Emerging Innovations in Metrology for medical devices technologies: advancing healthcare precision

AUTHORS

Delgado San-Martín, L. *; Sáenz Nuño, M. A. **; Esteban Temprano, Á. *; De Castro Asensio, I. *; Fernández Vicente, T. *; Ruiz González, S. *;Martín Megías, A. I. *.

*Spanish National Metrology Institute (CEM); ** Institute for Research in Technology (IIT) - ICAI Univ. Pontificia Comillas de Madrid, Spain

Contact Information:
Laura Delgado San Martín
ldelgado@cem.es

LABORATORY FOR HEALTH

The lack of uniformity among working standards for the calibration of medical devices poses a significant challenge in achieving comparable measurements across Spanish hospitals. **CEM** is addressing this challenge by leading three research projects focused on the calibration of medical devices, specifically targeting diagnostic imaging equipment such as *electrocardiographs (ECGs), echographs, computed tomography (CT) scanners and sphygmomanometers* to ensure measurement traceability **[1]**.

First CAT-Scan comparison in four volunteer hospitals, of a standard prototype based on a bone with steel spheres embedded in its surface.

National Congress of the Spanish Society of Electromedicine and Clinical Engineering (SEEIC). The Laboratory for Health received an award for innovation.

CAT-SCAN

AWARD

2015 **2019** **2021** **2024**
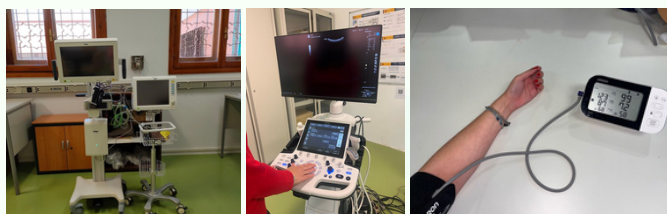
GT4BIOMET

CREATION

Creation of group AEN/CTN 82/GT4BIOMET Developing of standards in Health Metrology

Creation "Laboratory for Health" at CEM

PROJECT RESULTS AND CONCLUSIONS

The development of standardized calibration procedures to ensure homogeneity and traceability of measurements to the International System of Units (SI) aims to improve the accuracy and reliability of device results:

Electrocardiographs (ECGs): Quantification of captured voltage waveform values (mV) and comprehensive analysis of associated uncertainty are crucial steps in evaluating this devices **[2]**.

Diagnostic imaging equipment (echograph and CT equipment): Design and manufacture of a reference standard for length measurement verification **[3]**.

Sphygmomanometers (for blood pressure measurement): Essential validated non-invasive methods need refinement, while innovative approaches must be explored to enhance sphygmomanometer reliability and accuracy in clinical settings **[2]**.

FUTURE CHALLENGES

Swift advances in medical measurement and diagnostic equipment, driven by emerging technologies like *ML and AI*, necessitate the development of robust procedures to assess performance and quantify result uncertainty. **CEM** aims to support emerging technologies for analyzing complex ECG waveforms, enhancing diagnostic accuracy and operational efficiency in medical settings, focusing on reliable diagnosis in *electrocardiography.*

ADVANCING DIAGNOSIS CT

The progress of the CT and ultrasound projects is detailed in a poster for the 150th anniversary of the Metre Convention with the title: "The Use of Artificial Intelligence in Diagnostic Imaging", under the 7 topic of Digital Transformation, Artificial Intelligence, and Systems Metrology.

REFERENCES:
[1] Esteban, Á., Delgado, L., De Castro, I., Fernández-, T., Peña, M.L., Sáez, A., Martín, A.I., Sáenz, M.A. Nuevos retos en Metrología de la Salud. Revista e-medida. Número 25, 2024.
[2] Delgado, L., De Castro, I., Esteban, Á., Sáenz, M.A., Fernández, T., Peña, M.L., Sáez, A., Sánchez, C. New challenges in metrology for health: Looking for reliable diagnosis in electrocardiography and blood pressure measurement. Measurement: Sensors, 2024, 101515, ISSN 2665-9174.
[3] Esteban, Á., De Castro, I., Delgado, L., Sáenz, M.A., Fernández, T., Peña, M.L., Sáez, A., Sánchez, C. Emerging innovations in health metrology for diagnostic imaging, Measurement: Sensors, 2024, 101649, ISSN 2665-9174.

Plan de Recuperación, Transformación y Resiliencia

GOBIERNO DE ESPAÑA MINISTERIO DE INDUSTRIA Y TURISMO

CEM CENTRO ESPAÑOL DE METROLOGÍA

UNIVERSIDAD COMPLUTENSE

COMILLAS UNIVERSIDAD PONTIFICIA