A FURTHER STEP TOWARDS CONSENSUS ON HARDWARE PERFORMANCE AND TECHNICAL ASSESSMENT OF PRESSURE MEASUREMENT DEVICES: THE ESM2010 PROPOSAL.

Claudia Giacomozzi, Istituto Superiore di Sanità, Rome, Italy

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Preface on ESM, and ESM 2010.

ESM is the acronym for Emed Scientific Meeting, Emed being the plantar pressure measurement platform provided by the firm Novel gmbh (Munich, Germany; <u>www.novel.de</u>). ESM is a scientific event which takes place every two years, sponsored by the above company and hosted by important research and clinical centres all over the world. Briefly, the event was born nineteen years ago upon a proposal by Professor Leslie Klenerman, who approached the company and asked them to support the first "Emed User Group meeting", which the University of Liverpool hosted in 1992.

ESM main purpose is to provide a stimulating environment for the exchange of experience and results in pressure distribution measurements and technology, not only among Emed users but with anyone interested in pressure distribution measurements in the context of biomechanics of the human locomotor system. The format of the meeting consists in scientific and clinical presentations and workshops.

The 2010 ESM was held in Providence (Rhode Island, U.S.A.) on August 14-17 2010, hosted by the Brown University, The Centre for Restorative and Regenerative Medicine, in cooperation with the University of Rhode Island. An additional tool was used this year during the meeting: the podium discussion. Podium discussion 1 was titled "Pedography as a Diagnostic Method for Determining Foot Function: Technical, Methodological and Other Requirements (Hillstrom H., Kalpen A., Giacomozzi C., McPoil T., Rosenbaum D.)". One of the critical points that came out during the discussion –shared by panellists and audience alike- was the **need for standardisation in the field of pressure distribution measurement in terms of hardware performance, measurement protocols, data processing, parameters and indicators in diagnosis and therapy.**

Purpose of the current Document

The Italian National Institute of Health (Istituto Superiore di Sanità, ISS, Rome, Italy), Department of Technology and Health, has been involved for more than twenty years in the development, assessment and application of instrumentation and methodologies for plantar pressure

measurements. On May 10, 2010, ISS organized and hosted the workshop "Assessment of pressure measurement devices (PMDs) for their appropriate use in biomechanical research and in the clinical practice". A first document was presented at the workshop, dealing with methodological issues and some important recommendations to manufacturers and end users of PMDs, with special focus on the assessment of PMD hardware performance [1]. On the basis of the general positive feedback from the participants in the Rome workshop, a Document for a consensus proposal on recommendations and minimum requirements for assessment and appropriateness of PMD hardware performance has been prepared and submitted to the ESM 2010 Scientific Committee (Cavanagh P., D'Andrea S., Kalpen A., McPoil T., Morlock M., Rosenbaum D., Pisciotta J., Woo H.,). Soon after the ESM meeting, ISS activated a moodle-based interactive web page where ESM participants who agreed to be registered could find the above material and a form to send in suggestions, feedback and their eventual formal agreement to be officially part of the above Preliminary proposal for Consensus. Despite the short time elapsed between ESM 2010 and the i-FAB meeting, a lot of ESM participants showed their interest in going deeper into the proposed issue, and more than 20 of them asked for their account to the ISS moodle page, where they could surf the page, exchange opinions and have the chance to download and analyse the above documents. By Sept 10, eleven signed agreement forms had been sent in (names and affiliations are listed in Appendix 4).

Main goal

The present Document, which integrates the previous indications with the precious suggestions from ESM 2010 participants -specific suggestions are highlighted throughout the text- is thus intended as a further step towards the standardization process and the finalization of a *Consensus on recommendations and minimum requirements for assessment and appropriateness of PMD hardware performance*; hopefully, it will also represent a starting point for the wider standardization activity of the new i-FAB Pedography Group on all the relevant aspects of pressure measurements in the field of human motion biomechanics.

Reference person:

Claudia Giacomozzi, Senior Researcher, PhD in Bioengineering, Department of Technology and Health Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy e-mail c_giacomozzi@yahoo.com (preferred); claudia.giacomozzi@iss.it

Reference documents:

- Giacomozzi C. Hardware performance assessment recommendations and tools for baropodometric sensor systems. ANN IST SUPER SANITÀ 2010 | VOL. 46, NO. 2. In press (available at <u>http://www.iss.it/anna/rivi/cont.php?id=2395&lang=1&tipo=2&publ=3</u>, last visited May 24th 2010)
- 2. Giacomozzi C. Appropriateness of plantar pressure measurement devices: a comparative technical assessment. *Gait & Posture* 2010 Apr 15. [Epub ahead of print]
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- 4. Directive 93/42/EEC on Medical Devices, *Official Journal of the European Union*, July 12th, 1993.
- 5. Directive 2007/47/EC on Medical Devices, *Official Journal of the European Union*, Sept 21st, 2007.

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- 7. Directive 2009/3/EC amending Council Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement, *Official Journal of European Union*, May 7th, 2009.

Acknowledgements

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Summary of keypoints (red text: specific ESM 2010 contribution)

PMD use.

Plantar pressure measurement devices (PMDs) are widely disseminated:

- in biomechanical research contexts, where they are mainly used to acquire kinetic parameters of foot-floor interaction during gait, running and standing, even though few experimental studies are currently conducted to use PMD outputs as input for FEMs and in general for biomechanical models;
- in clinical contexts, as a support to diagnosis, early detection of pathologies, and monitoring during the treatment of orthopaedic diseases as well as degenerative or metabolic or systemic diseases, e.g., Diabetes and Rheumatoid Arthritis;
- as a key instrument for the prescription, design and construction of plantar orthoses, in some cases directly linked to CAD/CAM systems.

Terminology.

While pressure measurements are becoming increasingly widespread in research and clinical environments, great confusion is still present in the terminology used. The confusion is evident even in the definition of the discipline itself: terms like baropodometry, pedobarometry, pedobarography, pedography are currently used. There is a proposal for the adoption of the term pedography, even though a general agreement has not been reached as yet (Appendix 1).

A preliminary list of terms which need clarification has been suggested (Appendix 2).

Medical Devices Regulation.

While there is a general agreement on the "classification" of PMDs which should definitely be certified as Medical Devices with measuring function, some confusion is still present in PMD classification with respect to Medical Devices Regulations. Besides that, neither standard procedures nor guidelines have been devised up to now at the international level to assess PMD technical performance at the time of their placing on the market and/or periodically during their lifetime.

Standardization and comparability.

Pressure measurements should be comparable throughout the world-wide scientific scenario. It is thus mandatory to reach agreement and consensus on the procedures and criteria to standardise: i) the way to assess PMD technical performance and the minimum requirements they have to comply with in order to guarantee the appropriate performance over their whole lifetime; ii) the measurement setup and protocols; iii) the data processing, the relevant measured parameters, the algorithms and the way to estimate derived quantities and indicators, the minimum level of significance of parameter changes.

Co-operation.

ISS started the activity to address the keypoint regarding PMD technical assessment and performance. Within this specific activity, there is the need for consensus and agreement on common recommendations for tools and procedures for the technical assessment of PMDs, which should be suitable for application to all commercial PMDs and prototypes. There is also the need for concerted actions between the scientific communities and PMD manufacturers.

Abstract

Accurate plantar pressure measurements are mandatory in both clinical and research contexts. Differences in accuracy, precision, reliability of pressure measurement devices (PMDs) prevented so far the onset of a standardization processes and of the design of reliable reference datasets. The Italian National Institute of Health (ISS) approved and conducted a scientific project (2006-2008) aimed to design, validate and implement dedicated testing methods for both in-factory and on-the-field PMD assessment. A general-purpose experimental set-up was built, complete and suitable for the assessment of PMDs based on different sensor technologies, electronic conditioning and mechanical solutions. Preliminary assessments have been conducted on 5 commercial PMDs. The study led to the definition of: i) an appropriate set of instruments and procedures for PMD technical assessment; ii) a minimum set of significant parameters for the technical characterization of PMD performance; iii) some recommendations to both manufacturers and end-users for an appropriate use in the clinical and research environments.

Proposed Testing devices and measurement protocols

The ISS testing equipment consists of two devices: a custom pneumatic bladder pressure tester (PM), mainly thought for in-factory calibration, and a dedicated pneumatic-force testing device (PTD) also meant for on-the-field assessment. The equipment is completed by a 12-bit bnc-wired A/D converter and a notebook. A brief technical description is here reported, since the whole equipment has been widely described elsewhere (see reference documents).

With a PM pressure can be uniformly applied over the entire PMD sensor matrix in the range 0-1200kPa. The PM is a very heavy structure with a membrane to interface the inflated air and the PMD surface, completed with a set of wooden slots to exactly fit each tested PMD. It is used together with a digital pressure transducer (resolution 10Pa). The PTD (Figure 1a) consists of a dedicated pneumatic testing device with an on-off valve, a proportional valve, force and pressure controls (relative error <1%). Pressure is applied through a stainless steel pressure head which, once pressed against the PMD surface, forms a squared pressure chamber (7.03 cm²). Pressure may be applied in the range 0-600 kPa with negligible bar deflection under static and dynamic conditions. In order to assess COP coordinates, with an additional PTD tool known forces are applied through 3 pylons (Figure 1b). The tool consists of a graduated aluminium round table and a graduated positioning system. The table has three 3cm-diameter pylons placed at the angular distance of 120°, and a central hole covered by a semi-spherical loading point. By removing the latter, theoretical COP coordinates can be acquired by pressing a tip through the hole. A suitable protective case is used for the pressure chamber (Figure 1c) when coupling the table with the PTD.

To prevent damages to the PMD surfaces, and in order to render the application of the ISS testing equipment suitable for a uniform loading distribution with each and every PMD commercial cover, thin silicone rubber is used under the edge of the PTD pressure chamber and under the pylons of the graduated round table.



Figure 1 Test devices and tools: a) dedicated pneumatic-force testing device (PTD); b) graduated table of the tool to apply known forces through PTD; c) pressure chamber protective case, to be used when coupling the PTD with the table in b.

The ISS APPROVED PROTOCOL FOR TECHNICAL ASSESSMENT OF PMDs is thoroughly reported in the Reference Documents. In brief, it contains the following measuring sequences and related indicators:

a. **Pressure static measurements over short periods**: loading-unloading sequence from 0 to 600kPa, and down to 0kPa; step 100kPa; duration of each step 10s; pressure down to 0 between two successive pressure steps; sampling rate: 50Hz; PMD sampling rate: at least 5Hz. 5 repetitions for each selected area. Indicators to be calculated for the test: regression curves and equations; RMSE (expressed in kPa); mean RMSE and sd over the five areas.

b. **Pressure static measurements over a long period (creep)**: pressure is fixed at 300kPa, and maintained for 60s. ISS sampling rate: 50 Hz. PMD sampling rate: at least 5 Hz. 1 repetition for each selected area. Indicators to be calculated for the test: plots and regression curves and equations of read pressure *vs*. time; mean differences between applied and read pressure; pressure gradient $(\Delta P/\Delta t)$, expressed in kPa/s, for each area and averaged over the five areas.

c. **Pressure sinusoidal loading-unloading measurements**: sinusoidal loading-unloading, frequency 0.75 Hz, pressure range 0-500kPa; ISS sampling rate: 250 Hz. PMD sampling rate: at

least 20Hz. Acquisition of 30 cycles per area. Indicators to be calculated for the test *i*) for each area: plots of cumulative regression curves of read *vs*. applied pressure; %hysteresis (expressed as a % of the applied pressure range); correlation of loading-unloading curves; RMSE (expressed in kPa); *ii*) over the five areas: mean RMSE and standard deviation.

d. **Pressure pulse measurements with synchronization**: pulses at 400kPa + high-active-TTL synch signal; ISS sampling rate: 500 Hz. PMD sampling rate: maximum available. Duration of acquisition: 3s. 1 repetition – containing at least 3 pulses – per area. Indicators to be calculated for the test: regression curves (and equations) of read *vs*. applied pressure; RMSE (expressed in kPa); mean RMSE and sd over the five areas; time delay (expressed in s) between the applied and the read maximum pressure.

Load measurements with PTD + RT: they are obtained by using the PTD + a rigid cover e. for the pressure chamber + a positioning device + the aluminium round table (RT) with three large pins and two interposed soft layers. The initial condition is: 300kPa under each pin. Initial marking of the Centre of Force – acquisition with a pin vertically pressing in the small hole at the centre of RT -, to be compared with the estimated location of COP. The sequence is based on: 10s of static acquisition in position 0 of each area; rotation of 20° around the centre of the area; acquisition in position 1; rotation of 20° around the centre of the area; acquisition in position 2; rotation of 20° around the centre of the area; acquisition in position 3; rotation of 20° around the centre of the area; acquisition in position 4; rotation of 20° around the centre of the area; acquisition in position 5; rotation of 20° around the centre of the area; acquisition in position 0. Maximum load is recorded by PD load cell. 1 repetition per area. ISS sampling rate: 50 Hz. PMD sampling rate: at least 5Hz. Indicators to be calculated for the test: for each area: plots of the superimposed spatial distributions of pressure for each angular position together with the estimated COP positions and the theoretical COP; RMSE for accuracy (with respect to the theoretical COP) and for precision (with respect to the mean coordinates); RMSEs averaged over the five areas;

f. **Pressure static measurements over a wide area**: they are obtained by using PM + digital pressure transducer. The sequence is an incremental loading from 0kPa to 1200kPa and down to 0kPa with 10s of static loading followed by a ramp of 10s to perform a step of 100kPa. Company suggested sampling rate: 5 Hz. ISS reading of digital value of applied pressure. Indicators to be calculated for the test: maximum and mean pressure values; RMSE (expressed in kPa); regression curve of mean pressure values *vs.* applied pressure.

The protocol should be applied to 5 randomly selected spot areas; centre of each area should be at least 7.0 cm far from the border of the sensitive surface.

Legend to the protocol: PTD = pressure testing device; RT = round table; PM = press machine; COP = centre of pressure; RMSE = root means square error; PMD = pressure measurement device

Recommendations to manufacturers

The following main recommendations are suggested for manufacturers

- to implement in-factory technical assessment procedures to characterize the technical performance of each device in its final commercial arrangement. A suitable testing equipment should be prepared and validated, similar -in terms of performance- to the equipment proposed by ISS. In any case, the testing equipment must have higher precision and accuracy than expected for the PMD. At least, it must have pressure resolution below 10 kPa, force resolution below 1N, spatial positioning re-positioning error lower than 2 mm, and sinusoidal loading-unloading cycles must be applied with a frequency in the 0.5-1.0 Hz range. Finally, the testing equipment should allow the investigation of the entire PMD range of pressure;
- to assess the PMD technical performance at least with respect to: i) sensor response variability all over the platform; ii) sensor response in terms of absolute value of pressure;

iii) sensor hysteresis, measured with a loading-unloading frequency not greater than 1Hz; iv) sensor response in terms of creep (loading time not less than 60 s, loading not less than 200 kPa); v) platform response in terms of accuracy and repeatability (precision) of COP coordinates estimation;

- to correctly inform the user on the above assessed technical performance at the time of device delivery and installation: a proper report on the in-factory technical assessment of the specific PMD should be delivered to the users in order to let them understand the quality of the measurements they are going to obtain; a list of reference values of the "ideal" platform should be also reported for user information, values which guarantee the stability, accuracy and reliability of measurements, i.e.: accuracy < 5% and variability < 10 kPa over the entire platform and for the entire pressure range; hysteresis < 5% with a loading-unloading range up at least half of the entire pressure range; creep < 5 kPa/s in case the PMD is only intended for dynamic analysis, or creep < 0.15 kPa/s in case the PMD is also intended for static posturography; spatial accuracy and precision error lower than the PMD spatial resolution along each axis. As for the PMD pressure range, the user should be made aware that in presence of pathologies like Diabetes or Rheumatoid Arthritis peak pressure may well overcome the 1000 kPa;</p>
- to correctly form the users to the effective, safe and correct use of the device; it is here mandatory that the manufacturer delivers with a high degree of transparency the information the user needs to know about all the implemented data processing procedures: especially relevant is, for example, the availability of transparent data display and export procedures;
- to guarantee that an adequate quality of PMD performance is maintained during time; this may be achieved by periodically calling back the device and re-testing it in factory, by implementing periodic spot-checks on-site, or by giving the users adequate instructions so that they may perform proper spot-checks on-site to easily detect significant changes in PMD performance and promptly alert the manufacturer.

Recommendations to end-users

The following main recommendations are suggested for end users.

- Ask the manufacturer for the complete report about the results of the in-factory technical assessment the manufacturer should have performed on the specific PDM in its final commercial arrangement. At least, the report should contain information on the specific PMD, e.g., overall accuracy, variability, pressure range and resolution, spatial resolution and COP accuracy and precision, hysteresis, creep. Examples on the effect of PMD technical performance on the final outcome i.e., measured *vs.* theoretical peak pressure, maximum vertical force, COP estimation might be requested by the user for better clarification.
- Ask the manufacturer for the proper documentation and information for the appropriate, effective, safe and correct use of the device;
- Monitor the quality of PMD performance during time. The procedure to optimise this phase should be discussed with the manufacturer at the time of PMD delivery and installation. Some firms already give instructions to users to compare the overall force outcome of the PMD with the corresponding outcome of a superimposed force platform [6]. This might represent a useful means for PMD monitoring, but the reference force platform must be itself correctly maintained and calibrated and, most important, this sort of check must be performed under repeatable and controlled conditions starting from the first PMD installation. ISS proposes a simple, low-cost portable tool for periodic spot-checks, which only allows to monitor static pressure and force response at low pressure (up to 400kPa), and COP coordinates estimation. The device is described in detail in Appendix 3.

Recommendations to Editors and Reviewers of peer-reviewed Journals

Special attention is requested to Reviewers and Editors of peer-reviewed Journals in order to avoid the publication of non-consistent baropodometric datasets.

Appendix 1: might the discipline be defined "Pedography"?

ESM2010 participants started a discussion right on the basics of plantar pressure terminology. More specifically, as a first step, the discussion has focused on the fundamental term to refer to "measurements obtained by using electronic devices to locally record pressure (or vertical forces over well known areas) exerted under the sole of the foot during its interaction with the ground".

Peter Seitz has proposed PEDOGRAPHY rather than baropedometry, baropodometry, podobarometry, and so on. A summary of his explanation is reported below, and a couple of first answers given through the Forum tool of the ISS moodle page. The discussion is still open on the page.

Why PEDOGRAPHY (P. Seitz)

"We should get away from "weather reports" and not talk about Pedobarography or baropedometry or such. In common sense baro is always weather and we all know that pressure is in many foot-cases much less important than forces.

What we really do is the graphy of foot function. It's more widely understood as the registration of foot function in combination with gait, which is surely more than local pressure. It could also include video or 3-D gait analysis.

An instrument that writes a track is commonly named "XXXgraph". This is why Pedography should be used.

This discussion was made already in 1984, when Prof. Mehnert (the most famous German Diabetologist), and Prof. Rosemayer (Uni Munich Head of Orthopaedy) as well as Prof. Diebschlag (Uni Munich Head of Industrial Medicine) proposed Pedography as a good desicription of what is done."

Comments by C. Giacomozzi

"Basically I agree with the need to "free" plantar pressure measurements from the link with "weather" issues. I like the term PEDOGRAPHY; my only doubt is that I'm not sure PEDOGRAPHY fully encompasses each and every "quantity" or kind of information we can obtain by using plantar pressure measurement devices, both alone or in conjunction with other gait analysis tools. I also suggest to keep some reference to "pressure" in order to avoid any misunderstanding with outomes from force platforms.

My own experience: several years ago my group and I designed an integrated device made of a 6components force platform and a pressure plate. When we had the need to give a proper name to this device, we decided to call it "piezo-dynamometric platform", in order to associate "dynamometry" to a device - the force platform - able to fully measure the interaction with the ground in terms of the 3D vectors of force and of moment respectively, and "piezo" (coming from the Greek and basically referred to the action of exerting a pressure in between two bodies) to a device again dealing with force measurement but only able to measure those local forces which act perpendicularly to a surface."

Comments by T. Pataky

"I understand the connection between "barography" and weather, so I can certainly understand the wish to avoid "xxxxbarography". But I must respectfully disagree with Dr. Seitz that "baro", by itself, implies weather. "Baroreceptor" is commonly used to refer to mechanically sensitive sensory organs, and "baroreflex" refers to blood pressure control, for example. Other examples from medicine/biology include: barotrauma and barodontalgia.

Secondly, while I agree that an "XXXgraph" is an instrument that writes a track, I think that we should consider "-graphy" as separate from "-graph"; the former can have a much broader meaning than the latter. For example: "choreography", "biography", "calligraphy".

Thirdly, I like "pedograph", because this implies time series and/or image analysis. Nonetheless, "pedography" has a much broader meaning, as Dr. Seitz states, referring also to kinematic and dynamic analysis. If we take "pedography" to mean pressure, kinematic, dynamic, and other analyses of the foot, then one problem may be that titles of papers may become less precise. "A pedographic study of ..." is not as precise as "A kinematic study of ..." or "A dynamic study of ...". So I agree with Claudia's point that retaining 'pressure' would be beneficial. I believe that the literature for foot pressure (specifically) is sufficiently expansive that it could have its own name. I don't have a particular preference for a name, but I would prefer a name that contains both 'foot' and 'pressure'."

Appendix 2: preliminary list of pressure measurement terms

ESM 2010 - LIST OF TERMS IN NEED OF DEFINITION

1-step pedography 2-step pedography free gait pedography static measurement quasi static measurement dynamic measurement dynamic posturography 2-d scan (Photocopy) 3-d scan (3-d scanner) 2-d digital video from several planes 3-d motion analysis complete roll-over full gait cycle peak pressure at one frame (only 1 sensor) peak force at one frame peak force at one frame in one area centre of force line centre of pressure line contact times of foot areas foot axis in pressure picture foot axis in 3-d supination and pronation in pedography lateral/medial force indexes

Appendix 3: brief description of a simple device for spotchecks.

The tool, a Portable Pressure Testing Device, hereafter referred to as PPTD, basically consists of a graduated round table, a vertical rod, and a small brass rod with a retractile bottom piece. Loading is obtained here by using commercial disks for weight lifting (Fig. 3.1).



Figure 3.1 the PPTD main components and measuring setup

The system is intended for use with 10kg disks of 278mm external diameter; 30mm internal diameter; 33mm thickness. The vertical rod of the table has been dimensioned to safely stack up to 5 disks. Similarly to the PTD graduated round table, three small pylons – 20 or 30 mm diameter according to PMD spatial resolution - are fixed to the bottom of the table in correspondence with the three vertexes of an inscribed equilateral triangle. Thus, the centred load is equally distributed over the three pylons. The small brass rod has a retractile thinner bottom piece which ends in a 2mm diameter semi-sphere. The retractile part, driven by means of a small piston on the top of the rod, is intended to be used at the beginning of the assessment session, with the table unloaded, to detect the theoretical COP. For a correct positioning and re-positioning of the PPTD onto the PMD, ISS suggests the use of a very thin, adaptable polyethylene sheet, to be reliably fixed to suitable references of the PMD frame, with ad-hoc holes – 1mm larger than pin size, $20^{\circ}/30^{\circ}$ of angular distance one from the other – depending on pin size (Fig. 3.2).



Figure 3.2. The PPTD positioning mask

Recommendations for the proper use of PPTD for on-site spot checks.

It is not possible to perform a complete PMD technical assessment with the PPTD alone. PPTD is just suggested as an example of easy-to-use, portable test device which may be used on-site for periodic spot-checks.

During each spot-check, once the PPTD has been correctly set in the desired position, the operator should:

- press on the top piston to acquire the coordinates of the theoretical COP;
- stack up the 5 disks and acquire pressure distribution for 10s at a recommended sampling rate of 5samples/s;
- remove the disks and perform a PPTD angular shift of 20° or 30° (depending on pin size);
- reload the PPTD and perform a new measurement;
- repeat the above steps up to a total angular shift of 120°.

For each measurement, COP coordinates, max. and mean pressure, and overall vertical force should be calculated at the midpoint of the loading period. RMSEs should then be calculated for each of the above parameters over the 6 measurements. For COP coordinates, RMSE must be calculated for both axes and, for each axis, for both accuracy (with respect to the theoretical coordinates) and precision (among the 6 measurements).

For an appropriate and effective use of the device, the procedure proposed hereby might be followed:

- the first spot-check should be performed at PMD installation in the lab; if results significantly differ from the technical data delivered by the manufacturer, he should be asked for an ad-hoc meeting to clarify the doubts and repeat the PPTD test, if necessary;

- during the first spot-check the exact position of the PPTD on the platform must be accurately recorded and proper references must be taken on the PMD frame; successive periodic tests should be scheduled;

- upon each successive spot-check, significant changes of RMSEs of COP coordinates, pressure or force should activate a call-for-assistance procedure to the manufacturer. "Significance" should be established *a priori* according to the intended use of the PMD within the lab. In any case, ISS suggests that RMSE variations be considered significant when: i) greater than PMD spatial resolution for COP coordinates; ii) greater than 10kPa for pressure; iii) greater than 10N for vertical force.

Appendix 4: acknowledgments and list of ESM2010 supporting participants

Name	Affiliation
Antonius De Lange	Fontys University of Applied Sciences, the Netherlands
James A. Furmato	Temple University School of Podiatric Medicine, Philadelphia, PA,
	U.S.A.
Axel Kalpen	novel biomechanics lab, Munich, Germany
Thomas W. Kernozek	University of Wisconsin-La Crosse, U.S.A.
XueCheng Liu	Dept. of Orthopaedic Surgery, Children's Hospital of WI, Medical
	College of WI, U.S.A.
Isabel C.N. Sacco	School of Medicine, Physical Therapy, Speech and Occupational
	Therapy Dept., University of Sao Paulo, Brazil
Peter Seitz	Novel gmbh, Munich, Germany
Julie Stebbins	Oxford Gait Laboratory, Nuffield Orthopaedic Centre, Oxford, UK
Sang-hyun Sung	Sangwoo Scientific Corp /Korea
Deydre Teyhen	Baylor University, U.S.A.
Christian Wyss	Movement Analysis Laboratory, Department of Orthopaedic
	Surgery, Cantonal Hospital Aarau, Aarau, Switzerland

The following ESM 2010 participants sent in their precious comments and signed agreement

Special thanks also go:

- to the ESM 2010 members of the Scientific Committee, who approved the initiative and asked the organizers to find a proper space within the meeting schedule for the presentation of the Consensus Proposal;
- to Dr. Todd Pataky who gave his contribution to the discussion on "pedography" on the ISS moodle page;
- to Prof. Benno M. Nigg who revised the draft of this Document and gave his precious comments and suggestions. Besides the indication for an overall text editing of the Document, he also reported the following specific comments:
 - "I see two aspects: (a) the quantification of the performance of a pressure measuring device and (b) the rules and regulations when and how to apply such devices. Where I don't see many problems with (a) I see more problems with (b).
 - There may be a philosophical problem with the demand that there should be minimal requirements and standardisation of the use of pressure measuring devices. In my view, the important point is that the specifications are well declared in any application. The variables selected for a project or a test depend on the question to be answered.
 - I also suggest that a difference should be made between research and clinical testing. It may be that clinical testing should follow some guidelines and procedures. However, research projects may or may not follow these guidelines (depending on the question at hand)".