MEDICAL AND BIOLOGICAL MEASUREMENTS

Laser medicine, born at the juncture of quantum electronics, photobiology, and medical practice, has come into broad use in Russia and is continuing to grow rapidly. In this context, it is important to resolve problems related to the metrological support, standardization, and unitization of laser medical technologies that are currently in use or in the developmental stage.

The below collection of articles presents the results of research conducted by the All-Russian Scientific Research Institute of Optical-Physical Measurements, which is the leading scientific metrological center in the given field. In addition to reporting on the current state of the research and its findings, the articles include proposals, approved by the Russian State Committee on Standards, the Russian Ministry of Health, and the main manufacturers and users of laser medical technology, to improve the metrological support of laser medicine.

STATUS AND PROSPECTS OF METROLOGICAL SUPPORT FOR LASER MEDICINE AND LASER MEDICAL TECHNOLOGY

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This article examines trends and prospective developments in the metrological support of laser medicine and the design of laser-based medical instruments. The main characteristics of the measurement procedures being developed to calibrate, test, and certify laser medical equipment are presented.

The development and improvement of laser technology in the last 25 years and its introduction into many spheres of human activity, including medicine, have led to the establishment of a new discipline — laser medicine. The main uses here are laser surgery (destructive action of sufficiently high-energy laser radiation on living tissue) and laser therapy (reversible nondestructive action of low-intensity laser radiation). The use of lasers in lithotripsy, angioplasty, dermatology, and other types of treatment constitutes another application that is intermediate between the two fields mentioned above. Certain unique properties of laser radiation used in medical science make laser medicine one of the most promising trends in medicine for the XXI Century. Production of the instruments for laser medicine has given rise to a relatively new, science-intensive sector of industry — laser medical instrument manufacturing. The stock of laser-based medical instruments currently in use can be estimated as follows.

There are now roughly 3000–4000 laser surgical units in the country (the most common types are the “Raduga,” “Romashka,” “Skal’pel,” “Yantar,” and “Yatagan”), which usually emit radiation with wavelengths of 10.6 and 1.06 μm.

The number of laser therapeutic units (LTUs) presently in active use in different medical organizations is estimated to be from 55,000 to 65,000. There are more than 60 different types and modifications of such units. From 5300 to 6500 additional units are built each year. According to numerous expert estimates, the minimum demand in the domestic healthcare industry for LTUs is within the range from 80,000 to 100,000 units. Considering that the service life of an LTU is 6–8 years, 10,000–12,000 LTUs will be needed every year to replace other units that have reached the end of service.

A foundation that is quite strong from the scientific-medical, scientific-technical, and manufacturing standpoints has already been created in this country to provide laser medicine and the necessary equipment for a broad segment of the population, provide courses to prepare medical specialists in the field, etc. Russia is recognized as a world leader in many areas of
laser medicine. Generalizing the knowledge obtained thus far will make it possible to gage the prospects for the future expansion of laser medicine and identify corresponding trends in the manufacture of laser-based instruments.

The historical growth of laser medicine has taken it from a focus on obtaining purely qualitative results to investigation and understanding of the mechanism by which laser radiation interacts with the tissues of a living organism. As a result, researchers have acquired an understanding of the basic physico-chemical and medical-biological mechanisms underlying laser medicine both in laser surgery and in laser therapy.

The findings from numerous studies conducted over many years have established the main parameters and characteristics of laser radiation that ensure the most positive healing effect, as well as the limitations that prevent laser radiation from harming tissues. Among these parameters and characteristics are the following:

- the wavelength of the laser radiation;
- the energy parameters (mean power, maximum power, radiation energy);
- the irradiation regimes (continuous and pulsed).

These parameters and characteristics determine the efficiency of the laser-based medical equipment used in surgery and therapy.

In surgery, the above parameters and characteristics in aggregate determine the amount of charring that takes place and the possibility of coagulation when tissue is cut, in addition to the depth of the region damaged by heat, the width of the cut, and several other factors.

In therapy, the aggregate of the parameters and characteristics determine whether or not physico-chemical reactions will occur in tissues, the magnitude of the response in the physiological reactions of the organism as a whole and in its functional systems, the depth to which the radiation penetrates the tissue, etc.

It follows from this that it is necessary to monitor and be able to control different parameters and characteristics of the radiation not only to obtain the most positive possible therapeutic effect, but also to protect the patient from injury. This becomes especially important in connection with the fact that the instrument is operated not by specialists trained in laser technology but by qualified medical personnel having relatively superficial knowledge of quantum electronics and physics. In fact, it is often only the intuition and practical skills of the physician that allows laser technology to be used as an effective tool in healing.

While being important for laser medicine as a whole, these issues are most important for laser therapy because of the widespread use of LTUs and certain specific features of the methodology of laser therapy. Thus, in the subsequent discussion we will give special attention to problems related to monitoring the parameters of the radiation in laser-based instruments used in therapy.

Due to a broad range of objective and subjective factors that have come into play, nonmedical methods of healing have gained in importance in recent years. Laser therapy in particular has gained an important role in physical therapy.

Many years of experience in the use of low-intensity laser radiation for therapeutic purposes has shown it to be highly effective as a means of dealing with disorders in a wide range of disciplines (gynecology, gastroenterology, stomatology, proctology, dermatology, neurology, cardiology, pulmonary disorders, surgery, etc.). This has been manifest in a shortening of healing time by a factor of 1.5-2, a significant reduction in the amount of drugs required by patients with an accompanying recuperative, stimulating effect from the laser therapy, an improvement in the immune system and allergic conditions, etc. There has also been a sharp reduction in the number of contraindications. The equipment used is environmentally safe and the procedures that are performed are antiseptic and painless.

The experience gained thus far from the medical and technical vantage points confirms that the most effective and most widely used laser therapy units are fairly similar in terms of the characteristics that determine the outcome of the therapy. There are just a few of these characteristics [2]. Among the main ones are:

- spectral range, i.e., the wavelengths of the radiation;
- irradiation regimes (continuous, pulsed, modulated);
- energy range, i.e., the power of the radiation;
- frequency range for pulsed and modulated radiation;
- time range, i.e., time of exposure.

Of these characteristics, the spectral, frequency, and time ranges and the radiation regimes are determined by fundamental and structural constants or design features which ensure that the characteristics' accuracy and reproducibility are high enough so that the parameters of the unit either remain constant over its entire service life or change so little that there is no adverse effect on the therapeutic process. At the same time, the energy parameters of the radiation depend to a significant extent on a large number of physical, mechanical, electrical, and other types of factors (degradation, maladjustment, changes in the