PDM Management at novel

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Many clinicians daily assess the dynamic pressure distribution of the patient's foot and make clinical decisions based on this data. Accurate and reliable pressure information is indispensable for the clinician to decide for appropriate treatment. Depending on the loading pattern of the foot and the pathology of the patient the local pressure values of the foot can reach up to 1.2 MPa, or even higher [1]. The actual value of local pressure is extremely important in patients with pathologies such as the diabetic foot. Therefore, it is necessary that every sensor within a pressure system displays the accurate, absolute pressure value.

To provide clinicians and researchers with accurate pressure distribution data novel has offered high quality emed® pressure platform systems since 1984. Each system contains individually calibrated, accurate, reliable capacitive sensors.

Any sensor used for pressure distribution measurement is deformed by applied pressure therefore a well-defined spring balance element inside the sensor is required. This deformation is translated into an electric signal. To get accurate and reliable results it is very important that the deformation of the sensor is reproducible and stable over a long period of time. The loading should be reversible during off-loading, resulting in a small hysteresis. To meet these requirements novel uses unique elastic materials as a spring balance element inside the pressure sensors. An exceptional calibration procedure using the patented trublu® calibration system was developed to define the relationship between the applied pressure and the displayed sensor signal. Each individual sensor is calibrated throughout the entire pressure range. This results in accuracy better than +/- 5% for pressure values up to 1.25 MPa. The hysteresis of the novel emed® systems is less than 3%. For more detailed results see reference [2]. Based on the local pressure values, local and total forces can be alculated from the loaded areas and the applied pressure.

Since the sensor properties may change slightly over time, calibration must be checked periodically. It is recommended to do this at least once a year. This assessment is offered from novel as a service for its users. Also, the user should periodically perform some simple tests to check the calibration. Subjects should be asked to stand with one foot on the platform. Without revealing the subject's bodyweight to the system, the emed® platform will display the subject's bodyweight, within 5%. However, the only way to determine the exact accuracy of each individual sensor it is indispensible to use the trublu® calibration system.

Pedography systems used in clinical routine are regulated according to the Medical Device Directive Law of the European Community. They are Confirmed Medical Products Class I with measuring function ("Im") and have to strictly follow the official specified conformity assessment. An official Notified Body, such as ISS or TUEV is required, to approve the quality standards for the measuring function. All emed® platform systems are produced with the approval by a Notified Body and documented by a valid CE Certificate. Systems without this approval may not be distributed in the Common Market.

Literature:
[1] Cavanagh, P.R., Ulbrecht, J.S., Clinical plantar pressure measurement in diabetes: rationale and methodology, The Foot 1994, 4, 123 – 135
[2] Hillstrom, H.et al, The novel emed-x and tekscan matscan plantar measurements systems, esm abstracts, 2006, p. 87