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ANALYSIS OF ADEQUACY OF A FORCE PLATFORM FOR STABILOMETRIC CLINICAL INVESTIGATIONS

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1. INTRODUCTION

Evidence Based Medicine (EBM) has become more popular in the clinical setting. Due to this, the introduction of the quality control (QC) of data collection has become necessary. This involves an attentive evaluation of devices used.

As nowadays the use of instrumentation for measurement is standard in every day clinical practice, they must be designed and produced with a defined specificity and sensibility. In particular, the actual data measured must not be influenced by the mechanical or the electrical components of the instrument. Therefore, in designing a new measuring device, rigorous logical verification processes must be followed.

The process begins by evaluating the physiological function one wishes to study, identifying the physical variables that are measurable and that give significant information on the physical status of the subject. It is then necessary to proceed with an experimental and/or literature search to define the range of variability and dynamics of the signal to determine the resolution the device requires. The last step is the verification of the accuracy of the hardware and software of the instrument in respect to the measured signal.

The entire process can be outlined in 6 steps:

1. Diagnostic method analysis: to understand its significance and to identify the basic physical phenomena.
2. Analysis of physical phenomena: to define variables and modalities of acquisition.
3. Analysis of biomechanical variable characteristics: to define sample variability, dynamics, and required resolution.
4. Analysis of acquisition and elaboration processes: to collect and process data that provide clinically significant parameters from observed variables.
5. Analysis of system requirements: to assure correct signal acquisition and data processing.
6. Verification.

This paper summarizes the procedure applied to a stabilometric platform (ARGO, produced by RGM S.p.A. – Medical Devices Division) for the verification of the sensitivity and specificity of the instrument.

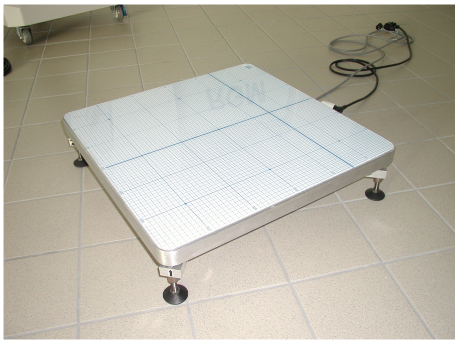

Fig. 1. Stabilometric platform ARGO

This procedure in turn can be applied to prototypes or to mass-produced instruments of this same type (QC and periodic functionality tests).

2. DIAGNOSTIC METHOD ANALYSIS

For its specificity in identifying deficits and proprioceptive integration disturbances, the Romberg Test is an instrument of renewed interest for the measurement of the interferences of proprioceptive control, for the identification of acute and chronic "dysfunctional" disturbances, secondary to many pathologies, both local and systemic. [1,2]

Information on the global functionality and of each level of regulation which partake in the process of maintaining a quiet stance, can be abstracted via the clinician's exam and the movement of the contra-pressure of the subject on the platform (Center of Pressure, COP).

Static posturography is extremely rich of information for the study of both the availability of feedback control and the anticipatory capability of the subject (needed to compensate for the delay in feedback). These elements are indirect indicators of superior aspects of motor control.

Therefore, the principal role of the force platform is to help assigning therapy to be used to treat the subject by determining the type of disturbance and as a tool to monitor the therapy effectiveness.[3]

3. ANALYSIS OF PHYSICAL PHENOMENA

The physical phenomena under study is orthostatic equilibrium, that is the movements a subject makes to maintain a quiet stance. [3-5]

It is not possible to measure stability directly: it is not a magnitude, but merely an amplitude, enabling the body to return close to its position of equilibrium whenever it strays from it. However stability has characteristics that can be measured using force platforms.

The distance travelled by the Centre of Pressure (COP) in order to stabilize the Centre of Gravity (COG) is a measurable magnitude correlated to the energy spent by the stabilization mechanisms. [3,6]

We can then consider the COP coordinates (x, y) as the variable of interest to measure.

A force platform with 3 components, able to measure the 3 kinetic magnitudes M_x, M_y e F_z, can give the trajectory of the COP.

$$x_{COP} = \frac{M_y}{F_z}; \qquad y_{COP} = -\frac{M_x}{F_z}; \tag{1}$$

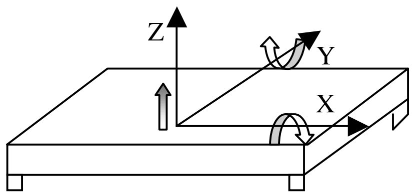

Fig. 2. Measured forces

4. ANALYSIS OF BIOMECHANICAL VARIABLE CHARACTERISTICS

The "inverted pendulum" model is used to study quiet stance. It mimics the biomechanical behavior of the subject's body and its unstable dynamics. [5]

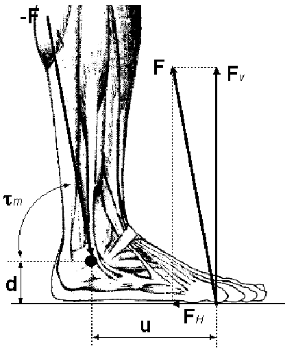

Fig. 3. Biomechanic model

The following is the equation that defines the system:

$$I_P \ddot{\vartheta} = mgh \cdot sin(\vartheta) + \tau_m + z \tag{2}$$

where ϑ is the angle of oscillation, m and I_p are the mass and moment of inertia of the body (not including the foot) respectively, h is the distance of the COM from the ankle, g acceleration of gravity, τ_m ankle torque (due to the active and passive properties of the muscle) and z represents the possible internal and external disturbances (i.e. respiration, heart beat, environmental noises, etc.) which influence posture. The ankle torque must also satisfy the equilibrium equation:

$$\tau_m + F_V \cdot u + F_H \cdot d \approx 0 \tag{3}$$

where F_V and F_H are the vertical and horizontal components of the ground reaction force (applied by definition in the COP) and u is the position of the COP. [7] F_H is very small in respect to F_V (which is approximately equal to body weight) and can be ignored. The following equation describes how variations of the ankle torque are immediately and linearly transcribed into variations of the COP position.

$$u(t) \approx \frac{1}{mg}\tau_m \tag{4}$$

The sway movements during quiet stance are defined by the following:

$$F_V - mg = m\ddot{z} \approx 0 \tag{5}$$

$$F_H = m\ddot{y} \tag{6}$$

$$\tau_m + mgy = \frac{d}{dt}\left(I\dot{\vartheta}\right) \approx I\ddot{\vartheta} \approx mh^2 k_s \frac{\ddot{y}}{h} = mhk_s\ddot{y} \tag{7}$$

Equations (5) and (6) can be combined to obtain an explicit relation between y and u describing oscillation dynamics. Applying justified assumptions to static postural oscillations the final equation is created:

$$\ddot{y} = \frac{g}{h_e}(y - u) + z' \tag{8}$$

where $h_e = k_s h + d$.

From a motor control point of view, this equation defines the transfer function of the body, therefore $y(t)$ can be considered the controlled variable while $u(t)$ the variable of control.

Hence the trajectory of the COP, that is the actual point of application of counter-force of the ground, represents exhaustively $u(t)$.

As the literature dictates, it is estimated that the maximum variation of COP sway can occur between 5 and 25 mm, with a frequency band of 5 Hz. Recent clinical studies have shown that the resolution and bandwidth necessary as to not loose pertinent information are 0,1 mm and 5 Hz respectively. [7]

5. ANALYSIS OF ACQUISITION AND PROCESSING

To extract the trajectory of the COP a rigid, flat force platform placed on either three or four load cells, able to measure with high precision their instantaneous load, is used. [9] While the platforms which utilize three load cells offer the advantage of a simpler calibration (three points define just one plane), those with four offer the advantage of a greater utilizable surface area and a simpler processing of data. Anyway, both instruments utilize elaboration processes based on the equations discussed below.

ARGO is a square platform with four load cells.

The signal that is supplied by the load cells is processed by a series of pre-amplifiers with very low noise to bring it to the voltage level needed by the A/D converter (12 bit) range. The signal then arrives to a microprocessor that calculates the COP coordinates. The coordinates calculation algorithm is characterized by the compensation of the platform tare, without which the precision of the instrument is limited. The values that leave the microprocessor (COP coordinates, expressed in absolute Cartesian coordinates in mm) are sent to the PC via a RS-232 serial canal or USB.

5.1 Calculation of the COP utilizing a 4 cells platform.

The process requires the resolution of the static equilibrium equation: the ratio between the distances of the COP from the measurement points is inversely propotional to the ratio of the forces.

Here we will consider only one spatial direction (X), the process is completely analogous for the other (Y).

Assuming the platform as a rigid link (so that flexions and torsions of the plate due to the subject's weight can be assumed zero) we can consider:

$$\begin{cases} W_1 = W_{cell1} + W_{cell4} \\ W_2 = W_{cell2} + W_{cell3} \end{cases} \qquad (9)$$

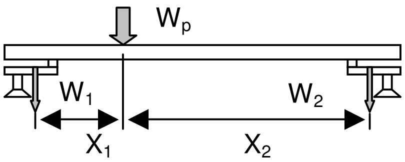

Fig. 4. Forces on the plate

The unknown variables X_1 and X_2 (*x* coordinate of the COP) are calculated by equalling the moments.

It must be noted, that the result of the above calculation is the trajectory of the points on which the resultant of the reaction force due to the weight of the subject (the actual study object) and of the plate is applied. The effect of this error is inversely proportional to the ratio of the weight of the subject plus that of the plate and directly proportional to the distance between the centre of the platform and the position of the COP. Considering this, it is not a neglectable error and should be corrected on a reliable force platform.

5.2 *Tare compensation*

The weight of the force platform is significantly less than that of the subject (ratio of approximately 1:5), however it represents a component of error in determining the coordinates of the COP.

By dynamically compensating the force platform's tare that is, by compensating the influence of the force platform's weight on its mechanical baricenter a measurement specific to the position of the subject on the platform is obtained.

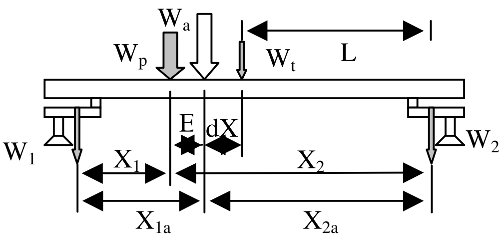

Fig. 5. Forces on the plate

Taking this into consideration the previous formulas must be adjusted and, in particular, we must consider the weight, W_t, and the coordinates of the baricenter (that is L/2).

This way we have an apparent Weight, W_a, that represents the actual weight to be compensated. In modifying the equation the COP coordinates are abstracted (X_1) considering the error, E, due to the tare of the force platform.

$$X_1 = \frac{L}{2} \cdot \left[1 + \left(1 + \frac{W_t}{W_2 + W_1 - W_t} \right) \cdot \frac{W_2 - W_1}{W_2 + W_1} \right] \qquad (10)$$

This measurement gives the COP position in respect to the position of the load cells, therefore to obtain the absolute value the following equation is used:

$$X_{COP} = X_1 + X_{cell1} \qquad (11)$$

6. ANALYSIS OF SYSTEM REQUIREMENTS

The project must have the goal of assuring clean and transparent data represented in the COP trajectory. [10]

To respect this goal, it is necessary to consider the following:

- the sensors (load cells) must be sensitive, have a high resolution and accuracy in static measurement and be dynamic as to fulfill any diagnostic need;
- the bandwidth – electrical and mechanical – must be calculated and measured within a good margin in respect to the information limit of the frequency indicated in literature for the movement of the COP;
- the acquisition and pre-processing algorithms of the signal must compensate for the movement of the platform mass to obtain a measurement that is independent of the weight and the position of the subject;

As seen in literature the COP coordinates, expressed in mm, should have a precision of at least 0,1 mm and the system should guarantee a signal acquisition with a bandwidth of about 15 Hz. The maximum capacity of the system should be at least 150 Kg. [11,12]

TABLE I. Summary of system requirements

Resolution	< 0.1 mm
Bandwidth	> 20 Hz
Capacity	≥ 150 Kg

7. VERIFICATIONS

During the verification phase of the project/product the following must be performed: [11]

- a mechanical verification, to ascertain that the platform does not mechanically alter the signal;
- an electrical verification, to ascertain that the chain of acquisition and processing events provides a trustworthy and repeatable signal;
- software processing verification, to assess that, starting from the electric signal, the phenomenon is

analyzed with the appropriate resolution, accuracy, and repeatability required.

7.1 Mechanical verifications: mechanical bandwidth and maximum deformation.

Since the exam is thorough and sensitive, it is necessary to be sure that the platform transmits the subject's movements without amplitude and frequency distortions. Therefore the platform must be:

- light, that is have a low inertia, as to not alter the course of the movements of the subject to the sensors and without attenuating their path;
- rigid, to transmit to the sensors the real amplitude of the subject's movements.

Hence the characteristics of the plate are defined as following:

- resonance frequency that is not similar to that of the subject's movements;
- linear deformations, within the loads considered, to transmit to the cells only the loads due to the subject's movements.

The model utilized for the study of the platform is based on a three-dimensional plate. The purpose of the computation model is to obtain a structure that represents the actual behaviour of the structure. The model is constructed using Finite Elements Method (FEM) and two load modalities are hypothesized:

1. with the "heavy zone" corresponding to the area where the subject's feet are placed, obtained by varying the specific weight of the material, equal to the subject weight of 75 Kg;
2. the concentrated weight (75 Kg), in varying placement on the plate diagonal.

The first model is used to evaluate the actual behaviour of the platform subjected to the lowest proper vibration frequencies.

TABLE II. Mechanical bandwidth

Vibration mode		Resonance frequency
First	Vertical oscillation	95 Hz
Second	Alternate oscillation	112 Hz

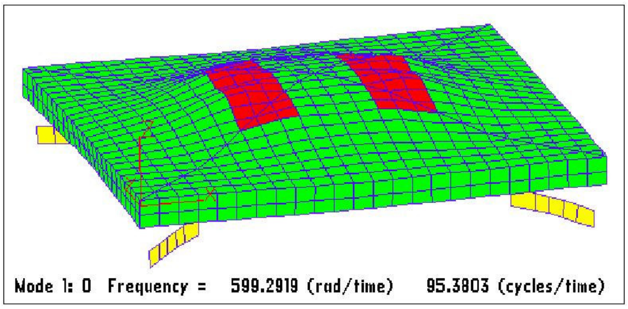

Fig. 6. Vertical Oscillation

Other analysis verified the vibrational behavior of the platform without subject weight to foresee its behavior with subjects weighing other than 75 Kg. Without the weight, the vibration modes verify frequencies 10-20% higher.

The second model is used to estimate the maximum deformation: the result is 0,04 mm, much smaller than 0.1 mm, as recommended in literature.[7,10]

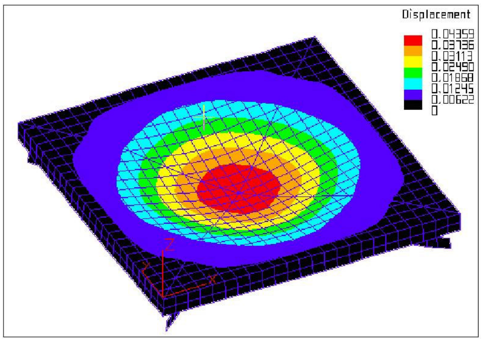

Fig. 7. Maximum deformation

Moreover, the load cells should have a precise reading of the subject movements, providing a value proportional to the actual movements of the subject. The linearity of the load cells values has been checked and verified for movements within 100 mm from the center of the plate.

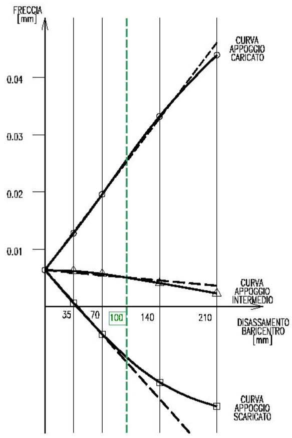

Fig. 8. Cells output

All the mechanical verification has been implemented by Studio Tecnico Marittimo s.a.s. (Genoa).

7.3 Electrical verifications

Particular attention in the planning of the system must be paid to total dynamics and to the resolution of data acquisition and processing.

The COP sample frequency is fixed at 100 Hz to ensure that all information is contained in the acquired signal. [7]

To guarantee the maximum capacity (150 Kg), 4 load cells (strain gage) were used each with a load maximum of 50 Kg.

To evaluate the COP spatial resolution it is necessary to analyze the chain of acquisition made up of: a load cell; a pre-amplifier/equalizer; a converter (A/D converter); and a microprocessor.

Each single characteristic can be analyzed and the concurrence can be verified with the specification.

TABLE III Measurement chain

	Strain gage	Preamplifier	Conv. A/D
Dynamic	0-50 Kg	0-5 V	0-5 V
Bandwidth	20 Hz	10 Hz	100 Hz
Combined error	< +/- 0.04% full scale	-	-
Linearity	-	< 0.05%	-
Resolution	-	-	12 bit
Quantization Error	-	-	+/- 1 bit

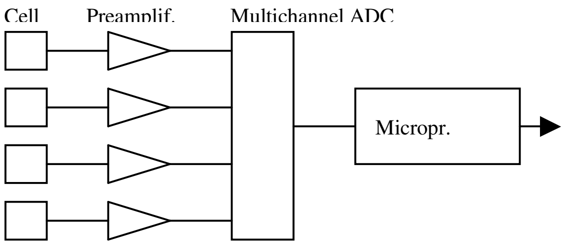

Fig. 8. Measurement chain

Therefore, the chain of acquisition of each single cell introduces an error, the sum of which is equal to 0,09% of its maximum load (50 Kg) and hence equal to 45 g of each cell's measurement and 180 g of the complete system (200 Kg).

Since the error introduced by the A/D converter (± 10 g) is less than all the other errors put together, they are not considered.

Therefore, the load cell coordinates which are inserted in the firmware as a reference for the COP coordinate calculation is the critical point in this process. These values are not directly defined. Figure 5, the details of the load cell position are represented.

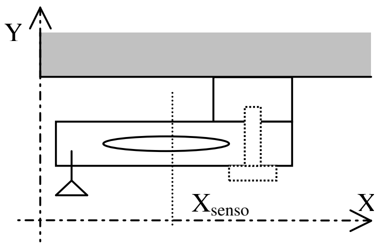

Fig. 9. Strain gage position

The values used are the ones geometrically indicated in Fig. 9 and correspond to the point where the sensor is positioned on the structure. The verification of this hypothesis was shown experimentally by positioning a weight on the corresponding point and verifying the concurrency of the values given.

7.4 Processing algorithm verification

A sequence of elementary functions was defined to allow an immediate and unequivocal verification of the posturographic parameter calculation algorithms.

Creating waveforms with simple geometric patterns, it is possible to calculate the exact value of a parameter and therefore it is possible to compare it with the one obtained by the software.

These were used to test the software (results in the table below).

TABLE IV Calculated parameter verification

Parameter		Units	Value	Calculated value	% Error
Sway Path		mm	188,5	188,2	0.16
Sway Area		mm^2	3600	3596.4	0.10
Max Oscillation LL		mm	47.5	47.5	0.00
Max Oscillation AP		mm	47.5	47.5	0.00
Confidence Ellipse	Major Axis	mm	67.1	67.1	0.00
	Minor Axis	mm	0.0	0.0	0.00
	Inclination	deg	45	45.02	0.04
Main Frequency		Hz	1.00	1.025	2.50

7.5 System test

A simple empirical static verification of the quality of the instrument is to position significant weights on precise points of the platform. The verification of the values given by the acquisition program is immediate.

Due to the specific application of the instrument, it is also necessary to verify correct dynamic behavior.

During collaboration between two Italian universities (DIST-Genoa and ISS-Rome) a prototype (Accu-stab) of a mechanical system was created utilizing a ballast of opportune mass (30 Kg, to simulate normal load conditions) and a smaller mass (2 Kg), which rotates eccentrically (R = 30 cm) in respect to the vertical axis. This device is placed on the force platform via a support with the surface area similar to that of human feet. [13] The rotating mass is spun off by a manual impulse and the rotation is then freely slowing down.

The movement of the smaller mass causes a spiral COP trajectory that tends to a circle whose radius is dependant from the ratio between the static and the rotatory mass.

It is then significant to compare the theoretic COP trajectory with the one actually measured by the platform itself.

ARGO has been tested with Accu-stab confirming the required performances.

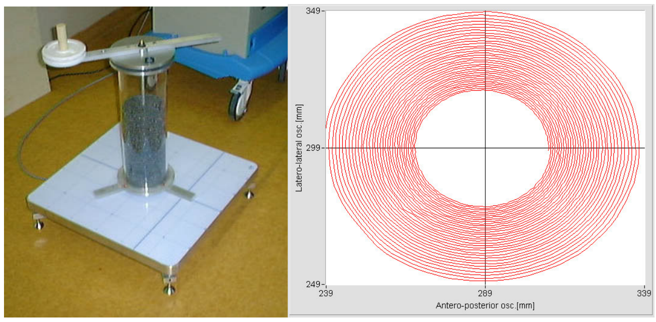

Fig. 10. Accu-stab

8.0 CONCLUSIONS

While confirming ARGO compliance to the project's requirements, the purpose of our study is to extract from our experimental tests a report to check stabilometric platforms. The applicability of this can be extended not only to the verification of prototypes, but also to the periodic verification of the proper function of products as well as in Quality Control.

In fact, along with the efforts for the standardization of the Romberg Test modalities, there should also be a standardization of the specific requirements of this type of device. This is needed in order to validate the clinical use of stabilometric platforms and to define guidelines for the periodic check of their functionality, as is already required for most measurement devices.

This is all in response to the goal of reaching the level of quality required by European Standards (ISO900, etc.) in order to offer a diagnostical service that is repeatable and comparable.

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