Creation of a System for Providing Metrological Control of Output Parameters of Ultrasound Medical Equipment

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Abstract

A project of creating a system of metrological control of the initial parameters of ultrasound medical equipment, the introduction of which will improve the control of ultrasound medical equipment and ensure the safety of medical and diagnostic care to the population is considered in this paper. Ultrasound in modern medicine is one of the basic methods for diagnosing many diseases, which are successfully used to detect developmental abnormalities and various pathologies. High diagnostic efficiency during its reduction can be achieved only by using serviceable and calibrated equipment. The introduction of a comprehensive system for monitoring the output parameters of ultrasound medical equipment will improve the control of ultrasound medical equipment, which is widely used in health care facilities, prevent the use of defective or uncredited equipment, and ensure the safety of medical services for diagnosis and treatment. The proposed system should provide a clear interpretation of measurement results, identify the main errors and uncertainties of measurement and ensure traceability of measurements to national standards.

Keywords 1

Calibration, error, traceability of measurement results, ultrasonic medical equipment, ultrasonic power, ultrasonic pressure.

1. Introduction

In recent decades, there has been a steady trend in the world to expand the scope of ultrasonic measurements in the sectors of the economy. They have made special progress in medicine, where the use of ultrasound in the development of diagnostic, surgical and therapeutic systems is rapidly being introduced. In general, ultrasound medical equipment can be classified according to the methods of clinical application (diagnosis, therapy, surgery, cosmetology) and the types of ultrasound fields that they generate. The acoustic output of such medical equipment is characterized by the following acoustic parameters: ultrasonic power, ultrasonic pressure, intensity of ultrasonic radiation, frequency of radiation, mechanical and thermal indices [1].

To ensure the unity of measurements, a clear identity of units is required, in which all means of technical measurements of the same physical quantity would be graduated. This is achieved by accurately reproducing and preserving the units of physical quantities adopted at the International Conference on Measures and Weights and transmitting their dimensions to measuring instruments.

Reproduction, storage and transmission of unit sizes is carried out using standards and sample measuring instruments. The highest link in the metrological circle of transmission of the sizes of units of measurement of physical quantities are standards. Given the extreme importance of the reference base for the national economy, the Government of Ukraine approved the State Program for the Development of the Reference Base for 2006–2010[2].

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Within the framework of this program it was necessary to create 29 and improve 24 state primary standards, 21 secondary standards were created and 5 were improved to ensure uniformity of measurement in the state [3]. In particular, the creation of a standard unit of ultrasound power was included in the State program for the development of the reference base for 2006-2010 to ensure the unity and accuracy of measurements in the field of megahertz (medical) ultrasound in the aquatic environment.

The short wavelength determines the radial nature of the propagation of ultrasonic waves, and near the emitter, the transverse size of the beam is approximately equal to the size of the emitter. On large obstacles (or inhomogeneities) the reflection and refraction of the ultrasonic beam is regular, on small – there is a scattered wave, which allows you to form in optically opaque media sound image of objects. Shortwave ultrasound is also associated with the ability to focus the ultrasound beam and concentrate sound energy at a given point in the medium.

Intense interaction of ultrasound with substances, significant absorption of ultrasound by the medium, its interaction with light, the occurrence of acoustic currents, radiation force when interacting with an obstacle, dispersion of the speed of sound in the environment, cavitation, etc. are also associated with short wavelength ultrasound [4].

An indispensable condition for the effective use of ultrasound in all these cases is accurate measurements of its characteristics and reliable control of the initial acoustic parameters of the equipment. In medicine, for example, if the level of ultrasound is insufficient, the therapeutic effect is not achieved, and a reliable diagnosis cannot be made. At the same inflated level of ultrasound, living tissues of the human body are destroyed due to heating and / or cavitation, which is dangerous for both patients and nurses [5].

That is, the safe and efficient use of ultrasound requires sufficient accuracy and reliability of measurement results, which would be traced to the standards of the SI system of units and would be recognized internationally. Until recently, Ukraine did not have a system of metrological support for measuring acoustic quantities in the megahertz frequency range as such: there were no standards and a scheme of metrological verification (verification scheme) to ensure traceability. Methods and means of metrological support developed in hydroacoustics for sound and infrasonic frequencies cannot be used in the range of megahertz ultrasound due to its specific features.

This Program was designed to promote the development and implementation of new precision measuring equipment, as well as improving the quality of products, works and services; conducting research projects relevant to the economy, creating the latest technologies; as well as: creating conditions for the implementation of the Agreement on the Elimination of Technical Barriers to Trade, in order to sign the Agreement on Conformity Assessment and Acceptance of Industrial Goods and Access of Domestic Products to the International, in particular European, Market; increasing the level of ensuring the uniformity of measurements during production and conformity assessment of products; conducting scientific research in compliance with the requirements of the Law of Ukraine "On Metrology and Metrological Activities", harmonization of technical regulations and other regulations in the field of metrology and metrological activities; introduction of modern methods of measurement and means of measuring equipment in the process of development of perspective technologies; bringing the capabilities of the reference base and the system of transmission of the size of units of measurement in line with the needs of the economy, strengthening control over the state of health and safety of working conditions.

As part of this program, it was necessary to create 14 new and improve 17 existing state primary standards, to ensure the accuracy, unity and traceability of measurements in the state.

It should be noted that the creation of a primary standard of the unit of ultrasound power in the aquatic environment and a primary standard of the unit of ultrasonic pressure in the aquatic environment was included in this program to ensure accuracy and uniformity of measurements in the field of megahertz (medical) ultrasound in the aquatic environment. Subsequently, this program was changed and a new program for the period 2018-2022 was formed.

Emitted ultrasonic power and ultrasonic pressure are one of the main initial parameters of ultrasonic equipment. Regarding the ultrasonic power, the small wavelength determines the radial nature of the propagation of ultrasonic waves, and near the emitter, the transverse size of the beam is approximately equal to the size of the emitter. On large obstacles (or inhomogeneities of the propagation medium) the reflection and refraction of the ultrasonic beam is regular, on small ones -

there is a scattered wave, which allows to form a sound image of objects in optically opaque media. Shortwave ultrasound is also associated with the ability to focus the ultrasound beam and concentrate sound energy at a given point in the medium.

Intense interaction of ultrasound with substances, significant absorption of ultrasound by the medium, its interaction with light, the occurrence of acoustic currents, radiation force when interacting with an obstacle, dispersion of the speed of sound in the environment, cavitation, etc. are also associated with short ultrasound wavelengths.

An indispensable condition for the effective use of ultrasound in all these cases is accurate measurements of its characteristics and reliable control of the initial acoustic parameters of the equipment, which would be traced to the standards of the SI unit and would be recognized internationally.

Until recently, Ukraine did not have a system of metrological support for measuring acoustic quantities in the megahertz frequency range, as such: there were no standards and schemes of metrological verification (traceability schemes) to ensure traceability. Methods and means of metrological support developed in hydroacoustics for sound and infrasonic frequencies cannot be used in the range of megahertz ultrasound due to its specific features.

Ultrasound power and ultrasonic pressure are parameters that need to be monitored, as they determine the safety of using ultrasound equipment for both the patient and the medical staff.

2. Main part of research

It should be noted that in the field of ultrasound measurement, in particular the megahertz range, which is most widely used in medicine, excessive power or intensity of radiation can damage organs and tissues of the body due to excessive heating, and thus endanger the health of the patient. In case of insufficient power or intensity of radiation, there is a possibility of incorrect diagnosis on diagnostic equipment, or failure to achieve a therapeutic effect on therapeutic equipment. For surgical equipment, control of ultrasonic power and pressure is necessary to determine the duration of action of ultrasound in order to determine the required dose of radiation. Research of initial parameters Ultrasonic medical equipment is carried out by manufacturers of such equipment as requirements to them are described in a number of the international standards concerning safety of use. In particular, the standards of the series IEC 60601-2-5 [6], IEC 60601-2-37 [7], IEC 61157 [8] and IEC 61689 [9] establish requirements and limits of error for measuring the initial parameters of ultrasonic medical equipment.

Since the protection of life and health of citizens belongs to the field of legally regulated metrology (Law of Ukraine on "Metrology and Metrological Activities"), periodic monitoring of ultrasound medical equipment is essential.

Therefore, in our opinion, in Ukraine it is necessary to create a system of control of initial parameters Ultrasonic medical equipment, which should provide a clear interpretation of measurement results, determine the main errors and uncertainties of measurement and ensure traceability of measurements to national standards. Such a control system should include:

- national standards,
- working standards of transmission of units and means of measuring equipment,
- test objects,
- verification and calibration methods,
- national safety standards for the use of ultrasonic medical equipment.

To create a comprehensive system, there was a project proposal, which was supported and state enterprise research institute "System" (Lviv) was instructed to implement the task. To implement them, a project was developed to create a system of metrological control of ultrasonic medical equipment.

In developing the project relied on the standard PMBOK – a Guide to the Project Management Body of Knowledge (Project Management Guide, then just PMBOK) 10 areas of knowledge which define: project life cycle, group of processes, methods, external and internal organizational factors that have impact on project success and are used in project design and management. Forming sub-stages of project implementation used the recommendations formed in the section Project Content

Management, understanding content management - a set of processes that allow sampling, filtering and grouping of those works that are necessary for the project manager to successfully complete. Project content management is directly related to defining and controlling what will be included in the project.

To implement the project to create a system of metrological control Ultrasonic medical equipment, you must perform the steps listed in the Table. 1.

Table 1.

Stages of project implementation to create a system of metrological support of ultrasonic medical equipment

№	The name of the stage
1	Stage 1. Analysis of the current state of metrological support for measuring the initial parameters of ultrasonic medical equipment
1.1	analysis of modern fleet of ultrasonic medical equipment and control and measuring equipment
1.2	analysis of the state of the national regulatory framework to ensure the accuracy and reliability of the results of measuring ultrasonic parameters
2	Stage 2. Calculation of economic indicators and social effect from the project implementation to create a system of metrological control of the initial parameters of ultrasonic medical equipment
2.1	calculation of economic indicators on the effectiveness of the application of working standards and precision measuring equipment
2.2	calculation of the social effect
3	Stage 3. Development of proposals for the creation of a comprehensive system of metrological control of the initial parameters of ultrasonic medical equipment

The first stage of the study – initiation is seen as a process of formal approval of a new project or the transition to its next phase. Project initiation is usually preceded by an initiation phase, in which a feasibility analysis, cost-effectiveness assessment, pre-planning or other similar analysis is performed, initiated independently of the project.

This stage is called "Analysis of the current state of metrological support for measuring the initial parameters of ultrasound medical equipment" is divided into two sub-stages, each of which involved a number of preparatory processes typical of the first stage of IT projects.

At the first sub-stage of the first stage of the project, an analysis of the modern fleet of ultrasonic medical equipment and control and measuring equipment was conducted, which showed that today in Ukraine there is a large fleet of ultrasound equipment, and mainly imported devices, namely:

- ultrasonic echo-pulse scanners;
- diagnostic ultrasound devices for diagnostics of abdominal organs and cardiovascular system;
- ultrasonic scanners with spectral Doppler;
- obstetric fetal monitors;
- sinuscopes for the maxillofacial part;
- therapeutic ultrasound devices;
- surgical ultrasonic lithotriptors and others.

According to the resolution of the Cabinet of Ministers of Ukraine № 347 of June 4, 2015 on "Approval of the list of categories of legally regulated measuring instruments subject to periodic verification" and the order of the Ministry of Economic Development and Trade of Ukraine № 1719 of 21.12. 2015 on "Approval of time required for calibration of legally regulated measuring equipment in operation", the updated editions of documents included only ultrasonic diagnostic devices, in particular: echo-ophthalmoscopes and ultrasonic ophthalmic scanners, ultrasonic Doppler diagnostic and.

Moreover, the devices of ultrasound therapy and means of measuring the parameters of the power of ultrasonic radiation, which were previously in the list of means subject to periodic verification, were removed.

Regarding traceability of ultrasonic measurement results: today two national standards have been developed and are functioning in Ukraine: the National Standard of Unit of Ultrasound Power in Aquatic Environment [10] and the National Standard of Unit of Sound Pressure in Aquatic Environment [11], which are stored in a state enterprise research institute "System" (Lviv).

It is known that the national standard of the unit of ultrasound power in the aquatic environment is designed to reproduce, store the unit of ultrasonic power in the aquatic environment – Watts (W) and transmit the unit size (during calibration) to working standards, precision measuring instruments and ultrasonic equipment, which are used in the sectors of the economy and in the social sphere in order to ensure the unity of measurement in the country and the traceability of measurement results to the standards of the system of SI units.

The standard consists of a set of the following measuring instruments:

- a set of tools for generating and measuring electrical signals;
- set of reference ultrasonic transducers;
- ultrasonic unit;
- data processing unit;
- control and measuring devices and auxiliary equipment.

The range of values of ultrasound power in the aqueous medium, reproduced by the standard, is from 0.005 W to 10 W in the frequency range from 0.5 MHz to 15 MHz.

The standard provides reproduction and storage of a unit of ultrasound power with an uncertainty not exceeding:

- standard uncertainty for type A: uA = 0.7%;
- standard uncertainty for type B: uB = 5.3%;
- total standard uncertainty: us = 5.4%;
- extended uncertainty U = 10.7% (with coverage factor k = 2 with a confidence level of P = 0.95) depending on power and frequency.

The standard is used to calibrate and transmit the size of a unit of ultrasound power in an aqueous medium by direct measurement.

The national standard of the ultrasonic pressure unit in the aquatic environment is designed to reproduce, store the ultrasonic pressure unit – Pascal (Pa) and transfer the unit size to working standards and working means of measuring pressure used in the country to ensure uniformity of measurement and traceability of measurement results to SI system standards.

The standard consists of a set of the following measuring instruments:

- a set of measuring equipment;
- a set of auxiliary ultrasonic transducers;
- set of measuring hydrophones;
- coordinate-rotary device for positioning hydrophones and measuring capacity;
- water treatment system;
- control and measuring devices and auxiliary equipment.

The standard provides reproduction and storage of the unit of ultrasonic pressure in the frequency range from 0.5 MHz to 10 MHz within the levels of ultrasonic pressure from 10 kPa to 100 kPa.

The standard provides reproduction and storage of a unit of ultrasonic pressure with an uncertainty not exceeding:

- standard uncertainty for type A: uA = 5.8%;
- standard uncertainty for type B: uB = 6.6%;
- total standard uncertainty: us = 8.8%;
- extended uncertainty U = 18.0% (with the coverage factor k = 2 with a confidence level of P = 0.95).

The standard is used to calibrate and transmit the unit size of ultrasonic pressure in an aqueous medium by direct measurement.

Calibration laboratories of Ukraine are equipped with a number of precision measuring equipment, including ultrasonic power meters such as: UPM-DT (made in the USA), IMU-Quantum (domestic production), IMA-2, IMU-3 and IMUTAP (Russian Federation production), a number of acoustic ultrasonic phantoms (measures of acoustic length) such as phantom "549", Gammex 1430 LE and MAD-05; measures of blood flow velocity type MBV-03 and measures of frequency of heart rate type MFHH-02.

However, this equipment only calibrates the geometric dimensions of objects, but at the same time does not control such parameters of the devices as: ultrasonic pressure and ultrasound intensity, the measurement of which determines the safety characteristics of the output acoustic parameters of ultrasonic medical equipment.

Regarding measurements of ultrasonic pressure and intensity Ultrasonic medical equipment, such equipment is available only at the National Metrological Institute, state enterprise research institute "System" – a set of interchangeable needle hydrophones with a pre-amplifier and a spatial scanning system.

In the second sub-stage of the first stage, work was carried out to analyze the state of the national regulatory framework to ensure the accuracy and reliability of the results of measuring ultrasonic parameters.

One of the main regulatory problems of metrological support and standardization of ultrasonic measurements in Ukraine is the outdated, inherited from the Soviet Union, regulatory and regulatory framework of the 70–90s of last century, which does not meet modern requirements.

In particular, there is a lack of quality standards, many methods of measurement and verification of the former USSR in accordance with the laws of Ukraine have become invalid, and since there were no Ukrainian analogues of these methods, their use is virtually illegal.

An analysis of recent publications has shown that in Ukraine since independence there have been no harmonized methods of measurement, calibration or calibration, no requirements for ultrasound medical equipment, taking into account the requirements of international standards.

In order to bring the regulatory framework of ultrasound measurements in Ukraine in line with the European one, the harmonization of domestic standards with international ones and the development of own methods is extremely important.

Thus, in July 2020, verification methods (in the range of national standards) came into force in Ukraine, in particular: calibration of ophthalmic ultrasound devices [12], fetal monitors [13] and diagnostic Doppler devices [14]. However, the latter does not include a control point for ultrasonic pressure and radiation intensity.

At the initiative of state enterprise research institute "System", international standards in the field of measuring ultrasonic radiation parameters came into force. Ultrasonic medical equipment [15 – 21], which relate to diagnostic, therapeutic and surgical ultrasound equipment.

However, the standards are accepted only by the method of confirmation, which means that they are available only in the original language.

In order to be able to fully apply them, it is necessary to translate and officially adopt them in accordance with the Law of Ukraine on Standardization.

3. Substantiation of expediency of creation of system of metrological control

The created system will ensure compliance with the requirements of the Law of Ukraine on Metrology and Metrology and Technical Regulations "On Medical Devices", and will give impetus to increase the number of calibration and calibration laboratories, organizations for repair and maintenance of medical ultrasound equipment.

Let's consider how the economic component of this project will work on the example of calibration of ultrasonic diagnostic devices.

As a basis we will take the data used at creation of national ultrasonic standards [22]. The number of ultrasound diagnostic tests and ultrasound diagnostic devices used in medical institutions and the need for their verification are shown in the Table 2.

Table 2.

Quantitative characteristics of the use of ultrasonic diagnostic devices

№	Territorial unit	Number of Ultrasound diagnostic tests	Devices of Ultrasound tests		Number of Ultrasound diagnostic tests per 1 device
			Available	Attorneys	
1	Vinnytsia	1 164 022	201	170	6 847
2	Volyn	825 203	153	129	6 397
3	Dniprovsk	2 317 415	515	448	5 173
4	Donetsk	796 363	183	160	4 977
5	Zhytomyr	867 634	218	190	4 566
6	Transcarpathian	903 742	169	148	6 106
7	Zaporozhye	734 508	214	190	3 866
8	Ivano-Frankivsk	1 398 112	206	181	7 724
9	Kyiv	1 023 928	256	231	4 433
10	Kirovograd	784 569	154	121	6 484
11	Luhansk	286 468	92	75	3 820
12	Lviv	1 964 981	332	306	6 422
13	Mykolayiv	829 782	118	108	7 683
14	Odessa	1 758 759	319	299	5 882
15	Poltava	980 791	202	172	5 702
16	Rivne	1 319 523	153	143	9 227
17	Sumy	677 426	167	149	4 546
18	Ternopil	742 909	117	109	6 816
19	Kharkiv	2 688 851	516	465	5 782
20	Kherson	1 182 221	132	114	10 370
21	Khmelnytsky	671 598	193	160	4 197
22	Cherkasy	1 019 363	156	142	7 179
23	Chernivtsi	1 016 417	131	118	8 614
24	Chernihiv	674 234	137	119	5 666
25	Kyiv	3 506 251	951	856	4 096
In general		30 135 070	5985	5 303	5 683

In the second stage of the study, the content was determined, with the main results of the project divided into smaller, more manageable components to form a basic project plan. At the same time, the global goal of the project was decomposed into several components, the structure of the project work was formed, the list of project works was determined, their duration was determined, restrictions were established, links were established, resources were fixed and the basic project plan was fixed. The process of determining the content is aimed at: improving the accuracy of cost estimates, duration of work and required resources, development of a basic plan as a basis for measuring the implementation and management of the project.

As part of the first sub-stage of the second stage of the project, the calculation of economic indicators on the effectiveness of working standards and precision measuring equipment. The price of one calibration of the Ultrasonic diagnostic device makes from 3 650 UAH (including VAT). The estimated number of calibrations on working standards and precision measuring equipment per year is 5,303 calibrations. Determine the estimated annual gross income (income from sales) calibrations:

3 650x5 303=19 355 950 UAH

According to Order № 1719 of 21.12.2015 of the Ministry of Economic Development, the standard time for calibration of one ultrasound diagnostic device is 16.7 hours, the norms of working hours for 2020 under the condition of a forty-hour five-day working week are 2002 hours [23]

5 303x16,7/2 002= 44,2 units

That is, 45 units of precision ultrasonic measuring instruments and / or working standards must be involved in the maintenance of the diagnostic equipment fleet. Calibration of this equipment requires the presence of national standards or their calibration must be carried out abroad. Given the situation with customs clearance and prices for metrological services abroad, the cost of calibration abroad will be much higher than in Ukraine.

The calculation of economic indicators on the effectiveness of the use of national standards in the implementation of the first sub-stage of the second stage of the project, showed that the number of required calibrations of measuring instruments on national standards is 45 units. The estimated cost of calibration of one precision tool is UAH 5,560 UAH (including VAT).

Determine the annual gross income (income from sales) calibrations on the primary standards.

5 560×45=250 200 UAH

4. Calculation of the social effect (substage two of stage two)

Ultrasound in modern medicine is one of the basic methods for diagnosing many diseases[24], which are successfully used to detect developmental abnormalities and various pathologies. High diagnostic efficiency during its reduction can be achieved only by using serviceable and calibrated equipment. Unfortunately, the results of metrological supervision indicate that medical institutions of the Ministry of Health of Ukraine do not comply with metrological norms and rules of application of Ultrasound medical equipment. And, as a result, the results of research obtained on non-attested Ultrasound medical equipment may be incorrect and lead to misdiagnosis and misdiagnosis.

According to the data given in [22], in the period of 2016, 30,135,070 ultrasound examinations were performed on 5,303 ultrasound diagnostic devices. Based on the calculations above, the results of the Ultrasound examinations could be inaccurate in 3,616,209 cases (provided that 12% of the Ultrasound diagnostic devices were probably not certified) and dangerous for patients and medical staff. It should be borne in mind that the inaccuracy of the results of ultrasound examinations leads to an increase in the length of stay of patients in treatment. Based on the above considerations, it is possible to determine the social effect [25–30] of the implementation of verifications, including security parameters, which will reduce the cost of the hospital payment fund.

In addition, new jobs will be created in calibration and calibration laboratories, which will provide employment for up to 30 people, the social effect of creating one job in this industry is 15 000 UAH, respectively, for 30 people it will be 450, 0 thousand UAH per month.

Therefore, in order to implement the project on introduction of the system of metrological control of initial parameters of ultrasonic medical equipment it is necessary, within the framework of the third stage of the project the following is offered:

- submit proposals to the Ministry of Economy and the Ministry of Health regarding organizational and administrative documents on control of parameters of ultrasonic medical equipment;
- to harmonize a number of European standards in the field of ultrasound measurements and safety of ultrasound in medicine;
- to create measuring devices for spatial scanning of ultrasonic fields, which will allow to measure the level of ultrasonic pressure radiation and its intensity, to equip calibration and calibration laboratories with them[31–35];
- to equip calibration and calibration laboratories with test objects and other standard samples for imitation of human tissues and organs with the use of artificial intelligence technologies;
- to develop methods of calibration of the created working standards and test objects;
- review and update existing verification methods.

5. Conclusions

The introduction of a comprehensive system for monitoring the output parameters of ultrasound medical equipment will improve the control of ultrasound medical equipment, which is widely used in health care facilities, prevent the use of defective or uncredited equipment, and ensure the safety of medical services for diagnosis and treatment.

The proposed system should provide a clear interpretation of measurement results, identify the main errors and uncertainties of measurement and ensure traceability of measurements to national standards.

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