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Technical Note

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

Almir Badnjevic[a,b,c,d], Amar Deumic[a,b], Zijad Dzemic[e] and Lejla Gurbeta Pokvic[a,*]
[a]*Verlab Research Institute for Biomedical Engineering, Medical Devices and Artificial Intelligence, Sarajevo, Bosnia and Herzegovina*
[b]*Medical Device Inspection Laboratory, Verlab Ltd., Sarajevo, Bosnia and Herzegovina*
[c]*Faculty of Pharmacy, University of Sarajevo, Sarajevo, Bosnia and Herzegovina*
[d]*International Federation of Medical and Biological Engineering (IFMBE), Sarajevo, Bosnia and Herzegovina*
[e]*Institute of Metrology of Bosnia and Herzegovina, Sarajevo, Bosnia and Herzegovina*

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Abstract.
BACKGROUND: Anaesthesia machines, as moderate to high-risk medical devices intended for use on patients during surgical procedures must be safe and reliable with traceable performance every time they are used in healthcare practice. 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 evidence-based method for conformity assessment testing of anaesthesia machines for post-market surveillance purposes.
METHOD: The novel method is developed according to the International Organisation of Legal Metrology (OIML) guidelines and is to be used for the purpose of conformity assessment testing of anaesthesia machines with respect to their technical and metrological characteristics during PMS.
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 anaesthesia machines as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of anaesthesia machines 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, anaesthesia machine, performance, testing, standardisation, post-market surveillance

*Corresponding author: Lejla Gurbeta Pokvic, Verlab Research Institute for Biomedical Engineering, Medical Devices and Artificial Intelligence, Sarajevo, Bosnia and Herzegovina. E-mail: lejla@verlabinstitute.com.

1. Introduction

According to the Food and Drug Administration (FDA) [1] a gas machine for anaesthesia is a medical device (MD) used to administer to a patient, continuously or intermittently, a general inhalation anaesthetic and to maintain patient's ventilation. On the other hand, according to the Medical Device Regulation (MDR) [2], anaesthesia machines are classified as Class IIb, meaning that it is a device with a moderate to high risk that requires special controls. Such devices are considered as active therapeutic devices intended for use in a potentially hazardous manner, taking into account the nature of the substances involved, the appropriate part of the body and the method of application. This classification determines regulatory scrutiny to which devices are subjected to before placing on the market.

Measurements are crucial part of every application, but there is so little or none attention drawn to it. Measurements are important aspect of anaesthesia machines as well. From the engineering perspective, anaesthesia machines can be categorised as medical devices with a measuring function (MDMF) [3] because they measure the volume, pressure, or flow of liquids or gases given to or eliminated from the human body. Medical devices' measuring tools or sensors are used to get measurements of medical products. The effectiveness of the MD's measuring tools and sensors directly affects the product's overall level of quality. Regardless of the variations in types, all anaesthesia machines perform the same function which is delivery of oxygen and anaesthetic gases to the patient and removal of carbon dioxide from the patient body. Therefore, the end user is affected by the level of delivered gases. Each predetermined value of oxygen volume and concentration of anaesthetic gases used by anaesthesia devices has a specific function. Dangerous adverse events can occur when the anaesthesia machine does not supply the body with compliant concentration of anaesthetic gases and compliant oxygen volumes such as undermining the anaesthetic action in case of low anaesthetic gases concentrations or inducing coma in case of high anaesthetic gases concentrations. 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.

Post-market surveillance (PMS) of medical devices is prescribed in the Medical Device Regulation [2] but the procedure according to which PMS, in terms of testing of performance ought to be conducted is not defined. Hence, there is a significant discrepancy in terms of PMS on the medical device market. Conformity assessment testing during device usage are not harmonized. Hence, there is no effective mechanism for complete, strategic, oversight of medical devices. In light of digital technologies such gap poses a risk to overall accuracy and reliability of devices used on patients and there is a pronounced need to define an effective methodology for conducting PMS.

Post-market surveillance of anaesthesia machines should be focused on evaluating the accuracy of delivered volumes of oxygen and anaesthetic gases concentrations. It is of fundamental need to ensure traceability of its and performance of anaesthesia machines as well as their safety to both patients and physicians. Prior to introduction of MDR, an extensive set of standards is used to demonstrate compliance with the essential safety and performance requirements of anaesthesia machines according to Annex I of the Medical Devices Directive (MDD) [4]. However, as it is crucial that the device delivers a gas mixture of exactly known composition to the respiratory system, in addition to safety inspections PMS should focus on inspection of the device in terms of volume, pressure, flow and concentration of anaesthetic gases delivered which are all parameters affecting the patients.

This paper presents the novel methodology for conformity assessment of anaesthesia machines during usage taking into account the International Organisation of Legal Metrology (OIML) 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 anaesthesia machines used in healthcare during PMS.

2. Method

To present the novel methodology, the 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 anaesthesia machines
2. Definition of metrological requirements for anaesthesia machines
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 anaesthesia machines was done by using two etalons, Fluke Biomedical ESA 620 electrical safety analyser [6] and IMT Medical PF-301 flow analyser [7]. 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 anaesthesia machines according to the OIML guidelines and the second part consists of the validation report of this methodology done in real-time by appointed, independent inspection bodies in Bosnia and Herzegovina and Republic of Serbia.

3.1. Novel method for conformity assessment of anaesthesia machines

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 anaesthesia machines

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 anaesthesia machines once they enter the market and once, they are used in clinical settings the periodical testing 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 anaesthesia machine, 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.
- Compliance with IEC 60601-2-13: Medical electrical equipment – Part 2–13: Particular requirements for the safety and essential performance of anaesthetic systems [9].
- Concentration of anaesthetic gases:
  - CO_2: 0–20%
  - NO_2: 0–100%
  - Halothane, Isoflurane, Enflurane: 0–12%
  - Sevoflurane: 0–15%
  - Desflurane: 0–22%

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 anaesthesia machines, the metrological requirements are formalised in the following manner:

- Measurement unit
  - Flow measurement [l/min]
  - Volume measurement [litres]
  - Pressure measurement [cmH_2O, mbar, kPa]
  - Concentration of oxygen [%]
  - Concentration of anaesthetic gases [%]

Litre is a unit of volume in the International System of Units (SI) (NIST 2019). It is equal to 1 cubic decimetre (dm^3), 1000 cubic centimetres (cm^3) or 0.001 cubic metre (m^3).

Litre per minute is a derived unit of volumetric flow rate of a gas in the International System of Units (SI). It is defined as the rate with which one litre of substance crosses a certain surface during a time period equal to one minute.

The pascal is the unit of pressure in the International System of Units (SI) and is defined as one newton per square metre.

The bar is a metric unit of pressure, but not part of the International System of Units (SI). It is defined as exactly equal to 100,000 Pa (100 kPa), or slightly less than the current average atmospheric pressure on Earth at sea level (approximately 1.013 bar).

- Measuring range and division

- Flow measurement range:
  - Low flow (0–40) [l/min]
  - High flow (40–200) [l/min]
- Pressure measurement range:
  - Output pressure (0–140) [cmH_2O]
- Volume measurement range:
  - Output volume (0–4) [litres]
- Concentration of oxygen:
  - 18–100 [%]
- Concentration of anaesthetic gases:
  - 1–8 [%]
- Outside this working range no energy reading and no measurement result shall be displayed.
- Division: Measurement point are defined and distributed evenly on the whole measurement range.
- 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 from 21°C to 26°C, the maximum permissible error for the measurements is as follows:
  - Flow $\pm$ 10% of reading
  - Pressure $\pm$ 5% of reading
  - Volume $\pm$ 10% of reading
  - Concentration of oxygen $\pm$ 5% of reading
  - Concentration of anaesthetic gases $\pm$ 1% 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/anaesthesia machines
- 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).

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

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?	

3.1.2.2. Electrical safety inspection

a) Equipment

The prerequisites for electrical safety inspection are:

– Device under test/anaesthesia machines
– Reference electrical safety testing equipment/analyser

b) Procedure

The procedure starts with connecting the anaesthesia machines 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.

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 [9]. 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:

Table 3
Example of performance evaluation for flow parameter in range 2–12 [l/min]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Flow measurement Xs [l/min]	Flow reading Xm [l/min]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**2**	2.1	5.0	$\pm$ 10%	Pass
2.	**4**	4.1	2.5	$\pm$ 10%	Pass
3.	**6**	6.2	3.33	$\pm$ 10%	Pass
4.	**8**	7.7	3.75	$\pm$ 10%	Pass
5.	**10**	9.8	2.0	$\pm$ 10%	Pass
6.	**12**	12.4	3.33	$\pm$ 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.

- Device under test/anaesthesia machine
- Reference testing equipment/analyser

b) Procedure

Performance inspection is performed by the method of direct comparison (comparative method) with the reference standard (testing etalon) at the measured points along the entire measuring range of the device, checking the fulfilment of the prescribed requirements. To conduct the performance inspection a testing etalon is required. Before the inspection itself, every anaesthesia machine must be prepared for inspection individually. Hoses for oxygen, air or any other available gases that the machine uses, must be properly connected to either the bottle of oxygen/air or the central gas system in the healthcare institution. Etalon for inspection is placed on the even and clean surface ensuring safe and reliable results. Patient circuit is connected with the etalon. When the device is ready to be tested, the measuring range of the device is determined and the measuring points are defined. Units that are measured during the performance inspection of anaesthesia machine are volume, flow, pressure and concentration of anaesthetic gases.

To ensure the test is conducted under same conditions every time, defined parameter values are set on the device as follows:

- Inspiratory time (Ti): Expiratory time (Te) = 1:1
- Breaths per min (bpm or f) = 15 bpm
- PEEP = 5

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 anaesthesia machines, 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.

Relative error calculation:

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

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

Table 4
Example of performance evaluation for pressure parameter in range 10–60 [mbar]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Pressure measurement Xs [mbar]	Pressure reading Xm [mbar]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**10**	10.3	3.0	± 5%	Pass
2.	**20**	19.4	3.0	± 5%	Pass
3.	**30**	29.5	1.67	± 5%	Pass
4.	**40**	38.3	4.25	± 5%	Pass
5.	**50**	47.1	5.80	± 5%	Fail
6.	**60**	53.9	10.17	± 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.

Table 5
Example of performance evaluation for volume parameter in range 100–1000 [ml]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Volume measurement Xs [ml]	Volume reading Xm [ml]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**100**	92	8.0	± 10%	Pass
2.	**200**	191	4.50	± 10%	Pass
3.	**400**	370	7.50	± 10%	Pass
4.	**600**	571	4.83	± 10%	Pass
5.	**800**	734	8.25	± 10%	Fail
6.	**1000**	927	7.30	± 10%	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 6
Example of performance evaluation for concentration of oxygen parameter in range 18–100 [%]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Oxygen measurement Xs [%]	Oxygen reading Xm [%]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**18**	18.4	2.17	± 5%	Pass
2.	**30**	31.2	3.85	± 5%	Pass
3.	**50**	51.6	3.10	± 5%	Pass
4.	**70**	73.4	4.63	± 5%	Pass
5.	**85**	81.2	4.68	± 5%	Pass
6.	**100**	96.7	3.41	± 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.

the international standards followed during the production of the anaesthesia machines. 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 anaesthesia machines 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. Moreover, accuracy of instruments and control, charging time, internal electrical power source.

Table 7
Example of performance evaluation for concentration of anaesthetic gases parameter in range 1–8 [%]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Gas measurement Xs [%]	Gas reading Xm [%]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**1**	0.87	0.13	$\pm$ 1%	Pass
2.	**2**	1.85	0.15	$\pm$ 1%	Pass
3.	**4**	3.89	0.11	$\pm$ 1%	Pass
4.	**6**	5.78	0.22	$\pm$ 1%	Pass
5.	**8**	7.55	0.45	$\pm$ 1%	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.

3.2. Method validation

Method validation was done by inspection bodies appointed by the national metrological institutes in Bosnia and Herzegovina and 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 anaesthesia machines over the years the method was validated. The decreasing trend persists throughout the years.

Any detected non-compliance in case of anaesthesia machines poses a great threat to patients since these devices are used in critical situations. The majority of non-compliance was related to the delivery of anaesthesia gases. The detected non-compliance presents the deviation in performance which was not detected by medical professionals using the machines, nor it was detected during self-test of the machine. 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 anaesthesia machines being used in medical practice. If there was no performance inspection, most of the non-compliant anaesthesia machines would persist in usage as healthcare professionals would remain unaware of the non-compliance of the output values of the measured volume and the concentration of anaesthetic gases.

All of the aforementioned results confirm the necessity of independent periodical inspection of technical and metrological requirements for the anaesthesia machines 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

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 [11]. 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 [12,13] 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 anaesthesia machines 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 [14,15]. The introduction of standardized conformity assessment method for testing of safety and performance of anaesthesia machine 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 [16]. 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 [17–22]. 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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