STANDARDIZATION OF APPARATUSES FOR ARTIFICIAL LUNG VENTILATION AND INHALATION NARCOSIS IN RUSSIA

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An adequate supply of apparatuses for artificial lung ventilation (ALV) and inhalation narcosis (IN) to health service organizations is a necessary condition for efficacious surgery, intensive therapy, obstetric aid, dentistry, disaster medicine, and emergency care. More than 20 models of domestic ALV and IN apparatuses have been developed to solve this problem. These apparatuses are presently mass-produced in 10 plants.

Standardization of technical requirements has a clear positive effect on the development, production, and use of the apparatuses. In a broad sense, standardization includes:

- unified and unambiguous classification and terminology which are in conformance with international standards;
- adaptation of internationally accepted safety requirements for patients and medical personnel;
- unification of the connective elements produced by domestic manufacturers and their adjustment to the international standards; reduction to a minimum of the likelihood of incorrect assembly of the apparatuses due to inappropriate fit of connective elements;
- use of typical unified circuitry, modular elements, and design which are adapted to specific conditions of Russian medical organizations.

The solution of the problems should be based on the analysis of worldwide experience through the documents of the international organizations committed to standardization of medical equipment: International Standardization Organization (ISO) and International Electrotechnical Commission (IEC).

The concept of standardization, which is accepted in Russia both for medical equipment and in general, is based on introduction of international standards and bringing national standards to international requirements. In terms of legitimacy, this is based on the participation of Russian representatives in the Technical Committee No. 121 ISO and Technical Committee No. 62 IEC.

Consider the results achieved and prospects for standardization of ALV and IN apparatuses.

General Requirements for Medical Equipment

Organization requirements for the development of medical equipment are set in the GOST (State Standard) R 15.013-94, where interaction between designer, manufacturer, and user are specified. This document emphasizes the leading role of the Russian Ministry of Health and Medical Industry and the most experienced and skilled specialist physicians in the determination of basic trends in the development of new medical equipment, in its clinical and technical testing, and adoption for medical use.

GOST R 50444-92 determines general requirements for the classification of medical equipment by its reliability, mechanical and weather resistance, and electric power supply. This document also specifies the requirements for mass, noise level, and radio interference created by a medical device. The types of medical testing (including mandatory certification tests, performed by an independent organization; safety tests; environment pollution tests) are also specified. The regulations for labelling, packing, transportation, and storage of medical equipment are also specified by the Standard.

GOST R 50267.0-92 introduces the IEC Standard 601-1-88 into national practice and plays an important role in safety requirements. It is well known that this document specifies multilateral requirements for electrical safety of medical equipment. With reference to ALV and IN apparatuses, these requirements are made explicit in the acting particular standards. It should be
emphasized that both the general and the particular standards do not cover pneumatically- or manually-driven ALV and IN apparatuses.

The requirements for the reliability of medical equipment for various purposes and testing methods for monitoring of reliability are listed in GOST RD 50-707-91. Methods of decontamination (presterilization treatment, sterilization, and disinfection) of medical equipment as well as devices for such decontamination are specified in the Standard OST 32-21-2-85. This document is supplemented with special recommendations for the treatment of ALV and IN apparatuses.

In addition, a group of standards specifies individual technical and organization aspects of the use of medical equipment (e.g., installation regulations for electrical appliances, lists of necessary technical documentation, development of technical requirements, etc.).

Specific Requirements for ALV and IN Apparatuses

National standard GOST 17807-83, which has been valid in Russia for many years, contains description of 104 terms and definitions, including: ALV and IN apparatuses and their elements, respiratory contours, air conductors, tracheal tubes, connectors, valves, and specifications of ALV and IN apparatuses. The Standard is of indispensable use in technical documentation, and it is recommended for scientific and technical medical literature. In general, it is consistent with the ISO Standard 2135-79, although it contains additional terms and classification. Some terms are revised. The Appendix to the Standard gives description of 20 terms of general anesthesiology. The Standard gives authentic definitions of the terms in Russian, English, German, and French as well as abbreviated forms of some terms.

Although GOST 17807-83 has long been valid, development of new medical techniques and operating modes of ALV and IN apparatuses and new standards of ISO and IEC motivated its revision.

GOST 18856-81 (general technical requirements for basic parameters, performance, and testing methods of ALV and IN apparatuses) has been valid in Russia for more than 14 years. This standard put national standards for the ALV and IN apparatuses into correspondence with actual and even pending international standards. It specifies not only safety requirements but also (in contrast to the ISO standards) requirements for differential functional characteristics of ALV and IN apparatuses. Thus, this Standard slightly extends the requirements of the ISO Standard 5369-87.

For example, the safety limits were specified for: ranges of minute volume of lung ventilation, ventilation frequency, inhalation-to-exhalation duration ratio, maximum working pressure, and ALV resistance. The ALV apparatuses were divided into five classes (three for adult patients and two for child and neonate patients). The requirements of the Standard were formulated to allow further technical progress of the ALV and IN apparatuses. The requirements for reliability, mechanical and weather resistance, noise level, etc. were also specified.

In contrast to international standards, the national standards of Russian Federation attribute the ALV and IN apparatuses, designed to employ flammable mixtures of anesthetics, only to the highest safety class APG rather than to the class AP. This is valid for apparatuses of any design rather than for electrically-driven apparatuses alone. This Standard is supplemented by GOST R 50663-94 (analog of the ISO Standard 8328), which specifies requirements for manual ALV apparatuses.

It is important to note that GOST 18856-81 specifies requirements for testing procedure that fully comply with international standards. Alternative testing procedures are added to some recommended tests. Metrological requirements are specified for all the testing devices and instruments.

GOST 24264-80, which is presently a part of the new GOST R 50237.1-92 (analog of the ISO Standard 5356-1-87), has long regulated the compatibility of the connecting elements of the respiratory contours of ALV and IN apparatuses. This standard is supplemented with an amendment for connecting elements of other parts of the apparatuses.

Following the adoption of GOST R 50267.0-92 (General Standard IEC 601-1-88), two particular international standards for ALV and IN apparatuses were adopted. Because Russian specialists contributed significantly to the development of both general and particular standards, all the requirements of the documents are met by the national standards.

Development and certification of ALV and IN apparatuses is routinely based on the ISO standards, which have not yet been legally adopted in the Russian Federation. In addition to the ISO Standard 5369-87 (see above), the ISO Standards 5358-80 (continuous-flow IN apparatuses), 5359-89 (gas-intake pipes), 8185-88 (humidifiers), etc. are also in common use. For example, the NIST system of incompatible connectors (ISO Standard 5369-89) has long been used for designing connections between ALV or IN apparatuses with gas cylinders. A group of standards for respiratory pipes, tracheal tubes, etc. is also used in general practice.