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METROLOGICAL SUPPORT OF PULSE OXIMETERS

Abstract. The experience of the International Medical Device Regulators Forum in the use of products for oxygen therapy based on the study of guidelines, international and European regulations on medical devices is considered. Emphasis is placed on issues related to the metrological support of pulse oximeters. The global situation with the pandemic increases the relevance of selected topics. Continuous monitoring of blood oxygen saturation is one of the most important elements in the diagnosis and treatment of COVID-19. Despite the fact that the use of pulse oximeters does not require special medical knowledge, calibration and special maintenance, it is still necessary to control their reliability and accuracy of measurement. The study of pulse oximeter MD300M in accordance with the requirements of DSTU 8893:2019 "Metrology. Pulse oximeters. Calibration Method" 2020. Analysis of MD300M pulse oximeter calibration results revealed that this pulse oximeter was calibrated by the saturation and pulse measurement channel, as the maximum deviation of the measured saturation value from the pulse oximeter calibration measure does not exceed the pulse oximeter measurement documentation specified in the operating documentation. The discreteness of the MD300M pulse oximeter and the discreteness of the reference device MPPO-2, which are specified in the passports for the respective devices, have the greatest influence on the measurement uncertainty.

Keywords: metrological support; pulse oximeter; COVID-19; verification; international standards.

Introduction

Pulse oximetry as a medical technology appeared thirty years ago. More than fifteen years ago, pulse oximeters have been introduced into a wide range of clinical practice. Today, due to the spread of the coronavirus pandemic, this portable medical device is at its first stage of gaining popularity and is becoming an integral part of both specialized medical institutions and everyday life. The global situation with the pandemic increases the relevance of selected topics. Despite the efforts of scientists in many countries – a cure for the disease has not yet been invented and the fight against symptoms comes to the fore. Pulse oximetry is a non-invasive method of measuring two parameters: blood oxygen saturation and heart rate, which are most important during anesthesia, intensive care, resuscitation, and coronavirus disease. Continuous monitoring of blood oxygen saturation is a special metric element in the diagnosis and treatment of COVID-19. Despite the fact that the use of pulse oximeters does not require special medical knowledge, calibration and special maintenance, it is still necessary to control their reliability and accuracy of measurement.

Many publications have been devoted to the study of various problems related to the development and use of pulse oximeters. This is a study of choosing the most optimal location of the pulse oximeter sensor, which was conducted on 20 respondents. Based on the results obtained, the authors issued specific recommendations for the use of portable devices [1]. Different designs of portable pulse oximeters are presented in publications [2–3]. An interesting study was conducted in 29 hospitals in the UK [4] based on the involvement of 847 pulse oximeters of different types and different manufacturers. Significant shortcomings in the construction of the electrical circuit have been invented, which has a significant impact on the accuracy of measurements. It was found that 30.5% of the total number of devices did not meet the manufacturer's specifications. In addition, there is no system of periodic calibration of devices. Evaluation of the pulse oximeter based on the methodology of the international standard ISO 80601-2-61: 2011 is presented in [5]. Based on the results of experimental studies, it is proved that the proposed device meets the requirements of the standard. The issue of reliability and accuracy is covered in the study [6]. The authors touched on the important problem of measuring the accuracy of special pulse oximeters, which are designed for very young children and children with disabilities. Various issues of metrological support and reliability of heart rate monitor measurements have been studied in [8–12]. In particular, in the publication [9] the authors proposed a scheme for calibration of pulse oximeters and two variants of devices for its implementation. An analysis of the scientific literature on the identified problem suggests that there is no separate study on the metrological support of pulse oximeters and the state of the regulatory framework for the use of these medical devices in Ukraine.

The purpose of the article is to analyze the current regulatory framework of Ukraine in the field of medical devices and study the metrological support of the pulse oximeter based on the involvement of DSTU 8893:2019 "Metrology. Pulse oximeters. Calibration method" 2020.

Presentation of the main material

According to the purpose, pulse oximeters are divided into autonomous (compact, mounted directly on the finger), portable (device with display, signal cable and sensor for various purposes) and stationary (designed for long-term monitoring of various physiological parameters). Pulse oximeters are used both for a single test, that is one measurement of SpO2, and for long-term monitoring of SpO2 levels. Established in 2011, the International Medical Device Regulators Forum (IMDRF) has developed a number of documents aimed at establishing global cooperation in international trade, harmonizing activities in the field of safety, efficiency and quality of medical devices. Within the IMDRF there is a special group for the harmonization of medical devices. The IMDRF includes the following countries: Japan, the Russian Federation,

the United States, Australia, Brazil, Canada, China and the European Union. There are also branches of the Asian Harmonization Group and the Pan American Health Organization. IMDRF has created a number of guidelines that summarize the different approaches to the use of pulse oximeters. Technical specifications, instructions for use of products for oxygen therapy are given [13–17]. International legal documents, as well as documents of IMDRF member countries and Ukraine, applicable to the manufacturer, production technology and conditions of use of medical devices, including pulse oximeters, are summarized in table 1.

Table 1 – **Regulatory documents applicable to pulse oximeters** [13–19]

Level	Regulatory documents
International	ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
	ISO 14971 Medical devices – Application of risk management to medical devices
	ISO 80601-2-61 Medical electrical equipment. Part 2-61: Specific requirements for basic safety and essential performance of pulse oximeter equipment
	IEC 80001-5-1 Health software and health IT systems safety, effectiveness and security. Part 5-1: Security – Activities in the product life cycle
	IEC 60601-1 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-1 Medical electrical equipment. Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
	IEC 60068-2-31 Environmental testing: Part 2-31: Tests. Test Ec: Rough handling shocks, primarily for equipment type specimens
	IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices
	IEC 62133 Secondary cells and batteries containing alkaline or other nonacid electrolytes. - Safety requirements for portable sealed secondary cells. Part 1: Nickel systems, Part 2: Lithium systems
	ISO/IEEE 11073-10404 Health informatics. Personal health device communication. Part 10404: Device specialization. Pulse oximeter
Regional	21 CFR Part 820 – QUALITY SYSTEM REGULATION (USA)
	21 CFR § 868.5440 – Portable oxygen generator (USA)
	MHLW Ministerial Ordinance No. 169 (2004) (Japan)
	Regulation (EU) 2017/745
	Ukraine
	DSTU EN ISO 13485:2018 (EN ISO 13485:2016+ EN ISO 13485:2016 / AC:2016, IDT) Medical devices – Quality management systems – Requirements for regulatory purposes
	DSTU EN ISO 14971:2015 Medical devices. Application of risk management to medical devices (EN ISO 14971:2012, IDT; ISO 14971:2007, IDT)
	DSTU EN ISO 11607-1:2015 (EN ISO 11607-1:2009, IDT; ISO 11607- 1:2006, IDT). Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
	DSTU EN ISO 11607-2:2015 (EN ISO 11607-2:2006, IDT; ISO 11607- 2:2006, IDT) Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
	Technical regulations for medical tests, approved by the decree of the Cabinet of Ministers of Ukraine № 753 dated 02.10.2013.

The analysis of normative-legal documentation allowed to establish that a number of normative documents in the field of medical devices have been developed in Ukraine. According to the resolution of the Cabinet of Ministers of 2019, pulse oximeters and 12 other categories of measuring instruments for medical purposes were excluded from the Technical Regulations of Legislatively Regulated Measuring Instruments. Meanwhile, the instruments remain legally regulated measuring instruments and are subject to periodic verification as particularly important during the COVID-19 pandemic. Of course, it is an indisputable fact that the quality and safety of medical services depends on the technical condition of medical devices. Therefore, systematic metrological verification directly affects the quality of medical procedures [18–19].

Since 2020, Ukraine has an updated regulatory document DSTU 8893:2019 "Metrology. Pulse oximeters. Calibration method". It applies to pulse oximeters and pulse oximetric channels of medical monitors, which allow to assess the degree of oxygen saturation of human hemoglobin in non-invasive blood by measuring the modulation coefficients of light flux passing through human tissues in two bands and wavelengths. Also this document establishes the method of calibration of pulse oximeters: calibration operations, calibration tools, personnel qualification requirements, calibration conditions, safety requirements, preparation for calibration, processing of measurement results and registration of calibration results. This standard is used for periodic verification, post-repair verification (which does not change the type of measuring equipment), and it can be used for extraordinary, inspection and expert verification in accordance with the requirements [20].

Based on DSTU 8893:2019, the MD300M pulse oximeter, which is widely popular in the Ukrainian market of medical devices, was calibrated. This is a high-precision instrument for professional use, which has the following parameters when measuring oxygen saturation SpO2: measuring range from 0% to 100%;

measurement step – 1%; measurement accuracy: in the range of 80 ... 100% – ± 2%, in the range of 70 ... 79% – ± 3%, in the range of ≤ 69% – not precisely defined. Auxiliary equipment required for calibration is a measure for calibration of pulse oximeters (MCPO). The calibration conditions have been maintained, that is the ambient temperature is (20 ± 5) °C; relative humidity – from 30% to 80%; atmospheric pressure – (100 ± 6) kPa. An external inspection of the device was carried out, no mechanical damage was detected, during testing it turned out to be operational. The results of experimental studies are summarized in table 2, 3. Determination of metrological characteristics of the pulse oximeter is performed for the saturation measurement channel and the pulse rate measurement channel.

Table 2 – **Calculation of metrological characteristics of the saturation measurement channel**

№	S_{MCPO}, %	S, %					ΔS, %					ΔS_{max}%	ΔS_{PO}
		1	2	3	4	5	1	2	3	4	5		
1	99	98	98	97	98	100	-1	-1	-2	-1	1	2	2
2	95	96	96	93	97	96	1	1	-2	2	1		
3	85	84	87	83	83	88	-1	2	-2	-2	3	3	3
4	75	75	72	75	75	77	0	-3	0	0	2		
5	70	71	70	71	73	70	1	0	1	3	0		

Table 3 – **Calculation of metrological characteristics of the pulse rate measurement channel**

№	F_{MCPO}, min^{-1}	F, min^{-1}					ΔF, min^{-1}					ΔF_{max}, min^{-1}	ΔF_{PO}, min^{-1}
		1	2	3	4	5	1	2	3	4	5		
1	40	41	40	39	41	41	1	0	-1	1	1	2	2
2	70	70	68	70	70	69	0	-2	0	0	-1		
3	120	121	121	122	121	120	1	1	2	1	0		
4	180	181	181	180	181	179	1	1	0	1	-1		
5	240	238	240	241	240	241	-2	0	1	0	1		

The pulse oximeter is considered to have passed the calibration according to this parameter, because the maximum deviation of the measured saturation value from the set for calibration of pulse oximeters does not exceed the absolute error of saturation measurement specified in the operating documentation for pulse oximeters – ±3%.

The pulse oximeter is considered to have passed the calibration according to this parameter, because the maximum deviation of the measured value of the pulse rate from the specified measure for calibration of pulse oximeters does not exceed the absolute measurement error specified in the operating documentation – ±2 min^{-1}.

We will calculate the uncertainty when measuring saturation with a pulse oximeter MD300M. The equation for measuring the absolute error of saturation has the form

$$\Delta S_{PO}=S_i - S_{MCPO}, \quad (1)$$

where S_I – the result of the i-th measurement of saturation PO, %; S_{MCPO} – the reference value of saturation reproduced by MCPO, %.

Uncertainty of measurement pulse oximeter readings S_I are estimated by type B uncertainty, given the discreteness

$$U_B(S_i)=\frac{a}{2\sqrt{3}}. \quad (2)$$

Uncertainty of measurement $S_{МППО}$ the readings of the reference measuring instrument are evaluated by two components of type B:

– taking into account the error of the reference measuring instrument Δ_p

$$u_B^1(S_{MCPO})=\frac{\Delta_p}{\sqrt{3}}; \quad (3)$$

– taking into account the discreteness of the reference measuring instrument a_e

$$u_B^2(S_{MCPO})=\frac{a_e}{2\sqrt{3}}. \quad (4)$$

Total standard uncertainty of determining the main error of saturation measurement

$$U_c(\Delta S_{PO})=\sqrt{u_B(S_i)^2+u_B^1(S_{MCPO})^2+u_B^2(S_{MCPO})^2}. \quad (5)$$

Extended uncertainty equals the product of the total standard uncertainty $u_c(\Delta S_{PO})$ and the coverage factor k (k=2 at a given probability P=95%) and is determined

$$U(\Delta S_{PO})=k\cdot u_c(\Delta S_{PO}). \quad (6)$$

Table 4 presents the budget of uncertainty in determining the absolute error in measuring saturation.

Table 4 – **Budget uncertainty in determining the absolute error in measuring saturation**

Input value	Estimation of input value	Standard uncertainty	Sensitivity coefficient	The contribution of uncertainty
S_i	S_i	$\frac{a}{2\sqrt{3}}$	1	$\frac{a}{2\sqrt{3}}$
S_{MCPO}	S_{MCPO}	$\frac{\Delta_p}{2\sqrt{3}}$	–1	$-\frac{\Delta_p}{2\sqrt{3}}$
S_{MCPO}	S_{MCPO}	$\frac{a_e}{2\sqrt{3}}$	–1	$-\frac{a_e}{2\sqrt{3}}$
Measuring value	Measurement result	Total standard uncertainty	Coverage ratio	Extended uncertainty
ΔS_{PO}	ΔS_{PO}	$u_c(\Delta S_{PO})=\sqrt{u_B(S_i)^2+u_B^1(S_{MCPO})}$	2	$U(\Delta S_{PO})=k\cdot u_c$

The MD300M pulse oximeter has the following input characteristics specified in the passport (saturation measurement mode): discreteness – 1%. The reference measuring instrument (MCPO-2) has the following input characteristics specified in the passport: error of the reference measuring instrument Δ_p – ± 0,05%; discreteness – 0,5 %. The results of uncertainty calculations in determining the absolute error in measuring saturation at $S_{МППО}$ = 85% presented as an uncertainty budget in the table 5, ΔS_{PO}=(3,00±0,64)%.

Table 5 – **The uncertainty budget of the absolute error in measuring saturation S_{MCPO} = 85%**

Input value	Estimation of input value	Standard uncertainty	Sensitivity coefficient	The contribution of uncertainty
S_i	88	0,29	1	0,29
S_{MCPO}	85	0,014	–1	-0,014
S_{MCPO}	85	0,14	–1	-0,14
Measuring value	Measurement result	Total standard uncertainty	Coverage ratio	Extended uncertainty
ΔS_{PO}	3	$\sqrt{0,29^2+(-0,014)^2+(-0,14)^2}=0,32$	2	0,64

Analysis of the result of the uncertainty calculation of the absolute error in measuring saturation allows us to draw the following conclusion. The discreteness of the MD300M pulse oximeter, which is indicated in the passport for the device, has the greatest influence on the measurement uncertainty. Thus, it is impossible to reduce this contribution by repeated observations or in any other way, and for a more accurate result you need to choose a device with less discretion. Let's calculate the uncertainty when measuring heart rate with MD300M pulse oximeter. The equation for measuring the absolute error of the heart rate has the form

$$\Delta F_{PO}=F_i - F_{MCPO}, \quad (7)$$

where F_I – the result of the i-th measurement of heart rate PO, %; F_{MCPO} – the reference value of pulse rate reproduced by MCPO, %.

Uncertainty of measurement F_I – readings of pulse oximeters is estimated by uncertainty of type B, considering discreteness

$$U_B(F_i)=\frac{a}{2\sqrt{3}}. \quad (8)$$

Uncertainty of measurement of the readings F_{MCPO} of the reference measuring instrument are evaluated by two components of type B:

– taking into account the error of the reference measuring instrument Δ_p

$$u_B^1(F_{MCPO})=\frac{\Delta_p}{\sqrt{3}}; \quad (9)$$

– taking into account the discreteness of the reference measuring instrument a_e

$$u_B^2(F_{MCPO})=\frac{a_e}{2\sqrt{3}}. \quad (10)$$

Total standard uncertainty for determining the main error of saturation measurement

$$U_c(\Delta F_{PO})=\sqrt{u_B(F_i)^2+u_B^1(F_{MCPO})^2+u_B^2(F_{MCPO})^2}. \quad (11)$$

The extended uncertainty is equal to the product of the total standard uncertainty $u_c(\Delta F_{PO})$ on the coefficient of coverage k (k=2 at a given probability P=95%) and is determined by the formula

$$U(\Delta F_{PO})=k\cdot u_c(\Delta F_{PO}). \quad (12)$$

The uncertainty budget for determining the absolute error in measuring heart rate is presented in table 6.

The MD300M pulse oximeter has the following input characteristics specified in the passport (pulse rate measurement mode):

– discreteness – 1 min^{-1};

The reference means (MCPO-2) of measurements has the following input characteristics which are specified in the passport: limits of admissible absolute error of values of pulse rate Δ_p – ±0,2 min^{-1}; discreteness – 1 min^{-1}.

The results of calculations when measuring heart rate at F_{MCPO}=240 min^{-1} presented as an uncertainty budget in the table 7: ΔF_{PO}=(2,00±0,82) min^{-1}.

Conclusions

Thus, the study of international and European experience in the use of oxygen therapy medical devices indicates an increase in attention to these medical devices in a pandemic. Over the past three years, the International Organization IMDRF has developed more than 10 methodological documents containing technical recommendations, specifications, accompanying guidelines for improving the availability of technologies and the use of pulse oximeters.

Table 6 – **Uncertainty budget in determining the absolute error in measuring heart rate**

Input value	Estimation of input value	Standard uncertainty	Sensitivity coefficient	The contribution of uncertainty
F_i	F_i	$a/2\sqrt{3}$	1	$a/2\sqrt{3}$
F_{MCPO}	F_{MCPO}	$\Delta_p/2\sqrt{3}$	–1	$-\Delta_p/2\sqrt{3}$
F_{MCPO}	F_{MCPO}	$a_e/2\sqrt{3}$	–1	$-a_e/2\sqrt{3}$
Measuring value	Measurement result	Total standard uncertainty	Coverage ratio	Extended uncertainty
ΔF_{PO}	ΔF_{PO}	$u_c(\Delta F_{PO})=\sqrt{u_B(F_i)^2+u_B^1(F_{MCPO})^2+u_B^2(F_{MCPO})^2}$	2	$U(\Delta F_{PO})=k\cdot u_c(\Delta F_{PO})$

Table 7 – **Uncertainty budget in determining the absolute error in measuring heart rate F_{MCPO} = 240 min^{-1}**

Input value	Estimation of input value	Standard uncertainty	Sensitivity coefficient	The contribution of uncertainty
F_i	238	0,29	1	0,29
F_{MCPO}	240	0,058	–1	-0,058
F_{MCPO}	240	0,29	–1	-0,29
Measuring value	Measurement result	Total standard uncertainty	Coverage ratio	Extended uncertainty
ΔF_{PO}	-2	$\sqrt{0,29^2+(-0,058)^2+(-0,29)^2}=0,41$	2	0,82

The study of pulse oximeter MD300M in accordance with the requirements of DSTU 8893:2019 "Metrology. Pulse oximeters. Calibration Method" 2020 Analysis of the MD300M pulse oximeter calibration results revealed that this pulse oximeter was calibrated by the saturation and pulse measurement channel, as the maximum deviation of the measured saturation value from the pulse oximeter calibration measure does not exceed the pulse oximeter ± 3%. The maximum deviation of the measured value of pulse rate from the set measure for calibration of pulse oximeters does not exceed the absolute measurement error specified in the operating documentation on the pulse oximeter – ±2 min^{-1}. Analysis of the result of calculating the uncertainty of the absolute error in measuring saturation allows us to conclude that the greatest influence on the uncertainty of measurement have the discreteness of the pulse oximeter MD300M and the discreteness of the reference device MCPO-2, which are specified in the passports.

Thus, it is impossible to reduce this contribution by repeated observations or in any other way, and for a more accurate result it is necessary to choose a device with less discreteness or not to consider this parameter as influencing the result when calculating.

REFERENCES

1. Juliana, N., Azmani, S., IdroseS., Amirfaiz, N., Roslan, A. (2017). Reliable monitoring of oxygen saturation via pulse oximetry: Which site to choose? *Journal of Fundamental and Applied Sciences*, No. 9, pp. 122–129. doi: 10.4314 / jfas.v9i4S.54.
2. Putu, Anna Andika, Rahmawati, Triana, Ridha, Mak M. (2019). Portable Pulse Oximeter. *JEEMI*, vol. 1, no. 1, pp. 28–32. doi: 10.35882/jeeemi.v1i1.6.
3. Sidhartha, G., Dwarakanath, M.L., Vineeth, K.C., Sukruth, R. (2021). IoT Based Pulse Oximeter. *International Journal for Research in Applied Science & Engineering Technology*, vol. 9, is. VIII, pp. 2946–2951.
4. Milner, Q.J., Mathews, G.R. (2012). An assessment of the accuracy of pulse oximeters. *Association of Anaecthetists,* vol. 67 (4), pp. 396-401. doi: 10.1111 / j.1365-2044.2011.07021.
5. Choi, Byung-Moon, Kang, Bong Jin, Yun, Ho-Yong, Bokyoung, Jeon, Bang, Ji-Yeon, Noh, Gyu-Jeong (2019). Performance of the MP570T pulse oximeter in volunteers participating in the controlled desaturation study: a comparison of seven probes. *Anesth Pain Med*, vol. 15. no. 3, pp. 371–377. https://doi.org/10.17085/apm.20028.
6. Jyotirmoy, Das, Amit, Aggarwal1, Naresh, Kumar Aggarwal (2010). Pulse oximeter accuracy and precision at five different sensor locations in infants and children with cyanotic heart disease. *Indian Journal of Anaesthesia*, vol. 54, iss. 6, pp. 531–534.
7. Podmasteryev, K.V., Dunaev, A.V., Kozyura, A.V., Zherebtsov, E.A. (2012). Metrological support of biomedical devices and technologies for functional diagnostics. *Metrology in biomedical engineering*. *Biotechnosphere*, no. 5–6 (23–24), pp. 92–96.
8. Sotova, B.I., Boriskina, M.O. (2013). Study of metrological reliability of pulse oximeters by statistical methods. *News of TulGU. Technical science*, vol. 6. (1), pp. 3–10.
9. Konopelko, L.A., Rumyantsev, D.V., Suvorov, V.I. (2003). Metrological support of pulse oximeters. *Scientific Instrumentation*, vol. 13, no. 3, pp. 44–45.
10. Tverytnykova, E., Drozdova, T., Demidova, Yu. (2020). Environmental management as a component of an integrated management system for gas condensate and oil processing enterprises. *Advanced information systems*, vol. 4, no. 1, pp. 133–138. doi: 10.20998/2522-9052.2020.1.06.
11. Tverytnykova, E, Demidova, Yu., Drozdova, T. (2021). Management system of occupational safety at ukrainian enterprises: international and european dimension. *Advanced information systems*, vol. 3, no. 1, pp. 45–53. doi: 10.20998/2522-9052.2021.1.06.
12. Kushnir, K. (2019). Problems of Metrological Provision of Activities of Primary Medical-Sanitary Assistance Bodies. *Metrology and instruments*, no. 3. pp.67–71. doi: 10.33955/2307-2180(3)2019.67-71.
13. WHO (2019). *Technical specifications for oxygen concentrators. Geneva: World Health Organization*; available at: http://www.who.int/medical_devices/publications/tech_specs_oxygen-concentrators/en/.
14. Amene, Mulueta M., Bradley, Beverly, Karlstrom, Jonas, Hemmi, Andrew. (2019). *WHO-UNICEF technical specifications and guidance for oxygen therapy devices. Geneva: World Health Organization and the United Nations Children's Fund*. WHO medical device technical series, 132 p.
15. Technical (2020) *Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients*. Pan American Health Organization, 18 c.
16. WHO (2020). *Priority medical devices list for the COVID-19 response and associated technical specifications. Interim guidance 19 NOVEMBER 2020*, 176 p.
17. WHO (2020). *Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients. Interim guidance 7 August 2020*, 18 p.

18. Technical regulations (2013) *Technical regulations on medical devices, approved by the resolution of the Cabinet of Ministers of Ukraine* №753 of 02.10.2013, available at: https://zakon.rada.gov.ua/laws/show/753-2013-%D0%BF/.
19. Resolution (2015) *Resolution of the Cabinet of Ministers № 374 About the statement of the list of categories of legally regulated means of measuring equipment which are subject to periodic verification*, available at: https://zakon.rada.gov.ua/laws/show/374-2015-%D0%BF#Text.
20. DSTU 8893:2019 (2020), *Metrology. Pulse oximetry. Method of verification*, Kyiv, 10 p.

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Метрологічне забезпечення пульсоксиметрів

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Анотація. Розглянуто досвід організації International Medical Device Regulators Forum із застосування виробів для кисневої терапії на основі дослідження методичних рекомендацій, міжнародних та європейських нормативних документів щодо виробів медичного призначення. Акцентовано увагу на питання, пов'язані з метрологічним забезпеченням пульсоксиметрів. Світова ситуація з пандемією підсилює актуальність обрано теми. Постійний моніторинг рівня насиченості крові киснем тобто сатурації є одним з важливіших елементів діагностики та лікування COVID–19. Незважаючи на те, що використання пульсоксиметрів не потребує спеціальних медичних знань, калібрування та особливого обслуговування, все-ж таки необхідно контролювати їхню надійність і точність вимірювання. Проведене дослідження пульсоксиметру MD300M згідно вимогам ДСТУ 8893:2019 «Метрологія. Пульсоксиметри. Методика повірки» 2020 р. Аналіз результатів повірки пульсоксиметра MD300M виявив, що даний пульсоксиметр пройшов повірку за каналом вимірювання сатурації та пульсу, оскільки максимальний відхил виміряного значення сатурації від заданого мірою для повірки пульсоксиметрів не перевищує зазначеної в експлуатаційній документації на пульсоксиметри абсолютної похибки вимірювання сатурації. Найбільший вплив на невизначеність вимірювання мають дискретність пульсоксиметра MD300M та дискретність еталонного приладу МППО-2, що зазначені в паспортах на відповідні прилади.

Ключові слова: метрологічне забезпечення; пульсоксиметр; COVID–19; повірка;, міжнародні стандарти.

Метрологическое обеспечение пульсоксиметров

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Аннотация. Рассмотрен опыт организации International Medical Device Regulators Forum по применению изделий для кислородной терапии на основе исследования методических рекомендаций, международных и европейских нормативных документов по изделиям медицинского назначения. Акцентировано внимание на вопросах, связанных с метрологическим обеспечением пульсоксиметров. Мировая ситуация с пандемией усиливает актуальность избранной темы. Постоянный мониторинг уровня насыщенности крови кислородом, т.е. сатурации, является одним из важнейших элементов диагностики и лечения COVID–19. Несмотря на то, что использование пульсоксиметров не требует специальных медицинских знаний, калибровки и особого обслуживания, все же необходимо контролировать их надежность и точность измерения. Проведено исследование пульсоксиметра MD300M согласно требованиям ДСТУ 8893:2019 «Метрология. Пульсоксиметры. Методика поверки» 2020 г. Анализ результатов поверки пульсоксиметра MD300M обнаружил, что данный пульсоксиметр прошел поверку по каналу измерения сатурации и пульса, поскольку максимальный отклон измеренного значения сатурации от заданной степени для поверки пульсоксиметрии не превышает указанной в эксплуатации. Наибольшее влияние на неопределенность измерения имеют дискретность пульсоксиметра MD300M и дискретность эталонного прибора МППО-2, указанные в паспортах соответствующих приборов.

Ключевые слова: метрологическое обеспечение; пульсоксиметр; COVID–19; поверка; международные стандарты.