Technology and Health Care 31 (2023) 339–346
DOI 10.3233/THC-229009
IOS Press

Technical Note

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

Almir Badnjevic[a,b,c,d], Amar Deumic[a,b], Azra Ademovic[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: Therapeutic ultrasounds are medical devices used for treatment of conditions such muscle spasms, joint contractures or general muscle pain. Their function relies in the delivery of ultrasonic pulses that generate heat in tissue thus relieving the symptoms of aforementioned conditions. Accuracy of the delivered pulses directly affects the quality and effectiveness of the treatment and has to be ensured throughout the utilization of the therapeutic ultrasound in 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 method for conformity assessment testing of therapeutic ultrasounds for post-market surveillance purposes.
METHOD: The method was developed based on metrology characteristics of therapeutic ultrasounds and includes visual, electrical safety and performance inspections of therapeutic ultrasounds to ensure that both safety and treatment reliability are achieved.
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 therapeutic ultrasounds as a method used during PMS contributes to significant improvement in devices' accuracy and reliability.
CONCLUSION: A standardized approach in conformity assessment testing of therapeutic ultrasounds 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, therapeutic ultrasound, 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

Therapeutic ultrasounds are medical devices used for applying therapeutic deep heat for selected medical conditions to specific areas of the body using ultrasound energy [1]. Ultrasound energy is a type of mechanical energy characterized by vibrating or moving particles within a medium. Typically, a frequency between 20 and 40 kilo (k) hertz (Hz) is used for medical purposes to generate deep heat within body tissues. This has healing effects and serves as the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures. As this type of medical device involves transfer of energy to human body, an appropriate classification based on associated risk is performed.

According to the Medical Device Regulation (MDR) 2017 [2], therapeutic ultrasounds are classified as Class IIb which corresponds to a medical device with a moderate to high risk. This classification determines regulatory scrutiny to which these devices are subject to before placing to the market. These devices are considered as active therapeutic devices as they administer or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy [3].

Each predetermined value of power used by therapeutic ultrasound has a specific function. Dangerous adverse events can occur when therapeutic ultrasound fails to detect a patient's various musculoskeletal problems, such as tissue injury or muscle spasms, undermining their purpose. As the essence of therapeutic ultrasound lies in the power they deliver, post-marketing surveillance is aimed at inspecting the accuracy of the delivered values of the specified measurement quantity.

The classification suggests that this device is a moderate to high-risk category as it uses heat and energy to increase circulation, reduce pain, increase flexibility and accelerate healing. For this reason, it is crucial that there are no limiting irregularities that disrupt its reliable operation. An extensive set of standards is used to demonstrate compliance with the essential safety and performance requirements of therapeutic [4] during the premarketing phase. These standards can be grouped into three categories, general quality standards, electrical safety standards, special standards for therapeutic sounds. However, no standards are imposed onto the post-market oversight of therapeutic ultrasounds.

This paper presents a novel methodology for conformity assessment of therapeutic ultrasounds during usage taking into account the metrological characteristics of the device and utilizing the approach defined for other types of medical devices with measuring functions. The presented method can be used by national regulators as a standard in defining the regulatory framework for post-market 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 therapeutic sounds
2. Definition of metrological requirements for therapeutic sounds
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 therapeutic sounds was done by using two etalons, Fluke Biomedical ESA 620 electrical safety analyser [6] and Ohmic Instrument UPM-DT-100 Ultrasound Power meter [7]. Both of these devices were periodically calibrated in EN ISO 17025 accredited laboratories [8]. The novel method was validated during the 2018–2021 time period. The presented data was analysed using a statistical approach.

3. Results and discussion

The results are presented in two parts. The first part consists of reporting the novel methodology for conformity assessment testing of therapeutic sounds 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 therapeutic sounds

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 therapeutic sounds

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 therapeutic sounds 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 therapeutic sounds, 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.
- Relative humidity: 20–80%.
- Compliance with IEC 60601-2-62 Medical electrical equipment – Part 2–62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment [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 all 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 therapeutic sounds, the metrological requirements are formalised in the following manner:

- Measurement unit
  - Output power of the measuring devices which are part of therapeutic ultrasound is set and measured in Watts [W].

Watt is a derived unit of power in the International System of Units (SI) (NIST 2019). It is described as the time speed of performing work or delivering energy. One joule of energy transferred in a second is equal to 1 Watt. 1 Watt = 1 J/s

- Measuring range and division
  - Output power range (depending on the device type):
    - 0–30 W
  - Outside this working range no energy reading and no measurement result shall be displayed.
  - Division: 0.5 W.
  - 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 to 26°C, the maximum permissible error for the measurement of the output power at any point of the scale range shall be ± 0.2 W for therapeutic ultrasound in use.

3.1.2. Method of test

3.1.2.1. Visual inspection

a) Equipment

The prerequisites for performing visual inspection are:

- Device under test/therapeutic sounds;
- 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.

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

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 performance inspection are:

– Device under test/therapeutic sound
– Reference testing equipment/analyser

b) Procedure

Based on device measuring range select measuring points to cover the entire measuring range. Test the output power in every measuring point. Connect the therapeutic ultrasound probe to the reference testing device. To test the output power in every measuring point, select the desired power level on the DUT. Initiate the therapy on the device. Every ultrasound was evaluated for their performance by measuring the delivered power at the same level multiple times in order to check for consistency in the delivered power.

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 therapeutic ultrasounds, the performance inspection result is reported as the absolute error between the indicated power of the device under test and the corresponding readings of the calibrated reference testing equipment.

3.1.3. Performance inspection

Absolute error calculation:

$$\Delta X = X_{measured} - X_{set} \tag{1}$$

The conformity assessment testing in performance inspection is determined by the value of this error. The allowed performance error is presented in Table 2. It was formulated based on the international

Table 2
Example of performance evaluation for range 0.5–10 [W]

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
No.	Set power Xs [W]	Reading power Xm [W]	Deviation ΔX [W	Maximum deviation [± W]	Conformity assessment testing Pass/Fail
1.	**0.5**	0.5	0.0	0.2	Pass
2.	**1**	1.2	0.2	0.2	Pass
3.	**1.5**	1.6	0.1	0.2	Pass
4.	**2**	2.2	0.2	0.2	Pass
5.	**2.5**	2.6	0.1	0.2	Pass
6.	**3**	3.1	0.1	0.2	Pass
7.	**4**	4.0	0.0	0.2	Pass
8.	**6**	6.1	0.1	0.2	Pass
9.	**8**	8.1	0.1	0.2	Pass
10.	**10**	10.2	0.2	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 absolute error; Column 5 = Maximum deviation; Column 6 = Conformity assessment testing statement.

standards followed during the production of the therapeutic ultrasounds. 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 therapeutic ultrasounds in this study were inspected for following qualitative features that influence their performance such as chassis integrity (technical requirements) in terms of: strain reliefs, ultrasound probes, 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 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 best indicator of the effectiveness of the developed method is the decrease in the percentage of non-compliant therapeutic sounds over the years the method was validated. The decreasing trend of non-compliant devices persists throughout the years. The method revealed non-compliance in devices which were considered safe and accurate by medical professionals, however during performance inspection significant deviation was detected. In most of the cases, the deviation on performance didn't cause any adverse event, but the clinical effectiveness of the treatment was doubtable. If there was no performance inspection, most of the non-compliant therapeutic sounds would persist in usage as healthcare professionals would remain unaware of the non-compliance of the output parameters.

This strengthens the conclusion that the medical device inspection method according to OIML metrological standards is the most effective way of preventing non-compliant therapeutic sounds being used in medical practice. 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.

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 therapeutic ultrasound 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 therapeutic ultrasound 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] Ohmic Instruments UPM-DT-100 Ultrasound Powermeter, 2022 [online], available at: http://www.ohmicinstruments.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.