

### Original research article

## Key measurement principles to strengthen the reliability of loading device technologies: Implications to health care practice



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#### ABSTRACT

Introduction: In practice, reliability of the load measurement device is carried out as a standard practice prior to data collection to eliminate errors in measurement. However, reliability alone cannot confirm the goodness of a measurement device. The other key measurement variables such as accuracy, hysteresis, eccentricity error, uncertainty could affect the device output. This study highlights the importance of several key measurement principles to strengthen the reliability of loading device technologies in health care practice. Aim: To describes a method of testing the key measurement principles necessary to test the goodness of a load measurement technology at clinical or research setting.

Material and methods: A customized load measurement device was used to elucidate the calibration procedure. To determine the accuracy and hysteresis, a series of ten equally spaced standard loads ranging 10–100 kg was applied from no load to maximum load over device platform. The applied loads were removed in the same order as initially placed. In addition, the repeatability was tested with a load of 20 kg for five trials. Furthermore, the eccentricity error was determined by applying loads over five different quadrants.

*Results and discussion*: The result of the method demonstrated that the device has excellent accuracy and repeatability, with no errors in hysteresis, uncertainty, eccentricity.

Conclusions: In addition to reliability, the other proposed key measurement variables are proven essential to test the goodness of a loading device in research and clinical practice. © 2016 Warmińsko-Mazurska Izba Lekarska w Olsztynie. Published by Elsevier Urban & Partner Sp. z o.o. All rights reserved.

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#### 1. Introduction

In healthcare practice, it is fundamental to objectively measure the kinematic data such as limb loading, center of gravity, and force integrals. The current technology to quantify force related measurements in clinical and research practice requires equipments such as the force platform, dual weighing scale, and Nintendo Wii balance board.<sup>1,2</sup> These devices were used to measure static and dynamic vertical ground reaction forces in pounds or kilograms with certain possible inaccuracies.<sup>3</sup> As a gold standard practice, the calibration of measurement devices is carried through approved national accreditation bodies. Nevertheless, the calibration process is challenging when considering the cost, time, portability of the system and the frequency of calibration.<sup>4</sup>

In common health care practice, any measurement data obtained from load measurement technologies needs to be valid and reliable.<sup>5,6</sup> Specifically, the device must give a true representation of the load with a variable of measurement quantified as errors. One of the possible causes of error or inconsistency in measurement technologies is attributed to poor calibration.<sup>7,8</sup> If the initial calibration is poor, then the data derived from such measurement devices propagates errors all along the measurement output. Consequently, the device output results may affect the clinical and research outcome.

In practice, reliability of the loading device is carried out as a standard practice prior to data collection as a calibration procedure to eliminate errors in measurement data. However, reliability alone cannot confirm the goodness of a measurement device. The other key measurement variables such as accuracy, hysteresis, eccentricity error, uncertainty could affect the device output. Accuracy and uncertainty are important as any inconsistencies in the loading measurement could have a negative impact on patient care in terms of errors in diagnosis and treatment.<sup>9</sup> In common practice, loading measurement is commonly evaluated in standing, hence postural sway or any shift of body weight could increase or decrease the loading values. If there are errors in hysteresis the difference or change in loading values could not be captured by the measurement device with accuracy. Further, in practice for the evaluation of loading, the participant is required to stand in the middle of loading platform. If the participant stands at any segment of the platform other than the center, ideally the reading should be the same as that of the center. If there is eccentricity error in the device, the measurement reading differs between segments of the same measurement platform.

The ability of a practitioner to objectively test the key calibration measurement variables prior to its clinical or research application may produce good output results. To our knowledge, no literatures have discussed on the clinical or lab calibration procedures of these measurement systems. Therefore, this study describes a method of in-house calibration appropriate for calibration of load measurement devices used to measure vertical ground reaction force in practice. Such knowledge of key calibration measurement variables may enable clinicians and researchers to understand and carried out calibration in day-to-day practice for weighting accuracies.

#### 2. Aim

The aim of this paper was to describe a method of testing the key measurement principles necessary to test the goodness of a load measurement technology at clinical or research setting.

#### 3. Materials and methods

The common terminologies related to calibration are explained in Table 1. The procedure of calibration was tested using a customized clinical load measurement device (CLMD). The followings are the technical specification of CLMD, it consists of a square platform measuring  $15 \times 15$  cm with a maximum weighing capacity of 100 kg and a precision of 0.02 kg. When a load is applied, the resultant force is acquired by the square sensor platform. The platform produces electrical signals of 2.5 mV/kg, which is applied, to the amplifier to obtain single

| Table 1 – Common terminologies related to calibration. |   |  |  |  |  |
|--|---|--|--|--|--|
| Terminologies  | Descriptions  |  |  |  |  |
| Error  | Error refers to any deviation in the measurement output values to the true value.   |  |  |  |  |
| Accuracy   | The capability of the platform scale to provide the measurement output values as close as possible to the actual measurement value. |  |  |  |  |
| Precision/repeatability                                | The capability of a device to show consistent measurement values under the same conditions.   |  |  |  |  |
| Eccentricity test/Shift                                | Eccentricity test is a method of testing the platform scale where the platform is loaded asymmetrically in                          |  |  |  |  |
| test/Corner test                                       | a distinct way.   |  |  |  |  |
| Hysteresis   | Hysteresis is the difference in the measurement output of a device as the applied load increases from                               |  |  |  |  |
|  | minimum value to a maximum value, and consequently decreases from maximum to minimum over the                                       |  |  |  |  |
|  | same range.   |  |  |  |  |
| Uncertainty  | Uncertainty is a measurement variable describing the range of values within which the true value of a                               |  |  |  |  |
|  | load measurement quantity lies.   |  |  |  |  |
| Standard weight  | Standard weight is the weight that complies with the recommendation of the International Organization                               |  |  |  |  |
|  | of Legal Metrology (OIML)/global legal metrology.   |  |  |  |  |
| Applied load   | Applied load refers to the standard load administered to the platform scale for the purpose of calibration.                         |  |  |  |  |
| Reference load   | Reference load an object or material of any shape of known weight usually calibrated against standard                               |  |  |  |  |
|  | weights. Reference loads and used in calibration in the absence of standard weights.  |  |  |  |  |
| Maximum operating                                      | Maximum operating capacity refers to the maximum weight applied to the load-receiving component of                                  |  |  |  |  |
| capacity   | the platform scale under standard operating conditions.   |  |  |  |  |



Fig. 1 – Eccentricity error testing – position for placement of loads on a square shape device platform: center (1) and eccentric positions (2–5).

ended measurement output and zero to full-scale calibration. The device amplifier has high accuracy, low power with highprecision voltage reference. The measurement output is further applied to the analog input of the microcontroller and finally to the display unit. Prior to calibration, the zero setting (automatic) in the device output was ensured under no load condition. If automatic zero setting was not attained, then manual zero setting was carried by the press of a button given in the device. To determine the accuracy and hysteresis, a series of ten equally spaced standard loads ranging 10-100 kg were applied from no load to maximum load in ascending order over the CLMD platform. The calibration was conducted under controlled clinical laboratory condition using certified standard test loads of varying weighing capacity. Certified standard test loads are weights used for calibration, which complies with the appropriate approvals of the national or international metrology center. The applied loads were removed in the same order as initially placed. In addition, repeatability/precision and eccentricity error were also calculated. The repeatability test is carried out with a load of 20 kg and repeated for four more times to get five data points to compute the reliability of the measurement device. To determine the eccentricity error, the CLMD platform was divided into five quadrants as shown in Fig. 1. Center of the platform was indicated by position 1 followed by other peripheral quadrants as position two, three, four, and five. In practice, the applied load to test eccentricity should be at least third part of the maximum capacity of the device.<sup>10</sup> Therefore, a standard test load of 35 kg was chosen to test the eccentricity. An applied load of 35 kg was placed to the center of the platform at position one (P1) and the output value (O1) was recorded. Consecutively the same standard load was placed at position two  $(P_2)$ , position three  $(P_3)$ , position four  $(P_4)$  and position five  $(P_5)$  and the output measurement values given as O<sub>2</sub>, O<sub>3</sub>, O<sub>4</sub> and O<sub>5</sub> were documented respectively.

Table 2, illustrated the mathematical formula used in the calculation of key measurement variables. The accuracy of the measurement technology was analyzed by calibrating the device with a range of standard weights. For each calibration load, the difference between the applied load and the measurement output values were calculated (formula 1,<sup>11</sup> Table 2). When the differences were shown to be zero, the device measurement values are accurate, while the values are

| Table 2 – Key measurement variables calculation method. |  |   |  |  |  |  |
|---|--|---|--|--|--|--|
| No.   | Formula                                    | Explained   | Variables                              |  |  |  |
| 1   | $L_{\rm S}-L_{\rm o}$                      | $L_{\rm s}$ – true value of standard load $L_{\rm o}$ – device output value for the same standard load  | Accuracy                               |  |  |  |
| 2   | $\frac{O_i - O_d}{L} \times 100$           | $O_i$ – device output when adding a known load<br>$O_d$ – device output when decreasing a known load<br>$O_i - O_d$ – span error, difference in value of the output when increasing<br>and decreasing the same load<br>L – applied load | Hysteresis                             |  |  |  |
| 3   | $SD = \sqrt{\frac{\sum (X-\mu)^2}{n-1}}$   | SD – standard deviation<br>μ – mean<br>x – individual load values<br>n – number of trials   | Repeatability                          |  |  |  |
| 4   | ecc (P) = $O_c - O_p$                      | ecc – eccentricity<br>P – position<br>O <sub>c</sub> – output at center<br>O <sub>p</sub> – output at periphery   | Eccentricity error<br>at each position |  |  |  |
| 5   | $E_{max} = \Delta E \times \frac{Max}{3L}$ | $E_{max}$ – eccentricity maximum<br>$\Delta E$ – maximum $O_c$ – $O_p$<br>Max – maximum capacity of the device<br>L – applied load  | Eccentricity error                     |  |  |  |
| 6   | $U = ku_c$                                 | k – coverage factor<br>$u_c$ – standard deviation   | Uncertainty                            |  |  |  |

| Table 3 – Accuracy and hysteresis test of the device. |                  |            |       |                           |                             |            |  |  |
|---|------------------|------------|-------|---------------------------|-----------------------------|------------|--|--|
| Range   | Applied load, kg | Output, kg | Error | As-found value $\uparrow$ | As-found value $\downarrow$ | Hysteresis |  |  |
| 0–100   | 0                | 0          | 0.0   | 0                         | 0                           | 0.0        |  |  |
|   | 10               | 10         | 0.0   | 10                        | 10                          | 0.0        |  |  |
|   | 20               | 20         | 0.0   | 20                        | 20                          | 0.0        |  |  |
|   | 30               | 30         | 0.0   | 30                        | 30                          | 0.0        |  |  |
|   | 40               | 40         | 0.0   | 40                        | 40                          | 0.0        |  |  |
|   | 50               | 50         | 0.0   | 50                        | 50                          | 0.0        |  |  |
|   | 60               | 60         | 0.0   | 60                        | 60                          | 0.0        |  |  |
|   | 70               | 70         | 0.0   | 70                        | 70                          | 0.0        |  |  |
|   | 80               | 80         | 0.0   | 80                        | 80                          | 0.0        |  |  |
|   | 90               | 90         | 0.0   | 90                        | 90                          | 0.0        |  |  |
|   | 100              | 100        | 0.0   | 100                       | 100                         | 0.0        |  |  |
| Error = applied load - output.                        |                  |            |       |                           |                             |            |  |  |

away from zero signifies error or inaccuracy.7 Secondly, the hysteresis was calculated for each of the calibration loads. The difference between the increase and the decrease of applied load gives the span error. The obtained span error was further computed in formula 2<sup>12</sup> (Table 2) to analyze the hysteresis. Thirdly, to determine the repeatability/precision, a standard test weight was weighed five times in a systematic manner. The output measurement values were documented and computed to calculate the mean and the standard deviation (formula 3,<sup>11</sup> Table 2). The value of the standard deviation expressed the repeatability.<sup>13</sup> Furthermore, the eccentricity error of each corner/quadrant of the platform was derived by formula 4<sup>12</sup> (Table 2). In addition, the eccentricity maximum  $(E_{max})$  of the device was evaluated by the  $E_{max}$  formula 5<sup>12</sup> (Table 2). Lastly, the uncertainty is calculated by the formula 6<sup>12</sup> (Table 2). Ideally, the constant k to compute uncertainty must be in the range of 2–3, where k = 2, defines level of confidence ( $\alpha$ ) greater than 95% and k = 3 where  $\alpha > 99\%$ .<sup>13</sup> For uncertainty analysis k = 3 was chosen with p = 0.99.

#### 4. Results

#### 4.1. Accuracy

The accuracy of the CLMD device was shown as the error in Table 3. The error was demonstrated to be zero or no error for the range of applied loads.

#### 4.2. Hysteresis

Table 3 showed no difference when adding or subtracting the same load to the device platform. Therefore, the error for the applied load is zero (0). The hysteresis was calculated as

$$\frac{O_i - O_d}{L} \times 100.$$

For example, for a applied load of 10 kg, if there is no difference between adding and decreasing loads then

$$\frac{0{-}0}{100}{\times}100 = 0$$

Similarly, hysteresis was proved zero for all the applied load values.

#### 4.3. Repeatability

The repeatability or the precision of the device is demonstrated to be excellent as there is no or zero variance exist among the measurement (Table 4).

#### 4.4. Eccentricity

The maximum capacity of the device is 100 kg, applied load (L) is 35 kg (more than third part of the maximum capacity of the device), and the maximum difference in the output from the center ( $\Delta E$ ) is 0.0, as shown in Table 5. The eccentricity result was obtained by substituting the values in the  $E_{\rm max}$  formula:

$$E_{max} = \Delta E \times \frac{Max}{3L} = 0.0 \times \frac{100}{S \times 20} = 0.0$$

#### 4.5. Extended uncertainty

The measurement uncertainty (U) of the device CLMD was estimated to be  $\pm 0.00$  kg. This reported uncertainty is based on a standard uncertainty (SD  $\pm 0.0$  kg) multiplied by a coverage factor k = 3, as the level of confidence was set at 99%.

| Table 4 – Repeatability test.        |                    |                |                |                |                |      |
|--------------------------------------|--------------------|----------------|----------------|----------------|----------------|------|
|                                      | Measurement trails |                |                |                |                |      |
|                                      | 1                  | 2              | 3              | 4              | 5              | SD   |
| Applied load, kg<br>Output value, kg | 20.00<br>20.00     | 20.00<br>20.00 | 20.00<br>20.00 | 20.00<br>20.00 | 20.00<br>20.00 | 0.00 |

| Table 5 – Eccentricity error test. |       |       |          |       |                  |
|------------------------------------|-------|-------|----------|-------|------------------|
| Applied load                       |       |       | 35.00 kg |       |                  |
| Order of measurement               | 1     | 2     | 3        | 4     | 5                |
| Position                           | $P_1$ | $P_2$ | $P_3$    | $P_4$ | $\mathbb{P}_{5}$ |
| Output value                       |       |       | 35.00 kg |       |                  |
| Difference in the output           | 0.0   | 0.0   | 0.0      | 0.0   | 0.0              |
| from the center                    |       |       |          |       |                  |

#### 5. Discussion

The method of calibration of load measurement technologies varies from the model of the device and the manufacturer.<sup>10</sup> The calibration of most medical devices is done with a press of a single button.<sup>5</sup> Such calibration could assist the device output to attain zero setting; however, it does not confirm the internal calibration or the measurement accuracies of the system. Therefore, external standards of comparison with standard test loads are necessary to measure five key variables indicating the performance of load measurement technologies prior to its use in practice. This study describes an easy to use in-house calibration method to calibrate static load measurement devices, which is highly adaptable in clinical and research settings.

The result demonstrated that the CLMD device had excellent accuracy and repeatability, with no errors in hysteresis, uncertainty, eccentricity. The calibration results from the device were important in clinical and research practice. A measurement device is considered valid if it has both precision and accuracy. The accuracy of the individual data obtained from load measurement devices primarily depend on the accuracy of the device. In addition, testing the reproducibility demands precision in the results when repeatedly weighing a known load measurement at different point of time. Therefore, it is necessary that the results obtained from load measurement system needs to be consistent and close to the acceptable measurement value.<sup>14</sup> Furthermore, mechanical movement, force loading, wear, and tear of mechanical components might cause hysteresis error.5

The following were the operational guidelines followed prior to calibration:

- (1) Optimal temperature of 19 °C-24 °C was ensured in the lab setting, as changes in extreme temperature might affect the load cells, cables, and the system mechanics.<sup>15</sup> The CLMD system was refrained away from heat generating equipment and sunlight as fluctuating temperatures might lead to error in the loading output. In addition to heat, environmental factors such as snow and wind are taken control as they might affect the measurement output.<sup>13</sup> Nevertheless, in standard practice the recommended temperature for calibration of device may vary with the device and manufacture. In general the calibration of a device would be carried out at a temperature as close to the operating environment.<sup>13</sup>
- (2) The device was refrained from agitation, vibration, shock loading, electromagnetic interference, and radio frequency interference as these factors might cause output errors in the system.<sup>10</sup>
- (3) The casing and the exterior of the measurement platforms were visually inspected for cleanliness and material form, which included but not limited to intact housing and hardware, no signs of damage or spilling or dirt, and functional batteries.<sup>13</sup>
- (4) Leveling of the device platform in reference to the operating surface was ensured. The platform was leveled through adjustable feet using a bubble level device by

ensuring the bubble within the inner marked circle.

Load measurement devices must be regularly calibrated in order to deliver measurement accuracy. There is no rule of thumb to recommend on the frequency of calibration. However, calibration of the scale should be carried out following a repair and modification. In addition, the frequency of calibration is also subjected to manufacturers recommendation, influence of environment, frequency of use, type of loading (e.g. Static, dynamic, high impact), accuracy and precision required. Furthermore, it is recommended to maintain a control chart for every platform scale system in which the calibration values obtained from the successive calibrations are plotted against time line. These plotted points need to be computed further mathematically to predict the changes in the calibration values and hence will help the clinicians or researchers to determine the necessity for device recalibration. The calibration procedure demonstrated in this study is unbounded to calibration of Nintendo Wii balance board, force platform, digital and mechanical weighing devices for static loading conditions. However, the dynamic load calibration of platform devices needs to be tested by different methods and requires further validation studies.

#### 6. Conclusions

The method of calibration procedure is valid to provide information on key measurement variables accuracy, precision, and errors in terms of hysteresis, eccentricity, and uncertainties. These key calibration variables are crucial to predict the goodness of any static load measurement device used in healthcare practice. Periodical calibrations of clinical and laboratory load measurement systems are necessary as part of the quality-control program to enhance measurement accuracies. By following the procedures and guidelines discussed in this paper, one can effortlessly carry an in-house calibration test of any load measurement system in practice.

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#### **Conflicts of interest**

No authors had any financial or personal relationships with other people or organizations that could have influenced this study.

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