Technology and Health Care 31 (2023) 367–376
DOI 10.3233/THC-229012
IOS Press

Technical Note

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

Almir Badnjevic[a,b,c,d], Amar Deumic[a,b], Ammar Trakic[a] 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*

Received 1 September 2022
Accepted 20 November 2022

Abstract.
BACKGROUND: Mechanical ventilators are medical devices used in intensive care units when patients are in need of mechanical aid to facilitate the process of breathing. As the function of breathing is the exchange of gases, the mechanical ventilator takes over that function while the patient is incapable to spontaneous breathing. As these devices are used to maintain the life of patents, their performance must be ensured and there cannot be significant deviations in the volumes and pressure of gases they introduce to the patient. 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 mechanical ventilators for post-market surveillance purposes.
METHOD: The method was developed on the basis of metrology characteristics of mechanical ventilators and evaluation of their vital safety and performance parameters. In addition to the evaluation of essential safety and visual integrity of mechanical ventilators, their performance in terms of volume of oxygen delivered to the patient as well as the flow and pressure of the delivered gas is evaluated.
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 mechanical ventilators as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of mechanical ventilators 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, mechanical ventilator, 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 mechanical ventilator is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. The Medical Device Regulation (MDR) 2017 [2] classifies mechanical ventilators as Class IIb medical devices. This classification determines regulatory scrutiny to which devices are subjected to before placing on the market and class II medical devices impose moderate to high risk towards the patients hence they requires special controls. Considering the nature of the drugs involved, the suitable part of the body, and the mode of application, such devices are regarded as active therapeutic devices, the use of which can be potentially dangerous to the patient.

Because mechanical ventilators quantify the amount of gases supplied to patients using flow metres, they are classified as medical devices with a measuring function (MDMF) [3]. The performance of sensors and measurement tools such as flow meters of mechanical ventilators directly impacts the device's overall quality. Each predefined setting for mechanical ventilators' volume, flow, and air pressure serves a particular purpose. When mechanical ventilators fall short of their intended goal of providing the human body with suitable quantities and composition of air, dangerous adverse outcomes may result, therefore the post-marketing monitoring is concentrated on the precision and security of the provided values of the three measuring quantities mentioned earlier.

The classification suggests that this device is in the moderate to high risk category since it is a device that takes over the work of breathing when a person is not able to breathe spontaneously. For this reason, it is crucial that the device delivers an air mixture with an exactly known oxygen concentration to the respiratory system with the appropriate volume, flow, and pressure. As there is no proposed methodology for post-market surveillance of mechanical ventilators, the variability in the methods applied throughout the world results in absence of traceability of performance of mechanical ventilators as well as significant discrepancy in the quality of healthcare services provided by mechanical ventilators in the world [4].

This problem was recognized and this paper presents the novel methodology for conformity assessment of mechanical ventilators in use in healthcare institutions. This method takes into account both essential safety and structural integrity of mechanical ventilators accompanied with their performance in terms of volume, flow and pressure delivered to the patient during mechanical ventilation.

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 mechanical ventilators
2. Definition of metrological requirements for mechanical ventilators
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 mechanical ventilators 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 mechanical ventilators 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 mechanical ventilators

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 mechanical ventilators

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 mechanical ventilators 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 mechanical ventilators, 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:
  - Charging time < 6 h
  - Working time on battery for ventilator minimum 1 hour and maximum 7 hours
  - Working time on battery for ventilator and compressor minimum 30 min and maximum 2 hours
- Concentration of oxygen and air (18–100) %.
- Compliance with IEC 60601-2-12 Medical electrical equipment – Part 2–12: Particular requirements for the safety of lung ventilators – Critical care ventilators [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 mechanical ventilators, 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 [%]

Litre is a unit of volume in the International System of Units (SI) (NIST 2019). Is defined as the volume of one kilogram of water under standard conditions.

Litre per minute is a derived unit of volumetric flow rate of a gas in the International System of Units (SI) (NIST 2019). 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). 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 %
  - Outside this working range no energy reading and no measurement result shall be displayed.
  - Division: Measurement points 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 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:

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

* Flow ± 10% of reading
* Pressure ± 5% of reading
* Volume ± 10% of reading
* Concentration of oxygen ± 5% 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/mechanical ventilator
– 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 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/mechanical ventilator
– Reference electrical safety testing equipment/analyser

b) Procedure

The procedure starts with connecting the mechanical ventilator 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

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?	

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. 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/mechanical ventilator
- 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 ventilator must be prepared for inspection individually. Hoses for oxygen, air or any other available gases that the ventilator 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

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 Δ [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**2**	2.1	5.0	± 10%	Pass
2.	**4**	4.1	2.5	± 10%	Pass
3.	**6**	6.2	3.33	± 10%	Pass
4.	**8**	7.7	3.75	± 10%	Pass
5.	**10**	9.8	2.0	± 10%	Pass
6.	**12**	12.4	3.33	± 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 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.

using terms of error. In metrology error can be expressed using absolute error or relative error. In case of mechanical ventilators, 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:

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

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 conformity assessment testing in performance inspection is determined by the value of this error. The allowed performance error is presented in Tables 3–6 (above). It was formulated based on the international standards followed during the production of the mechanical ventilators. 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 mechanical ventilators in this study were inspected for following qualitative features that influence their performance such as chassis integrity (technical requirements) in terms of 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.

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. During method validation, mechanical ventilators were inspected dominantly in healthcare institutions of secondary and tertiary level. Part of inspected devices was allocated in urgent care units at primary level healthcare institutions.

The best indicator of the effectiveness of the developed method is the decrease in the percentage of non-compliant mechanical ventilators over the years the method was validated. The largest difference in the percentage of non-compliant mechanical ventilators occurred between the first two years of method implementation in practice. The decreasing trend persists throughout the years, but is less intensive. The results presented during validation are worrying since they indicate existence of performance deviation even though majority of inspected devices was subject to regular service.

All of the aforementioned results confirm the necessity of independent periodical inspection of technical and metrological requirements for the mechanical ventilators 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 [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 mechanical ventolator 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 mechanical ventolator 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 [16–21]. 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.

References

[1] Food and Drug Administration (FDA) www.fda.gov.
[2] Medical Devices Regulation (MDR): Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002.

[3] European Union. 2017. The European Union Medical Device Regulation – Regulation (EU) 2017/745 (EU/MDR). Accessed December 20, 2021. https://eumdr.com/.
[4] Badnjević A, Pokvić LG, Deumić A, Bećirović LS. Post-market surveillance of medical devices: A review. Technology and Health Care, (Preprint), 2022; 1-15.
[5] Organisation Internationale de Métrologie Légale (OIML). 2015. National metrology systems – Developing the institutional and legislative framework. Accessed December 15, 2021. https://www.oiml.org/en/files/pdf_d/d001-e20.pdf.
[6] Fluke ESA620 Electrical Safety Analyzer, 2022 [online], available at: www.flukebiomedical.com.
[7] IMT Medical PF-301 Flow Analyzer, 2022 [online], available at: https://www.imtanalytics.com/.
[8] ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories, International Organisation for Standardisation, Geneva, Switzerland, ISO standard, 2017.
[9] IEC 60601. Medical electrical equipment – all parts, International Electrotechnical Commission, Geneva, Switzerland, IEC standard, 2021.
[10] Badnjević A, Pokvić LG, Džemić Z, et al. Risks of emergency use authorizations for medical products during outbreak situations: A COVID-19 case study. BioMed Eng OnLine. 2020; 75: 19. doi: 10.1186/s12938-020-00820-0.
[11] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
[12] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
[13] Badnjević A, et al. Post-market surveillance of medical devices: A revie. Technology and Health Care. 2022; 30(6): 1315–1329.
[14] Badnjević A, Cifrek M, Magjarević R, žemić Z. (eds). Inspection of Medical Devices. Series in Biomedical Engineering. 2018. Springer, Singapore.
[15] Gurbeta L, Badnjević A. Inspection process of medical devices in healthcare institutions: software solution. Health Technol. 2017; 7(Issue 1): 109–117. doi: 10.1007/s12553-016-0154-2.
[16] Badnjević A, Pokvić LG, Hasičić M, Bandić L, Mašetić Z, Kovačević Ž, Kevrić J, Pecchia L. Evidence-based clinical engineering: Machine learning algorithms for prediction of defibrillator performance. Biomedical Signal Processing and Control. September 2019; 54: 101629.
[17] Kovačević Ž, Gurbeta Pokvić L, Spahić L, Badnjevic A. Prediction of medical device performance using machine learning techniques: infant incubator case study. Health Technol. 2019. doi: 10.1007/s12553-019-00386-5.
[18] Badnjević A, Avdihodžić H, Gurbeta Pokvić L. Artificial intelligence in medical devices: Past, present and future. Psychiatria Danubina. 2021; 33(suppl 3): 101–106.
[19] Spahić L, Kurta E, Cordic S, Becirovic M, Gurbeta L, Kovacevic Z, Izetbegovic S, Badnjevic A. Machine Learning Techniques for Performance Prediction of Medical Devices: Infant Incubators. In: Badnjevic A, Škrbić R, Gurbeta Pokvić L. (eds) CMBEBIH 2019. CMBEBIH 2019. IFMBE Proceedings, vol 73. Springer, Cham. 2020.
[20] Hrvat F, Spahic L, Gurbeta Pokvic L, Badnjevic A. Artificial Neural Networks for prediction of medical device performance based on conformity assessment data: Infusion and perfusor pumps case study. IEEE 9th Mediterranean Conference on Embedded Computing (MECO), Budva, Montenegro. 08–11 June 2020.
[21] Gurbeta Pokvic L, Deumic A, Lutovac B, Badnjevic A. Possibility of Managing Medical device Post-market Surveillance using Artificial Intelligence and Standardized Methodology. IEEE 10th Mediterranean Conference on Embedded Computing (MECO), Budva, Montenegro. 07–10 June 2021.