Technology and Health Care 31 (2023) 327–337
DOI 10.3233/THC-229008
IOS Press

Technical Note

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

Almir Badnjevic[a,b,c,d], Amar Deumic[a,b], Adna Softic[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: Patient monitors are medical devices used to monitor vital parameters such as heart rate, respiratory rate, blood pressure, blood oxygen saturation, and body temperature during inpatient treatment. As such, patient monitors provide physicians with information necessary to adjust the treatment as well as evaluate the overall status and recovery of the patient. Measurements made by intrinsic sensors of patient monitors must be compliant and provide reliable readings in order to ensure safety and optimal quality of care to the patients.
OBJECTIVE: This paper proposes a novel method for conformity assessment testing of patient monitors in healthcare institutions for post-market surveillance purposes.
METHOD: The method was developed on the basis of metrology characteristics of sensors used to monitor vital parameters observed by patient monitors and evaluation of their vital safety and performance parameters. In addition to the evaluation of essential safety and visual integrity of patient monitors, their performance in terms of accuracy of the readings 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 patient monitors as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of patient monitors 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, patient monitor, 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] patient monitors can be remote or wearable remote monitoring devices that measure or detect common physiological parameters. According to the Medical Device Regulation (MDR) 2017 [2], patient monitors are classified as class IIa, except if they are intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case they are classified as class IIb. As this classification determines regulatory scrutiny to which devices are subjected to before placing on the market, patient monitors are medical devices with a moderate to high risk that requires special controls.

The fact that patient monitors measure the patient's vital signs allows us to refer to them as medical devices with a measuring function (MDMF) [3]. Sensors or measurement tools included in patient monitors directly influence their ity. Every pre-programmed setting for voltage signal amplitude identified by ECG, heart rate, respiration, non-invasive blood pressure, invasive blood pressure, skin temperature, blood oxygen saturation and CO2 and O2 concentration has a designated sensor or a means by which it can be detected using a patient monitor. Since the patient monitor is used to measure the patient's vital signs, any anomalies that arise during its usage may have a detrimental impact on the patient.

Since the patient monitor's effectiveness is based on the accuracy of measurement of ECG voltage signal amplitude, heart rate, respiration, non-invasive blood pressure, invasive blood pressure, skin temperature, blood oxygen saturation, and CO2 and O2 concentrations, post-market surveillance focuses on accuracy in readouts of the given values of the indicated measuring quantities.

A comprehensive number of standards is used to demonstrate conformity with essential safety and performance requirements of patient monitors [4] prior to their release on the market. These standards can be grouped into three categories, general quality standards, electrical safety standards, particular patient monitors standards. However, there is no designated standard nor a guideline on how to perform post-market surveillance of patient monitors, regardless of the fact that post-market surveillance is deemed mandatory by the new MDR [2].

This paper presents the novel methodology for conformity assessment of patient monitors during their utilization in healthcare institutions as well as the results that successful application of this methodology can have on the overall quality of healthcare services provided to the patients.

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 patient monitors
2. Definition of metrological requirements for patient monitors
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 patient monitors was done by using two etalons, Fluke Biomedical ESA620 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 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 patient monitors 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 patient monitors

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 patient monitors

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 patient monitors 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 patient monitor, 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 (12–24 V).
- Temperature: 21–26°C.
- Relative humidity: 15–95%.
- Compliance with IEC 60601-2-4 Medical electrical equipment: Particular requirements for the basic safety and essential performance of cardiac patient monitors [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 patient monitor, 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 (30–300) [bpm]
  - Respiration [breaths per minute (brpm)]
  - Non-invasive blood pressure (NIBP) [mmHg]
  - Invasive blood pressure (IBP) [mmHg]
  - Skin temperature [°C]
  - Blood oxygen saturation SpO_2 [%]
  - Concentration of CO_2 and O_2

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.

Breaths rate per minute, number of breaths in one minute.

A millimetre of mercury is a manometric unit of pressure, but not part of the International System of Units (SI). It was previously defined as the extra pressure generated by a column of mercury one millimetre high, and currently defined as exactly 133.322387415 pascals.

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.

- Measuring range and division
  - 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 (30–300) [bpm]
  - Respiration (0–150) [brpm]
  - NIBP (10–270) [mmHg]
  - IBP (10–300) [mmHg]
  - Skin temperature (30–43) [°C]
  - Blood oxygen saturation SpO_2 (0–100) [%]
  - Concentration of CO_2 (0–30%) and O_2 (0–100%)
  - Outside this working range no energy reading and no measurement result shall be displayed.
  - 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 ± 5% of reading
  - Heart rate in a time interval of 1 minute ± 2% of reading
  - Respiration ± 2% of reading
  - NIBP ± 5 mmHg of reading
  - IBP ± 1 mmHg of reading
  - Skin temperature ± 0.1°C of reading
  - SpO_2 ± 2% of reading
  - Concentration of CO_2:
    - ± 0.1% for 0–1%,
    - ± 0.2% for 1–5%,
    - ± 0.3% for 5–7%,
    - ± 0.5% for 7–10%,
  - Concentration of O_2:
    - ± 1% for 0–25%,
    - ± 2% for 25–80%,
    - ± 3% for 80–100%.

3.1.2. Method of test

3.1.2.1. Visual inspection

a) Equipment

The prerequisites for performing visual inspection are:

- Device under test/Patient monitor;
- 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 the 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/patient monitor
- Reference electrical safety testing equipment/analyser

b) Procedure

The procedure starts with connecting the patient monitor to electrical safety testing equipment. Test of the electrical safety of a device under test is performed according to the requirements of IEC 60601-

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?	

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. 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/patient monitor
- Reference 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. Test the amplitude of voltage signal, heart rate in a time interval of 1 minute, respiration, NIBP, IBP, skin temperature, blood oxygen saturation, concentration of CO_2 and O_2 (if available). All these parameters are tested in every measuring point. To test these, choose the desired values on the reference testing device. This will simulate the signals and they will be interpreted by the DUT.

Table 3
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 4
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.

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 patient monitors, the performance inspection result can be reported as both relative and absolute error between the indicated values, depending on the parameter. Error for parameter of blood pressure is expressed as absolute error, while errors for amplitude, heart rate, respiration and blood oxygen saturation 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 patient monitor. 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.

Table 5
Example of performance evaluation for the respiration in range 15–150 [brpm]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set respiration Xs [brpm]	Reading respiration Xm [brpm]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**20**	20	0	± 2%	Pass
2.	**80**	80	0	± 2%	Pass
3.	**100**	99	1.00	± 2%	Pass
4.	**150**	148	1.33	± 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.

Table 6
Example of performance evaluation for the blood oxygen saturation in range 70–100 [%]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set saturation Xs [%]	Reading saturation Xm [%]	Deviation ΔX [%]	Maximum deviation [%]	Conformity assessment testing Pass/Fail
1.	**70**	69	1.0	± 2%	Pass
2.	**80**	81	1.0	± 2%	Pass
3.	**90**	88	2.0	± 2%	Pass
4.	**95**	96	1.0	± 2%	Pass
5.	**100**	100	0.0	± 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.

Table 7
Example of performance evaluation for the nibp in range 50–200 [mmHg]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set pressure Xs [mmHg]	Reading pressure Xm [mmHg]	Deviation ΔX [mmHg]	Maximum deviation [mmHg]	Conformity assessment testing Pass/Fail
1.	**50**	51	1	± 5	Pass
2.	**80**	84	4	± 5	Pass
3.	**100**	104	4	± 5	Pass
4.	**150**	155	5	± 5	Pass
5.	**200**	205	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 absolute error; Column 5 = Maximum deviation; Column 6 = Conformity assessment testing statement.

In addition to quantitative testing, as proposed in this methodology, all patient monitors in this study were inspected for following qualitative features that influence their performance such as chassis integrity (technical requirements) in terms of: strain reliefs, ECG electrodes, non-invasive blood pressure connectors, invasive blood pressure connectors, blood oxygen saturation connectors, connectors, switches, displays, alarms, battery.

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 devices were predominantly inspected in healthcare institutions of secondary and tertiary level – hospitals and clinical centres. The best indicator of the effectiveness of the developed method is the decrease in the percentage of non-compliant patient monitors over the years the method was validated. The decreasing trend persists throughout the years. If there was no performance inspection, most of the non-compliant patient monitors would persist in usage as healthcare professionals would remain unaware of the non-compliance of the output parameters. This is worrying since, as mentioned above, devices are used at the secondary and tertiary level, usually for monitoring of patients in critical or risky situations. It is of outmost importance for these devices to have safe and accurate performance each time they are used.

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. Such approach optimized management of devices in healthcare institution, but also revealed interesting details about device performance over the years. The most critical parameter for these devices was blood pressure measurement followed by measurement of SpO2.

4. Conclusion

The regulatory framework for medical devices varies around the world, but it has been improved in the 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 patient monitors 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 patient monitors 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] EU Medical Device Directives: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices, Official Journal of the European Communities, L 331, 2000.
[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] Fluke ProSim 8 Vital Signs Patient Simulator, 2022 [online], available at: www.flukebiomedical.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.