



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Bureau
International des
Poids et
Mesures



Ultrasound methods for clinical and healthcare diagnostics

A Russian primary standard for ultrasound power, intensity, and pressure was developed to ensure reliable and metrologically traceable measurements of medical ultrasound equipment

*Russian Metrological Institute of Technical Physics and Radio Engineering
Russia (RU)*



The Challenge

The rapid development of ultrasound methods as diagnostic tools and non-invasive treatments has made it challenging for metrological institutes to establish a metrological basis for their accurate and reliable calibration in healthcare applications. Modern ultrasound diagnostic equipment has become more complex and specific due to the use of complex modulated ultrasonic signals with frequencies beyond the capabilities of existing measuring instruments.

Previously, the Russian Federation has lacked the ability to conduct safety testing of medical ultrasound equipment. Any registration with regulatory authorities has only been achieved based on test results conducted in foreign laboratories. There have been relatively few approved types of measuring instruments used in Russia to verify these medical devices. To monitor the imaging parameters of ultrasound diagnostic devices, acoustic length measures (phantoms) are used. However, their characteristics (i.e., the speed of sound and attenuation) were not subject to periodic monitoring. Systems that use hydrophones to measure various characteristics of ultrasound fields have not undergone official metrological verification but are instead certified as testing equipment specifically for assessing the performance of medical devices.

Furthermore, no single medical ultrasound device has been classified as an "approved type" of measuring instrument. This current situation reflects the lack of standards and accuracy-based regulatory control for such measuring instruments. Repeated acoustic power testing during repair or maintenance of such equipment has not been conducted and creates a potential risk of harm to patients.

The Solution

In 2019, the State Primary Standard for the Unit of Ultrasound Power in Water was developed and approved, fully meeting the metrological support needs of medical ultrasound equipment in terms of output power. In 2025, the Russian Primary Standard for Ultrasound Power, Intensity, and Pressure in Water was developed and implemented, providing a comprehensive solution to the problem of metrological support for medical ultrasound equipment. The newly developed standard represents the top tier in the metrological traceability chain for acoustic output parameters of ultrasound medical devices. Current efforts are now focused on building a suite of measurement tools to ensure high-quality measurements of ultrasound equipment that will inform performance and quality control specifications.

A Quantifiable Impact

Improving the accuracy of the developed standard enabled us to develop more accurate methods for measuring the power and intensity of ultrasound in water. More than 170 new ultrasound power meters have been put into circulation, providing metrological control of ultrasound therapeutic equipment. As a result, 37 types of medical ultrasound equipment were tested for compliance with safety requirements according to the IEC 60601-2-5:2009 and IEC 60601-2-37:2024 standards, which enabled their registration with Roszdravnadzor¹ for use as medical devices. The tests included ultrasound therapy devices compliant with GOST R 70479,² shock-wave therapy devices, portable ultrasound diagnostic devices, fetal monitors, and ultrasound gels. The acoustic properties of the gels were tested, as they had to be registered as medical devices.

Initial measurements revealed that most devices failed to meet their stated specifications and were returned to the manufacturer for modification and their characteristics were subsequently re-tested. It is difficult to determine exactly how many are currently in circulation, however it is estimated that the total could potentially reach tens of thousands of units. These initial efforts have identified deficiencies in medical equipment that could have caused harm to health or led to improper use (diagnosis or treatment of diseases). This metrological intervention has demonstrated that these deficiencies can be subsequently corrected by the manufacturer before mass production of devices commences.

POCs: Georgy S. Lukin, lukin@vniifttri.ru; Sergey I. Kuznetsov, sergantex@vniifttri.ru

¹ Roszdravnadzor (Russian Federal Service for Surveillance in Healthcare).
<https://roszdravnadzor.gov.ru/en>

² GOST R 70479-2022. Apparatus for ultrasonic therapeutics. General specifications