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Technical Note

A novel method for conformity assessment testing of electrocardiographs for post-market surveillance purposes

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Abstract.
BACKGROUND: Monitoring cardiac parameters is the fundamental aspect of every diagnostic process and is facilitated by electrocardiography (ECG) devices. This way, continuous state-of-the-art performance of ECG devices can be ensured. The new Medical Device Regulation (MDR) defines medical device post-market surveillance (PMS) as performed by independent, third-party, notified bodies more strategically in hope to improve traceability of device performance. However, there is still an apparent gap in terms of standardised conformity assessment testing methods.
OBJECTIVE: This paper proposes a novel method for conformity assessment testing of ECG devices for post-market surveillance purposes.
METHOD: The method was developed on the basis of International Organisation of Legal Metrology (OIML) guidelines and applied in healthcare institutions from 2018 to 2021.
RESULTS: The developed method was validated in healthcare institutions of all levels. The results obtained during validation suggest that conformity assessment testing of the ECG device as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of ECG devices during PMS, besides increasing reliability of the devices, is the first step in the digital transformation of the management of these devices in healthcare institutions opening possibility for use of artificial intelligence.

Keywords: Medical device, performance, ECG, testing, standardisation, post-market surveillance

1. Introduction

According to the Food and Drug Administration (FDA) [1] an electrocardiography is a medical device

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(MD) which creates, analyses, and displays electrocardiography data, and can provide information for identifying cardiac arrhythmias. These devices are classified according to the risk posed to a patient when the device is being used. According to the Medical Device Regulation (MDR) [2], ECGs are classified as Class IIa. This classification determines regulatory scrutiny to which devices are subjected to before placing on the market and Class II indicates that a medical device is of moderate to high risk and requires special controls.

As a type of medical device with a measuring function (MDMF), electrocardiographs are used to measure the electrical activity of the heart in order to identify any abnormalities [3]. Measurements of medical devices are carried out using sensors or measuring equipment of medical devices. The total degree of product quality is directly impacted by how well the MD's sensors and measurement devices perform. Every pre-programmed setting for heart rate and ECG voltage signal amplitude has a designated function. Since the ECG is used to quickly identify cardiac issues and monitor overall heart health, any anomalies that arise during its usage will unavoidably have a detrimental impact on the patient. Given that the heart rate and voltage signal amplitude are factors in the evaluation of the electrocardiogram, which forms the foundation of their efficacy, post-market surveillance is concentrated on the accuracy of the determined values of the mentioned measuring quantities as well as the overall safety of the medical device.

Prior to its placement on the market, each ECG device is thoroughly tested and evaluated to avoid any faults in its function. However, upon market placement, the regulatory oversight is disharmonized and there are no standards indicating how it should be performed [4]. Regardless of the variations in types, all devices of this type perform the same function. Therefore, the end user is affected by the measured parameters. Measurements, therefore, have great impact in patient care and can be considered compliant, only if they can be controlled, i.e. if they can be traceable to internationally adopted standards of measurement. In order to ensure accuracy and safety of all ECG devices used in healthcare institutions, a methodology for their performance assessment must be established and developed.

This paper presents a novel methodology for conformity assessment of ECG devices during usage taking into account the International Organisation of Legal Metrology (OIML) approach defined for other types of medical devices that perform measurements. The presented novel method can be used by national regulators as a gold standard in defining regulatory framework considering conformity assessment of devices used in healthcare.

2. Method

To present the novel methodology, the accepted concept of OIML guidelines for other medical devices with measuring functions such as thermometers or sphygmomanometer was followed [5]. The method, developed under OIML recommendations, is reported as a coherent structure, through the following parts:

1. Definition of technical requirements for ECGs
2. Definition of metrological requirements for ECGs
3. Description of method for visual inspection
4. Description of method for electrical safety inspection
5. Description of method for performance inspection
6. Summary and expression of test results

During method validation, the performance assessment testing of ECGs was done by using two etalons, Fluke Biomedical ESA 620 electrical safety analyser [6] and Fluke Biomedical ProSim 8 Vital Signs

Patient Simulator [7]. Both of these devices were periodically calibrated in EN ISO 17025 accredited laboratories [8]. The novel method was validated during the 2018–2021 time period. The presented data was analysed using a statistical approach.

3. Results and discussion

The results are presented in two parts. The first part consists of reporting the novel methodology for conformity assessment testing of ECGs and the second part consists of the validation report of this methodology done in real-time by inspection bodies in Bosnia and Herzegovina and Republic of Serbia.

3.1. Novel method for conformity assessment of ECGs

The method for conformity assessment defines technical and metrological requirements for the device and methods to test these requirements in the environment where the device is used.

3.1.1. Technical and metrological requirements of ECG

Technical and metrological requirements are defined based on the regulatory requirements stated in directives/regulation, manufacturers' technical specifications and international standards defining safety and performance of medical devices.

3.1.1.1. Technical requirements

In order to ensure safety and reliability of ECGs once they enter the market and once they are used in clinical settings the periodical inspection of their technical requirements is very important. In order to ensure traceability of the devices, labels and markings shall be visible, legible and indelible, and it is not possible to remove them without permanent damage. In case of the ECG, the technical requirements are formalised in the following manner:

- Label and marking
  - Name and/or trademark of manufacturer
  - Production mark (basic type)
  - Year of fabrication
  - Unique serial number
  - CE mark of appropriate administrative marking
- Construction of the device that guarantees security against any interference to metrological characteristics.
- The display shall be designed and arranged so that the information including measuring values can be read and easily recognized.
- Power supply: 220–240 V AC, 50/60 Hz; Battery supply (12 V):
  - Working time on battery for ECG devices is a minimum of 1 hour
  - Input impedance > 10 MΩ
  - Calibration voltage 1 mV $\pm$ 2%
- Compliance with IEC 60601-2-25 Medical electrical equipment - Part 2–125: Particular requirements for the basic safety and essential performance of electrocardiographs [9].

For inspection of all above mentioned requirements, a testing method needs to be adopted. As per OIML recommendations, the testing of these types of the requirements is to be carried out by visual inspection and by electrical safety inspection in accordance with IEC 60601 [9].

3.1.1.2. Metrological requirements

Reliability of medical devices can be proven with its compliance with metrological requirements. Metrological parameters such as error, accuracy and uncertainty are quantitative parameters specific for every device that serve as an evidence of device reliability. For every measurement device specific parameters are defined by its manufacturer such as measurement unit, range and division and accuracy. Following the OIML guideline, in case of the ECGs, the metrological requirements are formalised in the following manner:

- Measurement unit
  - Amplitude of voltage signal identified by ECG is set and measured in millivolts (0.5–2.0) [mV].
  - Heart rate in a time interval of 1 minute is set and measured in beats per minute [bpm]

The volt is a derived unit of electric potential, electric potential difference (voltage), and electromotive force in the International System of Units (SI) (NIST 2019). A millivolt is 1/1000 of a volt (0.001 V or 10^{-3} V). One volt is defined as the electric potential between two points of a conducting wire when an electric current of one ampere dissipates one watt of power between those points (SI base units: $kg{\cdot}m^2{\cdot}s^{-3}{\cdot}A^{-1}$). Beats per minute (heart rate), the number of heartbeats detected during one minute.

- Measuring range and division
  - Amplitude of voltage signal identified by ECG is set and measured inmillivolts (0.5–2.0) [mV].
  - Heart rate in a time interval of 1 minute is set and measured in beats per minute (30–300) [bpm]
  - Outside this working range no energy reading and no measurement result shall be displayed.
  - Division:
    - Amplitude of voltage signal identified by ECG in millivolts: 0.5, 1.0, 1.5 and 2.0 [mV]
    - Heart rate in a time interval of 1 minute: 30, 40, 60, 80, 90, 100, 120, 140, 150, 160, 180, 200, 210, 220, 240, 260, 270, 280, 300 [bpm]
  - Performance accuracy stated by the manufacturer in the technical specification.

For inspection of all above mentioned requirements, a testing method needs to be adopted. As per OIML recommendations, the testing of these types of the requirements is to be carried out by performance inspection presented in Section 3.2. of the results. A test report shall be prepared according to Part 3.2. of the results. With a performance inspection method the metrological conformity assessment testing is done. The metrological conformity assessment testing requirement can be formulated as per OIML recommendations as follows:

- For any set of conditions within the ambient temperature range of 21°C to 26°C, the maximum permissible error for the measurements is as follows:
  - Amplitude of voltage signal $\pm$ 5% of reading,
  - Heart rate in a time interval of 1 minute $\pm$ 2% of reading.

3.1.2. Method of test

3.1.2.1. Visual inspection

a) Equipment

The prerequisites for performing visual inspection are:

- Device under test / ECG;
- Manufacturers specification;

Table 1
Technical requirements and pass/fail criteria

No.	Technical requirements	Result	Conformity assessment testing
1.	Prescribed labels and markings on the device under test	– Name and/or trademark of manufacturer – Production mark (basic type) – Year of fabrication – Unique serial number – CE mark of appropriate administrative marking	Pass/Fail
2.	Construction of the device	– The integrity of the device under test in respect to the manufacturer's specification – The ity of the device under test in respect to the manufacturer's specification	Pass/Fail
3.	Performance of the device	– Measurement range – Measurement unit	Pass/Fail

b) Procedure

The procedure for visual inspection for a device under test consists of checking label/marking and construction integrity. The device must comply with the manufacturers' specification in terms of ity and accompanying parts.

c) Summary and expression of test results.

The results are expressed as Pass/Fail answers to the tested criteria (Table 1).

3.1.2.2. Electrical safety inspection

a) Equipment

The prerequisites for electrical safety inspection are:

– Device under test / ECG;
– Reference electrical safety testing equipment /analyser;

b) Procedure

Based on device measuring range select measuring points to cover the entire measuring range. Connect the ECG electrodes on the defined spots on the testing device (Fig. 1). Test the amplitude of voltage signal and heart rate in a time interval of 1 minute in every measuring point. To test these two parameters, choose the desired values on the reference testing device. This will simulate the signals and they will be interpreted by the DUT.

c) Summary and expression of test results

The decision of conformity assessment testing is obtained after the analysis of the results of the conducted tests. The OIML recommends a summary of the results in the form of tables. As it could be seen, visual inspection is reported in the form of qualitative analysis. Simple YES/NO answers to the criteria states the conformity assessment testing. For the performance inspection, the results are expressed using terms of error. In metrology error can be expressed using absolute error or relative error. In case of ECGs, the performance inspection result can be reported as the relative error between the set values of the device under test and the corresponding readings of the calibrated reference testing equipment.

Table 2
Example of performance evaluation for the amplitude of voltage signal in range 0.5–2 [mV]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set amplitude Xs [mV]	Reading amplitude Xm [mV]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	0.5	0.5	0	± 5%	Pass
2.	1	1	0	± 5%	Pass
3.	1.5	1.5	0	± 5%	Pass
4.	2	2.1	5	± 5%	Pass

Column 1 = Measuring point; Column 2 = Values set on the device under test; Column 3 = Values measured by calibrated testing equipment; Column 4 = Deviation expressed as relative error; Column 5 = Maximum deviation; Column 6 = Conformity assessment testing statement;

Table 3
Example of performance evaluation for the heart rate in range 30–300 [bpm]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set heart rate Xs [bpm]	Reading heart rate Xm [bpm]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	30	30	0	± 2%	Pass
2.	80	80	0	± 2%	Pass
3.	120	120	0	± 2%	Pass
4.	180	177	1.67	± 2%	Pass
5.	270	268	0.74	± 2%	Pass
6.	300	295	1.67	± 2%	Pass

Column 1 = Measuring point; Column 2 = Values set on the device under test; Column 3 = Values measured by calibrated testing equipment; Column 4 = Deviation expressed as relative error; Column 5 = Maximum deviation; Column 6 = Conformity assessment testing statement.

3.1.3. Performance inspection

Relative error calculation:

$$\Delta X =_{set} -X_{measured}/X_{set} * 100 \tag{1}$$

The conformity assessment testing in performance inspection is determined by the value of this error. The allowed performance error is presented in Tables 2 and 3 (below) It was formulated based on the international standards followed during the production of the ECG. Based on this requirement the conformity error is formulated as follows:

If the error is less than the greatest allowed limit, then the device is compliant with metrological requirements.

In addition to quantitative testing, as proposed in this methodology, all ECGs in this study were inspected for following qualitative features that influence their performance such as chassis integrity (technical requirements) in terms of: strain reliefs, electrodes, connectors, switches, displays, alarms, battery. Moreover, accuracy of instruments and control, charging time and internal electrical power source were tested.

3.2. Method validation

Method validation was done by inspection bodies appointed by the national metrological institutes in Bosnia and Herzegovina of the Republic of Serbia. Both of the inspection bodies are accredited by ISO 17020 standard for testing and inspection.

During method validation, in both countries, devices were inspected in both private and public healthcare institutions. The best indicator of the effectiveness of the developed method is the decrease in the percentage of non-compliant ECGs over the years the method was validated. As it can be seen, the largest difference in the percentage of non-compliant ECGs occurred between the first two years of method implementation in practice. The decreasing trend persists throughout the years, but is less intensive. Furthermore, this strengthens the conclusion that the medical device inspection method according to OIML metrological standards is the most effective way of preventing non-compliant ECGs being used in medical practice. If there was no performance inspection, most of the non-compliant ECGs would persist in usage as healthcare professionals would remain unaware of the non-compliance of the output values of the measured heart rate and amplitude of voltage signal. All of the aforementioned results confirm the necessity of independent periodical inspection of technical and metrological requirements for the ECGs in use, as the performance test revealed the performance variations that were not detected during usage or periodical preventive and corrective maintenance. Moreover, all the data collected during the inspection of the devices was standard, traceable, accurate and was immediately transferred into the digital database specially developed for this purpose.

4. Conclusion

Access to health is fundamental human right. However, various adverse event involving medical devices pose a risk to patients' safety and well-being. The importance of safe and compliant medical devices has been especially demonstrated during COVID-19 pandemics [10]. Lately, regulators have been working in improving post-market surveillance of medical devices to ensure that number of incidents and adverse events including medical devices is lowered. Specifically, in the European Union, Medical Device Regulation (MDR) introduces the EUDAMED database [11,12] containing all information regarding the adverse events associated with medical devices and reported by the end users that may be physicians, medical technicians or patients themselves. However, current databases collect information for each database from both voluntary sources and mandatory reports. Judging by the number of reported incidents involving medical devices it can be concluded that the limitations of the databases are that the data submitted include "incomplete, inaccurate, untimely, unverified, or biased data." In addition, many use errors stay underreported and data format unknown. Moreover, current databases are limited to administrative data only including manufacturers and distributor data, vigilance and clinical studies data, hence the surveillance is not taking its full capacity. Also, baseline evidence for medical device safety and performance cannot be established due to lack of traceable data.

This paper lays out a novel methodology for conformity assessment testing of ECG device for post-market surveillance purposes. The novel methodology was developed based on OIML guidelines for technical and metrological characteristics and performance evaluation. Developed methodology has been validated by the work of two inspection bodies for medical devices working under the legal metrology framework which has been adopted for medical devices in Bosnia and Herzegovina and Republic of Serbia [13,14]. The introduction of standardized conformity assessment method for testing of safety and performance of ECG device produced traceable, accurate, complete, verified, nonbiased and standardized data. All data resulting from the inspection carried out by independent appointed inspection bodies has been entered in database specially developed for this purpose – eLab [15]. This practice showed that significant cost-effectiveness can be achieved in management of maintenance in healthcare institutions because standardized data showed certain patterns for healthcare institutions.

The work demonstrated how standardized method for conformity assessment testing produces complete, accurate, verified, traceable and unbiased data. Following the trend of digital transformation and application of artificial intelligence, the researchers investigated application of artificial intelligence on this database [16–20]. The hypothesis of predictive management of maintenance of medical devices has been set up. Indeed, as medicine is shifting toward personalized medicine clinical engineering should follow the path of predictive approach.

Conflict of interest

None to report.

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