynamic pressure on the transducers is an important contribution to the validation of the Parotec system.

It was demonstrated that the technique used for dynamic evaluation of the performance of the Parotec system was useful and the use of the proportional Festo valve with a pulse generator allows the operation of the system in dynamic mode to be simulated, thus, allowing evaluation of the system in conditions close to the mode of the operation of the system when a subject is walking.

It is believe that the main advantages of the Parotec system is the hydro cell technology however the number of sensors is no enough for recording pressure in areas at-risk such as the 5^{th} toe, MTH1, MTH4 and MTH5, according to the results from the X-ray study

VI. ACKNOWLEDGMENT

This project participated to the research line of Bioengineering upon the summons of COLCIENCIAS governmental organization witch promote research projects. Investigations groups and it obtained B classification as well as a bonus for a value of US 8000 It was officially registered at Bioengineering and Signals Analysis and Images Processing group.

VII. REFERENCES

[1] **Kraemer F.W. Parotec** (1995).System instruction manual. Neubeurn. German: Paromed.10-12.

[2] **Liu W., Miller J., Stefanyshyn D., & Nigg B. M.** (1999) Accuracy and reliability of a technique for quantifying foot shape, dimensions and structural characteristics. *Journal of Ergonomics.* 42(2), 346–358.

[3] **Mochimaru M. & Kouchi M.** (1997) Automatic calculation of the medial axis of foot outline and its flexion angles. *Journal of Ergonomics.* **40**(4) 450– 464.

[4] **Schlotthauer G., Nicolini G.A., Gamero M., Torres M.E.** (2002) Type1 diabetes: modeling, identification and non-linear model predictive control, proceeding of the second joint EMBS/BMES Conference Houston, TX, USA

[5] **Urry S.** (1999).Plantar pressure-measurement sensors. Means. Sci. Technol. Vol (10):R16-R32. Printed in the U.K.

[6] *IEEE Criteria for Class IE Electric Systems* (Standards style), IEEE Standard 308, 1969.