НАУЧНО-ТЕХНИЧЕСКИЙ ЖУРНАЛ
SMART
90.03.03:
DOI 10.64513/Smart/2025.1.2
Теоретические вопросы измерений, оценки точности и нормирования метрологических характеристик, средств измерений и информационно-измерительных систем

ҚАЗАҚСТАН РЕСПУБЛИКАСЫНЫҢ ГРАВИМЕТРИЯ САЛАСЫНДАҒЫ МЕТРОЛОГИЯЛЫҚ ҚАМТАМАСЫЗ ЕТУ ТУРАЛЫ

АҢДАТПА

Аңдатпа: Бұл мақалада өкпені жасанды желдету құрылғыларының тексеру әдістері мен метрологиялық сипаттамалары қарастырылады. Біз верификация үшін өкпе моделінің MLP-1E үлгісін қарастырамыз, оның ішінде минималды көлемдік оттегі концентрациясын бағалау, өлшеудің белгісіздігін есептеу және тексеру процедурасын жүргізу тәртібі ҚР СТ 2.320-2015 «Желдендіргіштер. Тексеру әдісі», EN ISO 13485-2016 және EN ISO 9001-2015 стандарттары, 93/42/EEC - 2021 директивасы және EURAMET калибрлеу жөніндегі нұсқаулық № 3, 2.0 нұсқасы - 2024. Тыныс алу көлемі, тыныс алу қысымы сияқты сапа көрсеткіштері бағаланды және жабдықтың дәлдігі мен сенімділігіне әсер ететін ең жоғары қысым. Алынған нәтижелер жабдықтың қауіпсіздігін және нормативтік талаптарға сәйкестігін қамтамасыз ету үшін тұрақты метрологиялық мониторинг жүргізу қажеттілігін растайды.

Түйінді сөздер: Өкпені жасанды желдету құрылғысы, тексеру, өлшеу белгісіздігі, медициналық жабдық.

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КОНТРОЛЬ И ОЦЕНКА МЕТРОЛОГИЧЕСКИХ ХАРАКТЕРИСТИК АППАРАТА ИСКУССТВЕННЫХ ВЕНТИЛЯЦИИ ЛЕГКИХ

АННОТАЦИЯ

Аннотация: В данной статье рассматриваются методы проведения поверки и метрологические характеристики аппаратов искусственной вентиляции лёгких. Рассматривается прибор модель легких МЛП-1Э для проведения поверки, включая оценку минимальной объёмной концентрации кислорода, расчёт неопределённости измерений и порядок проведения процедуры поверки в соответствии с СТ РК 2.320-2015 «Аппараты ИВЛ. Методика поверки», стандартам EN ISO 13485-2016 и EN ISO 9001-2015, Директиве 93/42/ЕЭС – 2021 и Руководство по калибровке EURAMET № 3, версия 2.0 – 2024. Проведена оценка показателей качества, такие как объём дыхания, давление вдоха и пиковое давление, влияющие на точность и надёжность работы оборудования. Полученные результаты подтверждают необходимость регулярного метрологического контроля для обеспечения безопасности и соответствия оборудования нормативным требованиям.

Ключевые слова: Аппарат ИВЛ, поверка, неопределённость измерений, медицинское оборудование.

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MONITORING AND EVALUATION OF METROLOGICAL CHARACTERISTICS OF ARTIFICIAL LUNG VENTILATION APPARATUS

ANNOTATION

Abstract: This article discusses the verification methods and metrological characteristics of artificial lung ventilators. The article considers the MLP-1E lung model device for verification, including the assessment of the minimum volumetric oxygen concentration, the calculation of the measurement uncertainty and the verification procedure in accordance with ST RoK 2.320-2015 "Ventilators. Verification Methodology", EN ISO 13485-2016 and EN ISO 9001-2015 standards, Directive 93/42/EEC - 2021 and EURAMET Calibration Guide No. 3, version 2.0 - 2024. An assessment of quality indicators such as respiratory volume, inspiratory pressure and peak pressure, affecting the accuracy and reliability of the equipment, was carried out. The results obtained confirm the need for regular metrological control to ensure safety and compliance of the equipment with regulatory requirements.

Keywords: Mechanical ventilator, calibration, measurement uncertainty, medical equipment.

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INTRODUCTION.

Verification of ventilators is a procedure aimed at checking the metrological characteristics of the device to determine its compliance with established standards and technical requirements. This process includes measuring parameters such as the accuracy of tidal volume delivery, pressure control, oxygen concentration, respiratory rate and other indicators that directly affect the life and health of patients [1]. Regular verification is a mandatory requirement within the framework of legal regulation established by international standards EN ISO 13485:2016 and national laws such as ST RoK 2.320-2015 "Ventilators. Verification Methodology", ST RoK 2.4-2019 "Verification of Measurements of Means. Organization and Procedure for Carrying Out", the Law of the Republic of Kazakhstan "On the Uniformity of Measurements". It allows you to identify possible deviations in the operation of the equipment, preventing potential risks to patients. In addition, verification ensures compliance with operating rules and extends the service life of the device, maintaining its accuracy and reliability. In the context of the growing dependence of modern medicine on technologically complex equipment, including ventilators, the importance of metrological control is difficult to overestimate. This procedure not only guarantees compliance with established standards, but is also an important link in the chain of ensuring a high level of medical care.

This article examines the metrological characteristics of artificial lung ventilation (ALV) devices, as well as methods for their verification. The devices used, methods for assessing parameters, and the procedure for carrying out the procedure in accordance with ST RoK 2.320-2015 "Ventilators. Verification Methodology" are considered [2].

Among the medical devices used in intensive care units, artificial lung ventilation (ALV) devices occupy a special place. These devices play a critical role in supporting and restoring respiratory function in patients with acute and chronic respiratory diseases, including severe forms of respiratory failure. One of the most modern and high-tech solutions in this area is the Hamilton-S1 device, designed to provide effective and safe ventilation, regardless of the complexity of the patient's condition. The Hamilton-S1 ventilator complies with international standards and the requirements of ST RoK 2.320-2015 "Artificial lung ventilation devices. Verification methodology". Its production was carried out on the basis of a certified quality management system that complies with EN ISO 13485-2016 and EN ISO 9001-2015 standards, Directive 93/42/EEC - 2021 and EURAMET Calibration Guide No. 3, version 2.0 - 2024 [3].

MATERIALS AND METHODS

Metrological characteristics of medical equipment such as the Hamilton S1 ventilator (Figure 1,2).

1. Volume respiration (tidal volume, Vt):
- range: from 20 to 2000 ml;
- accuracy: ± 3% or ± 10 ml (whichever is greater).
2. Frequency respiration (respiratory rate, RR):
- range: from 2 to 100 breaths per minute;
- accuracy: ± 1 breath.
3. Inspiratory pressure:
- range: 0-60 cm H2O;
- accuracy: ± 1 cm water column.
4. Support pressure (PEEP - Positive End-Expiratory Pressure):
- range: from 0 to 30 cm H2O;
- accuracy: ± 1 cm H2O.
5. Peak pressure (peak inspirational pressure (PIP):
- range: from 0 to 80 cm H2O;
- accuracy: ± 1 cm H2O.
6. Gas-air circumference (flow):
- range: from 1 to 250 l/min;
- accuracy: ± 10% of the measured value.
7. Ventilation modes:
- controlled mechanical ventilation (CMV);
- automatic breathing support (ASB);
- intermittent ventilation with forced breaths (IMV);
- synchronized IMV (SIMV) [4].

Figure 1,2: Ventilator Hamilton S1

Hamilton S1 used the MLP-1E lung model. The MLP-1E is a mannequin simulating human lungs, which is designed to validate and verify artificial lung ventilation devices, breathing apparatuses and many other medical devices used to work with the respiratory system. There are features of MLP-1E model that can be useful while checking and verifying artificial lung ventilation devices:

Simulates the respiratory system - allows you to simulate different lung conditions, such as breathing with resistance, changing pressure and volume depending on the ventilator setting.

Adjustment parameters - parameters such as respiratory volume, respiratory rate, airway resistance can be adjusted, allowing you to fine-tune the ventilator for different clinical cases.

Use for calibration - using the MLP-1E model, it is possible to test and calibrate the pressure, volume and flow monitoring system in the ventilator, as well as check the accuracy of the device in various ventilation modes [5].

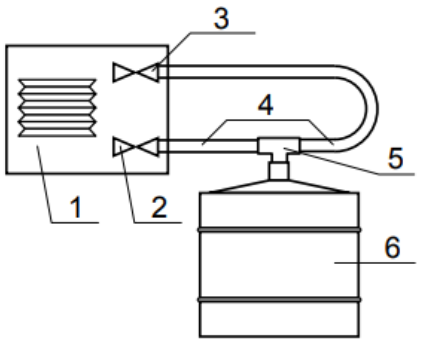
The principle of operation of the lung model: during the testing of the ventilator during the inhalation phase created by the ventilator or its simulator, air enters the lung model container. At the same time, the pressure in the container increases. After the end of the inhalation phase, air leaves the container, and the pressure in it decreases to the value of the end-expiratory pressure. The diagram of the inclusion of the lung model during testing of the ventilator is shown in Figure 3.

The volume meter automatically determines the beginning and end of the inhalation phase by the pressure in the container. Based on the pressure difference, the meter determines and displays the value of the respiratory volume, determined by the formula:

$$V = C\,(P_{max} - P_{min}),\ (1)$$

where C is the capacity extensibility, P_{max} is the maximum pressure, P_{min} is the minimum pressure.

The volume meter measures atmospheric pressure, temperature, the rate of air flow into the lung model container and makes the necessary correction of the measured volume depending on the value of the listed parameters [6].



1. Ventilator.
2. Ventilator exhalation valve.
3. Ventilator inhalation valve.
4. Connecting hoses.
5. Gas tee.
6. MLP-1E lung model.

Figure 3. Scheme of inclusion of the lung model during testing of the ventilator

Verification is carried out under the following conditions, where the ambient air temperature should be (20±5) ˚C, relative air humidity no more than 80%, atmospheric pressure from 84.0 to 106.7 kPa [7].

The minimum volume concentration of oxygen in the mixture is determined. The minimum volume concentration of oxygen in the mixture is determined at an oxygen flow rate of 1 l/min. To do this, the ventilator was turned on at maximum oxygen and nitrogen flow rates. Then the oxygen flow rate was smoothly changed to 1 l/min. At the same time, a decrease in the nitrogen supply valve was observed. In this case, the volume concentration of oxygen in the mixture should not be less than the minimum value specified in the operating manual, and the absolute error of the minimum volume concentration of oxygen in the mixture is calculated using the formula:

$$\Delta k = К_{avl} + К_a \quad (2)$$

where $К_{avl}$, $К_a$is the volume concentration of oxygen in the mixture, according to the readings of the ventilator, and the readings of the oxygen analyzer, respectively.

The absolute error of the minimum volumetric concentration of oxygen in the mixture is determined by the formula:

$$\Delta k = К_a + К'_a \quad (3)$$

where $К_a$is the volumetric concentration of oxygen in the nitrogen of the test gas mixture, $К'_a$, is the certified value of CO corresponding to the permissible value of the minimum concentration of oxygen in the mixture, %.

The relative error of the minimum volumetric concentration of oxygen in the mixture is calculated from the formulas, respectively:

$$\delta_k = \frac{K_{avl} - K_a}{K_a} \times 100\% \quad (4)$$

When verifying in accordance with the "Guide to the expression of uncertainty in measurement" ISO/IEC Guide 98-3:2008, the uncertainty of measurement is estimated and calculated [8].

The measurement result of a quantity must be given a quantitative characteristic of its quality so that the reliability of the obtained value can be assessed. Without this information, it is impossible to compare the results with each other or compare them with the values specified in technical specifications or standards. This requires the use of a simple, generally accepted and understandable procedure for assessing and expressing the quality of measurements, namely their uncertainty. Uncertainty as a quantitative measure of quality is a relatively new concept in metrology, even though the notions of error and error analysis have been employed for a long time. It is now recognized that even after taking into account all identified systematic errors and making appropriate corrections to the measurement result, there remains an uncertainty reflecting the degree of doubt in the accuracy of the obtained value. The uncertainty of the measurement result shows the lack of complete knowledge of the true value of the measured quantity. Even after correction for systematic effects, the measurement result remains only an estimate, since it retains uncertainties due to random factors and the limited accuracy of the corrections made [9].

RESULTS.

Table 1 presents the calculated data for estimating the measurement error of the minimum concentration volume, including the initial parameters, calculated dimensions and absolute error.

As a result of the verification of the devices, the error value of the minimum volume of the gas mixture was determined to be ±1.7%. The obtained indicator is within the permissible error value of the minimum volume concentration of anesthetics in the mixture, specified in the technical documentation of the manufacturer.

The uncertainty budget, which is shown in Table 2, is a structured analysis of all factors that contribute to the final uncertainty of measurement results. It is a tool for assessing the accuracy of measurements that helps identify and quantify the contribution of each component to the overall uncertainty. It allows for the precise identification of the main sources of uncertainty and their impact on the result, which is critical for making decisions on the accuracy and reliability of measurements, as well as for improving quality control procedures [10].

The total standard uncertainty is determined by the formula:

$$u_c(\Delta P) = \sqrt{u_A^2(P) + u_B^2(\Pi_d) + u_B^2(\Pi\Delta P_э) + u_B^2(\Pi d_э)} = \sqrt{0{,}2^2 + 0{,}289^2 + 0{,}289^2 + 0{,}00289^2} = 0.4559 \text{ mm Hg}, \quad (5)$$

The final value of the expanded uncertainty is calculated using the formula:

$$U_P = 2u_c(\Delta\tau) = 2\times 0,4559 = 0.9 \text{ mm Hg} \quad (6)$$

The uncertainty calculation results confirmed that even when taking into account all the identified systematic errors, there remains a residual uncertainty due to random effects and limited accuracy of adjustments. The obtained values of expanded uncertainty are within the permissible standards, which guarantees the reliability and accuracy of the ventilator [11].

Table 1. Calculation table for determining the error of the minimum concentration volume

Set point of range	Measured values by the device, mm Hg					Average reading, mmHg	Absolute error (no more than ±3)	Extended uncertainty, mmHg
300	300	301	300	300	300	300.2	0.20	0.9
250	250	250	251	250	250	250.2	0.20	0.9
200	200	200	200	200	200	200,0	0	0.8
150	149	149	149	149	149	149.0	-1.00	0.8
100	99	99	99	99	99	99	-1.00	0.8
20	20	20	20	20	20	20.0	0,00	0.8

Table 2. Uncertainty budget

Input value, x_i	The value of the input quantity, X_i	Unit of measurement	Distribution probabilities	Type of uncertainty	Standard uncertainty, u (x_i)	Sensitivity coefficient, with $_i$	Contribution of uncertainty, u (y_i) = c_i u (x_i)
$\bar{P}$	$\bar{P}$	mmHg	normal	A	$u_A(\bar{P}) = \sqrt{\frac{\sum_{i=1}^{n}(P_i - P)^2}{n(n-1)}}$	1	$u_A(\bar{P})$=0.2
$P_э$	$P_э$	mmHg	-	-	-	-	–
Πd	0	mmHg	rectangular	IN	$u_B(\Pi d) = \frac{d}{2\sqrt{3}}$	1	$u_B(\Pi d)$= 0 , 289
$\Pi\Delta P_э$	0	mmHg	rectangular	IN	$u_B(\Pi\Delta P_э) = \frac{\Delta P_э}{\sqrt{3}}$	-1	- $u_B(\Pi\Delta P_э)$= 0 , 289
$\Pi d_э$	0	mmHg	rectangular	IN	$u_B(\Pi d_э) = \frac{d_э}{2\sqrt{3}}$	-1	$-u_B(\Pi d_э)$= 0 , 0289
ΔP	$\bar{P} - P_э$	mmHg	-	$u_c(\Delta P) = \sqrt{u_A^2(\bar{P}) + u_B^2(\Pi d) + u_B^2(\Pi\Delta P_э) + u_B^2(\Pi d_э)}$			

DISCUSSION

Metrological control of artificial lung ventilation (ALV) devices plays a key role in ensuring the safety of medical equipment and the effectiveness of treatment. The studies conducted in the article confirm the importance of regular verification, which allows identifying deviations in the operation of equipment, minimizing risks to patients and increasing the accuracy of diagnosis and therapy. The parameters considered, such as respiratory volume, inspiratory pressure, oxygen concentration, are critical for ensuring the reliability of ALV in real clinical conditions.

Calibrating ventilators is crucial to ensure these medical devices provide accurate and dependable respiratory support to patients. Proper calibration helps maintain patient safety and ensures the ventilator operates as intended. Proper calibration and maintenance of ventilators are essential for patient care, particularly in critical care environments. Adhering to manufacturer guidelines and maintaining a strict calibration schedule ensures the ventilator operates reliably and accurately. Data from Asia Hospital, Patna, collected between January and July 2023, reveals that out of 23 ventilators, a notable pass rate was achieved following successful calibration and maintenance (Figure 4).

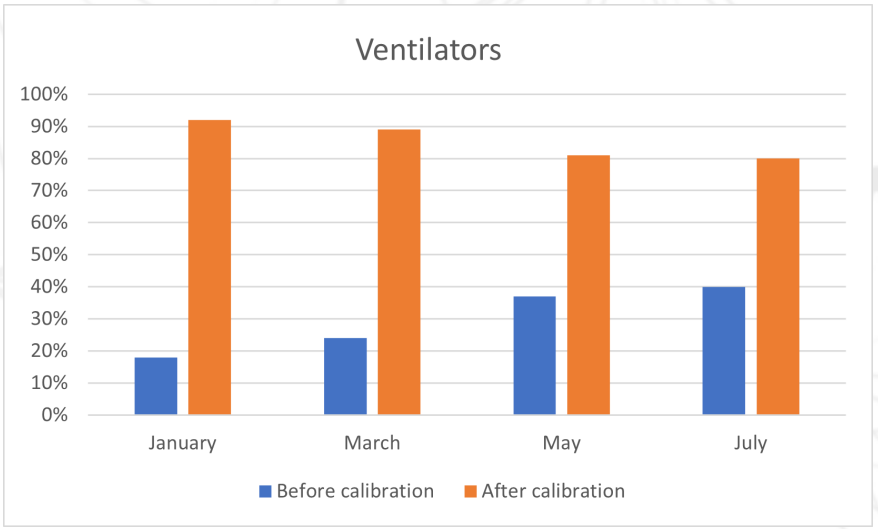


Figure 4. Graph of pass percentage before and after calibration of ventilators.

The article pays special attention to the MLP-1E lung model, which has demonstrated high efficiency in simulating various clinical conditions. The use of this device allows for the most accurate assessment of the performance of ventilators by simulating their functioning in conditions close to real ones. The article describes in detail the measurement methods, including the calculation of errors and uncertainties. This approach complies with international standards ISO/IEC Guide 98-3:2008, which emphasizes the high accuracy and reproducibility of the results. The data obtained indicate that ventilators tested using the proposed methodology comply with regulatory requirements and are suitable for safe use in clinical practice. This is especially important in conditions of high load on medical institutions, for example, during pandemics, when the quality and reliability of equipment can directly affect the lives of patients [12].

Verification of artificial lung ventilation (ALV) devices is directly related to the achievement of the UN Sustainable Development Goal SDG 3, aimed at ensuring healthy lives and promoting well-being for all at all ages. The reliability and accuracy of medical equipment play a key role in providing quality medical care, especially in intensive care units, where the condition of patients is critical. Regular verification of ventilators helps improve the quality of diagnosis and treatment, minimize risks to patients' health and prevent errors associated with incorrect operation of equipment. These aspects are fully consistent with the UN SDG Goal 3, which provides for access to quality health care and safe medicines. In addition, metrological verification of ventilators helps strengthen health systems, which is especially important in the context of pandemics and other global challenges that require a high degree of preparedness from health care facilities and the use of reliable equipment.

An important conclusion of the article is the confirmation of the need for further improvement of verification methods and development of the regulatory framework. Modern challenges associated with the introduction of high-tech equipment require adaptation of existing methods of metrological control. The results presented in the work are a contribution to the development of metrology of medical equipment and improving the quality of medical services.

CONCLUSION

Artificial lung ventilators (ALV) are a critical element of medical equipment used in intensive care and resuscitation departments. Their reliability and accuracy directly affect the health and lives of patients, which makes metrological control and verification an integral part of the operation of such devices. The verification was carried out using the MLP-1E lung model, which made it possible to simulate the real operating conditions of the equipment and ensure an accurate assessment of its characteristics. Particular importance was attached to measuring the minimum volume of oxygen concentration in the gas mixture and analyzing the associated errors in accordance with the requirements of ST RoK 2.320-2015. As part of the work, the error and uncertainty of measurements were calculated, which complies with modern international requirements, such as ISO / IEC Guide 98-3: 2008 and EURAMET Calibration Guide No. 3 Version 2.0. The uncertainty budget calculation presented in the work made it possible to identify the main sources of errors and their impact on the final measurement result. The resulting uncertainty values confirmed the equipment's compliance with the established regulatory requirements and its suitability for use in clinical practice. The data obtained showed that the residual uncertainty remains within the permissible values, which guarantees high accuracy of the ventilators.

The study also emphasized the importance of regular metrological control to maintain the reliability of medical equipment and minimize risks to patients. The results confirm the need to implement modern methods for monitoring the technical characteristics of ventilators to ensure a high level of quality of medical care. Thus, the work done demonstrates the effectiveness of using the lung model and approaches to calculating uncertainty for metrological verification of ventilators. It contributes to improving the control processes of medical equipment, which is especially important in the context of growing requirements for the safety and accuracy of medical technologies.

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