A HISTORY OF SERIAL PRODUCTION OF CRYOSURGICAL EQUIPMENT

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Progress in medical industry under modern economical conditions is rather a complicated process. The Kriomeditsinskii Tekhnologii Scientific-Manufacturing Association produces cryosurgical equipment and can be regarded as an example of an enterprise successfully working in new economical conditions.

Cryomedicine is an independent branch of medical science and technology that dates back to the 1960's. The Soviet Union was one of the world leaders in this branch of medical science. Very interesting technologies and methods were developed in Kharkov, Kiev, Moscow, Odessa, Omsk, Tomsk, etc. However, introduction of these techniques into practical medicine was much slower than in Western Europe and America. This was explained by insufficient volume of cryosurgical equipment production. Only large clinics could afford cryosurgical devices.

The Kriomeditsinskii Tekhnologii Company was established in 1992 to develop and manufacture cryomedical devices for mass-scale medicine. In the development of the first mass-produced KMT-01 device, the previous experience of development of cryosurgical equipment was taken into account. The KMT-01 performance, parameters, circuitry, and functions were constructed using methods of systemic analysis.

Selection of the device functions was based on the following criteria: efficacy of cryosurgery for treating various pathologies; incidence of these pathologies; availability of cryosurgical methods of treatment of these pathologies; availability of foreign equipment with the same functions.

The main field of application of the device is gynecology. Up to 80% of adult women suffer to some extent from diseases of the neck and cervical canal of the uterus. Treatment of erosions and precancerous diseases of the neck of the uterus is one of the main problems of gynecology. The method of cryogenic destruction of pathological tissues of the neck of the uterus is generally recognized in the world and recommended by the Ministry of Health of the Russian Federation as a highly efficacious method of surgical treatment. Cryogenic devices for gynecology are available from manufacturers in USA, Japan, and Europe.

The design and performance of the KMT-01 device were developed with due regard to its friendly use. The following requirements were satisfied:

- the device should be convenient in use in medical institutions of any level, including small rural hospitals;
- it should be permanently ready for operation;
- it should be easy to operate by medical personnel.

It is obvious from these requirements that a gaseous cryogenic agent that can be stored in a cylinder for a long time should be preferred to use in the device. Medical nitrous oxide used for anaesthesia is the best for the purpose; this cryogenic agent is easily available for all medical institutions. With regard to these considerations the device scheme based on Joule-Thomson effect was preferred. In such a system the site of operation is cooled only by nitrous oxide supply directly to the working tip of the cryoinstrument.

The device was designed with regard to its reliability, cryogenic agent consumption, and cost. Commercially available nitrous oxide is not pure enough to provide sufficient reliability of the device. Therefore, the device is equipped with a four-stage purification system that makes its reliability virtually independent from the nitrous oxide quality.
Comparison of the Parameters of the Cryosurgical Devices

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cryoapplicator model</th>
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<tr>
<td>Consumption of cryogenic agent</td>
<td>Several available models of cryoapplicators</td>
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<td>Tolerance to the contamination of the cryogenic agent</td>
<td>High expenditure of nitrous oxide</td>
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<td>Safety of patient and medical personnel</td>
<td>Often clogging; operation without filters is unstable</td>
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<tr>
<td>Maintenance service</td>
<td>Exhausted nitrous oxide is discharged to the operation field</td>
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<td></td>
<td>Not available</td>
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Fig. 1. General view of the KMT-01 device. Explanation in text.

To decrease the operation cost of the device, it is supplied with a highly efficient system of regeneration of cold. Such systems have been used before only in microcryogenics. This system allows the gas expenditure to be reduced more than threefold in comparison with the best foreign models.

In general case, electronic and pneumatic systems of measurement, regulation, and automation significantly contribute to the total cost of the device.

In cryosurgery systems of automation are used for control of operation and maintenance of temperature and time parameters at stable levels.

The KMT-01 design provides stability of temperature and time parameters without using a system of automation. This significantly increases the device operation reliability and reduces its cost.

The cold regeneration system providing low gas consumption (replacement of cylinder every 3-6 months) made a system of pressure regulation and control unnecessary. Usually such systems are used for regulation and stabilization of the device operation.

All details of the device can be manufactured on general-purpose machines as well as on special equipment, including program-driven machines.

All this apparently made the developed device the least expensive, although fully competitive with the devices of this type.

The KMT-01 device successfully passed standard tests and was adopted by the Russian Ministry of Health for serial production and medical use.

The parameters of KMT-01 are compared in the table with those of similar devices commercially available in Russia. The KMT-01 device is highly competitive with these models, whereas its cost at the domestic market is presently 2.5-4 times lower.