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## Emerging innovations in health metrology for diagnostic imaging

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## ABSTRACT

The Spanish National Metrology Center (CEM) is dedicated to advance the understanding of the essential role of measurements in the healthcare sector.

CEM has created a laboratory in healthcare metrology to ensure the accuracy of measurements in medical equipment, including computed tomography (CT). The primary objective of this project is to design a system considered as a standard, called Phantomer, which allows the traceability of dimensional measurements obtained from diagnostic imaging to the International System of Units (SI).

For this purpose, the Phantomer has been graphically designed and numerical simulations have been performed to examine its response to environmental conditions and to evaluate the relative contributions of uncertainty to the dimensional measurements, primarily due to thermal and mechanical forces and torsion sources. Subsequently, the standard undergoes metrological characterization in dimensional terms, and the results are disseminated to the research community.

## 1. Introduction

The Spanish National Metrology Institute (CEM) plays a crucial role in coordinating metrology activities within the country and representing Spain internationally. It maintains strong collaborations with national and international metrology-related organizations. One of CEM's key responsibilities is conducting research and development (R&D + I) projects in the healthcare sector, aligning with its strategic objectives.

It started almost ten years ago (2015), when it was considered beneficial to strengthen the use of metrology in the health field. This led to the creation of an interdisciplinary working group [1].

The main purpose would be developing the standards of management in the Health Metrology area. Alfonso M. Fernández-Sánchez also noticed the necessity to establish a metrological system that supports the health field. Supporting this ideas, Natividad Bermejo carried out a research study [2].

In that document, she faced the evaluation of the traceability of measurement equipment performed in several hospitals and laboratories by means of 3D measurement inter-laboratory comparisons.

CEM along with ICAI-IIT (Pontifical Comillas University) performed the first CAT-Scan comparison, by measurements of a standard bone carried out over a by four volunteer hospitals [3]. The main goal of this research was to identify differences inter-method and inter-hospital, if any, to ensure the reliability of dimensional measurements [1].

The last milestone in the Health Metrology of Spain (Fig. 1) is the collaboration between CEM and SEEIC (Spanish Society of Electromedicine and Clinical Engineering) [4]. This alliance along with the collaboration between CEM and ICAI-IIT (Pontifical Comillas University) will ensure that CEM, universities and hospitals will work together. Furthermore, CEM conducts scientific outreach activities and shares project updates through its social media channels to engage with a wider audience.

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The above work and research represent a further step towards the implementation of the Spanish metrological management system, whose scope in the metrological society is growing.

Since 2021, CEM has been implementing its strategic plans for 2021–2023 and the subsequent plan for 2024–2026, focusing on advancing metrological infrastructure in healthcare.

To achieve this, CEM has initiated three R&D + I projects, of which this project is one of them, funded through the Recovery and Resilience Facility. These projects aim to establish a robust metrological framework for healthcare in Spain, ensuring the accuracy of measurements in this critical domain.

With the experience and conclusion learned over these years, CEM has launched the following project based on development of a system that allows traceable diagnostic imaging.

Currently, the lack of standardized procedures hinders the comparison of measurements between hospitals and healthcare centers. The need for this project arises from the desire to guarantee the reliability and traceability of the dimensional measurements of imaging equipment in order to be able to compare results and obtain more accurate and faster diagnoses, with the consequent savings in the healthcare system.

At the international level, a key objective in metrology is to ensure the reliability and comparability of health measurements across different healthcare facilities [5]. Achieving this requires that diagnostic instruments provide traceable results to the International System of Units (SI) [6].

The project analyzed here focuses on diagnostic imaging devices, mainly computed tomography (CT) and ultrasound scanner. By developing and implementing these projects, CEM aims to improve the traceability and reliability of healthcare measurements, fostering the improvement of healthcare practices and outcomes.

This project is carried out in a new laboratory located in the CEM facilities. The laboratory has been equipped with state-of-the-art

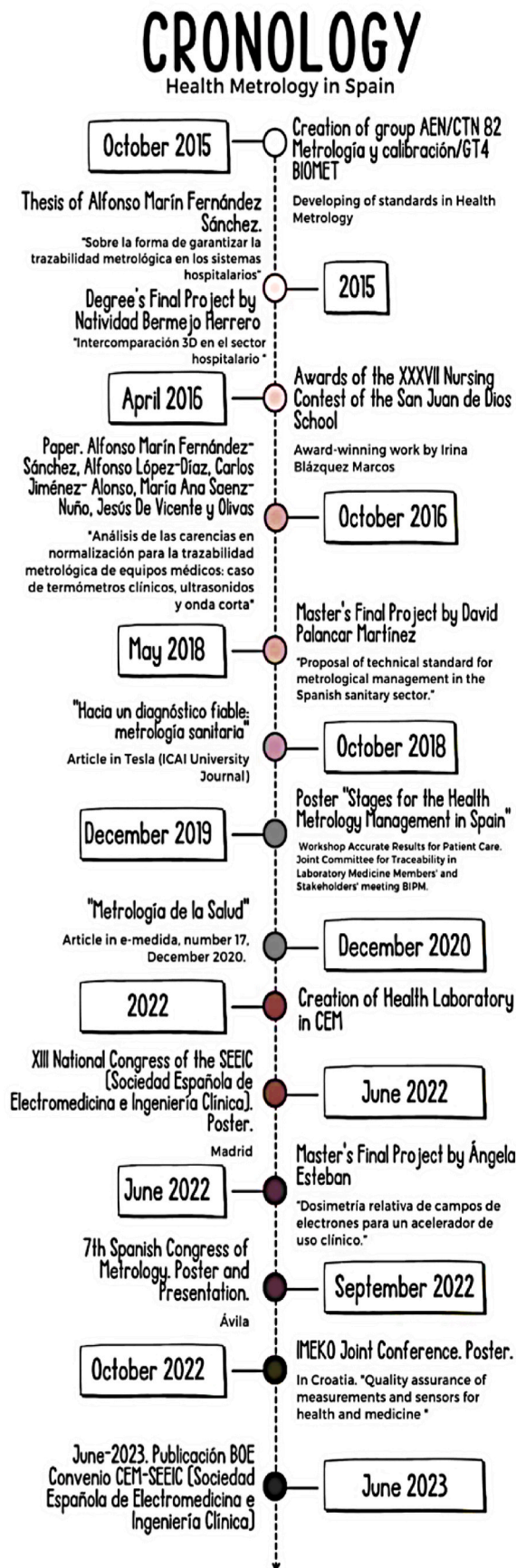


Fig. 1. Time-line of health metrology group in Spain.

ultrasound, electrocardiograph, blood pressure monitoring and measurement equipment.

It is already operational within the framework of the European resilience strategy, and the initial phase of the project has been presented at Spanish and international congresses [7] and seminars [8].

This paper presents the method used for the design and fabrication of the phantom, as well as the calibration and testing phases. As a novelty of the research, the results obtained for the thermal and mechanical simulations of the phantom are presented, as well as the next lines of work that the project intends to follow in the future.

### 1.1. Diagnostic imaging

Diagnostic imaging tools are widely used in the prognosis and monitoring of treatment. The reliability of their measurements is based on the early detection of pathologies in time to avoid the aggravation of diseases.

One of the main objectives at the international level in the field of metrology is that health measurements are reliable and comparable between different hospitals and even within the same hospital. To do this, it is necessary that the instruments used to make diagnoses and, therefore, to make decisions about treatments providing results that are traceable to the International System of Units (SI).

However, at present this is not the case, as there are not standards that allow us to compare measurements between different hospitals and health centers.

Therefore, the main objective of this project is to ensure the traceability of dimensional measurements of medical imaging equipment in order to compare results between hospitals and even within the hospital itself [7].

This project has been based on the development of a medical prototype that serves as a standard to provide traceability to the dimensional measurements of the instruments that allow for diagnostic imaging, initially CT and ultrasound scanner.

For this purpose, the participation of hospitals and laboratories with active collaboration was required. The obtaining of the Standard will allow a more in-depth knowledge of the variables of the equipment, which will allow medical staff to establish their diagnosis based on objective data from measurements and their uncertainties.

## 2. Methods and procedures

The project was initiated at the CEM health metrology laboratory in July 2023. In an earlier phase, the necessary equipment for the project was procured. To carry the project out, the following phases have been followed:

- Study and graphic design of the Phantometer.
- Carrying out trial tests. Study of possible improvements.
- Implementation of the Phantometer and its calibration.
- Providing traceability in units of length.
- Dissemination of the results and findings to the research community

The methodology followed at each stage of the project is described below.

### 2.1. Phantometer design study

Initially, a state-of-the-art study was conducted on the current situation of metrology in the field of diagnostic imaging, focusing on the theoretical study of the prototype of the Phantometer to be built and its graphic design.

The graphic design of the prototype was carried out using the numerical simulation tool SolidWorks® design and simulation software.

During the graphic design phase, it was approved to build the Phantometer with a polycarbonate parallelepiped structure.

Polycarbonate was chosen because it is an amorphous thermoplastic with high levels of mechanical, optical and electrical strength, as well as thermal properties that make it suitable for use in studies where there is high thermal dependence. Its unique property profile includes excellent impact resistance over a wide temperature range. In addition, it was chosen because it is transparent to CT radiation, reducing image artefacts.

Inside the structure, the screw threads are symmetrically arranged on the walls of the Phantometer. Cylindrical rods made of carbon fibre, a material used for its high mechanical strength and low thermal expansion, are screwed into these threaded holes.

A sphere made of a ruby-like material is attached to the end of the cylindrical rods. This ceramic material was chosen because of its high hardness and because it is visible to CT radiation, a property necessary to characterise the photometer in dimensional units.

For this purpose, the standard distances considered in the project to measure the Phantometer are the distance between the centers of the spheres and their diameters. Simulations based on the Monte Carlo method [9] were carried out to measure the distance between the centers of the spheres and to measure the diameters of the spheres under various thermal and stress conditions in order to study thermal expansion and deformations.

The calculation of the thermal expansion based on the linear thermal expansion of the ruby is seen below.

$$\Delta \varnothing = \alpha_{\text{Ruby}} \cdot \varnothing_0 \cdot \Delta T \quad (1)$$

$$\alpha_{\text{Ruby}} = 8.5 \cdot 10^{-6} \text{ K}^{-1} \quad (2)$$

Where  $\Delta \varnothing$  refers to the diameter variation,  $\alpha_{\text{Ruby}}$  is the linear expansion coefficient of the Ruby,  $\varnothing_0$  is the initial diameter and  $\Delta T$  is the temperature interval considered, in this case:

$$\Delta T = 305 \text{ K} - 291 \text{ K} = 14 \text{ K} \quad (3)$$

After the approval of the graphic design of the Phantometer, the numerical simulation phase has been started, also with SolidWorks® design and simulation software to study the physical conditions and mechanical properties of the Phantometer, as well as its behavior under environmental conditions to which it could be subjected in real conditions.

For this purpose, thermal and mechanical simulations in terms of torsion, strength, elasticity and rigidity were carried out on the Phantometer.

Fig. 2 shows a three-dimensional graphical representation of the thermal simulations (Fig. 2(a)) and mechanical simulations (Fig. 2(b)) in the Phantometer.

Regarding the thermal simulations of the Phantometer, they were carried out for a temperature range from 18 °C to 32 °C, an actual range in a hospital, from the surgery room to the hospital ward. Furthermore, it is taken into account that the calibration of the Phantometer is carried out at 20 °C in the CEM length laboratory.

The objective was to observe how the convection temperature affects the Phantometer material and subsequently analyze the contribution to the uncertainty associated with dimensional measurements due to the thermal expansion of the Phantometer materials.

Furthermore, mechanical simulations were conducted, focusing primarily on torsion, force, stiffness, elasticity, and strength, to optimize the design and properties of the Phantometer. Contributions to the uncertainty associated with dimensional measurements were studied due to the material's influence.

One of the future challenges of this project is to study the variation in length between the spheres due to the influence of temperature on the system under calibration, considering magnitudes of influence such as the distance of the CT or ultrasound equipment to the standard or the envelope of the standard.

In the next future line of the project, it is planned to analyze and study the Phantometer with water inside it, as well as with a liquid of

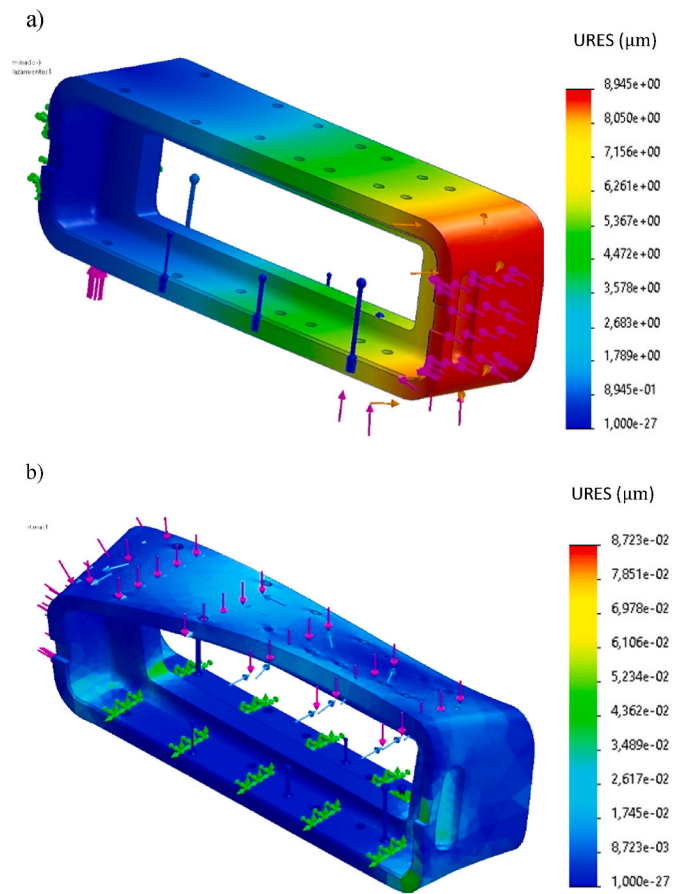


Fig. 2. 3D graphical result of thermal (a) and mechanical (b) simulation of the Standard. The simulations were carried out using SolidWorks® design and simulation software. URES refers to the resulting displacement in micrometres (µm).

varying density, for study by means of an ultrasound scanner.

## 2.2. Phantometer development

During this stage, the Phantometer components and equipment are acquired. Experimental tests are performed to verify the thermal and mechanical numerical simulations. The simulations will be compared with traditional GUM-based uncertainty contributions, recalling that the GUM method prevails over the Monte Carlo method [9].

## 2.3. Calibration of the Phantometer

During this stage the metrological characterization of the Phantometer and the development of the calibration system will be carried out. The Phantometer validation stage is the most extensive.

The construction and assembly of the Phantometer, as well as tests and trials to optimize it, were planned. The objective was to study the reliability and the intercomparison of the measurements of diagnostic imaging equipment and the results of laboratory measurements with those obtained in health centers.

As far as CT measurements are concerned, the maximum resolution and accuracy of hospital CTs manufactured by leading commercial manufacturers can be approximated [10–14]:

Metrotom 800 130 kV from Zeiss, has a maximum spatial resolution of 3.5 µm (ISO 15708) with a maximum permissible error of 2.9 µm + L/100.

Phoenix Nanotom from General Electric, has a resolution of 0.3 µm (ISO 15708).



MCT225 from Nikon Metrology, with a maximum permissible error of  $9 + L/50 \mu\text{m}$ .

FF20 CT from YXLON, with a maximum permissible error of  $3.9 \mu\text{m} + L/75 \mu\text{m}$ .

Werth TomoScope 200 with a  $4.5 \mu\text{m}$  of resolution.

On the other hand, the resolution of most hospital ultrasound scanners is in the range of  $0.1 \text{ mm}$ – $2 \text{ mm}$  [15,16].

For this purpose, the Phantomer will be dimensionally calibrated at CEM's Length Laboratory by means of a Coordinate Measuring Machine (CMM) in order to achieve traceability of the Phantomer developed by means of CEM's standards.

#### 2.4. Validation of the Phantomer

During this phase, the validation of the Phantomer is carried out. To do this, the shape defects are studied, understanding these as deviations from the ideal geometry of the piece with certain nominal values that adjust to specific shapes. In this case, the defects of shape are considered in the systems of cylindrical rods with spheres of the Phantomer.

The shape defects that have been taken into account are primarily roundness, cylindricity, parallelism, perpendicularity, repeatability, thermal expansion, vibrations, drift and hysteresis.

When calculating the uncertainty of dimensional measurements, contributions to the uncertainty have been considered, such as the influence of rotation error in the calibration of the probe; the range change; eccentricity drift; resolution; reference standard drift; the influence of the coordinate measuring machine and alignment error of the standard.

#### 2.5. Dissemination of results

Regarding the dissemination of project results and knowledge, the intention is to carry out the transfer and promotion through seminars, communications, and talks, targeting both the healthcare sector and the research community, especially in academic degree related to this topic.

### 3. Results and discussion

The results obtained from July 2023 to March 2024 for this project are presented.

#### 3.1. Thermal simulation results

Simulations have shown a significant thermal influence on the polycarbonate material of the Phantomer.

During these simulations, the distance between points on the Phantomer has shown to have a variation of the order of one tenth of a micrometre.

This change is considered as a contribution to the Phantomer uncertainty due to the fact that the CT have a resolution of the order of about  $1 \mu\text{m}$  [10–14] and is less relevant for ultrasound scanners with a resolution of  $0.1 \text{ mm}$ – $2 \text{ mm}$  [15,16].

It has also been observed that the linear expansion of the diameter of the probes increases with their diameter, so the variation in the distance between the probes due to the thermal difference is smaller for the larger probes.

#### 3.2. Torque and force simulation results

The study of the deformation of the structure gave an acceptable alteration of the order of  $0.01 \mu\text{m}/\text{metre}$  for a range of applied forces between  $10 \text{ N}$  and  $20 \text{ N}$ , considering that the CT devices have a maximum permissible error of a micrometre [10–14]. This is negligible for the ultrasound scanners which have a resolution of  $0.1 \text{ mm}$ – $2 \text{ mm}$  [15,16].

The main cause of phantom deformation can be thought to be due to handling by the technician during calibration and verification.

This mechanical contribution to the uncertainty of dimensional measurements of the distance between the spheres is less relevant than the contribution due to thermal expansion.

Fig. 3 shows the graphical representation of the torque (Fig. 3(a)) and force deformations (Fig. 3(b)) in the Phantomer for a range in the order of  $10 \text{ N}$  and  $20 \text{ N}$ .

### 4. Conclusions

The main objective of this project was based on designing a system called Phantomer that would allow the traceability of the dimensional measurements obtained from diagnostic imaging to the International System of Units (SI).

During this review, it is explained how the Phantomer is graphically designed and its behaviour under variations in thermal and mechanical environmental conditions is studied.

It was obtained that the thermal expansion of the ruby spheres undergoes variations of the order of one tenth of a micrometre for a temperature range from  $18^\circ\text{C}$  to  $32^\circ\text{C}$ , contribution to the uncertainty relevant for CT equipment.

Regarding the mechanical simulations, a deformation of the order of  $0.01 \mu\text{m}/\text{metre}$  has been obtained for a force range of  $10 \text{ N}$ – $20 \text{ N}$ , less relevant contribution than the thermal variation.

The metrology for health laboratory at CEM is committed to actively participating in European projects and networks related to health metrology, with the goal of ensuring international comparability. By

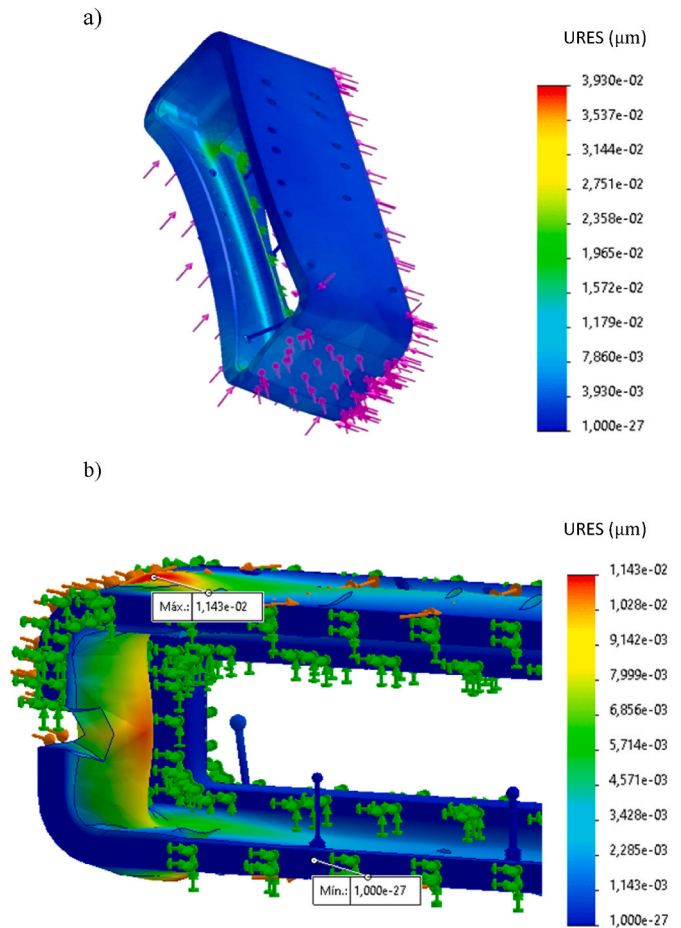


Fig. 3. 3D graphical representations of the torque (a) and force deformations (b) in the Phantomer for a range of the order of  $10 \text{ N}$  and  $20 \text{ N}$ . URES refers to the resulting displacement in micrometres ( $\mu\text{m}$ ).

engaging in international collaboration, the laboratory aims to achieve innovative goals and contribute to the advancement of this research field, leveraging the synergies and opportunities that arise from working together.

For this project, the challenge is to ensure that measurements from imaging equipment are reliable and comparable across different hospitals and healthcare centers.

This will enable metrological traceability to the International System of Units (SI) in length quantity, making results from different health and research centers comparable.

By doing so, CEM can contribute to the implementation of an Official Calibration Chain in length measurements in the field of Health Metrology.

Lastly, the main future challenges of the project are based on studying the variation of the distance between the spheres of the photometer and their diameters by carrying out simulations considering new conditions of the photometer taking into account liquids such as water or other liquids of varying density.

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