

Hardware performance assessment recommendations and tools for baropodometric sensor systems

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Summary. 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 standardization processes and of reliable reference datasets. The Italian National Institute of Health (ISS) approved and conducted a scientific project 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 technology, electronic conditioning and mechanical solutions. Preliminary assessments have been conducted on 5 commercial PMDs. The study lead 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 the PMD performance; iii) some recommendations to both manufacturers and end users for an appropriate use in clinics and in research context.

Key words: baropodometry, pressure measurement devices, technical assessment, accuracy, COP estimation.

Riassunto (*Raccomandazioni e strumenti per assessment delle prestazioni hardware di sistemi di sensori baropodometrici*). Misure accurate della pressione plantare sono fondamentali in contesti clinici e nella ricerca. Differenze di accuratezza, precisione e affidabilità dei dispositivi di misura di pressione (PMD) hanno impedito fino ad ora la messa in atto di processi di standardizzazione e la costruzione di database di riferimento affidabili. L'Istituto Superiore di Sanità (ISS) ha approvato e condotto un progetto scientifico al fine di progettare, validare ed implementare metodi di test dedicati, per la valutazione tecnica di PMD sia in fabbrica che sul campo. È stato costruito un set-up sperimentale, completo e adattabile all'*assessment* di PMD basato su differenti tecnologie, condizionamento elettronico, soluzioni meccaniche. Valutazioni preliminari sono state condotte su 5 PMD commerciali. Lo studio ha portato alla definizione di: i) un appropriato set di strumenti e procedure per l'*assessment* tecnico dei PMD; ii) un set minimo di parametri significativi per la caratterizzazione tecnica delle loro prestazioni metrologiche; iii) raccomandazioni a fabbricanti e utilizzatori per un utilizzo appropriato dei PMD in clinica e in contesti di ricerca.

Parole chiave: baropodometria, dispositivi di misura di pressione, valutazione tecnica, accuratezza, stima centro di pressione.

INTRODUCTION

Contrary to kinematic or force measurements, which gait analysis strongly relies on, plantar pressure measurement is hardly considered a powerful or meaningful diagnostic tool in clinics; even less consideration is deserved to pressure measurement devices (PMDs) in consolidated research contexts, although the potential of such measurements is highly recognized [1]. Reasons for such poor success may be found in a certain lack of accuracy and appropriateness of the existing PMDs. Differences in sensor technology, matrix spatial resolution, pressure range, sampling rate, calibration procedures, raw data pre-processing, lead to significant differences in the overall accuracy of PMDs response. In addition, critical potentially complicating practical problems interfere with the appropriate use of

PMDs, *i.e.* problems associated with patient behaviour/protocol, and problems associated with data post-processing. The whole set of the above problems have indeed played a role in preventing the definition of reliable reference databases. Clear examples of these concepts are found in the recent literature. In fact: i) not even interesting papers report the acquired absolute pressure values [2-5], which might help in understanding how much comparable different datasets are: rather, clinicians and investigators are often concerned about relative pressure values or relative pressure distribution changes, which come out as post-processing products and which should be treated with extreme care since they are greatly affected by differences in the PMD sensor response; ii) significant discrepancies are found among those which report such values, even when dealing with

same pathology, comparable population samples and comparable experimental setup [6-12]. As an example, Hallemans *et al.* [6] reports about toddlers acquired by means of an RSSCAN pressure mat; mean peak pressures for toddlers acquired during a period of 5 months after the onset of independent walking are 65.8 ± 38.3 kPa (heel), 58.6 ± 22.5 kPa (central metatarsals), 46.2 ± 21.4 kPa (medial metatarsals), 41.0 ± 22.9 kPa (first toe), 42.4 ± 16.9 kPa (midfoot). For a very similar sample of toddlers analysed by means of the NOVEL pressure platform under a comparable experimental setup, Bosch *et al.* [7] reports 130.5 ± 57.9 kPa (heel), 73.8 ± 19.7 kPa (midfoot), 106 ± 29.7 kPa (metatarsals), 127.8 ± 64.7 kPa (first toe). Other two studies [8-9] conducted on children by using NOVEL PMDs report datasets which are comparable with Bosch. In the field of Diabetes, where very high peak pressures are developed especially in presence of neuropathy, peak pressure thresholds are usually employed to early detect patients at risk of ulceration. Discrepancies in the measured pressure values surely contribute to generate confusion in the definition of such risk thresholds. Solano *et al.* [10] report absolute peak pressure data collected from diabetic neuropathic patients by using the NOVEL EMED SF-4: 552.4 ± 227.9 kPa for the Hispanic group and 810.1 ± 274.6 kPa for Caucasians. Giacomozzi *et al.* [11] used the NOVEL EMED ST-4 to analyse groups of diabetic neuropathic patients and reports mean peak pressures under the metatarsals ranging from 735.0 ± 166 kPa to 932.0 ± 150 kPa. Wrobel *et al.* [12] used a the TEKSCAN F-scan mat system calibrated by using patient's weight to analyse old male veterans with Diabetes who showed conservative or normal gait. Reported mean peak values, significantly lower than those reported in the above papers, are 374.0 ± 71.6 kPa for conservative gait and 380.0 ± 85.3 kPa for normal gait.

From a more technical point of view, very few studies have been published aiming at reviewing the state of the art in the field of pressure measurement techniques; the last relevant ones are dated between 1985 and 1995 [13-15]. One recent interesting paper [1] deals with repeatability of the NOVEL EMED ST-4 system alone; in the study, accuracy of the PMD was daily checked by using a simple but repeatable procedure: a subject was measured while standing still on one leg, and the overall force derived from the pressure measurements was compared with the subject's body weight. As for the implementation of calibration procedures before clinical application, Hallemans *et al.* [6] report about an on-line dynamic calibration of a Footscan system (Footscan Int, Belgium), which is performed by coupling the PMD to an AMTI force platform.

Finally, no studies have been found in the Medline database that deal with the technical assessment or comparison of different PMDs.

To overcome this need, in 2006 the Italian National Institute of Health (ISS) approved a two-year sci-

entific project aimed to design, validate and implement dedicated testing methods and instruments for PMD technical assessment. Official letters were then sent to Companies to invite them to take part in the study with their best product on the market. The defined testing protocol – basically aimed at assessing accuracy and reliability of measured pressure values, PMD hysteresis and accuracy and precision of centre of pressure (COP) coordinates – was sent to those Companies who asked for further details. The testing phase finished in December 2008. Two Companies – NOVEL and AM CUBE – agreed to participate in the study. Five PMDs were tested in all, three with resistive sensors (TEKSCAN, RSSCAN, MEDILOGIC), one with capacitive elastomer sensors (NOVEL), one with capacitive air sensors (AM CUBE). Tested devices revealed different level of accuracy and, in general, different overall performances – main results of the study being reported in [16] but for RSSCAN –; in any case the ISS assessment equipment was proved to be effective with respect to its main purposes. Thus, it is now part of the methodology ISS is proposing for the assessment of appropriateness of PMD hardware performance in research and in clinics. The whole methodology, which is here widely described in terms of equipment, testing protocols, parameters to be assessed and recommendations for manufacturers and users, specifically focuses on appropriate PMD sensor performance. Further studies will then be needed to address standardisation of PMD patient protocol and standardisation of PMD data post-processing, which represent the two successive steps towards a true appropriate and effective use of PMDs.

MATERIALS AND METHODS

Testing devices

The ISS testing equipment is made 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 already been widely described in [16].

The PM allows to uniformly apply pressure over the entire PMD sensor matrix in the range 0-1200 kPa. It 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 10 Pa). 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, an additional PTD tool allows the application of known forces through 3 pylons (*Figure 1b*). The tool consists of a graduated aluminium round table and a graduated positioning system. The table has three 3 cm-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.

Rationale for testing protocols and data processing

The following concepts have been taken into account to design a proper testing protocol:

- each PMD has to be considered as a whole with all its hardware and software components; it should be tested in its final commercial arrangement, thus taking into account each and every “contribution” to the sensor response within the final product (*i.e.* sensor arrangements, eventual cross-talk, mechanical or electronic constraints, software implementation, ...); thus, data acquisition should be done through the PMD commercial software application, by taking into account any implemented software calibration procedure
- and by performing the recommended on-site calibration or equilibration procedures if any;
- even though commercial PMDs may be used to measure kinetic parameters associated with several motor activities – *i.e.* level walking, orthostatic performance, sport motor tasks like running or jumping – they are here intended to be assessed with respect to the main use they have in research context and in clinics, namely the characterization of barefoot walking and the more recent use for static posturography; for this reason, pressure range and dynamic loading conditions during testing should be comparable with the intended conditions for use, *i.e.* pressure applied at least in the range 0-1000 kPa, frequency of loading cycle not greater than 1Hz, simultaneous loading of small areas for COP estimation (smaller than two adult feet total area), static loading time not shorter than 60s for assessment of creep (at a pressure of at least 200 kPa);
- as for local testing, a certain number of spot areas rather than only one should be selected to better investigate the entire surface; a reasonable compromise should be found to optimise complexity, time consume and reliability of the test;
- data acquisition should be performed at the most appropriate sampling rate, unless specific PMD constraints lead to a different, forced solution which must be clearly stated in the testing report; recommended sampling rate is at least 5 Hz for static measurements, and at least 20 Hz for dynamic loading; acquisition should be done through the proprietary PMD software;
- as for data processing, it should be assured that raw data are delivered in a standard file encod-

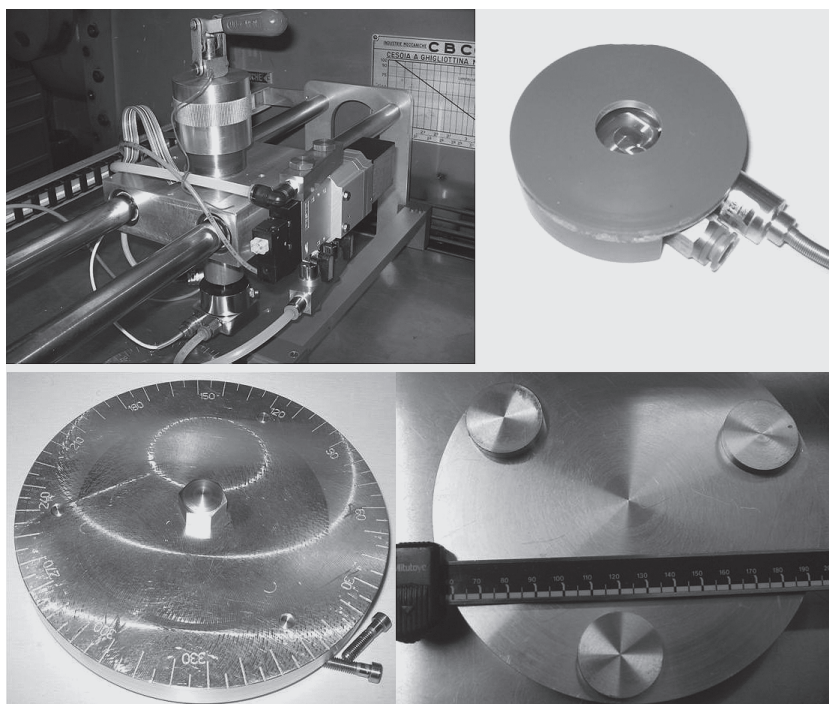


Fig. 1 | Organisation test devices and tools: a) dedicated pneumatic-force testing device (PTD); b) graduated table of the tool to apply known forces through PTD; c) pressure chamber protective case, to be used when coupling the PTD with the table in b.

ing, and that the successive data processing is performed on absolute pressure values and on spatial coordinates both expressed in S.I. related units (*i.e.* kPa for pressure values and mm or cm for spatial coordinates).

Rationale for identification of assessment parameters

The technical assessment should address the main PMD parameters for which the device is intended to be used – absolute pressure values, vertical component of the ground reaction force, spatial coordinates of COP –, and the measuring PMD features which may significantly affect them – spatial variability, hysteresis, variability during time (creep), linearity of pressure response. Each and every further parameter the PMD may deliver is necessarily the result of estimation or calculation algorithms, whose validity is certainly affected by poor reliability of the above basic measurements.

It is thus critical to address:

- i) sensor response variability all over the platform with respect to different pressure levels within the intended range: in case PMD technical constraints do not allow the simultaneous loading of the entire surface, the latter should be investigated by dividing it into sub-areas as large as possible;
- ii) sensor response in terms of absolute value of pressure averaged over a small, uniformly loaded area, within the loading range;
- iii) sensor hysteresis, measured with a loading-unloading frequency not greater than 1 Hz;
- iv) sensor response in terms of creep, intended as variation of pressure response during time; in this case time should be not less than 60 s, uniform and constant loading may be limited to the lower part of the pressure range – as it happens under static loading over both feet – but in any case not lower than 200 kPa;
- v) platform response in terms of accuracy and repeatability (precision) of COP coordinates estimation.

RMSE (root means square error) is considered as the most appropriate tool to estimate variability of the above parameters; hysteresis should be calculated with respect to half of the applied dynamics and expressed as a percentage of the dynamics itself.

Rationale for recommendations to manufacturers

When used on patients, and according to their specific intended use, PMDs might be classified as medical devices, and as such they must be compliant with the essential requirements indicated in the International Regulations, first of all with those guaranteeing safety of the users and correct delivery of the declared outcomes – pressure, force and COP measurements, in case of PMDs. In any case, generally speaking, manufacturers should follow the good manufacturing practice (GMP) for PMDs, and implement in-factory technical assessment procedures to characterize the technical performance of each

device in its final commercial arrangement. Besides that, they should correctly inform the user on the above assessed technical performance at the time of device delivery and installation, correctly form the users to the effective, safe and correct use of the device, and guarantee that an adequate quality of PMD performance is maintained during time. Included in the user's training, worth to be highlighted is the need for manufacturers' high degree of information and transparency about their data processing procedures.

Rationale for recommendations to end users

The end user should be made well aware of: i) the technical performance of the acquired PMD at the time of delivery and installation; ii) the needed on-site calibration or equilibration procedures to be implemented, if any, to obtain reliable measurements; iii) the eventual on-site spot-checks the user may set up to periodically assess the PMD technical performance.

RESULTS

ISS validated equipment, protocol, report and service

The ISS described equipment has been proved to be suitable and complete for the here proposed technical assessment of commercial PMDs with different assembly and sensor technology [16]. ISS published detailed technical information for the construction, validation and use of similar equipment for at least in-factory assessment [17]. At ISS premises the above equipment is currently available for giving assistance to both manufacturers and users in their first approach to this methodology. Requests for PMD technical assessment are examined and accepted on a FIFO basis.

The approved PMD technical assessment protocol is reported in detail in *Appendix 1*.

A standard PMD technical assessment report has also been prepared and used, which contains:

- a cover letter;
- details on the tested product;
- details on the testing devices: any variation with respect to the standard testing equipment is here explained in detail;
- details on the assessment protocol: any variation with respect to the standard testing protocol is here explained in detail;
- details on data analysis (with clear explanation of measured/calculated parameters or indicators);
- details on the specific measurement session;
- results.

With respect to the standard protocol reported in *Appendix 1*, the preliminary technical assessment conducted on 5 commercial PMDs and reported in [16] correctly followed the approved measurement protocol but for the pulse test, since most devices could not be easily synchronized with the testing device.

Recommendations to manufacturers

The following main recommendations to manufacturers came out from the above study:

- 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 ISS proposed one. In any case, the testing equipment must have higher precision and accuracy than those expected for the PMD. At minimum, 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 range 0.5-1.0 Hz. 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 1 Hz; 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 user in order to let him/her understand the quality of the measurements he/she is going to obtain; a list of reference values of the "ideal" platform should be also reported for user information, values which guarantee for 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;
- 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 and re-testing the device in factory, by implementing pe-

riodic spot-checks on-site, or by giving the user adequate instructions to perform himself/herself proper spot-checks on site to easily detect significant changes in the PMD performance and promptly alert the manufacturer.

Recommendations to end users

The following main recommendations to end users came out from the above study:

- to 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 minimum, the report should contain information on the specific PMD 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;
- to ask the manufacturer the proper documentation and information for appropriate, effective, safe and correct use of the device;
- to 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 Companies 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, extremely important, this sort of check must be performed under repeatable and controlled conditions starting from the first PMD installation. ISS proposes a simple and low-cost portable tool for periodic spot-checks which only allows to monitor static pressure and force response at low pressure (up to 200 kPa), and COP coordinates estimation. The device is described in detail in *Appendix 2*.

DISCUSSION AND CONCLUSIONS

Reliable testing equipments and procedures are mandatory for the assessment of accuracy and appropriateness of plantar PMDs in order to render them valuable instruments for biomechanical research and in the clinical context. The ISS suggested methodology and testing devices were designed and constructed so as to be used with as many PMDs as possible. They can be adapted to different platform sizes and shapes, sensor types, spatial and pressure resolutions, sampling rates. The preliminary results based on the assessment of 5 tested PMDs from different Companies and technologies showed the methodology and the equipment to be suitable at

least for the in-factory PDM technical assessment [16]. Feedback from the involved Companies was indeed encouraging: some of them started from the results of the ISS technical assessment to improve their own assessment methodology, some others disagreed with the obtained results but not with the applied methodology, one of them asked ISS to re-test its product after a significant hardware and software improvement successive to the first assessment. The overall outcome of this preliminary study was then an overall improvement in the quality of commercial PMDs, which is indeed one of the main ISS targets. The methodology is thus here widely described and shared with the scientific community, to the main aim of suggesting a first path towards diffusion and standardization of PMDs accurate technical assessment.

ISS strongly believes that the correct characterization of PMD hardware performance might indeed represent a key-point for a significant improvement in the appropriate use of PMDs and a valuable means for the user to better understand the meaning and the relevance of his/her own studies; furthermore, the sharing of information on PMD measuring features with the scientific community – *i.e.* indicating them on scientific publications – does represent a first mandatory step towards data reliable comparisons and database sharing among different research and clinical centres. Successive steps should then be the standardisation of patient protocols and the standardisation of PMD data post-processing.

The recommendations hereby formulated by ISS for both manufacturers and users mainly rely on the outcomes of validation and preliminary studies focussed on its PMD technical assessment methodology and equipment [16, 17], and on ISS expertise in the field of: i) plantar pressure gait measurement under physiologic or pathologic conditions [11, 20, 21]; ii) design, construction and validation of instrumentation for gait biomechanics, with special focus on plantar pressure measurement devices [22-25]; iii) ISS knowledge and involvement in medical devices international regulatory issues and GMP [26-29]. Nevertheless, they should be intended just as a first attempt towards formulation and standardization of methodology, procedures and guidelines for the appropriate use of PMDs. ISS main aim in this sense is the opening of a constructive discussion among scientific societies in the field of biomechanics and applied clinical biomechanics, manufacturers, and qualified research and clinical users.

Application of the above recommendations to current alternatives to PMDs

A certain number of low-cost “alternatives” to traditional PMDs are currently available on the market. Two main categories of products are briefly discussed here below.

A first category is formed by low-cost devices based on flexible thin films cut with any shape and

size from a sheet which includes a layer of tiny coloured microcapsules (Tactile Pressure Indicating Sensor Film PressureX by Sensor Products Inc., Madison, NJ, USA, available from: www.sensor-prod.com/pressurex.php). As an instantaneous pressure is exerted, the device delivers a topographical image of maximum pressure distribution. The pressure resolution is around 10% unless images are digitally read, which might increase resolution up to 2%. Such disposable devices are considered as static devices, since they are not able to acquire and reproduce a complete step process over time. Clear indications should be delivered by the manufacturers about their intended use, which is often at a qualitative level only – thus not to be used for baropodometry. In case they are intended for quantitative measurements of absolute maximum pressure only, a suitable subset of the testing protocols described in the paper might be applied to randomly selected parts of the same sheet the device is obtained from. Since storage conditions might significantly alter such devices performance, frequent monitoring of the sheet technical performance is recommended.

A second category is represented by devices based on matrices of “switches”, *i.e.* usually resistive sensors which react to pressure as simple on-off contacts. Usually, they are arranged in very long flexible and thin mats and are used to measure spatial and temporal parameters of gait [30]. Obviously, they cannot be used for pressure measurements, thus their technical assessment will not be taken into further consideration in the present paper. Anyway, since their intended use is clearly the quantitative measurements of patient's gait related spatial and temporal parameters, they should undergo to the same GMP recommendations as PMDs unless for pressure measurements. As a few examples: i) spatial resolution should be assessed to be higher than the minimum clinically relevant spatial variation; ii) sensitivity should be assessed to be uniform over the whole surface and not lower than 10-15 kPa; iii) sampling rate should be around 50 samples/s for gait purposes, higher for sport purposes. Being the long mats intended to be often rolled and unrolled, frequent check of the correct functionality of all the sensors is highly recommended.

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Conflict of interest statement

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Appendix 1

ISS APPROVED PROTOCOL FOR TECHNICAL ASSESSMENT OF PRESSURE MEASUREMENT DEVICES

Measurement sequences and related indicators

- a. *pressure static measurements over short periods*: they are obtained by using the on-off pneumatic valve of **PTD** in mode “step”. The loading-unloading sequence is identified as **S02**: from 0 to 600 kPa, and down to 0 kPa; step 1 kPa; duration of each step 10 s; pressure down to 0 between two successive pressure steps (0 kPa with chamber opened; 0 kPa with chamber closed; 100 kPa; 0 kPa; 200 kPa; 0 kPa; 300 kPa; 0 kPa; 400 kPa; 0 kPa; 500 kPa; 0 kPa; 600 kPa; 0 kPa; 500 kPa; 0 kPa; 400 kPa; 0 kPa; 300 kPa; 0 kPa; 200 kPa; 0 kPa; 100 kPa; 0 kPa chamber closed; 0 kPa chamber opened). ISS sampling rate: 50 Hz. PMD sampling rate: at least 5 Hz. 5 repetitions for each selected area. Data to be analysed will be related to central sensors (4 in case PMD spatial resolution is 4 sensors/cm²; 1 for lower spatial resolution); they will be referred to the mid point of the loading period. 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)*: they are obtained by using the on-off pneumatic valve of **PTD** in mode “step”. The sequence is identified as **CREEP**. Pressure is fixed at 300 kPa, and maintained for 60 s. ISS sampling rate: 50 Hz. PMD sampling rate: at least 5 Hz. 1 repetition for each selected area. Data to be analysed will be related to central sensors (4 in case PMD spatial resolution is 4 sensors/cm²; 1 for lower spatial resolution); they will be referred to the period in between 10 and 50 s of loading. 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*: they are obtained by using the proportional pneumatic valve of **PTD** in the mode “sin signal 0.75 Hz, 0-500 kPa”. The sequence is identified as **SIN**. ISS sampling rate: 250 Hz. PMD sampling rate: at least 20 Hz. Acquisition of 30 cycles per area. Data to be analysed will be related to one of the central sensors; they will be referred to three successive complete cycles starting from the fourth. Indicators to be calculated for the test: 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); mean RMSE and sd over the five areas;

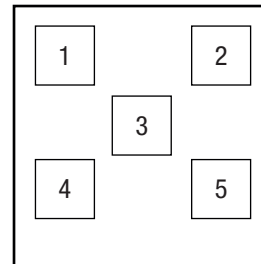
- d. *pressure pulse measurements with synchronization*: they are obtained by using the on-off pneumatic valve of **PTD** in mode “pulse”. The sequence is identified as **S06 (pulses at 400 kPa + synch)**. Pulse is fixed at 400 kPa. The synch signal is a high-active-TTL signal coming out from the device under test, if any. ISS sampling rate: 500 Hz. PMD sampling rate: maximum available. Duration of acquisition: 3 s. 1 repetition – containing at least 3 pulses – per area. Data to be analysed will be related to central sensors (4 in case PMD spatial resolution is 4 sensors/cm²; 1 for lower spatial resolution); they will be referred to each of the three pulse-related curves. 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.
- e. *load measurements with PTD + RT*: they are obtained by using the **PTD** + a rigid cover for the pressure chamber + a positioning device + the aluminium round table (**RT**) with three large pins and two soft layers interposed. The initial condition is: 300 kPa under each pin (surface 7.07 cm² each). Initial marking of the Center of Force – acquisition with a pin vertically pressing in the small hole at the center of **RT** –, to be compared with the estimated location of **COP**. The sequence is identified as **S04** (10 s of static acquisition in position 0 of each area; rotation of 20° around the center of the area; acquisition in position 1; rotation of 20° around the center of the area; acquisition in position 2; rotation of 20° around the center of the area; acquisition in position 3; rotation of 20° around the center of the area; acquisition in position 4; rotation of 20° around the center of the area; acquisition in position 5; rotation of 20° around the center 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 5 Hz. Data to be analysed will be related to the spatial coordinates of **COP** averaged over the period from 5 to 10 s of loading, for each angular position. 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 identified as **S 03** (0 kPa for 10 s; ramp of 10 s up to 100 kPa; 100 kPa for 10 s; ramp of 10 s up to 200 kPa; 200 kPa for 10 s; ramp of 10 s up to 300 kPa; 300 kPa for 10 s; ramp of 10 s up to 400 kPa; 400 kPa for 10 s; ramp of 10 s up to 500 kPa; 500 kPa for 10 s; ramp of 10 s up to 600 kPa; 600 kPa for 10 s; ramp of 10 s up to 700 kPa; 700 kPa for 10 s; ramp of 10 s up to 800 kPa; 800 kPa for 10 s; ramp of 10 s up to 900 kPa; 900 kPa for 10 s; ramp of 10 s up to 1000 kPa; 1000 kPa for 10 s; ramp of 10 s up to 1100 kPa; 1100 kPa for 10 s; ramp of 10 s up to 1200 kPa; same sequence from 1200 kPa down to 0 kPa). Company suggested sampling rate: 5 Hz. ISS reading of digital value of applied pressure. Data to be analysed will be related to the entire loaded area with the only exclusion of sensors included in the first 15 mm of the boundary, in correspondence with the midpoint of each loading period. 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.

Selection of spot areas

The 5 areas to be used with PD may be selected as suggested in the following scheme:



Center of area 1, 2, 4 and 5 should be at least 7.0 cm far from the border of the sensitive surface.

Requirements for measurements

The company should deliver:

- a pressure platform;
- the PC/notebook with the software;
- information about in/out trigger;
- ASCII files of the acquired data.

Legend

PTD = pressure testing device;
RT = round table;
PM = press machine;
COP = centre of pressure;
RMSE = root means square error;
PMD = pressure measurement device.

Appendix 2

PORTABLE LOW-COST PRESSURE TESTING DEVICE (PPTD) FOR PMD SPOT-CHECKS

ISS designed and constructed a simple, portable, low-cost tool based on the same functioning principle of the PTD graduated round table and addressed to work as a stand-alone system for the only assessment of COP coordinates estimation, local pressure and force at a fixed static load. The tool, from now on identified as PPTD (Portable Pressure Testing Device), is basically made of a graduated round table and a vertical rod with a retractile bottom part. Loading is here obtained by using commercial disks for weight lifting.

Overall description

The system is intended to be used with 10 kg disks for weight lifting, with: external diameter 278 mm; internal diameter 30 mm; thickness 33 mm. 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 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.

Dimensioning of the whole structure has been based on two main concepts: i) the total weight of the basic structure should act on the PMD sensors with a maximum pressure < 10 kPa, which usually represents the lower detectable value of pressure. This allows the PPTD to be positioned onto the PMD surface without activating any platform response; ii) the mean pressure obtained under the three loaded areas should be not less than 200 kPa.

Constructive details

The table is a graduated aluminium round table, diameter 280 mm, thickness 15 mm, graduation resolution 5°; each small pylon – diameter 20 mm, thickness 5 mm – is screwed to the bottom of the table in correspondence with one vertex of the established inscribed equilateral triangle. The aluminium vertical rod – diameter 29 mm, height 200 mm – has a retractile thinner bottom part which ends with a 2 mm 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. At regimen, during the assessment,

the semi-sphere is never in contact with the PMD surface. For better clarification, a perspective view of the PPTD model is showed in *Figure A1*.

Positioning details

A general purpose positioning system should take into account too many different mechanical arrangements commercial PMDs may have. Rather, each lab should develop its own, dedicated positioning system, the only recommendation being the accuracy of the positioning system, whose error should be less than 2 mm. ISS suggests the use of a polypropylene, very thin sheet, adaptable to be reliably fixed to suitable references of the PMD frame, with ad-hoc holes – 21 mm of diameter, 20° of angular distance one from the other – at least in correspondence of the central PMD area. An example of such a sheet is showed in *Figure A2* (white circles represent holes in the polypropylene sheet).

Recommendations for a proper use of PPTD for on-site spot checks

The here described PPTD does not allow to perform a complete PMD technical assessment. It is only suggested as an example of easy to use, portable test device which might be used on-site for periodic spot-checks.

During each spot-check, once the PPTD has been correctly positioned 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 the pressure distribution for 10 s at a recommended sampling rate of 5 samples/s;
- remove the disks and perform a PPTD angular shift of 20°;
- reload the PPTD and perform a new measurement;

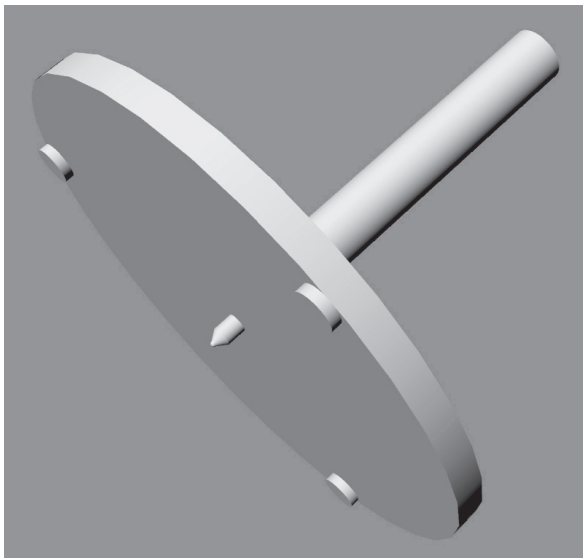


Fig. A1 | Perspective view of the PPTD model.

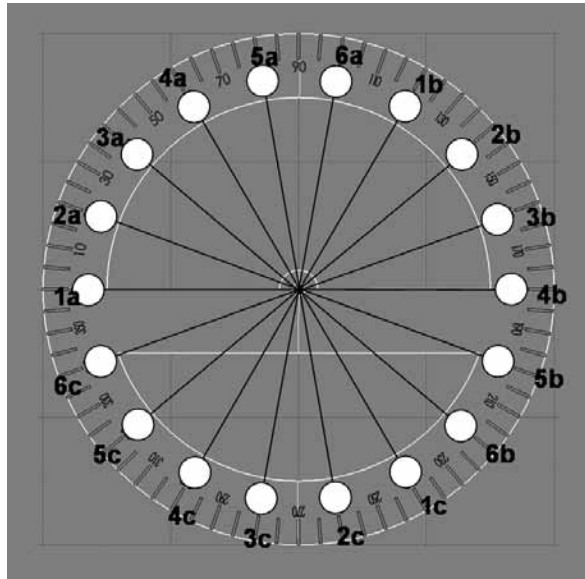


Fig. A2 | Example of polypropylene sheet to be used as a reference system for PPTD positioning on the PMD surface. In the scheme, each n.a, n.b and n.c set – n ranging from 1 to 6 – indicates the correct position of the three pylons for each of the 6 measurements.

- repeat the above steps up to a total angular shift of 100°.

For each measurement, COP coordinates, max and mean pressure, and overall vertical force should be calculated at midpoint of the loading period. RMSEs should then be calculated for each of the above parameter 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 here proposed procedure might be followed:

- the first spot-check should be performed at PMD installation in the lab; if results significantly differ from technical data delivered by the manufacturer, an ad-hoc meeting should be asked to the latter to clarify the doubts and eventually repeat the PPTD test;
- 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; scheduling for successive periodic tests should also be established;
- at 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. Anyway, ISS suggests to consider as relevant RMSE variations:
 - i) greater than PMD spatial resolution for COP coordinates;
 - ii) greater than 10 kPa for pressure;
 - iii) greater than 10 N for vertical force.