Radiology Japan

Japan Industries Association of Radiological Systems

August 2002 No. 45

Trends in the Japanese Market for Medical Imaging and Therapeutic Systems in the Year 2001

Medical Imaging and Therapeutic Systems (production, exports, imports, domestic market)

				From January	/ through I	December 200	1 Unit: M	fillions of yen	
Category	Proc	luction	Ex	aports	In	ports	Domestic Market		
Item	Amount	% to Previous Year	Amount	% to Previous Year	Amount	% to Previous Year	Amount	% to Previous Year	
1 X-ray	102,732	105	27,399	102	19109	94	94,442	103	
General-purpose R/F	31,415	106	6,787	96	399	78	25,027	109	
Cardio & angio	13,960	96	5,694	82	12,121	82	20,387	92	
General-purpose radiography	20,994	117	3,799	107	290	73	17,485	118	
Mobile	3,373	102	1,625	125	378	129	2,126	93	
• Dental	6,411	106	1,291	71	0		5,120	120	
• Others	26,579	99	8,203	133	5,922	136	24,297	98	
2 CT	78,526	95	39,825	107	10,885	102	49,585	88	
3 Nuclear medicine	3,493	76	278	44	4,694	86	7,910	84	
4 MRI	41,024	111	24,248	113	23,476	78	40,252	88	
5 Image processing systems	7,081	180	792	157	697	100	6,986	169	
6 Related items & accessories	22,354	107	7,378	125	1,855	62	16,831	94	
Diagnostic systems total	255,210	103	99,920	108	60,716	86	216,007	96	
7 Therapeutic systems	8,547	97	2,128	131	6,705	110	13,124	99	
Total	263,757	103	102,048	108	67,421	88	229,130	96	
Diagnostic ultrasound (reference)	62,036	111	37,405	112	5,011	56	29,642	94	

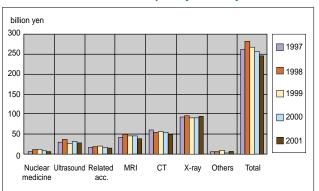
(Note 1) Domestic market: Calculated by the formula (Production - Exports + Imports).

(Note 2) Statistics from the Ministry of Economy, Trade and Industry (METI) were used for the calculation of market value for diagnostic ultrasound up to March 2001. JIRA's own statistics were used from April of the same year onward.

Review of 2001 results

Total production of major systems has fallen from 1998 to 2000, with imports and exports remaining almost flat throughout this period. The decline in domestic market showed no signs of bottoming out in 2001 due to a drop (-22% to the previous year) in imports for MRI. The results show 263.8 billion yen in production (about 103%), 102.1 billion yen in exports (about 108%), and 67.4 billion yen in imports (about 88%), amounting to a domestic market of 229.1 billion yen (about 96%), excluding diagnostic ultrasound.

Five-Year Outlook of the Diagnostic Imaging Market in Japan by Modality



Review of results for each category 1. X-ray

The market for this entire sector remained at almost the same level up to 2000, with the degree of fluctuation staying within $\pm 3\%$. In 2001, however, increases were observed in the production of general-purpose R/F systems, at 31.4 billion (106%), general-purpose radiography systems, at 21.0 billion (117%), and dental systems, at 6.4 billion (106%). As a result, the domestic market reached 94.4 billion (103%).

2. CT

Record highs were set for both exports, at 39.8 billion (107%), and imports, at 10.9 billion (102%), although the domestic market remained at 49.8 billion (88%) due to a decline in production to 78.5 billion (95%).

3. Nuclear Medicine

Both production and imports & exports declined, and the domestic market amounted to 7.9 billion (84%).

4. MRI

The domestic market amounted to 40.3 billion (88%) due to a drop in imports to 23.5 billion (78%) despite increases in production to 41.0 billion (111%) and exports to 24.2 billion (113%).

5. Related Items & Accessories

There are signs of improvement, with production amounting to 22.4 billion (107%), although the portion of exports was high at 7.4 billion (125%) and the domestic market accounted for 16.8 billion (94%).

6. Therapeutic Systems

Therapeutic systems are leveling off, with the domestic market amounting to 13.1 billion (99%).

Report on JRC 2002

JMCP Renamed JRC (Japan Radiology Congress)

JRC collectively refers to the annual meeting of JRS (Japan Radiological Society), annual meeting of JSRT (Japanese Society of Radiological Technology), and ITEM (International Technical Exhibition of Medical Imaging) promoted by JIRA. The theme of JRC 2002 was 'New Horizons of Radiology in the 21st Century'.

ITEM 2002 held in Kobe from April 4 to 6 in conjunction with the JRS and JSRT annual meetings

In his speech greeting the participants, Mr. Masamichi Katsurada, Chairman of JIRA, said, "This year's exhibition is the largest ever with the participation of 121 companies. Medical reform is believed to be an important part of structural reform in Japan, and medical technologies form the base of medical reform. The three organizations supporting JRC must cooperate and act as catalysts in transforming the slogan 'diagnostic imaging systems, networking and total efficacy' into reality".

The three-day exhibition was a great success, drawing in medical professionals right up to the closing ceremony. The number of participants increased by approximately 20% relative to 2001.

ITEM 2003 is scheduled to be held in Yokohama from April 11 to 13, 2003. Details will be provided in the next issue of Radiology Japan.

Ever	its (Congresses	Exhibition
	JRS	JSR	T ITEM 2002
Participants	Apr. 4 t	o 6 Apr. 4	to 7 Apr. 4 to 6
Radiologists Radiological	3146 (3	184) 2873(2	5003 (4209 2910) 13842(12125
technologists Comedicals Others			1201 (1031) 15975(12846)
Total	3146 (3	184) 2873(2	2910) 36021(30211)

Note 1) The numbers of visitors to the exhibition include repeat visitors. Note 2) The numbers in parentheses are the corresponding figures for 2001. Note 3) The number of registered exhibitor staff was 4514 (4230).



ITEM 2002

International Division

Meeting for MRA Between Japan and the EU –

A study meeting for MRA (Mutual Recognition Agreement) between Japan and the EU was held on March 3, 2002 at the Hotel Hilton Vienna. In attendance were five representatives of COCIR, including Chairman Reinhardt, Mr. Strattner, Mr. Linders, Mr. Lartigue, and Mr. Bursig, and four representatives of JIRA, including Chairman Katsurada, Mr. Ishikawa, Mr. Miura, and Mr. Hojo. Chairman Katsurada gave a presentation on the importance of MRA and the significance of the pilot study. The opening remarks by Chairman Reinhardt touched on the significance of MRA and the relationships between technological development, health care, and the economy. The following reports were then presented.

- 1. Mr. Ishikawa, Chairman of the Division, presented an outline of the legal reforms related to the draft revision of the Pharmaceutical Affairs Law (PAL) in Japan, which is scheduled for introduction in 2005.
- 2. Mr. Linders reported on discussions concerning classification schemes at the GHTF (Global Harmonization Task Force) Meeting, which was held immediately before this meeting.
- 3. Mr. Bursig presented a report on the current situation of MRA between the US and the EU and said that the confidence building period was not completed in December 2001 and has been postponed for another 2 years. Negotiations regarding the transition to the operational phase of MRA are still under way.
- 4. Mr. Miura expressed the basic concept and purpose of MRA (mutual trust in conformity assessment systems and exchange of conformity assessment results) for mutual understanding of MRA between Japan and the EU, and proposed that the objective of the preparatory meeting should be to confirm the conditions for mutual acceptance of the pre-market review and quality system audit results that are subject to MRA.

Discussions were held concerning the above points and the following decisions were reached. Mr. Bursig requested that the participants confirm these decisions.

- A 2-year preparatory phase will be set to include medical equipment in the current MRA between Japan and the EU. Reform of the PAL in Japan is expected to promote MRA.
- It is understood that the classification of X-ray systems under Class C would result in the application of stricter regulations in Japan and require a longer premarket review period. COCIR will prepare a detailed

comparative chart for Class B of the GHTF document and Class IIa of the Medical Device Directives (MDD) to analyze their impact while pointing out to the EC governments that a change to Class B should not give rise to problems regarding risk management.

- COCIR will prepare an official position paper concerning the classification of X-ray systems.
- COCIR will present additional information on MRA between the US and the EU to JIRA.
- JIRA will hold discussions with the Ministry of Health, Labour and Welfare concerning handling in the same manner as other DI in terms of regulation in the event that X-ray systems are classified under Class C.
- Post-market surveillance will not be included in the preparatory work for MRA between Japan and the EU.
- COCIR will inform JIRA regarding the selection process for the Notified Bodies in the EU.
- JIRA will send its representatives to the COCIR open meeting, which is to be held in April.

Standardization Division

The Technical Division, which had been active for 34 years since its start in 1967, was renamed "Standardization Division" based on the basic policies resulting from the reorganization review conducted by the Renovation for the 21st Century Committee, and ended its activities of the first year under the new name. The outcomes of the activities included the preparation of four JIS drafts (JIS Z 4704, JIS Z 4752-3-3, JIS Z 4761, and JIS Z 4571-2-29), five JESRA standards (JESRA: Japanese Engineering Standards for Radiological Apparatus), and six guidelines/manuals for JIS standards. Other public relations activities included publication of the Guidebook for Standardization of Diagnostic Imaging Systems (2002 version) and contribution of articles to JSRT.



Samples of manuals and standards

Medical Device Law Study Committee

This committee has continued Working Group activities on different themes since April 2000. When requested to provide comments on the reform of the Pharmaceutical Affairs Law (PAL) by the Ministry of Health, Labour and Welfare (MHLW), the committee compiled the outcomes of Working Group activities and submitted the opinions in writing to the Ministry. Consequently, the PAL reform bill incorporating some of these opinions was laid on the table in the Diet this year. The following items were discussed and reflected in the bill.

- 1. Clear definition of medical devices. The term "Medical Devices" was explicitly stated in the bill.
- 2. Handling of software as an independent medical device. This was one of the discussion items regarding the definition of medical devices.
- 3. How to conduct technical evaluations. An opportunity was given to incorporate industry opinions with regard to establishing the standards for third-party certification.
- Items related to Good Manufacturing Practice (GMP). 4. The concept of manufacturing practice based on ISO13485 was incorporated in the bill.
- 5. Expansion of the scope of applications for partial changes to approved products. The items to be expanded were discussed.
- 6. Relaxation of the requirements for manufacturing permission. The requirements were made less stringent.
- Clear definition of repair work. The concept of repair 7. work practice during the product life time was discussed.
- Simplifying product filing procedures. Changing the fil-8. ing system from "approval" to "self-certification" by introducing the third-party certification system was discussed.
- 9. Reclassification. Expansion of Class II or transfer of some items into Class I. This issue should be deliberated when third-party certification is introduced.

Regulation and Economy Division

- 1. Standard templates for medical device packaging inserts requested for filing of the product under the PAL According to the notification of the director of the Pharmaceutical and Food Safety Bureau (Notification No. 1340 issued on December 14, 2001), all medical devices are required to have a "medical device packaging insert", i.e. written documents summarizing the main parts of the instructions for use of the medical device. The Safety Committee is currently preparing the standard templates for different types of medical devices.
- 2. Guidelines for the installation adjustment of high-energy

radiotherapy equpment The guidelines were prepared.

3. Revising the standards for X-ray systems for medical use Further considerations are required to resolve the issues on the focus-to-skin distance of X-ray equipment for bone mineral density measurement, CT scanners, and angiographic equipment. The standards were revised following confirmation that they should be in accordance with the international standards (IEC), and approved by the Radiology Council.

The revised standards were published and came into force on March 27.

4. JIRA's approach to PAL reform

The bill for PAL reform is proceeding in the fiscal 2001 session of the Diet. The following items will be considered: (1) review of the approval system for pharmaceuticals and medical devices, (2) review of medical device safety measures, and (3) biological regulations. JIRA compiled and submitted opinions regarding these items.

5. Reforms to the medical reimbursement system Industry requests were submitted to the MHLW, focusing on three major items (1) positioning and assessment of maintenance and management expenses in terms of cost structures, (2) assessment of digital CRT diagnostic technologies, and (3) assessment of a functional software unit based on insurance coverage rules.

6. Activities of the Safety Committee A joint symposium on "risk management" was held at the Japan Radiology Congress on April 6. The Committee dispatched a representative to speak at the symposium.

Medical Radiation Facilities Safety Administration Center (MRC)

In order to ensure the safety and quality of diagnostic imaging systems (X-ray, CT, MRI, angiography, nuclear medicine) after the installation, MRC runs an industry-regulated "service engineer qualification system" for maintaining and promoting the level of engineers who are engaged in the maintenance and repair of such systems. Under this scheme, a "Service Engineers Qualification Workshop" is held for new engineers every year, and a "Service Engineers Re-registration Workshop" is conducted every three years. During fiscal year 2001, the 18th "Service Engineers Qualification Workshop" was held for 403 participants. To date, 4359 certificates have been issued: 1756 for X-ray, 1061 for CT, 734 for MRI, 574 for angiography, and 234 for nuclear medicine.

In addition, the 14th Re-registration Workshop was held as a correspondence course, and 517 trainees were granted service engineer certificates.

Development of Japanese Radiological Equipment in the Post-World War II Period (10)

Development of X-ray Tomography Systems

Sumio Makino Advisor, JIRA



Introduction

The development of X-ray tomography was based on the desire to obtain X-ray images focusing on the lesion by avoiding the problem that anatomical structures are superimposed in plain X-ray images, making it difficult to accurately assess internal structures. Although the development of tomography may be considered common knowledge today, this paper outlines the history of development of X-ray tomography systems in Japan. It is hoped that the reader finds this information useful.

Chronology of the Development of Tomography Systems

In October 1982, Dr. Yukio Tateno, then of the Clinical Imaging Section of the Medical Imaging Department at the National Institute of Radiological Sciences, presented a paper entitled "History of Tomography" in a special lecture session at the 11th meeting of the Japanese Association of Tomography. In 1991, Dr. Kazue Kimura, then serving as a Professor in the Department of Radiology of Fukushima Medical University, gave a presentation concerning the overall history of the development of X-ray tomography in a special lecture session at the meeting of the Japanese Association of Tomography. Dr. Tateno's presentation, entitled "History of Tomography", was published in the Japanese Journal of Tomography (Volume 10, No. 2) in March 1983. Dr. Kimura's presentation was published in the same journal (Volume 18, No. 2) with the title "History of Tomographic Imaging and Its Future Prospects", and a detailed description of his paper was also published in another medical journal, Innervision (November 1992), with the title "Diagnostic Imaging Equipment-From Analog to Digital" as a special supplement (published by Iryo-Kagaku-Sha on October 25, 1992).

Several excerpts from the above publications are presented below.

First, Dr. Yukio Tateno started his presentation (the Introduction section of "History of Tomography") by saying:

"Division into periods is very important in studying historical processes. In my opinion, the development of tomography can be divided into five phases. The first phase is the period starting from the initial development of X-ray imaging in 1895, in other words, the "prehistory" of tomography. The second phase is the period of blurring tomography, which started in 1921. The third phase is the period of computed tomography, beginning in 1972. In addition, a fourth phase developed in parallel with the third phase, the period in which the introduction of computed tomography led to the very rapid expansion of tomographic techniques to imaging modalities other than X-ray systems. The current period can be considered a fifth phase, in which we must move beyond the concept of tomography."

Dr. Tateno then went on to discuss the history of the development process in terms of these five phases.

Dr. Kazue Kimura assessed the history of tomography and concepts related to imaging equipment as "home-made" clinical studies. In his words:

"Since the discovery of X-rays in 1895, there has been a great deal of research into how to visualize the internal structures and lesions in the human body using X-rays. X-ray tomography can be said to one of the main areas of this research.

This paper introduces the development and history of tomography in terms of methods and time periods. The driving force for development in each area is the desire and passion of researchers who are eager to improve diagnostic imaging by visualizing lesions with greater accuracy and clarity based on their clinical experience. Small groups of researchers who were exploring new concepts designed and built "homemade models" to achieve their goals. The history of these pioneering efforts is described here.

Today, we researchers are surrounded by convenient technologies that have been firmly established. Therefore, there is a risk that we may begin to take such conveniences for granted and gradually lose our scientific drive to identify clinical problems and explore solutions on our own. In this respect, the present paper is not intended merely a memoir, but also as a basis for self-evaluation. It is hoped that this historical analysis will help lead to further progress."

The milestones of research in tomography identified by Dr. Kimura are shown in Fig. 1.

The author recalls that, in the ruins after World War II in Japan, some of our predecessors used wood and dull saws in poorly equipped surroundings to investigate the basic design of tomography systems together with the staff members in the Department of Radiology. In particular, the author has fond memories of the direct, passionate attitudes of clinical researchers up to early 1970s, when X-ray CT was introduced.

1895	X-rays Roentgen											1991 Present
1896		Artificia Rutherfo			manufacturing kaken	1951	RI imaging Cassen	1966	RI cross-section Kuhl			
1914	World War I											
1921	Tomography Bocage		Circular tor Grossmann	0.1	у	1	955 Multi-orb Matsukaw		ography			
1928	US Langevin			1	945 Firestone	195	2 B-method Wilde, Howry		2 Cossoff UI Octoson	1974 G	reenleaf	
1937	Cross-sectional image Watson	ging		194	4 Abreu Koga, Matsu		Takahashi	197	2 CT Hounsfield			
1939	World War II											
1946	NMR Purcell, Bloch						51 Gabillard	1971	Relaxation time Damadian	1973 Ima Oka	ging Ibe, Lauterl	our
1972	CT; To 1st, 2nd, 3rc Hounsfield	d, and 41	th generation							1989	Helical v Katakura Kalendei	ì,
1991	Present											

Figure 1. Milestones in research.

Early Research into Tomography in Japan

In 1935 and 1936, papers were presented one after another by the late Dr. Yoshihiko Koga of Tohoku University School of Medicine and the late Dr. Shotaro Miyaji of Nagasaki University School of Medicine.

(1) Yoshihiko Koga, Mikio Kiyono. X-ray imaging in deep regions. Practical Medicine and Clinical Study (Jichi-Iryo To Rinsho) 1935;12:9.

(2) Shotaro Miyaji. Deep-region X-ray imaging techniques. Nippon Acta Radiologica 1936;4-3. (Dr. Miyaji passed away in 1954.)

The above references are both cited in Dr. Kimura's paper.

Outside Japan, research was published by Bocage in France in 1921. Patents were examined by Pohl in Germany in 1927 and 1930. Further research was presented by Vallebona in Germany in 1933.

These researchers worked to develop tomography as a method to blur extraneous structures superimposed on the lesion in plain Xray images. Dr. Kazue Kimura describes the basic concept as follows:

"Keep a camera focused on a moving car and take a picture of the car over an extended period of time. As a result, objects in front of and behind the car are blurred and only the car is clearly visualized.

This groundbreaking idea is the basic principle in the development of tomography (Fig. 2)."



Fig.2 Photograph of a moving car.

The above-mentioned research in Japan must have been triggered by such overseas studies.

Figure 3 shows the concept of a tomography system developed by Dr. Shotaro Miyaji. The experimental setup clearly reflects the home-made and poorly equipped, but extremely passionate, research environment at that time.



Fig.3 Dr. Miyaji's experimental setup.

History of Tomography System Manufacturers in Japan

The history of manufacturing of tomography systems can be traced back to before World War II. Toshiba's historical chronology refers to "completion of a tomography system" in 1939. Another chronological record (Umegaki) states that it was in 1936. The author attempted to locate people with knowledge of this period of development, but failed to locate any witnesses and therefore cannot provide a detailed account of that period in the present article. Whether it was in fact 1936 or 1939, it was during this period that Dr. Koga, Dr. Miyaji, and others were actively conducting their research. Therefore, the development work must have been conducted jointly between academia and industry. Unfortunately, since the war started at around that time, it is difficult to find records from that period.

The author was close friends with these two professors, but did not specifically discuss this matter with them. It is likely that



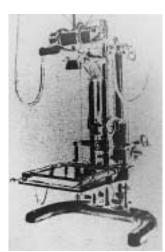


Fig.4 Tomography system produced by Shimadzu Corporation (taken from Dr. Tateno's paper).

Fig.5 Tomography system produced by Toshiba Corporation (taken from Dr. Tateno's paper).

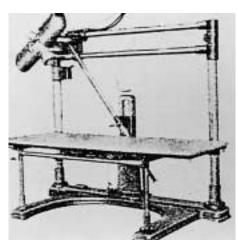


Fig.6 Model HLP-49 produced by Shimadzu Corporation.

Toshiba was asked to produce a prototype, as suggested in at least one historical record. In the oral presentation mentioned above, Dr. Yukio Tateno made the following statement:

"The first tomography systems were introduced into the market in 1936 by Toshiba and Shimadzu. Both of these systems were for imaging of the head (Figs. 4 and 5)."

Dr. Tateno continues:

"From the records of Shimadzu Corporation (History of Shimadzu Corporation, September 1967), the first equipment was launched in 1936, followed by the introduction of a simplified tomography system in 1939, a rotational tomography system in 1940, and an upright tomography system in 1941."

Similarly, Umegaki's chronology describes the introduction of tomography systems by Shimadzu Corporation: a simplified linear type in 1939 and a circular type in 1940.

Then, the history of development continued into the post-war period.

Dr. Tateno continued his recollections, based on the records of

Shimadzu Corporation:

"The model HLP-49 (Fig. 6), which was found to be very effective in anti-tuberculosis programs, was introduced in 1949."

After the war, in 1945, tuberculosis was considered to be the "national disease" of Japan, and the government instituted antituberculosis measures throughout the nation.

The following excerpts are taken from "Testing Results of a New Linear Tomography System" by Keiji Fujimoto and Hakuya Sano, published in the Shimadzu Review in December 1949.

Abstract

The present paper describes the manufacturing precision of a newly developed linear tomography system and its effectiveness in blurring structures outside the target plane. By presenting experimental examples, the authors demonstrate the advantages of the system and its clinical usefulness.

1. Introduction

As in the expressions "no medicine without X-rays" and "no science without X-rays", X-rays are recognized to be indispensable in scientific research and, in particular, in medical practice. However, the X-ray images obtained by conventional radiography are two-dimensional images in which the internal structures of the patient are superimposed, making it difficult to establish a diagnosis.

To overcome this problem, Bocage in France developed a method for displaying an arbitrary plane on one film in 1921. This idea excited great interest, but was not put into actual practice for many years. Japan is currently entering a period in which all medical efforts must be mobilized to eradicate pulmonary tuberculosis. The treatment of pulmonary tuberculosis is no longer limited to the field of internal medicine, but has expanded to include the field of surgery. Surgical procedures such as thoracoplasty and packing have been developed, establishing thoracic surgery as an independent field of medicine. In order to achieve higher surgical success rates and to improve the patient's prognosis, X-ray tomographic examination before and after surgery is essential.

In the meantime, several tomography systems had already been introduced commercially in Japan before the end of the war. These systems were used for the diagnosis of thoracic lesions, as well as for testing the propellers of airplanes and the internal structures of major components, but the range of applications was extremely limited. Moreover, when X-ray images are obtained using a tomography system, both the X-ray tube and the film must be moved, which means that a very high degree of manufacturing precision is required for the mechanical design. In addition, a tomographic image is evaluated by viewing the film obtained, and it is difficult to identify blurring that is due to imprecision in the mechanism by simply looking at the image. In other words, blurring in the plane of interest in the X-ray tomographic image results in a reduction in diagnostic capabilities. This problem has limited the value of conventional tomography systems in actual clinical practice.

Given this situation, tomography systems need to meet the requirements that structures in the target plane must suffer from minimal blurring and must be clearly depicted, while structures in planes other that the target plane must be severely blurred and effectively eliminated.

We focused on these points in the design and production of a new tomography system. The manufacturing precision of this system is 1/100

mm or less. Since the theoretical principles of tomographic imaging have already been discussed in the literature, the present paper focuses on describing the results of our experiments to assess the manufacturing precision and the degree of blurring of structures in planes other than the target plane. Clinical examples showing the advantages of the system are also presented.

In contrast with Shimadzu's records, almost all of the post-war records concerning Toshiba's tomography system have been lost. Therefore, although the details cannot be discussed here, some business activities were conducted as a part of the anti-tuberculosis measures. The production of the tomography system developed before the war (Fig. 5) was discontinued during the war and resumed in the post-war ruins. Then, the Type A Tomography System (circular tomography method) was introduced in 1949. It is said that this system provided good tomographic image quality and was well received.

At the same time, a national campaign was underway to eradicate pulmonary tuberculosis. The Japanese Ministry of Health and Welfare formulated a policy to promptly install tomography systems at medical care facilities throughout the nation. Consequently, in 1950, mass production of the Type A Tomography System was given high priority, which greatly contributed to Japan's post-war industrial recovery. The story has been passed down that this demand for a dramatic increase in production at a time when components and materials were scarce was met by the round-the-clock efforts of the Fuji Factory production team. It is recorded that the first President's Award of the company after the war was presented to the people who achieved this large-scale production increase to meet the demands of the nation.

(to be continued)

Dear readers!

Opinions or comments that might be of interest to international readers of Radiology Japan are welcome. Please contact the editor.



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