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New challenges in metrology for health: Looking for reliable diagnosis in electrocardiography and blood pressure measurement

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ABSTRACT

Improving awareness of the importance of measurements in the field of health is one of the objectives of the Spanish Metrology Centre (CEM). To achieve this, a health metrology laboratory has been set up to develop projects focused on ensuring the reliability of measurements in equipment such as electrocardiographs (ECGs) and sphygmomanometers. The laboratory's diverse equipment includes vital signs simulators, signal generators, oscilloscopes, multimeters and software such as Python®. These tools have enabled the analysis of simulated ECG reference signal models and the identification of appropriate equipment for sphygmomanometer calibration.

1. Introduction

The Spanish Centre of Metrology (CEM) is maximum metrological institution in the country, with the representation at the international level, maintaining close cooperation with national and international organizations related to metrology. Among its competencies, the execution of research and development (R&D + I) projects in Health metrological field, which is one of the strategies of CEM.

Since 2021, as part of its strategic plan from 2021 to 2023 and continuing with the recent plan from 2024 to 2026, CEM has promoted several R&D + I projects funded with credits from the Recovery and Resilience Facility. The strategic plan aims to provide Spain with a metrological health care infrastructure that ensures the reliability of measurements in this field.

CEM is making a great effort in the dissemination of metrology for health, for instance, in the academic field through a seminar at the University of Salamanca [1], and in the health sector through the Spanish Society for Electromedicine and Clinic Engineering [2], where the importance of metrology for health was communicated.

Additionally, within CEM, scientific dissemination talks are held, and outreach activities are carried out regarding the work conducted in the health laboratory, with the projects being accessible at CEM channels for social networks [3].

One of the main objectives at the international level in the field of metrology is that health measurements are reliable and intercomparable among different hospitals and even within the same hospital. To this end, it is necessary that the instruments used to perform diagnoses and, therefore, to make decisions regarding treatments provide results that are traceable to the International System of units (SI) [4].

However, this is not currently the case, as there are no procedures in place to establish, on the one hand, the complete calibration of the instrument and, on the other hand, to guarantee the reliability of the measurement. In order to solve that, the development of several R&D + I projects by CEM focused on medical equipment has started, such as sphygmomanometers and electrocardiographs (ECGs).

1.1. Electrocardiography

The technique of electrocardiography is a clinical diagnostic support method that uses electrocardiographs (ECGs) to capture, amplify, measure and record the electrical activity of the heart. The recording of heart activity allows for the detection of underlying heart diseases to make a diagnosis and prescribe treatment. Therefore, the reliability of the measurement is crucial for precise diagnosis and appropriate treatment [5].

This communication presents the work being carried out in the CEM health laboratory on the calibration procedures for electrocardiograph measurements. The project aims to design a reference calibration procedure for the homogeneity of electrocardiograph measurements, taking into account their significant points, such as the P wave and the QRS complex. The PQRS points are analyzed with their characteristic values, voltage and time, expressed as voltages in mV and heart rate, beats per minute (BPM) [6].

1.2. Blood pressure measurement

Blood pressure measurement is a parameter used frequently in clinical medicine to evaluate a patient's condition. Its importance is directly related to other diseases, conditions the administration of drugs and it is even used as a preventive factor. Hence, fundamental metrology must accompany equipment for this purpose in order to give traceability and reliability to the results.

Non-invasive methods for blood pressure measurement include the auscultatory and oscillometric methods. Both methods involve placing a cuff around the arm and measuring blood pressure by occluding the brachial artery and gradually releasing the cuff pressure. However, the auscultatory method is based on the listening of Korotkoff sounds, while the oscillometric method uses the pressure oscillations detected in the cuff [7].

Instruments to measure blood pressure are known as sphygmomanometers, which are classified based on the measurement method.

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Therefore, they are classified into auscultatory sphygmomanometers and oscillometric sphygmomanometers. International Standard Organization (ISO) recommends to use the former as a reference over the latter [8].

Commercial simulators of blood pressure appeared in the early 1990s [9]. These devices are able to simulate blood pressure signal by means of replication of pressure oscillations occurring inside the cuff of a sphygmomanometer. Several references have concluded that commercial devices are not suitable as standard for accuracy [10]. Meanwhile, ISO has issued the Technical Specification ISO/TS 81060–5:2020 [11] to assess the reproducibility and repeatability of these simulators.

The project on blood pressure measurement conducted at CEM involves the characterization of a blood pressure simulator. By using the results of these tests, a new procedure to evaluate the repeatability and reproducibility of sphygmomanometers will be developed. The newly developed procedure will help to ensure the reliability of these blood pressure instruments.

2. Methods and procedures

The works are being developed in the metrology for health laboratory, located at CEM facilities and launched in July 2023.

In a previous stage, part of the needed equipment for each project was acquired, and currently, a phase of experimentation and search for reliable results is in progress.

2.1. Electrocardiography

As a starting point for the project, the ECG reference signal models were characterized in three different ways. Block diagram summarizing the ECG project.: 1) using reference databases from the Physikalisch-Technische Bundesanstalt (PTB), specifically the PTB-XL [12], 2) generating a simulated signal based on the characteristic PQRS points, as shown in Table 1, and finally, 3) through a vital signs simulator of the Fluke model ProSim V8. In all three cases, a normal ECG is used as the starting point. Fig. 1.

The instrumentation currently available for the project is shown in the Fig. 2., where you can see from right to left, 1) a PC, 2) a signal generator (brand: keysight), 3) amplifier (brand:A-M System), 4) vital signs simulator (brand: Fluke; model: ProSim V8), and 5) oscilloscope (brand: Rigol).

The simulated signal was programmed using the Python® programming language, then generated through a signal generator and amplified. On the other hand, the vital signs simulator generates the ECG signal in two ways, one through a high-gain output and the other directly from the electrode terminals for 12 leads.

2.2. Blood pressure measurement

To perform tests and trials in the Blood Pressure Measurement project, the following devices have been provided to the lab: 1) non-invasive blood pressure (NIBP) simulator, (brand: Fluke; model: ProSim V8), 2) pressure standard (brand: Ruska; model: series 6200), 3) fixed volumes (40 mL and 500 mL, only shown the smallest), 4) non-invasive analogic sphygmomanometer, 5) non-invasive automatic sphygmomanometer (brand: Beurer; model: Model BM26) 6) syringe (as variable volume), among others. Fig. 3 shows one of the setups of the experiments used in this project.

Table 1
Normal ECG values [13].

Wave	Amplitude	Interval	Duration (s)
P	0.25 mV	P-R	0.12 to 0.20
R	1.60 mV	Q-T	0.35 to 0.44
Q	25 % R	S-T	0.05 to 0.15
T	(0.1–0.5) mV	P	0.11

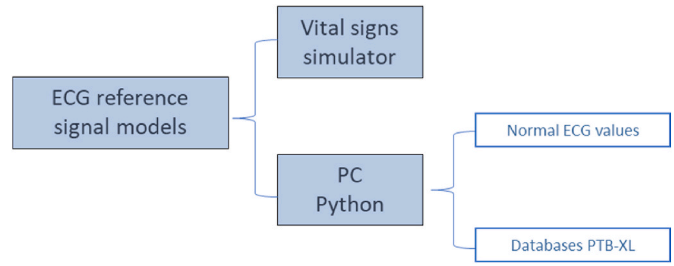

Fig. 1. Block diagram summarizing the ECG project.

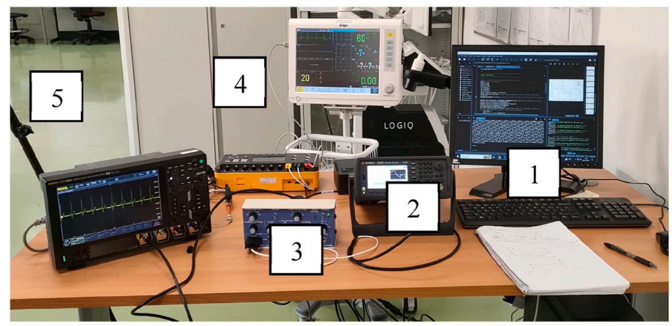

Fig. 2. Experimental setup for the generation simulated ECG reference signal models.

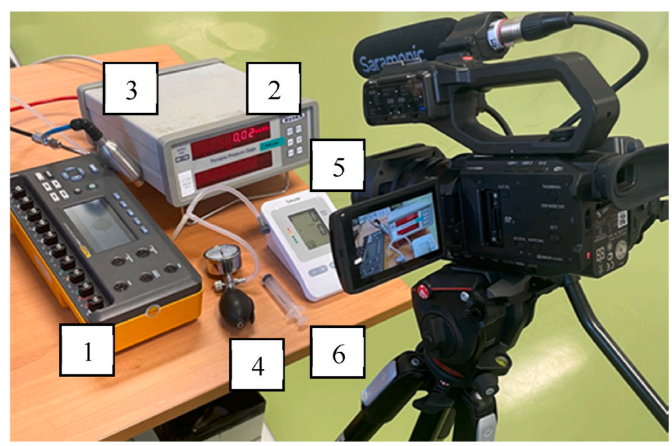

Fig. 3. Experimental Setup for the blood pressure measurement project.

In Fig. 4, the three main lines of the project are summarized.

Firstly, measurement tests were carried out with the vital signs simulator and the blood pressure monitor. In this case, the range of blood pressures were from (200–60) mm Hg in systolic pressure (PS), and from (180–40) mm Hg in diastolic pressure (PD). The objective was to evaluate the behaviour of the blood pressure monitor.

The second research line of study involved the characterization of the commercial blood pressure simulator. The evaluation of the equipment's performance was carried out through tests that determine the pulse volume[1] and pulse frequency[2] emitted by the simulator.

In these tests, the conditions were established to cover the range of blood pressure from (120–80) mm Hg. Therefore, the pressure oscillation at the cuff pressure above systolic (150 mm Hg) and below diastolic (60 mm Hg) were analyzed. Additionally, intermediate points such as

[1] The amount of air injected by the vital signs simulator every beat.
[2] Number of beats per minute, a characteristic parameter of the vital signs simulator.

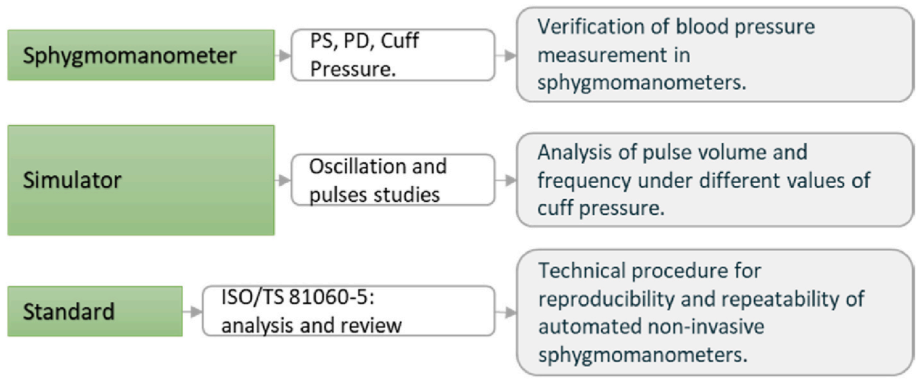

Fig. 4. Block diagram summarizing the project.

mean pressure (93 mm Hg), systolic pressure (120 mm Hg), and diastolic pressure (80 mm Hg) were evaluated.

The third and final research line was to follow the repeatability and reproducibility study detailed in ISO/TS 81060–5:2020 [11]. For this purpose, the guidelines and recommendations outlined in the Standard were implemented.

Any data collection with the set-up of the Fig. 3 was preceded by a leak test commanded by the simulator. It was verified that the air loss does not exceed the OIML R 149-1 recommended value of 0.8 kPa/min [14].

In some experiments, data recording with a video camera was required to register the information. In other cases, a code specifically developed in Python® was used to capture the signals in a computer from the pressure standard.

2.3. Exploitation and dissemination of the results. Transfer to the health sector

The final stages common to all projects are based on the Exploitation and Dissemination of Results through the publication of results obtained.

On the other hand, the dissemination of the results to the medical sector is of great importance, mainly through two proposals. The first is based on the transfer of results through seminars, symposia, conferences or specific training in hospitals, research centres or academic programmes with a health-related background. The second proposal is to provide specific training in Metrology to professionals and researchers working in the health sector to familiarise them with the field of Health Metrology.

3. Results and discussion

The results obtained from July 2023 to March 2024 for each of the two projects are presented.

3.1. Electrocardiography

The results verified that the ECG reference signal models, whether simulated with Python® or obtained directly from the signal simulator, were weak (around 1 mV) compared to the noise generated by the signal generator or the oscilloscope. The resolution of the electrocardiograph is 0.1mV, if taking the printed ECG paper as a reference. Signals as small as these make it difficult to detect and accurately measure the signal [6]. It is necessary for both signal filtering and amplification. An example of this is that the signal simulator with an estimated output gain of 500, as shown in the Fig. 5.

Fig. 5 displays the signal generated by the Fluke vital signs signal simulator along with the noise caused by the equipment.

To down the ranges in which an electrocardiograph works for a healthy heart, we analyzed the PTB XL database. The signals displayed on an ECG vary depending on the individual and their health status, and artefacts[3] are observed to make interpretation difficult. This was confirmed using the PTB XL database, where even healthy patients had a deviated isoelectric line, as shown in, Fig. 6 [12].

The aim was to identify, on one hand, the factors affecting the acquisition of the electrocardiogram signal and subsequently select appropriate filtering techniques to optimize signal processing, and on the other hand, establish the measurement ranges.

Once the signal has been characterized based on normal ECG parameters, different heart conditions could be simulated by modifying the measurement ranges [13].

It is worth noting that commercial ECG equipment has its own filters and can amplify the signal by selecting the gain.

It is worth noting that commercial ECG equipment has its own filters and can amplify the signal by selecting the gain.

All tests performed with signals programmed by Python and generated and the signal simulator will allow for the determination of certain contributions to uncertainty associated with the measurement process. These results will take part to the development of reliable verification and calibration procedures for electrocardiographs.

3.2. Blood pressure measurement

One of the first results obtained with the vital signs simulator and the sphygmomanometer was that the measurement of blood pressure read in the sphygmomanometer deviates from the specified in the simulator. This fact was already described previously by Amoore [10]. Additionally, it was verified that this deviation increases as the pulse pressure increases (difference between systolic and diastolic pressure), Fig. 7.

During the characterization of the vital signs simulator, the pressure signals obtained showed the volume variation in imposed by the simulator (pulse volume) is a function of cuff pressure. The value of this volume variation was calculated at different values of the cuff pressure, (cuff pressure set point). Around these set points, the pressure fluctuated between two values: the cuff pressure (upper and lower).

The volume variation imposed by the simulator was calculated with these upper and lower values. The resulting volume variation was found to fluctuate around the value specified in the vital signs simulator (1 ml/pulse), which should be the value at the mean pressure (93 mm Hg).

However, the results showed that it does not occur at the mean pressure, but that there is a deviation from what was expected, Table 2.

The tests performed and their results were used to develop the procedure for verifying the reproducibility and repeatability of sphygmomanometer.

[3] Traces of activity or movements other than the electrical activity of the heart that may distort the ECG components.

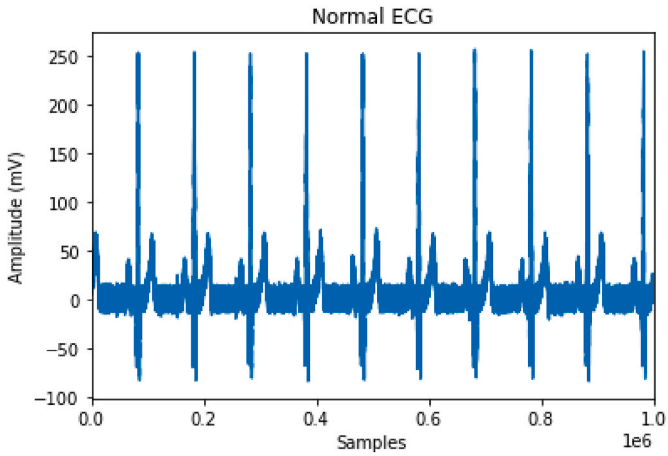

Fig. 5. Signal of Lead II from a normal ECG generated by the Fluke signal simulator, amplified from the output.

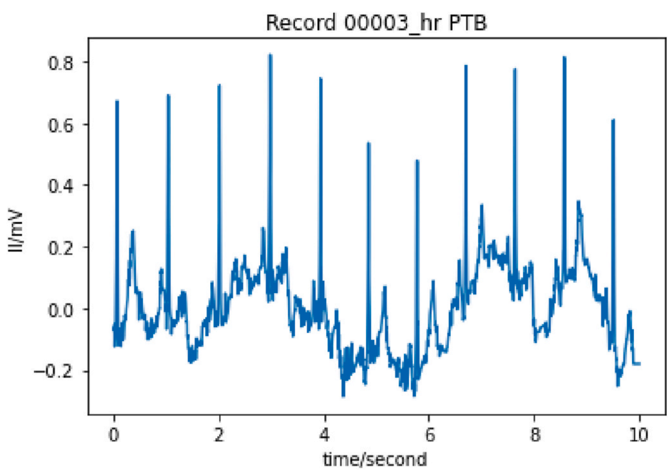

Fig. 6. Signal of Lead II from a patient normal ECG, database PTB XL.

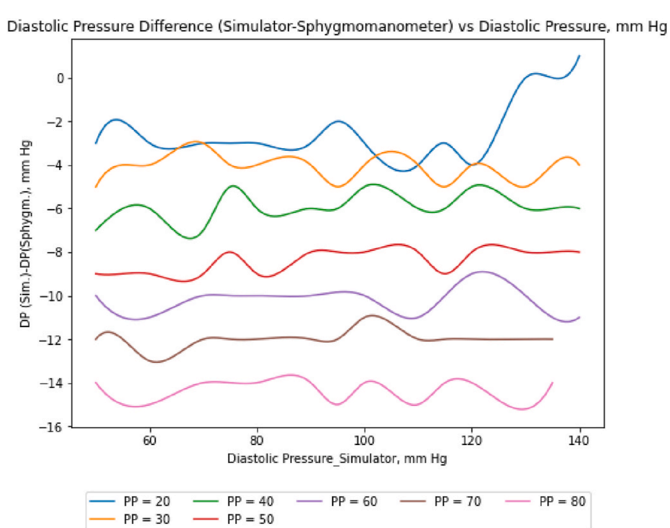

Fig. 7. Variation of the differences between the vital sign simulator value and the value measured by the sphygmomanometer with pulse pressure.

Table 2
Variation of volume increase with the cuff pressure value.

Set point of Cuff Pressure, (mm Hg)	Cuff Pressure (upper), (mm Hg)	Cuff Pressure (lower), (mm Hg)	Volume variation (mL),
150	152.8	152.2	0.3
120	123.2	121.8	0.9
100	104.8	102.9	1.2
93	96.8	95.5	0.8
80	82.9	82.4	0.3
50	54.5	54.2	0.2

4. Conclusions

One of the main aims of metrology for health laboratory at CEM, is the active participation in European projects and networks related to health metrology.

This will ensure the international comparability. We are firmly convinced that this will allow to achieve innovative goals and contribute to the advancement of this research field, taking advantage of the synergies and opportunities that may arise from international collaboration.

The challenge to be addressed in the context of ECG equipment is to ensure that these devices adhere to standardized calibration procedures in hospital settings, where measurement variations can lead to diagnostic errors. The project is currently in its initial stages and works to work towards achieving this objective.

The calibration of oscillometric sphygmomanometers started with the characterization of blood pressure simulators This is the main goal of the Blood Pressure Measurement project developed at CEM. This work and those to come contribute to further developing Health Metrology at the national level.

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