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Technical Note

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

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Abstract.
BACKGROUND: Premature born infants or infants born sick require immediate medical attention and decreasing the stress imposed onto their body by the environment. Infant incubators provide an enclosed environment that can be controlled to fit the needs of the infant. As such, their performance must be consistent and without significant deviations. The only manner to ensure this is by post-market surveillance (PMS) focused on evaluation of both safety and performance. 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 infant incubators for post-market surveillance purposes.
METHOD: The method was developed based on guidelines for devices providing measurements laid out by the International Organisation of Legal Metrology (OIML). The methodology was validated during a four year period in healthcare institutions of all levels.
RESULTS: The developed method was validated between 2018 and 2021 in healthcare institutions of all levels. The results obtained during validation suggest that conformity assessment testing of infant incubators as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of infant incubators during PMS, besides increasing reliability of the devices, is the first step in digital transformation of management of these devices in healthcare institutions opening possibility for use of artificial intelligence.

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

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1. Introduction

According to the Food and Drug Administration (FDA) [1], an incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care. On the other hand, according to the MDR 2017 [2], incubators are classified as Class IIb. Generally, Class II medical devices are subjected to special controls that include regular performance inspections due to the risk they impose to the patients [2].

Incubators can be referred to as medical devices with a measuring function (MDMF) [3] as they maintain ideal parameters such as temperature, humidity, and oxygen concentration. The sensors present within the infant incubators can be observed as regular measurement sensors and hence can be subjected to metrological controls. The efficiency of the MD's sensors and measurement devices directly impacts the overall extent of device quality. Each predefined setting for incubators' air temperature, skin temperature, oxygen concentration, relative humidity and weight serves a particular purpose. When incubators fall short of their intended purpose of ensuring the optimal conditions for the development of newborns, dangerous adverse outcomes may result. Thus, air temperature, skin temperature, oxygen concentration, relative humidity and weight are evaluated as part of the incubator inspection. As the essence of their performance lies in this, post-market surveillance is focused on the accuracy and safety of the delivered values of the specified measurement quantities.

An extensive set of standards is used to demonstrate compliance with the essential safety and performance requirements of incubators [4]. These standards can be grouped into three categories, general quality standards, electrical safety standards, special standards for incubators. Compliance to the requirements of all of these standards must be demonstrated prior to placing the infant incubator on the market. However, controls after the device has been installed in the healthcare institution is lacking in terms of post-market surveillance. As there is no standardized methodology to perform PMS, it relies on assessments on behalf of manufacturers that may be biased and not evidence-based [5,6].

This paper presents the novel methodology for infant incubators performance assessment and post-market surveillance taking into account the International Organisation of Legal Metrology (OIML) [7] approach defined for other types of medical devices with measuring functions. 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 incubators
2. Definition of metrological requirements for incubators
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 incubators was done by using two etalons, Fluke Biomedical ESA 620 electrical safety analyser [8] and Fluke Biomedical INCU I Infant incubator tester [9]. Both of these devices were periodically calibrated in EN ISO 17025 accredited laboratories [8]. The novel method was validated between 2018 and 2021. 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 incubators 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 incubators

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 incubator

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 incubators 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 incubators, 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.
- Temperature: 21–26°C.
- Pressure: 600 hPa–1060 hPa.
- Relative humidity 10–95% without condensation.
- Compliance with IEC 60601-2-19 Medical electrical equipment – Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators [11].

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 [11].

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 incubator, the metrological requirements are formalised in the following manner:

- Measurement unit:
  - Air temperature which is set and measured in Celsius [°C]
  - Skin temperature which is set and measured in Celsius [°C]
  - Oxygen concentration which is set and measured in percentage [%]
  - Relative humidity of air which is set and measured in percentage [%]
  - Weight which is set and measured in kilograms [kg]
  - Level of sound inside the incubator [dB]
  - Level of alarms [dB]
  - Stability of temperature
  - Uniformity of temperature
  - Regulator of air temperature
  - Incubator warming time
  - Time required for temperature change
  - Air movement speed

Celsius is a unit of temperature in the International System of Units (SI) (NIST 2019). Scale according to which it is defined based on the settings: 0° for the freezing point of water and 100° for the boiling point of water. Contains 100-degree intervals between defined points.

The kilogram is a unit of mass in the International System of Units (SI) (NIST 2019). It is defined by taking the fixed numerical value of the Planck constant h to be 6.626 070 15 $\times$ 10^{-34} when expressed in the unit J s, which is equal to kg $\times$ m^2 $\times$ s^{-1}, where the metre and the second are defined in terms of c and $\Delta\nu$Cs.

The decibel is a relative unit of measurement equal to one tenth of a bel (B). It expresses the ratio of two values of a power or root-power quantity on a logarithmic scale. Two signals whose levels differ by one decibel have a power ratio of $10^{1/10}$ (approximately 1.26) or root-power ratio of $10^{1/20}$ (approximately 1.12).

- Measuring range and division
  - Air temperature (13–42) [°C]
  - Skin temperature (13–43) [°C]
  - Oxygen concentration (18–99) [%]
  - Relative humidity of air (10–99) [%]
  - Weight (0–10) [kg]
  - Level of sound inside the incubator [dB]
  - Level of alarms [dB]
  - Stability of temperature (32–36) [°C]
  - Uniformity of temperature (32–36) [°C]
  - Regulator of air temperature [°C]
  - Incubator warming time [s]

- Time required for temperature change (32–36) [°C]
- Air movement speed
- Outside this working range no energy reading and no measurement result shall be displayed
- Division:
  - Air temperature: 30, 33, 34 and 35°C
  - Skin temperature: 36 and 38°C
  - Oxygen concentration 18, 30, 50, 70, 85 and 99%
  - Relative humidity of air: 80, 90, 95 and 99%
  - Weight:
    - for 0–2 kg: 0.5, 1, 1.5 and 2 kg
    - for 0–10 kg: 1, 2, 5 and 8 kg
  - Level of sound inside the incubator (1 point) [dB]
  - Level of alarms (1 point) [dB]
  - Stability of temperature: 32 and 36 [°C]
  - Uniformity of temperature: 32 and 36 [°C]
  - Regulator of air temperature: 36 [°C]
  - Incubator warming time: 1 point [s]
  - Time required for temperature change: 1 point between 32 and 36°C
  - Air movement speed: 1 point

– 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 results. A test report shall be prepared according to part 3.2 of 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 are as follows:
  - Air temperature ± 0.8°C
  - Skin temperature ± 0.3°C
  - Oxygen concentration ± 3 Vol.%
  - Relative humidity of air ± 10%
  - Weight:
    - ± 2% (for 0–2 kg)
    - ± 5% (for 2–10 kg)
  - Level of sound inside the incubator: Must not exceed 60 dBa
  - Level of alarms: Must be 65 dBa at minimum on 3 metres away
  - Stability of temperature: Must not exceed 0.5°C (or 1°C in case of transport incubators)
  - Uniformity of temperature: Must not exceed 0.8°C
  - Regulator of air temperature: Must not exceed ± 1.5°C
  - Incubator warming time: Must not exceed 20% of time needed as specified by manufacturer
  - Time required for temperature change: Must not exceed 15 minutes
  - Air movement speed: Must not exceed 0.35 m/s

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 integrity 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

3.1.2. Method of test

3.1.2.1. Visual inspection

a) Equipment

The prerequisites for performing visual inspection are:

– Device under test/incubator
– Manufacturers specification

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 manufacturers specification in terms of integrity 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/incubator
– Reference electrical safety testing equipment/analyser

b) Procedure

The procedure starts with connecting the incubator to electrical safety testing equipment. Test of the electrical safety of a device under test is performed according to the requirements of IEC 60601-1:2005 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance [9]. This test includes measurement of: mains voltage (live to neutral, neutral to earth, live to earth), protective earth resistance, insulation resistance (normal condition, mains to protective earth) earth leakage current (applied parts and normal condition, open neutral, normal condition – reversed mains, open neutral – reversed mains), enclosure leakage current (applied parts, normal condition, open neutral, normal condition – reversed mains, normal condition – reversed mains, open earth – reversed mains), patient applied parts leakage current.

Table 2
Example of electrical safety test report

Column 1	Column 2	Column 3
No.	Criteria	Conformity assessment testing **Pass/Fail**
1.	Are the requirements of the electrical safety regulations fulfilled?	

c) Summary and expression of test results

The results are expressed in terms of requirements of IEC 60601-1:2005 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance [11]. An example of an electrical safety test is depicted in Table 2.

3.1.3. Performance inspection

a) Equipment

The prerequisites for performance inspection are:

- Device under test/incubator
- Reference testing equipment/analyser

b) Procedure

Incubators for neonatal and paediatric patients should first be connected to the power outlet. The reference testing devices are placed in the incubator. Based on device measuring range select measuring points to cover the entire measuring range of temperatures, relative humidity, oxygen concentration and weight. Test all these parameters in every measuring point. To test them, adjust the parameters values on the incubator. When the device is ready and it reaches the desired values of either parameter, read the values from the reference testing devices.

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 neonatal and infant incubators, the performance inspection result can be reported as both relative and absolute error between the indicated values, depending on the parameter. Errors for parameters air temperature and skin temperature are expressed as absolute errors, while errors for oxygen concentration, relative humidity and weight are expressed as relative errors.

Relative error calculation:

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

Absolute error calculation:

$$\Delta X = X_{measured} - X_{set} \tag{2}$$

The conformity assessment testing in performance inspection is determined by the value of this error. The allowed performance error is presented in Tables 3–7 (above). It was formulated based on the international standards followed during the production of the incubator. Based on this requirement the conformity error is formulated as follows:

Table 3
Example of performance evaluation for air temperature in range 30–35 [°C]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set temperature Xs [°C]	Reading temperature Xm [°C]	Deviation ΔX [°C]	Maximum deviation [°C]	Conformity assessment testing Pass/Fail
1.	**30**	30.4	0.4	± 0.8	Pass
2.	**33**	32.5	0.5	± 0.8	Pass
3.	**34**	33.7	0.3	± 0.8	Pass
4.	**35**	34.1	0.9	± 0.8	Fail

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 4
Example of performance evaluation for skin temperature in range 36–38 [°C]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set temperature Xs [°C]	Reading temperature Xm [°C]	Deviation ΔX [°C]	Maximum deviation [°C]	Conformity assessment testing Pass/Fail
1.	**36**	35.9	0.1	± 0.3	Pass
2.	**38**	37.8	0.2	± 0.3	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 5
Example of performance evaluation for relative humidity in range 40–99 [°C]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set RH Xs [%]	Reading RH Xm [%]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**40**	45.4	5.4	± 10	Pass
2.	**60**	66.3	6.3	± 10	Pass
3.	**70**	74.8	4.8	± 10	Pass
4.	**99**	95.7	3.3	± 10	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 6
Example of performance evaluation for oxygen concentration in range 18–99 [%]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set concentration Xs [%]	Reading concentration Xm [%]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**18**	18.4	2.17	± 3	Pass
2.	**30**	29.7	1.01	± 3	Pass
3.	**50**	50.5	0.99	± 3	Pass
4.	**70**	71.6	2.23	± 3	Pass
5.	**85**	86.9	2.19	± 3	Pass
6.	**99**	98.4	0.61	± 3	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 7
Example of performance evaluation for weight in range 1–8 [kg]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set weight Xs [kg]	Reading weight Xm [kg]	Deviation ΔX [kg]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**1**	1.01	0.99	± 5	Pass
2.	**2**	2.03	1.48	± 5	Pass
3.	**5**	4.94	1.21	± 5	Pass
4.	**8**	7.56	5.82	± 5	Fail

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.

– 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 incubators in this study were inspected for following qualitative features that influence their performance such as chassis integrity (technical requirements) in terms of: strain reliefs, connectors, switches, displays, alarms, battery, plastic covers, holders for distilled water.

3.2. Method validation

Method validation was done by inspection bodies appointed by the national metrological institutes in Bosnia and Herzegovina and 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 devices were inspected in healthcare institutions of the secondary and tertiary level. The best indicator of the effectiveness of the developed method is the decrease in the percentage of non-compliant incubators over the years the method was validated. During validation, significant percentage of non-compliant devices was detected. The majority of non-compliance was due to deviation in parameter air temperature of the device. This finding is worrying since majority of the devices is subject to regular maintenance either by healthcare institution or by distributor. Second most usual cause of non-compliance was deviation of parameter relative humidity. These devices were regularly in use by medical professionals who were unaware of the parameter's deviation and had no means to check this. This strengthens the conclusion that the medical device inspection method according to OIML metrological standards is the most effective way of preventing non-compliant incubators being used in medical practice. If there was no performance inspection, most of the non-compliant incubators would persist in usage as healthcare professionals would remain unaware of the non-compliance of the output parameters.

All of the aforementioned results confirm the necessity of independent periodical inspection of technical and metrological requirements for the incubators 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 it was immediately transferred into the digital database specially developed for this purpose.

4. Conclusion

The regulatory framework for medical devices varies around the world, but it has been improved in the last decade. Almost all countries now have adopted a series of regulations to regulate medical device

development, manufacture quality control and conformity assessment testing prior to marketing as well as post-market surveillance. Continuous efforts are being made towards standardization and harmonization of these processes by different international organizations.

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 [12]. 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 [13,14] 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 infant incubator 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 [15,16]. The introduction of standardized conformity assessment method for testing of safety and performance of infant incubator 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 [17]. 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 [18–23]. 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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