Medical Equipment in Japan: Developing for the Future

By Kazuo Kobayashi

Trends in Medical Equipment Production

Production of medical equipment in Japan increased over the past 10 years at an average annual rate of 18%, quintupling in value during the period. However, the growth rate in fiscal 1975 and 1981 was low at 7% and 0% respectively. Production trends from fiscal 1971 to 1981, based on statistics compiled by the Ministry of Health and Welfare, are shown in Table 1, with particular reference to equipment for diagnosis and treatment.

Medical equipment is broadly classified into 17 categories. The categories which recorded the highest production in fiscal 1981 were equipment for clinics and hospitals, diagnostic apparatus, and convenient medical appliances (See Table 1). These three together accounted for about 50% of the total value of medical equipment production. Although surgical equipment ranked eighth, it is listed on Table 1 because it includes artificial organs and the laser scalpel, which have recently been the focus of considerable attention.

This report primarily takes up medical equipment which is worthy of note at present and will continue to be significant in the future. Although handy medical treatment devices merit attention in connection with the extended life span of the Japanese as well as with the increase in the elderly population, they are not included in this study because they need not be explained in detail with reference to scientific and technological progress.

Table 1. Production of Principal Medical Equipment in Japan

Monetary unit: ¥1 million

Description	Fiscal 1971		Fiscal 1976		Fiscal 1981	
	Value	Index	Value	Index	Value	Index
Medical apparatus (Note 1)	139,236	100	330,272	237	719,505	517
Medical equipment and attachments for use in clinics and hospitals (Note 2)	33,275	100	69,651	209	180,766	543
Diagnostic apparatus and equipment (Note 3)	12,763	100	35,533	278	84,087	659
Convenient medical appliances (Note 4)	9,496	100	24,786	261	68,461	721
Surgical apparatus and equipment (Note 5)	1,303	100	13,085	1004	43,180	3314

(Notes)
1. Operating table, lighting fixtures, sterilizers, incubators, X-ray diagnostic equipment, medical equipment using radioactive substances, physical therapy equipment, etc.
2. Stethoscope, clinical thermometer, blood testing equipment, blood pressure and pulse measuring devices, internal organ function testing equipment, ophthalmoscope, audiometer, medical mirrors, etc.
3. Hemorrhoid treatment appliances, home inhalers, vibrators, massaging appliances, etc.
4. Anesthetic administrator, internal organ substitutes, surgical electric appliances, ligation and stitching instruments, etc.

Table 2. Production of Principal Apparatus and Equipment for Clinics and Hospitals

Monetary unit: ¥1 million

Description	Fiscal 1971		Fiscal 1976		Fiscal 1981	
	Value	Index	Value	Index	Value	Index
Apparatus and attachments for clinics and hospitals	33,275	100	69,651	209	180,766	543
Medical X-ray equipment and related equipment	16,055	100	43,118	269	93,304	581
Medical equipment using radioactive substances and related equipment	566	100	2,992	529	8,649	1528
Physical therapy apparatus and equipment	12,527	100	14,767	118	60,057	478
Ultrasonic medical equipment	580	100	2,771	478	36,478	6289

Equipment for Clinics and Hospitals

Output

Production of equipment (including attachments) for use at clinics and hospitals increased about 5.4 times in value during the past 10 years, as shown in Table 2. It accounted for 24% of total output of medical equipment in 1971, but this proportion dropped to 21% in fiscal 1976 before recovering to 25% in fiscal 1981. The reasons for the recovery are as follows:

- Introduction of computer tomographic scanners (CT scanners) in the X-ray equipment category.
- Rapid development of nuclear medical apparatus using radioisotope (RI) and ultrasonic diagnostic equipment.

X-ray Diagnostic Equipment

The medical world is constantly seeking improvements in X-ray diagnostic equipment with respect to the quality of X-ray pictures and reductions in the quantity of X-rays to which patients are exposed. In

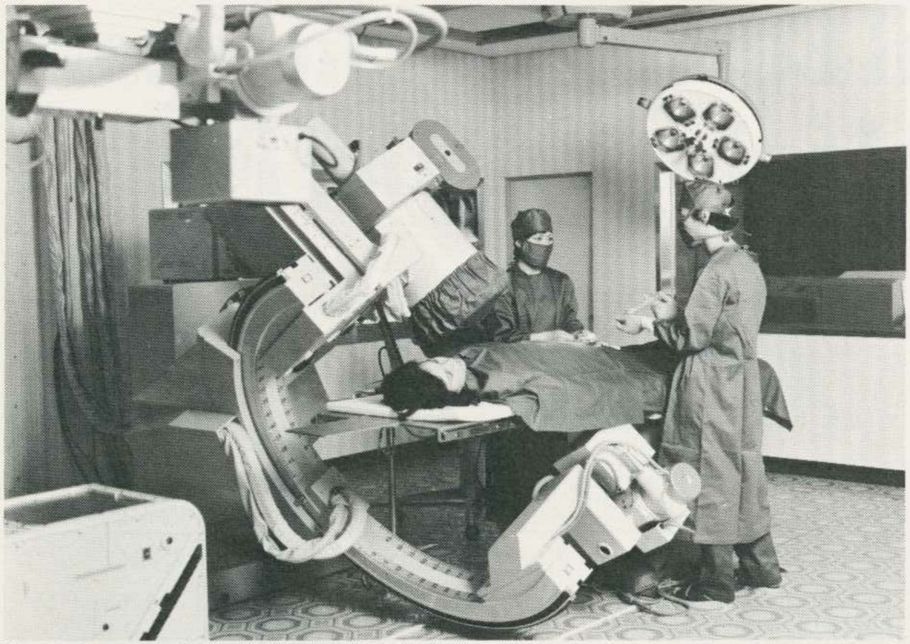

Photo 1: An example of X-ray unit for diagnosing circulatory organ disorders

Photo 3: An example of positron ECT (PECT)

response, makers have improved considerably on the performance of the sensitized paper and the image intensifier. Progress has been made in X-ray generator technology, leading to the production of X-ray motion pictures. The emergence of the micro-focus X-ray tube has made enlarged photography possible, and it is now widely employed in blood vessel photography. Three-dimensional photography has come in for renewed attention, and automatic exposure control is in popular use. There has been an appreciable increase in the number of X-ray units installed at medical care institutions for diagnosing circulatory organ disorders, as shown in Photo 1.

The biggest topic in X-ray diagnostic equipment is the CT scanner. The number of CT scanners for diagnosing the head and the neck and for diagnosing the whole body now installed at clinics and hospitals throughout Japan comes to about 1,800, a figure comparable to the approximately 2,000 units installed in the United States. CT scanners for diagnosing the whole body are expected to find wider use in the future, while requests to use X-ray CT for medical treatment planning and programming are likewise expected to increase.

Research is progressing on digital radiography, which converts X-ray pictures taken with the roentgenoscope system, consisting of a large-diameter high-precision image intensifier and a high-precision TV camera, into digital images for diagnosis by computer instead of the traditional X-ray film. This digital radiography system is now being employed in making diagnoses. With this system, conversion of gradation and comparison of a number of pictures can be performed easily in real time and clear contrast pictures of the heart and blood vessels obtained simply by injecting contrast medium into a vein. This makes it possible to examine the motions of internal organs in a single day so that the patient need not stay in hospital for prolonged examination. Photo 2 is a digital picture spotlighting the ilium arterial tube. The picture clearly reveals a stricture, marked with an arrow.

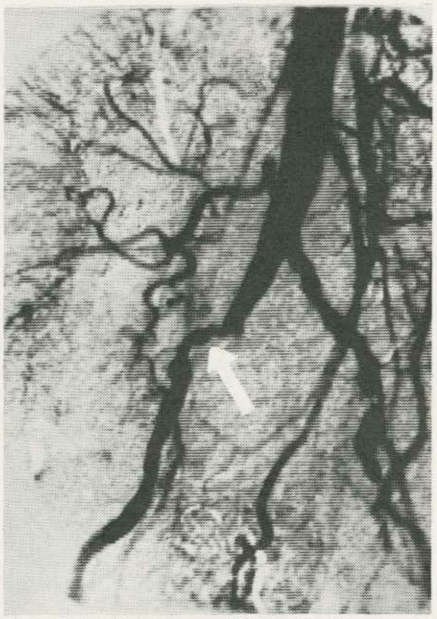

Photo 2: A digital picture spotlighting the ilium arterial tube. It reveals a stricture, marked with an arrow.

In an attempt to obtain an X-ray picture without using film, a system has been developed to record the X-rayed image on a highly sentitized clear imaging plate and then to convert it into a digital picture after scanning and reading it with laser beams. A remarkable feature of this system is that the amount of X-rays to which the patient is exposed is reduced to about one-100th the exposure in direct X-ray photography.

RI-Applied Diagnosis Equipment

As Table 2 shows, the output of medical equipment using radioisotopes (RI) increased some 15-fold in value over the past 10 years. This astonishing growth is attributable both to the fact that, consequent to the rapid progress in electronics and computer technology, the performance of RI-applied diagnostic equipment has improved year by year relative to the equipment price, and to the great progress in nuclear medicine.

The development of the computer technology to convert RI pictures into digital pictures has not only improved the quality of static pictures but has also made it possible to show pictures in animation. This clinical technology has increased tremendously the amount of valuable information that can be obtained.

The development of emission computer tomography (ECT) capable of producing tomographic pictures of the distribution of radioisotopes in the body will help nuclear medicine achieve even greater advances.

There are two types of ECT, one being a single photon ECT (SPECT) using ordinary radioisotopes and the other being a positron ECT (PECT) which uses radioisotopes emitting positron or positive elec-

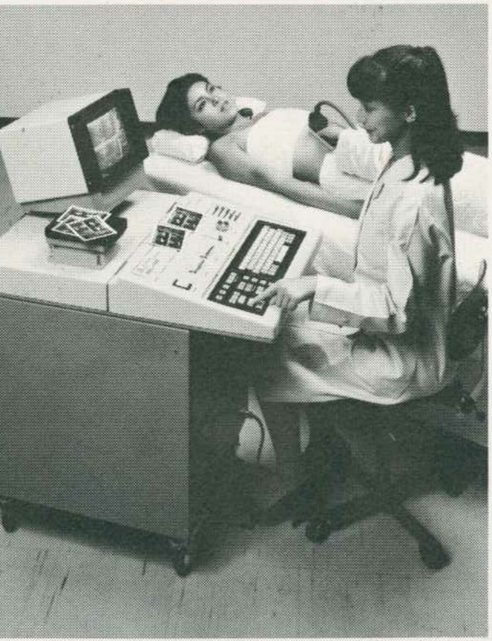

Photo 4: An example of the linear scan-type of ultrasonic diagnostic machine.

Photo 5: The world's most sophisticated testing device that can carry out 30 types of tests on 300 specimens per hour, or 9,000 tests per hour.

Table 3. Production of Principal Diagnostic Apparatus and Equipment

Monetary unit: ¥1 million

Description	Fiscal 1971		Fiscal 1976		Fiscal 1981	
	Value	Index	Value	Index	Value	Index
Diagnostic apparatus and equipment	12,763	100	35,533	278	84,087	659
Blood testing instruments and apparatus	302	100	5,469	1811	24,138	7993
Biochemical test apparatus and equipment	—	—	4,236	—	17,538	—
Blood pressure and pulse measuring devices and equipment	742	100	4,962	669	5,598	754
Internal organ function testing apparatus and equipment	4,851	100	8,736	180	17,974	371
Medical mirrors	2,341	100	11,119	474	22,571	964

trons. Photo 3 is an example of PECT. Great hopes are placed on the development of PECT because of the impact it will have on developing a new field in basic medicine. The great attention focused on the development of PECT is matched by keen interest in the development of small medical cyclotrons for producing nuclides and a chemical black box to manufacture short-life RI-labeled compounds which can be administered to humans. This field is called cyclotron nuclear medicine.

Ultrasonic Diagnosis Equipment

As shown in Table 2, the production of ultrasonic diagnostic equipment which produces real time tomographic pictures of internal organs using ultrasound has increased an amazing 60 times in value over the past 10 years.

This astonishing growth is attributable to a number of factors. Unlike X-rays and radioisotopes, ultrasonic waves do not harm the human body, while transducer performance has improved remarkably due to improvements in the ceramic materials used. Meanwhile, the incorporation of a microcomputer has greatly enhanced the picture processing function. The resultant increase in production of ultrasonic diagnostic machines has brought prices down to a moderate and affordable level.

Photo 4 is an example of the linear scan-type of ultrasonic diagnostic machine. Smaller portable machines have also been developed and put on the market recently. In the foreseeable future, doctors will be able to use ultrasonic diagnostic equipment as conveniently as they now use stethoscopes.

Promising New Products

Computerized tomography using nuclear magnetic resonance (NMR), which is often employed in chemical analysis, is now in the process of development for medical use, and some systems are already in service in clinical research. Unlike XCT and ECT, NMRCT is expected to become a powerful instrument for measuring metabolism or diagnosing cancer, as it can make tomographic pictures of the soft tissues of the human body. Research has just begun on comprehensive picture diagnosis to find out which imaging method—X-ray, RI, ultrasonic or other kinds of CT pictures—is best suited for which disease. The intent is to establish the limits of each image-based diagnostic method, and to determine which should be used when and for what kind of symptoms. Sooner or later, a system really helpful for comprehensive diagnosis will be developed.

Diagnostic Apparatus

Output

Of diagnostic apparatus, those for examining the functions of internal organs —such as electroencephalographs, cardiographs and phonocardiographs—were the most extensively produced in fiscal 1971. However, they were overtaken by blood testing equipment in fiscal 1981, as shown in Table 3. Blood testing equipment production has increased about 80-fold in value during the past 10 years. In contrast, the value of apparatus for testing internal organ functions increased slightly less than four-fold. Among instruments for use in diagnosis, production of medical mirrors rose about 10-fold during the decade, almost equaling the output of blood testing equipment.

Blood Testing Equipment

As shown in Table 3, biochemical testing apparatus accounted for most of the explosive increase in production of blood testing equipment (by value). The number of cases requiring clinical biochemical tests is increasing yearly in Japan. This is not only because biochemical tests are employed effectively in diagnosis but also because of their recent increased use in geriatric preventive medicine for health checks to detect diseases and for group physical examinations. The need to handle an enormous number of biochemical tests has made it necessary to replace conventional manual methods with automatic testing equipment and has accelerated the switchover from slow single-item testing to reliance on high-speed, multi-item test processing equipment. Photo 5 shows the world's most sophisticated testing device which can carry out 30 types of tests on 300 specimens per hour, or 9,000 tests per hour.

The preliminary preparation of specimens for automatic biochemical testing has yet to be automated. If an automatic blood collector, an automatic specimen transmission system, automatic serum separation equipment and automatic serum distribution equipment could be developed, it would be possible to automate the whole process from blood collection to testing.

It would of course, be far more convenient if blood taken from a patient could be tested without separating out the serum. Though only a few types of blood tests are actually conducted today, the number of test items will likely increase in the future. At the same time, bedside blood testing equipment which can conduct tests instantly without having the specimen sent to the laboratory are gradually coming into practical use. A miniature machine which can test blood as it is being drawn from the patient is quite feasible. It may even be possible in the near future to conduct a continuous series of tests by inserting the miniaturized terminal of a blood tester into the patient's blood vessel.

Quite apart from ordinary biochemical tests it is sometimes necessary to test an infinitesimal amount of blood elements in order to diagnose cancer or detect toxic drug traces. The development of a handy analysis method which shows specific reactions to the elements being tested for would be very welcome. Oxygen immunity reaction analysis and fluorescence immunity reaction analysis are attracting attention in this regard.

Surgical Apparatus and Instruments

Production

As is clear from Table 4, the production of surgical apparatus increased about 30 times in value during the past 10 years. Internal organ substitutes were responsible for much of this remarkable growth. The production of internal organ substitutes grew nearly 50 times over the past decade.

Internal Organ Substitutes

Of the internal organ substitutes, popularly known as artificial organs, artificial kidney production was greatest in value terms. Artificial kidneys accounted for about 7% of all artificial organ production in fiscal 1981. They were followed by artificial lungs, artificial hearts, artificial livers, and the artificial pancreas. Artificial valves to substitute for cardiac valves and artificial joints are also essential to present day surgical treatment.

There are many areas yet to be fully explored concerning artificial organs, including research on materials to take the place of biological substances. Development is underway of portable artificial' kidneys either of the shoulder-bag or belt-attached variety. It has become possible to artificially regulate blood sugar level disorders resulting from diabetes with an artificial pancreas made up of a blood sugar sensor, a microcomputer, and an insulin injector. More than 30,000 people die of serious liver disfunctions every year. If the liver function could be supplemented even temporarily, the lives of many people would be saved, and difficult liver surgery could be conducted more easily. Research on artificial livers is now underway, focusing on blood dialysis aimed at removing toxic substances and achieving metabolism outside the body.

A future goal in the development of artificial organs is to make devices that can be implanted in the body in pace with the development of anti-thrombosis materials. The bionic human being, with machines taking the place of some organs —that is, a total harmony of man and machine—will be a central research theme in fourth-generation medicine.

Laser Scalpel

The laser scalpel, which utilizes the energy of laser beams in surgical operations, is superbly effective in minimizing bleeding when blood vessels are severed. This drastically reduces the blood transfusions required in incision operations. Moreover, the use of laser scalpels shortens surgery, while the minimal damage caused to body tissues hastens post-operative recovery and leaves a less disfiguring scar. In addition, because the laser generates heat, it is a potent sterilizing agent, as it destroys malignant cells and prevents their metastasis.

Vaporized lasers, such as the carbonic acid gas laser and argon laser, as well as solid lasers such as the YAG laser, are used as laser scalpels. In the conventional instrument, the laser beam from the carbonic acid gas is transmitted to the scalpel section via synchronizing mirrors installed in the arm and joints of a light-transmitting vacuum tube. It is troublesome to match the optical axes and to operate the scalpel during surgery. However, because of the recent development of optical fiber which can transmit nearly 90% of the long wave length infrared light emitted by carbonic acid gas, it is expected that the laser scalpel will eventually become easier to use.

Although there are still problems with safety and price, the size of the market for laser scalpels should grow considerably in the future as these shortcoming are remedied. ●

Table 4. Principal Surgical Apparatus and Equipment

Monetary unit: ¥1 million

Description	Fiscal 1971		Fiscal 1976		Fiscal 1981	
	Value	Index	Value	Index	Value	Index
Surgical apparatus and equipment	1,303	100	13,085	1004	43,180	3314
Internal organ substitutes	726	100	11,386	1568	38,827	5348
Artificial kidneys	—	—	2,388	—	2,639	—
Surgical electric appliances and cauteries	105	100	259	247	1,156	1101
Electric scalpels	—	—	128	—	586	—

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Kobayashi, 58, joined Shimadzu Corporation in 1950 after graduating from the School of Technology of the University of Tokyo and later studying at the graduate school of the same university. After serving at the company's New York office 1963-65, he was appointed as a director and the chief of the system division in 1975 and promoted to his present post in June 1979.