

Biomedical instrumentation in the Soviet Union

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Burton, C., and R. M. Gardner. Biomedical instrumentation in the Soviet Union. *Med. Instrum.* 11: 124-126, 1977.-By utilizing biomedical instrumentation from other nations, and by designing and fabricating instrumentation in several institutes under the control of the Medical Industries Ministry and the U.S.S.R. Academy of Medical Sciences, the Soviet Union has attempted to bridge a 20- to 30-year technology gap. The lack of interagency cooperation and sophisticated manufacturing capability, combined with a system not directed to recognizing or exploiting innovation from within, suggests continued dependence on other countries. The Soviet system in these regards serves well as an example of a bureaucracy and system limiting technological advancement. It is hoped that future actions in this country, in response to the U.S. Food and Drug Administration's direct regulatory control over U.S. medical devices, will not lead to a similar stifling of technology development.

instrumentation; legislation; medical devices; Soviet Union

IN THE SUMMER OF 1974, the National Cancer Institute formed a U.S. delegation for an exchange visit with Soviet scientists concerned with biomedical instrumentation development and application. The mission was to exchange information and evaluate Soviet advances in human blood cell procurement and preservation, methods of cellular analysis, methods of soft tissue imaging, computer applications in intensive care and multiphasic screening, and technology related to the rehabilitation of cancer patients.

The authors were among the six individuals comprising the U.S. delegation selected to visit and comprehensively evaluate Soviet medical instrumentation-the system by which it is developed and standardized, foreign medical devices in use in the U.S.S.R., and the Soviet import system. The December 1974 visit stimulated a study that included reviews and translations of standards and other materials.

The highest level of hospitality and consideration was accorded our delegation. However, our hosts clearly showed only what they wanted our delegation to see. We made an equally conscious effort to be good guests, as well as to achieve a more realistic impression of actual circumstances.

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A review- of our observations during the visit and analysis of the factors that have resulted in a Soviet technology gap with the western world can serve as an example to the U.S. government in regulating medical devices.

U.S.S.R. Facilities

In general, hospital physical facilities resembled those seen in the United States during the 1930s and 1940s. With the dramatic exception of exhibition areas intended for foreign visitors, clinical areas and laboratories were poorly lighted and maintained. Rooms were dingy and revealed only rare effort directed to ornamentation or eye-pleasing color.

The bare atmosphere of the medical facilities was matched, in part, by a seemingly callous physician demeanor toward patients. In an environment where the concept of patients' rights is not apparent, the failure to gain informed consent even for new or experimental devices was explained by, one Soviet physician, who commented, "Why? It is for their own good."

The Moscow operative recovery-room shown in Figure 1 illustrates the actual level of illumination. A typical operating room such as that shown in Figure 2 would not meet our standards of sterility and electrical safety. Generally speaking, patient care areas were poorly maintained, in marked contrast to the brightly colored and illuminated medical instrument display halls typified by the All Union Scientific Institute of Instrumentation (Moscow).

Soviet Instrument Standards

Soviet medical instruments are designed and fabricated by several institutes under the control of the Medical Industries Ministry, the U.S.S.R. Academy of Medical Sciences, and the Ministry of Health of the U.S.S.R. under standards issued by the State Committee of Standards, of the Council of Ministers in Moscow. The translation of a representative standard, "Medical Instruments, General Technical Specification, (GOST 19126-73), indicates that many of the items mentioned are taken for granted in U.S. standards.

In design of packaging, it is necessary to consider compactness of arrangement, and convenience of use of the instrument and the possibility of color variations.

The representative samples also indicate that standards were often vague.

The manufacturer guarantees conformity of all released instruments to the requirements of the current standard, and also of standards or other technical documentation approved in a standard order, when the consumer adheres to the conditions of use and storage.

English-translated specifications and description; of medical instruments made in the Soviet Union were, at first glance, extensive. However, on closer examination, the specifications were found to be incomplete and lacking in important information, such as the band width of EKG amplifier recorders. Consistent with interagency experience in most countries, our impression was that there was little or no communication between institutes.

U.S.S.R. Instrumentation

Since all priorities are established by the State, areas of effort in instrumentation are predetermined. High in priority



Fig. 1. Operative recovery room in the Blokin Institute in Moscow. A new 2,000-bed institute has now been completed.

Fig. 2. Operating room in the Blokin Institute, Moscow.



are operating room equipment and devices relating to the treatment of heart disease and cancer. Instruments for "magnetic" treatment of cancer were noted a number of times, but their efficacy was unclear. Many gas anesthesia machines (Fig. 3) were in evidence. The most sophisticated instrument seen was an organ transplant maintenance device (Fig. 4). The units became less impressive when they turned out to be prototypes or limited production items not in general use. Close inspection revealed that many instruments were lesser quality copies of better known originals from other countries. Soviet copies of West German operating room microscopes and Swedish operating room lights (Fig. 5) were prominently exhibited.

Soviet-fabricated equipment generally appeared to be well assembled and designed for rugged service, with less atten-

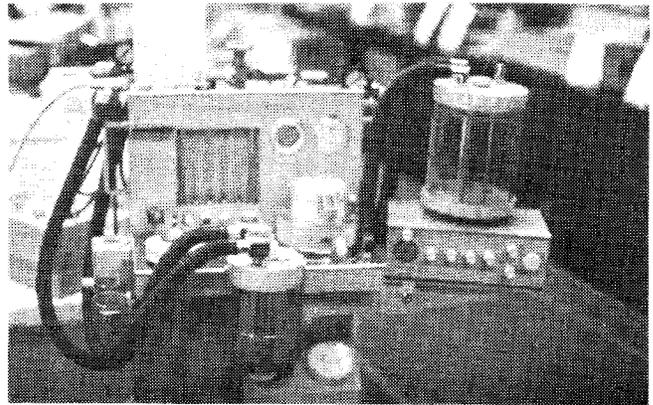


Fig. 3. Gas anesthesia machine in the exhibition hall at the All-Union Science Institute of Instrumentation, Moscow.

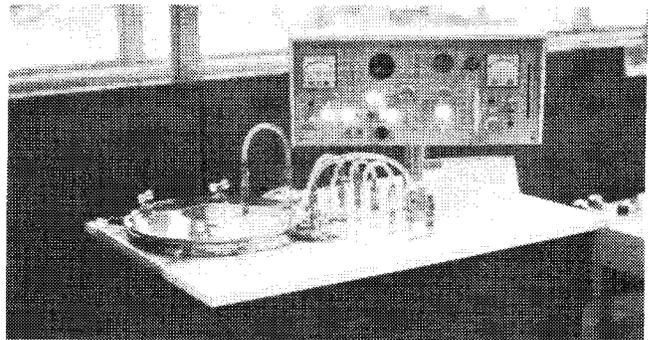
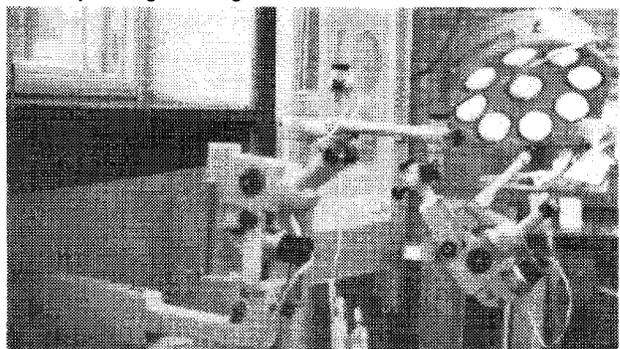


Fig. 4. Organ transplant maintenance machine, All-Union Science Institute of Instrumentation, Moscow. The organ to be maintained is placed in the container to the left. Perfusion and cooling are performed.

Fig. 5. Soviet copies of West German operating microscopes and Swedish operating room lights.



tion to fine finishing of components. Layout and hardware were neither particularly attractive nor functional. Standing in stark contrast to their less-than-impressive surroundings in some of the larger medical facilities were examples of some of the most technically sophisticated biomedical instrumentation known today. Computers, blood separators, monitoring devices, cryosurgical systems, fiberoptic endoscopes, and radiotherapy devices were in evidence. All were from outside of the U.S.S.R. and many devices were direct gifts from the United States. Aside from those intended for display Soviet medical instruments were generally antiquated. Oscilloscopes used in the general laboratory and in monitoring situations were of 1958 U.S. design and quality. Patient monitoring in the operating room and intensive care suite was not routine. An analog computer used in the Cancer Research Institute in Moscow was similar to that constructed in the United States in 1955. At the Pavlov Institute in Leningrad computer equipment was of vacuum tube and relay construction. Little use of state-of-the-art semi-conductor components was evident. Dual transistors in a single package were limited in application, and even fewer integrated circuits were seen. There were no dual-in-line packages, only all-metal cans. No light-emitting diodes were seen on medical equipment. The few digital displays in evidence were the "nixie-tube" type and of marginal quality.

Our impression that in the Soviet Union disassembly and study of foreign electronics takes place was confirmed on one occasion when our group wandered into a laboratory where an American Stratham monitor was being dissected. Our entrance was quickly followed by a host-provided exit.

We learned that all the cardiac pacemakers implanted by the Soviets originate in Poland or Hungary (although there is circumstantial evidence suggesting that the two members of the Supreme Soviet have pacemakers of American manufacture.

Many items we take for granted such as disposables, modern packaging, and soft paper goods, were uniformly absent. Yet, a number of examples of innovative use of standard devices was found, such as an ingenious microcatheter system for intracranial angiography seen at the Burdenko Institute in Moscow. The more effective use of existing technology and greater involvement in theoretics appears to be the Soviet course in light of their many deficits in achieving advanced and sophisticated medical instrumentation. The high point of the Soviet medical system is best demonstrated by the availability of medical care to all (1). One example of this is the outstanding Moscow ambulance service; ambulances do not have radio-physiologic-telemetry because physicians ride in the ambulances.



CHARLES BURTON received his undergraduate degree from Johns Hopkins University, Baltimore, Md., in 1956, and his M.D. from New York Medical College in 1960. He interned at Yale Medical Center, and was chief resident in neurological surgery at Johns Hopkins Hospital in 1966-1967. He was associate chief of surgery and chief of neurosurgery. USPHS Hospital, Seattle, Wash. (1967-1969), and neurosurgical research coordinator and Associate Professor of neurosurgery at Temple University Health Sciences Center (1970-1974). Since 1974, he has

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U.S.S.R. Medical Community

Of all Soviet physicians, 60 to 70 percent are women, although they represent the majority, we encountered few women M.D.s holding high office or rank in medical institutions. The level of esteem that medicine and medical practitioners hold in the Soviet Union is lower than in the United States. We noted even during our limited exposure that in the Soviet Union, the medical community is highly stratified, and that rank and associated privilege are precisely delineated and quite significant. Because everything is controlled by the State, and all are employed by the State, there is no unemployment. It appears that the incentive is to either try for the top or remain inconspicuous. The average Soviet seems to prefer avoiding visibility, and innovation appears to be a prerogative of the elite.

A basic scientific and technologic gap of 20 to 30 years is evident in the Soviet Union. The Soviets are rapidly bridging this gap by obtaining devices and technology from other countries presently superior in creativity and productivity. By purchasing, copying, and being presented with sophisticated devices, the Soviets are rapidly advancing, but still lack the means for effective distribution, thus limiting patient benefit.

How This Relates to the United States

On the basis of our observations, it seems that the basic strength of the present U. S. medical technology is the opportunity of entry afforded to the innovative mind and the motivation to produce that is offered by a free-enterprise, competitive system.

On May 28, 1976, the Medical Device Amendments of 1976 were signed into law by President Gerald R. Ford. With this legislation, enforced through the Food and Drug Administration, the federal regulatory state has been brought to bear directly on U.S. biomedical instrumentation. It would be unfortunate if federal regulatory agency control in this country were to eliminate these advantages by establishing unrealistic standards, controls, and unnecessary (but ever-increasing) paperwork. The ingenuity of the individual and the freedom to apply it are often taken for granted in this country and should be encouraged.

The progressively expanding U.S. regulatory system tends to respond to unfortunate occurrences e.g., the thalidomide disaster rather than to present or future needs. Man, legislation, and biomedical instrumentation are presently imperfect, and are likely to remain so despite the bureaucratic ideal of removing all patient risk to innovation. Innovation has always carried risks and always will. Safety is desirable, based on the risk-versus-benefit ratio.

The country now possesses great strength in biomedical instrumentation, made more evident by a comparative perspective with the Soviet establishment. Future trade-offs for increased device safety *must* be carefully considered so as not to place unwarranted restraints on innovation. While other societies can teach us much of value, we should also learn from and profit by their past errors.

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