

Radiology Japan

Japan Industries Association of Radiological Systems February 2003 No. 46

Review of the Japanese Market for January-June 2002

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

From January through June 2002 Unit: Millions of yen

Item	Category	Production		Exports		Imports		Domestic Market	
		Amount	% to Previous Year	Amount	% to Previous Year	Amount	% to Previous Year	Amount	% to Previous Year
1 X-ray		50,165	98	12,424	97	11,511	125	49,252	103
• General-purpose R/F		15,571	101	2,794	89	162	75	12,939	103
• Cardio & angio		5,068	66	1,993	86	7,950	138	11,025	100
• General-purpose radiography		11,119	114	2,016	115	425	348	9,528	117
• Mobile		1,511	76	534	52	159	79	1,136	96
• Dental		3,306	93	439	51	0		2,867	106
• Others		13,589	104	4,647	124	2,815	97	11,757	97
2 CT		37,474	100	19,064	101	2,777	43	21,186	84
3 Nuclear medicine		1,852	96	79	40	3,598	101	5,371	102
4 MRI		22,862	116	16,003	141	9,392	60	16,251	68
5 Image processing systems		5,426	142	329	87	592	208	5,688	153
6 Related items & accessories		13,892	125	4,816	138	984	93	10,060	116
• Systems		10,279	164	3,342	148	982	93	7,919	156
• Apparatus		312	92	78	101	0	-	234	90
• Supplies		3,301	74	1,396	122	2	-	1,907	57
Diagnostic systems total		131,671	105	52,716	112	28,853	80	107,808	94
7 Diagnostic ultrasound		32,512	-	20,555	-	1,725	-	13,682	-
8 Therapeutic systems		6,159	106	1,017	79	3,344	139	8,485	123
Total excluding ultrasound		137,829	105	53,734	111	32,197	83	116,293	96
Total		170,342		74,288		33,922		129,975	

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

The entire range of medical imaging and therapeutic systems (excluding ultrasound) amounted to 137.8 billion yen in production (about 105% relative to the previous year), 53.7 billion yen in exports (about 111%), and 32.2 billion yen in imports (about 83%), amounting to 116.3 billion yen (96%) for the domestic market as a whole.

The domestic market for major systems showed a declining trend in CT (about 84% relative to the previous year) and MRI (about 68%) but an increase in diagnostic X-ray systems with high-value component ratios (about 103%), other medical image processing systems for diagnosis (153%), and related items & accessories (116%). However, the domestic market as a whole experienced a decline from the previous year (96%).

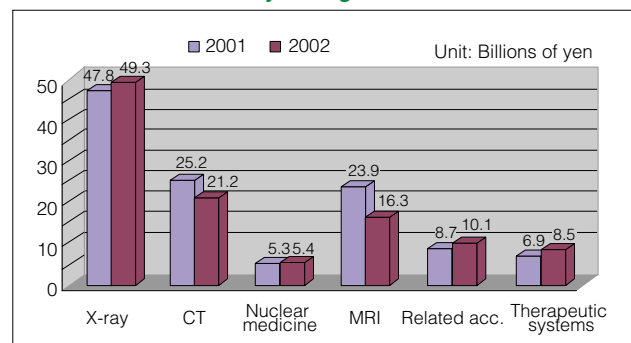
Factors behind the decline in the domestic market include:

1) The revision to the reimbursement (about a 6% reduction for CT and a substantial cut of about 30% for MRI in April 2002).

2) The decision to raise the amount of the personal share of medical bill payment to 30% starting in 2003, following the rise from 10% to 20% in 1997.

See the previous issue of Radiology Japan (No. 45) for the trends from 1997 to 2001.

Trends in the Japanese Market for Major Systems in January through June 2002



JIRA Activity Reports

Medical Imaging System Division – IHE-J Project –

The grand design to integrate information technologies in the field of healthcare in Japan was announced by the Ministry of Health, Labour and Welfare (MHLW), and its five-year action plan was revealed. The industry must strive to implement systems with the DICOM/HL7 standards as the rules for information exchange and to market products using these standards wherever possible. Healthcare providers are also required to build systems using these standards wherever possible. However, these standards allow various interpretations in the implementation phase, partly because they are intended to cover a broad range, which, in turn, may give rise to a need for discussion regarding detailed specifications in the actual implementation phase despite the fact that data are being exchanged using the standards. This implies the possibility of higher costs, despite the standard system architecture.

In the U.S., IHE (Integrating the Healthcare Enterprise), which aims for healthcare information systems based on standards, was started under the initiative of RSNA (Radiological Society of North America) and HIMSS (The Healthcare Information and Management Society) in 1999. IHE is aiming to establish common specifications by creating common scenarios that can actually be used and defining the use of the standards based on these detailed scenarios. The scope of IHE's activity consists of the implementation and performance of connection tests for evaluation, rather than the actual setting of the standard. As they clearly show that the standard can be used in practice, users are assured of the operabilities of the standard. Meanwhile, vendors can confidently move forward with product development because it has been shown that the standard is demanded by users. This framework is different from that of conventional standardization.

In Japan, the IHE-J Committee was created in August 2001 through the participation of relevant organizations such as JRS (Japan Radiological Society), JSRT (Japanese Society of Radiological Technology), JIRA (Japan Industries Association of Radiological Systems), JAHIS (Japanese Association of Healthcare Information Systems Industry), JAMI (Japan Association of Medical Informatics), and MEDIS-DC (Medical Information System Development Center). The goal of IHE-J lies in clarifying patient-centered use cases when introducing systems for securing real-time medical support based on the integration of information for quality improvement and the efficient offering of healthcare service, thereby indicating the solution guidelines (TF : Technical Framework) for workflow management.

The IHE International Conference held at the end of June 2002 confirmed the generation of a global movement in which

the U.S., Europe, and Japan take necessary steps at the same time. The TF was to be described by dividing it into the globally common portion (core) and extended portion for each country, and it was to be shared openly by the respective countries. For this reason, IHE-J has a role in representing Japan for communicating necessary information to the global portion. At the same time, it is necessary to examine whether the TF of IHE in the U.S. as of 2002 can be applied effectively within Japan.

IHE is also related to the issue of improvements in the security infrastructure in the field of healthcare. For instance, the privacy rules in HIPAA (Health Insurance Portability and Accountability Act) are scheduled to begin enforcement in April 2003 in the U.S., and an integrated profile concerning security in view of conformity with HIPAA rules is scheduled to begin in IHE Year 4. Necessary steps must be taken as part of infrastructure development, as similar laws are also scheduled in Japan through the enactment of the Act for Protection of Computer Processed Personal Data. JIRA is expected to take necessary steps since this cannot be dealt with at each vendor.

Medical Device Law Study Committee –Regarding the reform of the Pharmaceutical Affairs Law.–

The reformed Pharmaceutical Affairs Law (PAL) was submitted to the Diet on April 5, was passed on June 25, and was announced on July 31.

The purpose of this reform lies in building a safer and more efficient healthcare system in response to technological advances, changes in socioeconomic conditions, diversification of corporate activities, and international consistency, and is comprised of the following three perspectives.

- Comprehensive review of safety measures related to medical devices
- Confirmation of post-market safety measures and review of the approval and permission system
- Confirmation of security measures in response to the Century of Biological Genome

As this reform makes significant changes to the healthcare system, it requires a preparation period for building the new system and providing the operational regulations, and will be enforced from fiscal 2005.

Industry participation and proposals were requested in preparation for the operating regulations, including the governmental and ministerial ordinance. JIRA formed a working group under the Medical Device Law Study Committee for the purpose of playing a role in this process.

The original plan for the reform of the governmental and ministerial ordinance is scheduled to be prepared by the end of March 2003.

This working group reports on the five major themes of classifications, certification standards, manufacturing and marketing industry, distribution industry, and repair industry.

– Regarding classifications

Under the reformed Pharmaceutical Affairs Law to be enforced in 2005, the existing “General Terms and Classifications of Medical Devices (Pharmaceutical Announcement No. 1008, November 1, 1995)” and “Classifications of Respective Medical Devices (Pharmaceutical Agenda No. 547, March 31, 2000)” will be replaced by classifications based on JMDN (Japanese Medical Device Nomenclature/Japanese edition of Global MDN) and GHTF text under the policy of global harmonization.

Classifications

General Medical Devices (Risk Class I: Those presenting an extremely low risk to the human body in the event of failure), Manageable Medical Devices (Risk Class II: Those with relatively low risk), Medical Devices with Higher Risk (Risk Class III: Those with relatively high risk, and Risk Class IV: Those that may directly lead to risk of death).

The role of this classification lies in serving as criteria for the regulations in terms of the regulatory procedures for the distribution industry, the license application procedures for individual medical devices, and the range for the establishment of quality management for each risk classification.

The Classification Review Work Group performed the classifying work for JIRA-related items according to the above rules. However, a request for change was submitted to The Japan Federation of Medical Devices Associations (JFMDA) as some regulations will be strengthened from their present level. In addition, the JIRA Preliminary Draft for Comparison of New and Old Items will illustrate the corresponding relations.

As for the next step, discussions regarding the validity of class categorizations started at the Pharmaceutical and Food Hygiene Council in November 2002, and an opportunity to send in public comment is available on the MHLW's website.

Certification standards

These will come from the aforementioned “Comprehensive review of safety measures related to medical devices.” Manageable Medical Devices (Risk Class II) will shift from ministerial approval to a system in which a third-party certifying organization certifies conformity with the standards. The three items comprising the certification standards, are the basic requirements, the technical standards, and the JIS standards. Future challenges involve determining the provisions regarding performance in the governmental process for incorporating internationally recognized performance standards into the JIS or other technical standards. Handling of the performance requirements and measures for introducing a simplified JIS will be examined at the working group in the future.

Manufacturing and marketing industry

At present, the manufacture or the import of medical devices requires a medical device manufacturing license or a medical device import and distribution license, as well as the appointment of responsible persons. Such persons are held liable for medical devices in the market. In the reformed Pharmaceutical Affairs Law (PAL), a business category entitled “Manufacturing and Marketing Industry” will be created to take the places of “Manufacturing Industry” and “Import and Distribution Industry,” and “Manufacturing and Marketing Industry” will be held liable for medical devices in the market. This signifies a change in the licensing system from a manufacturing license into a marketing license.

The Industries will consist of three types: Type I Medical Device Manufacturing and Marketing Industry (handling Medical Devices with Higher Risk), Type II Medical Device Manufacturing and Marketing Industry (handling Manageable Medical Devices), and Type III Medical Device Manufacturing and Marketing Industry (handling General Medical Devices).

“The responsible persons” refers to persons responsible for general manufacture and marketing, persons responsible for safety administration, and persons responsible for quality control. Its purpose lies in performing comprehensive management of post-market safety administration and determining the measures for prevention of harm and damage. The governmental authorities should request that the “responsible persons” for general manufacture and marketing in the original plan can hold an arts degree, and not be restricted to those holding a science degree.

The major revisions concerning the distribution and lease industry include:

- Creation of a standard for the distribution and lease industry regarding medical devices, with higher risk in particular
- Creation of a standard for structures and facilities in the distribution and lease industry for medical devices
- Determination of the content to be included in the distribution and lease industry management accounts for task performance purposes
- Provision of the items to be recorded, such as medical devices with higher risk and their content
- Provision of courses to maintain the quality of managers in the medical devices distribution industry

Demands for security, improvements in the distribution and lease industry, and record storage will exist in the future, and JIRA will be required to strengthen its education system.

In regard to the repair industry, the newly created categorical definition of “Specific Medical Devices to be serviced” is “medical devices that require expert knowledge and skills for maintenance, inspection, repair, and other management, and may therefore exert grave impact on diagnosis, treatment, or prevention of diseases unless managed properly.” They will be designated by the Minister of Health, Labour and Welfare after consultation with the Pharmaceutical, Food and Hygiene

Committee.

Repair vendors will be required to obtain a distribution license to perform installation, and will also be required to perform qualification of responsible engineers, to indicate licensed medical devices, and to notify manufacturers.

Regulation and Economy Division

The activities of the Regulation and Economy Division in fiscal 2002 consisted of: 1) measures for reform of the healthcare system, 2) risk management for safety inspection, and 3) revision of reimbursement.

Interest increased in both risk management and the importance of accommodating safety inspection. For this reason, it is necessary to offer the information needed by users in an accurate, prompt, and safe manner, and there is a need to prepare guidelines for this purpose.

JIRA will adopt as its mission the "General Measures for Promotion of Safe Medical Practices -- For Prevention of Malpractice" announced by the MHLW in April 2002, and will deploy the following policies and activities from the reassurance and safety points of view:

- Formulation of overall design for securing safety
- Promotion of guideline creation

Measures for reimbursement

The Division has formulated a schedule for its action plan for the period from April 2002 to May 2003, in which contributions to the JIRA Bulletin, relevant events at the MHLW, Diet, physicians' associations, medical societies, radiological societies, the market, and the industry are listed in phase with the measures to be taken. The Division will put together a scenario for how each party will reflect its activities and objectives, and promote a common understanding among the committee members so that synergism arising from collaboration among the committees is achieved. It is considered essential to grasp the overall direction of JIRA's activities and to move in that direction.

Formulation of a vision for the medical device industry

Visions are being formulated for "strengthening the international competitiveness of Japan's medical device industry." A working group has been launched with participation by the members of the Medical Administration Bureau of the MHLW. To date, the WG has been discussing individual equipment, but from now on, it will clarify the direction of healthcare and the government's basic measures and divide their areas into categories. This will identify the technology and systems required for changes in the market, sort out the tasks involved in establishing the required technology, and organize the matters that require policy guidance through the legal and institutional system.

Approach to safety (Safety Committee)

1) Activities plan for the Safety Committee:

- Preparation of standard templates for safety notification to be attached to medical devices to be used by physicians or under the instruction of physicians
- Revision of JIRA standard JESRA X-84
- Preparation of a procedure manual, Good Post-Marketing Surveillance Practice

2) Collaboration with external affairs organizations: The establishment of a review committee for discussing the common subjects of equipment safety issues was agreed upon with JSRT at the JSRT Annual Meeting held in April 2002.

3) Topics regarding safety: As a result of analyzing malpractice cases that involved diagnostic imaging and radiotherapy systems, "lack of sufficient care in safety work during the installation of radiotherapy systems" and "ambiguities regarding delivery rules for radiotherapy systems" were identified.

Future tasks

A revised edition including the work inspection list was issued with regard to safety work during the installation of radiotherapy systems.

A decision was made to complete the Delivery Guidelines for Linear Accelerators and Therapy Planning Systems as well as the Guidelines for the Six-Month Dosage Measurement based on Paragraph 2 of Section 30 of the Enforcement Regulations of the Medical Service Law.

Future outlook

A Safety Measures Work Group needs to be established in JIRA to deal with post-marketing safety measures and the diversification of problems regarding safety measures.

GHTF-ISO/TC210 Committee

GHTF Chairman and Secretariat

Japan succeeded Australia as the GHTF (Global Harmonization Task Force) chairman and secretariat on July 7, 2002. Japan will hold these positions for 18 months until they are handed over to the EU at the end of December 2003. While GHTF membership consists of five countries/regions, namely, 1) Japan/Australia, 2) EU, and 3) U.S./Canada, the chairman and secretariat positions are assumed in turn every three years between the following 3 regions: 1) Asia Pacific, 2) Europe, and 3) America. Japan and Australia assume these positions for a period of 18 months each.

Japan's policy concerning GHTF and its background

Japan has a policy to actively incorporate GHTF documents into regulations for medical devices and will firmly demand that other member countries follow this policy by making a precedent of GHTF for pharmaceuticals and of ICH, which is a similar international organization. Activities for preparing and revis-

ing GHTF documents in such a way that they can be easily accepted in Japan is essential for incorporating GHTF documents into medical device regulations in Japan.

Draft reform of the PAL, which was debated in advance in the Upper House, was enacted after being unanimously approved in the Lower House on July 25, 2002. The relevant governmental and ministerial ordinances will be enacted by the end of 2002 and will go into effect within 3 years (the relevant governmental and ministerial ordinances for products of biological origin will go into effect within 1 year).

This systemic reform is based on the basic principles that were determined earlier at the Cabinet meeting: 1) review of the range of regulation (deregulation), 2) self-certification, and 3) global harmonization, and the following GHTF documents and international standards will be incorporated into the governmental and ministerial ordinances.

- Classifications: Four classes based on risk levels. Provides the classification rules. X-ray devices are Class III equivalent (proposed).

- Essential requirements: Essential requirements to be met by medical devices (e.g., safety, quality, performance).

- Summary Technical Documentation (STED): Application documents for pre-marketing conformity assessment (evaluation).

- ISO 13485:2003: Quality system standard for medical device regulations. Replaces GMP. Based on ISO 9001:2000, with more than 80% of the requirements shared between the two.

- GMDN: Catalog of medical device nomenclature. Classification is added to the Japanese translation version.

ISO/TC 210 activities

The 9th ISO/TC 210 Conference was held in Berlin from the 9th to the 13th of September 2002. Its focus was on discussing ISO/DIS 13485:2003, and a decision was reached to make the shift to the final stage of FDIS.

Preparations were made for the introduction of JIS to the symbols standard ISO 15223 and risk management standard ISO 14971. The software standard for medical devices under discussion, IEC/ISD 62304, concerns quality systems and risk management. A roundtable discussion on risk management was also held in Berlin. Risk management is attracting attention as a way to treat quality and safety equally.

Future activities

Japan will host the 10th GHTF General Assembly in Tokyo as the presidency holder from the 25th to the 28th of May 2003. This will connect with the Global Medical Devices Conference that will be held immediately after the Assembly. Meanwhile, GHTF documents are scheduled to be incorporated successively into Japanese statutes, and the organizations responsible for international activities related to medical devices (such as committees) are being integrated with organizations in charge of domestic activities in keeping with the intention of the MHLW.

It is the advent of an age in which GHTF documents and international standards are converted into domestic regulations without modification.

International Division

Promotion Study of Mutual Recognition Agreement Between Japan and the EU (International Affairs Committee)

A pilot study (PS) between COCIR and JIRA was implemented based on the decision made at the EU-Japan Business Dialogue Round Table (EJBDRT), and review sessions between the two industrial associations were held in March and April 2002. The following points were agreed and were reported to the EJBDRT Tokyo Conference in July.

- 1) Focus on diagnostic imaging systems as the review subject.

- 2) Target pre-marketing review (using Summary Technical Documentation (STED) of GHTF documents) and quality systems (using ISO 13485 as a requirement).

- 3) Exclude post-marketing surveillance from MRA targets.

- 4) Japan will include the regulation after the reform of the PAL in the review.

EJBDRT achieved the desired goals as the discussion started after both associations reached an agreement and started the review. PS will be continued until July 2004 as an industry initiative and will approach the governments on both sides to initiate MRA negotiation.

Visit to China (SDA, CQC, CNCA) (Overseas Regulations Committee)

A visiting group consisting of 3 committee members was sent to Beijing from July 1-5 for the purpose of studying the regulations related to medical devices in China. The group visited the State Drug Administration (SDA), the China Quality Certification Center (CQC), and the Certification and Accreditation Administration of the People's Republic of China (CNCA), while boosting exchanges with JIRA China Working Group (WG) in Beijing. Q&A information related to product registration and Q&A information related to compulsory certification systems were obtained from SDA and CQC/CNCA, respectively.



Discussions with SDA



Discussions with CQC



Discussions with CNCA

In addition, the “Book of Regulations for the Supervision and Administration of Medical Devices in China” and the “Book of Regulations for the New Compulsory Product Certification System in China” that JIRA issued in Japanese received high acclaim.

Lectures on “Trends of Medical Device Regulations in China” (Overseas Regulations Committee)

Lectures sponsored by JIRA and co-sponsored by The Japan Federation of Medical Device Associations (JFMDA) were held in Osaka and Tokyo on the 19th and 24th of July 2002, respectively. Attended by a total of about 150 participants, the lectures met a favorable reception by using the “Book of Regulations for the Supervision and Administration of Medical Devices in China” and

the “Book of Regulations for the New Compulsory Product Certification System in China” as teaching materials and by incorporating the content of the recent study visit to China.



JIRA Lecture

Japan-Korea Industrial Exchange (Overseas Regulations Committee)

The Korea Medical Instruments Industrial Cooperative (KMIC) and the Korea Testing Laboratory (KTL) visited on the



Japan-Korea Industrial Exchange Meeting

16th and 25th of July 2002, respectively, to exchange information about the “activities of JIRA and these organizations” and to present “the situation regarding pharmaceutical affairs systems in Japan and Korea.” JIRA was able to obtain information concerning the enactment of the PL Law in Korea and the creation of the Medical Device PL Center, as well as the discussion to shift the review work of the product standard and testing method for Class II devices to the private sector through the revision of the Pharmaceutical Affairs Law in Korea.

Standardization Division

A briefing session by a JSRT member was held as a diffusion activity for the JIS Z 4752-2-1 Draft (IEC 61223-2-1 (translated version of Evaluation and Routine Testing in Medical Imaging Departments – Part 2-1: Constancy Tests for Film Processors), which was published in the JIRA Bulletin.

Translated IEC 61223-3-3 Acceptance Tests -- Interventional X-Ray Equipment, DSA Systems, and prepared the JIS Z 4752-3-3 Draft.

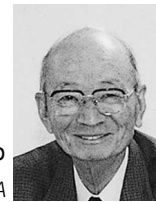
Translated IEC 60601-2-29 Medical Electrical Equipment – Part 2-29: Particular Requirements for the Safety of Radiotherapy Simulators, and prepared the JIS Z 4751-2-29 Draft. This draft defines individual requirements that manufacturers must comply with in the design and manufacture of radiotherapy simulators. JIS T 0601-1 shall apply to general requirements related to safety not covered by this draft.

Translated IEC 61168 Radiotherapy Simulators -- Functional Performance Characteristics, and prepared the JIS Z 4761 Draft. This draft provides items that indicate the performance of radiotherapy simulators and their recommended testing methods. It is applicable to X-ray simulators and is not applicable to CT simulators.

JIS Z 4704 X-ray Tube for Medical Use was reviewed to correct imprecise expressions and clerical errors in the 1994 revised edition, and a modified standard for the international standard was compiled. This corresponds to the integration of the following international standards:

- IEC 60336 1993 Characteristics of diagnostic X-ray tube focus
- IEC 60522 1999 Inherent filtration of X-ray tube systems
- IEC 60613 1989 Load characteristics of diagnostic rotating anode X-ray tubes
- IEC 60601-2-28 1993 Safety of diagnostic X-ray source systems
- IEC 60788 1984 Medical radiology terminology
- IEC 60601-1 1995 General principles of medical electric equipment safety
- IEC 60601-2-8 1999 Therapeutic X-ray high-voltage systems
- IEC 60601-1-3 1994 X-ray protection for diagnostic X-ray systems

Development of Japanese Radiological Equipment in the Post-World War II Period (11)



Sumio Makino
Advisor, JIRA

Development of X-ray Tomography Systems (Part 2) — Research to Develop Axial Transverse Tomography Systems

Outline of the story up to the last issue

As a part of the anti-tuberculosis programs that were initiated in Japan immediately after World War II, when tuberculosis was considered Japan's "national disease", X-ray tomography systems were regarded as essential tools in the fight against this disease. Industrial recovery to ensure the widespread manufacture and distribution of such systems was strongly promoted by the Japanese Ministry of Health and Welfare, contributing substantially to Japan's rise from its post-war ruins.

Of course, the tomography systems at that time could only provide planar cross-sectional images. The previous article described the efforts of Shimadzu Corporation in western Japan to develop and distribute such systems and the efforts of Toshiba Corporation in eastern Japan to increase production.

Laying the groundwork for X-ray CT — Building on Dr. Shinji Takahashi's research

Dr. Shinji Takahashi (1912 to 1985) served as a Professor at Hirosaki University, a Professor at Nagoya University, Vice President of the Hamamatsu University School of Medicine, and President of the Aichi Cancer Center. He was invested with the Junior Third Court Rank with the Grand Cordon of the Sacred Treasure and was also decorated with the Order of Cultural Merit Award.

By 1948, soon after the end of the war, Dr. Takahashi had already published a paper entitled "X-ray Rotational Imaging Method" in the Aomori Prefecture Atheneum.

Dr. Takahashi's research in the development of axial transverse tomography was based on the concepts outlined below. The details are discussed in his paper entitled "X-ray Anatomy of the Living Body" (Fig. 1), which was published in a supple-



Figure 1.

ment to the Journal of the Japan Medical Association in January 1973. It is not clear when Dr. Takahashi was first inspired by these concepts, but the author feels that Dr. Takahashi's work fostered a higher level of enthusiasm in those who followed him, reminding us all that it is essential to maintain our curiosity and to carefully consider every aspect of an issue under all circumstances.

The main points of his paper are quoted here:

"When anatomical or pathological findings are compared against conventional radiographic images, the images shown on X-ray films or displayed on a fluorescent screen are limited to two dimensions, while the structures in the human body are three-dimensional. X-ray imaging cannot capture this perspective dimension."

He was considering this fundamental difference between X-ray film images and actual anatomical structures as a key element of his own research. He then focused on the issue of the inherent nature of X-ray imaging:

"In X-ray images, anatomical structures are superimposed. When contrast is low, it may not be possible to visualize a lesion in such superimposed images. In postmortem examinations, the lesion can be examined by slicing the tissues in any desired plane. Would it be possible to do the same thing in radiographic examinations? Tomography is currently available, but such images are far from ideal because slices can only be obtained in the longitudinal direction and the images show significant distortion."

This issue could have been accepted with resignation and then simply ignored, but Dr. Takahashi felt that it was a problem that needed to be overcome and made it the central goal of his life-long research. He recognized that conventional radiography was incapable of providing accurate anatomical information in the human body (Roentgen anatomy). Although radiography was at that time considered to be the most advanced diagnostic imaging modality for examining the living body, it was still unacceptable. How could this problem be overcome? Dr. Takahashi considered this issue carefully and finally concluded that "axial transverse tomography" was the most promising approach in moving beyond the limitations of conventional radiography. This was soon after the end of World War II.

Then, he continued:

"Considering the issue as a whole, we had to conclude that radi-

ography should be ranked second behind postmortem pathological examination. However, even though radiographic findings may be inferior to those obtained at autopsy, radiography can be used to evaluate living patients, and it is therefore essential to improve radiographic examinations so that they can provide diagnostic information comparable to that obtained at autopsy.”

After discussing the limitations of radiographic examinations, he then considered methods that could be employed to improve them:

“If an object is rotated and imaged from every direction, although a cross-sectional image cannot be obtained directly, parts of the contour must be included in the X-ray images. If these parts could be combined in a certain way, it should be possible to obtain cross-sectional information concerning the object from the X-ray data.”

The author finds it truly amazing that Dr. Takahashi was speculating on these advanced issues immediately after the war,

and cannot help but be impressed anew with the groundbreaking nature of his work.

The author learned about this paper and the results of subsequent research, was guided by Dr. Takahashi, participated in his project to create a prototype system and then to produce a commercial axial transverse tomography system, and later gained experience in X-ray CT. Given all of the above, the author feels that Dr. Shinji Takahashi was a true prophet in the early development of X-ray CT.

Dr. Takahashi then formulated seven conceptual methods by which his ideas could be transformed into actual systems. The details of his methods are not described here, but conceptual diagrams are shown in Figs. 2 to 8. The author hopes that these will serve as useful references for subsequent generations of researchers. Of these seven conceptual methods, the fifth was considered to be the most likely to achieve practical realization.

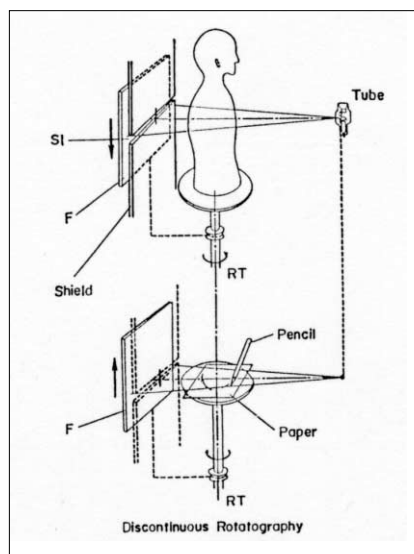


Figure 2. Principle of discontinuous rotatography. Top: Radiography. The tube focus (Tube), the rotating table (RT) on which the patient is placed, and the film behind the slit (SI) in the lead shield (Shield) are shown. The movement of the film is synchronized with the rotation (10°) of the rotating table. Bottom: Reconstruction of a cross-sectional image. The developed film (F) and the rotating table on which the drawing paper is placed are shown. The tube focus is located at the same position as in radiography. The contour of the X-ray image is drawn on the paper. The rotation of the rotating table is synchronized with the movement of the film.

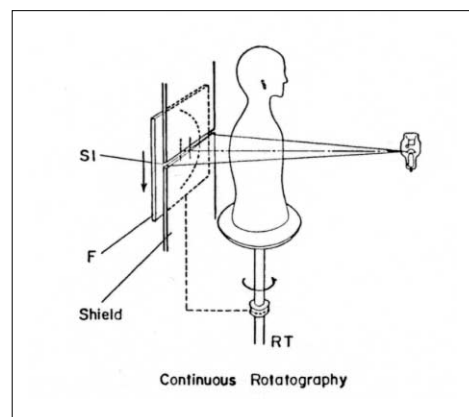


Figure 3. Principle of continuous rotatography. The slit in the shield is made narrower, and the rotating table (RT) is synchronized with film movement during radiography.

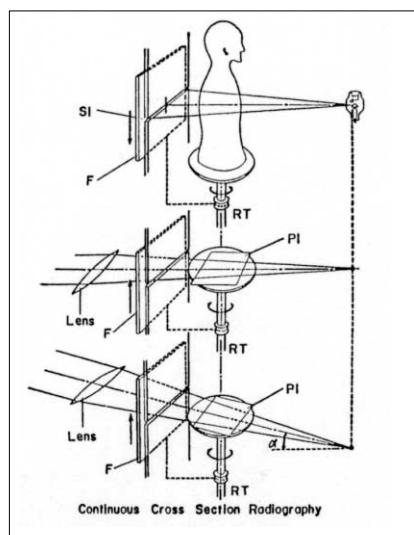


Figure 4. Principle of continuous cross-sectional radiography. Top: Continuous cross-sectional radiography. Middle: From the left side, the light is focused by a lens (Lens) and an image is formed at the position of the tube focus during radiography. The rotation of the photographic dry plate (PI) is synchronized with the movement of the radiographic film. In this case, however, a clear image is not formed on the photographic dry plate. Bottom: With the light traveling at α (4° or 7°), a cross-sectional image can be obtained.

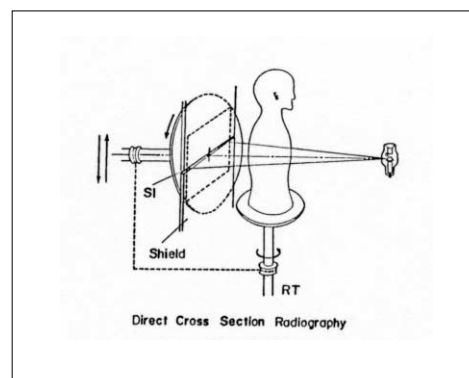


Figure 5. Principle of direct cross-sectional radiography. The rotating table on which the film is placed is rotated in synchronization with the rotating table on which the patient is placed. The film is moved vertically behind the slit (SI) in the shield while X-ray images are being obtained.

The author is still deeply moved when looking at the list that was made for that assessment.

“Currently, rotatory cross-sectional radiography (the fifth from the top in Table 1) is the most frequently employed in clinical practice. A description of this method was published in Japan in December 1949. In the 1950s, however, it was found that this imaging method had also been employed in Europe. At that time, the scientific journals published in West Germany had returned to the same high level of quality as before the war, but these journals were not available in Japan until the mid 1950s. The arrival of these journals revealed that the method developed for axial transverse tomography in West Germany was comparable to that in Japan. Nevertheless, there were still many differences between the Japanese method and those employed overseas because they had been developed completely independently.”

Dr. Takahashi analyzed the geometric aspects of axial trans-

verse tomography in precise detail:

“The tilt angle of the X-ray beam and the film was 15° to 20° in Japan, but 30° in Germany. In addition, the rotation of the rotating table was 0° to 180° in Japan, while it was 360° overseas. At that time, a tilt angle of 20° was also employed overseas, and 180° to 220° rotation had been approved. In the method developed in Japan, the theory of tomographic imaging was also incorporated into rotational imaging. This was extended to the concept of conformation radiography. In other words, this technique made it possible to obtain cross-sectional images of the human body regardless of the angle of the X-ray beam and the film, which means that transverse images of the body could be obtained at any height with the film placed at an arbitrary height on the rotating table. Furthermore, when two rotating tables are placed an arbitrary distance apart, transverse images with different magnification ratios can be obtained....”

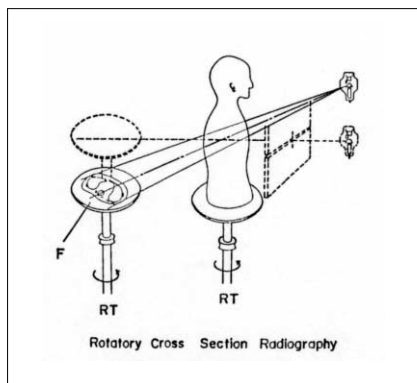


Figure 6. Principle of rotatory cross-sectional radiography. The lead shield with a tube focus slit, the rotating patient table, and the rotating film table are aligned. Using a horizontal X-ray beam, both tables are rotated in synchronization. However, because the contrast of the image is poor in this method, the center of the X-ray beams is tilted at approximately 20°.

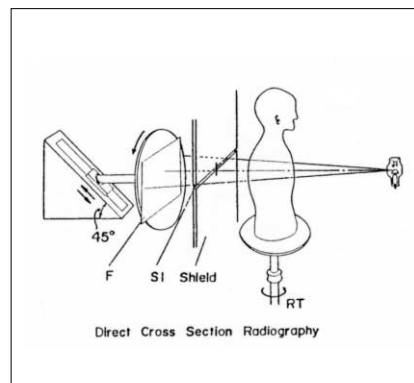


Figure 7. Direct cross-sectional radiography (modified method). The rotating film table is moved vertically along a 45° tilt angle.

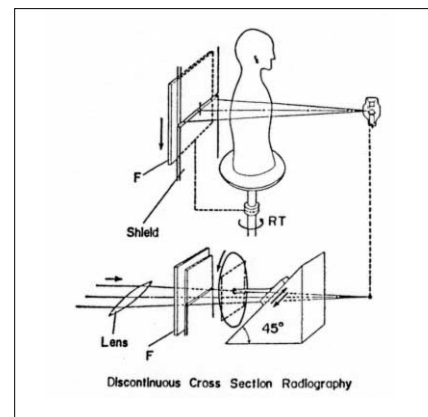


Figure 8. Discontinuous cross-sectional radiography (modified method). This method is a modified method for continuous cross-sectional radiography. The rotating film table is moved vertically along a 45° tilt angle. Cross-sectional images are obtained intermittently.

Table 1. Assessment of seven transverse tomographic methods

	Cross-sectional image	Image contrast	Image sharpness	Applicable regions	Operation	Reading	Patient exposure	Overall assessment
Discontinuous rotatography	Plotting	Excellent	Fair	All	Indirect	Easy	Medium	Fair
Continuous rotatography	X-ray	Excellent	Excellent	All	Direct	Difficult	Low	Fair
Continuous cross-sectional radiography (original method)	Dry plate	Good	Good	All	Indirect	Easy	Low	Good
Direct cross-sectional radiography (original method)	X-ray	Excellent	Fair	All	Direct	Easy	High	Fair
Rotatory cross-sectional radiography	X-ray	Good	Good	All	Direct	Easy	Low	Excellent
Direct cross-sectional radiography (modified method)	X-ray	Excellent	Good	All	Direct	Easy	High	Good
Discontinuous cross-sectional radiography (modified method)	Dry plate	Excellent	Excellent	All	Indirect	Easy	Low	Excellent

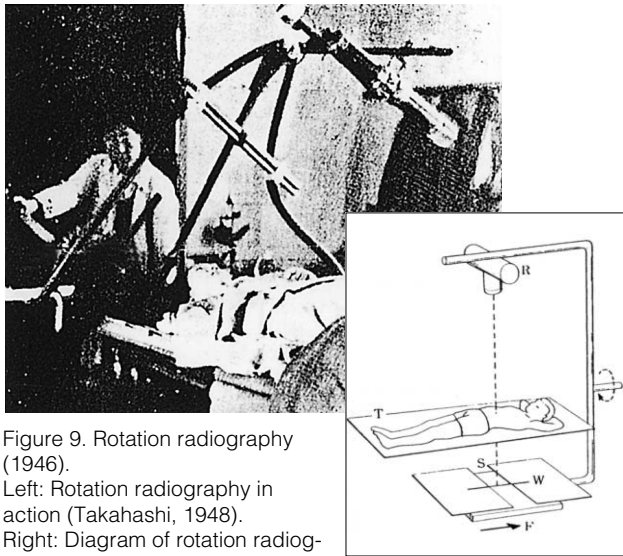


Figure 9. Rotation radiography (1946).
Left: Rotation radiography in action (Takahashi, 1948).
Right: Diagram of rotation radiography. The X-ray tube (R), the radiographic table (T), the lead diaphragm (W), the variable slit (S), and the film (F) are shown. (Reproduced from Takahashi, 1957.)

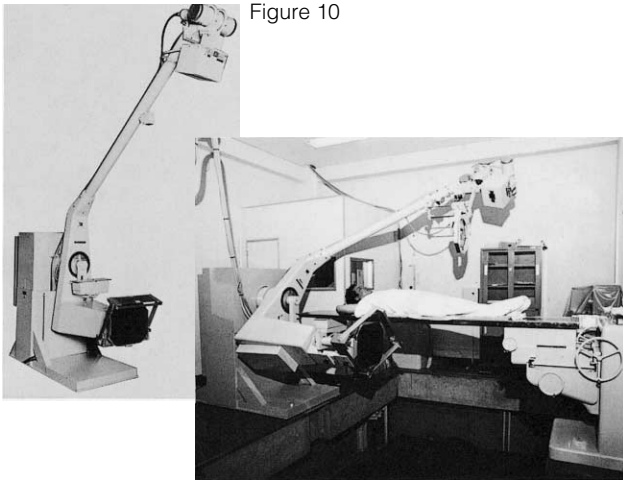


Figure 10

Figure 11

“In this imaging method, the size of the film can be changed freely. The film can be placed on the rotating table in any way one wishes, and any desired transverse slice can be obtained. This was demonstrated in model experiments in which, for example, a triangular pyramid was imaged with the film placed on the rotating table (parallel / perpendicular / oblique to the axis or on a curved surface) and accurate slice images were obtained....”

“In Japan, from the earliest stages, development work focused on systems for obtaining cross-sectional images with the patient placed in the supine position (Fig. 9). This has been found to be useful in clinical application.”

Based on these concepts, Japan’s first supine position axial transverse tomography system was produced as a prototype and then further refined (Figs. 10, 11).

Overseas evaluation

“Computer Tomography of Brain Lesions” was published in an overseas journal, *Acta Radiologica*, 1975, Stockholm Supplement, as an early report on X-ray CT applications in the brain (Fig. 12). In this report, Dr. Takahashi’s concept of an axial transverse tomography system was described as follows:

“The Takahashi tomogram. Takahashi (1957) developed several solutions to the difficult problems of performing transversal tomography with the projecting rays perpendicular to the rotation axis, i.e. with the Beam passing through the layer from edge to edge. In this report, this type of tomogram will be termed a Takahashi tomogram....”

As cited above, the “Takahashi tomogram” was recognized overseas as a proper noun. In fact, overseas researchers expanded on Dr. Takahashi’s early work, which eventually led to the development of the modern CT scanner (Fig. 13).

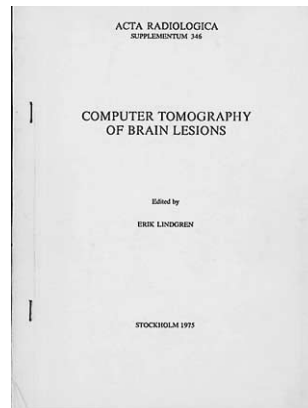


Figure 12.

Number of Axial Transverse Tomograph Unit		
U.S.A.		35
Sweden		4
France		3
U.S.S.R.		3
Netherlands		12
Yugoslavia		1
Finland		1
South Africa		1
Taiwan		1
Thailand		1
Mexico		1
		67 units

Major Hospital Where CS-B was installed		
INSTITUTION	LOCATION	SHIPPED
Marshall Hospital	New York	U.S.A. Sept. 1967
University of Chicago	Chicago, Ill.	U.S.A. Sept. 1967
Henry Ford Hospital	Detroit, Mich.	U.S.A. Sept. 1967
Washington University	St. Louis, Miss.	U.S.A. Aug. 1968
Karolinska Institute	Stockholm	Sweden Sept. 1968
Hospital of Ohio	Milwaukee	U.S.S.R. Sept. 1968
Cleveland Clinic	Cleveland, Ohio	U.S.A. Oct. 1968
University of Minnesota	Minneapolis, Minn.	U.S.A. Oct. 1968
Albany Medical Center	Albany, N.Y.	U.S.A. Feb. 1969
Lund	Lund	Sweden Mar. 1969
City of Hope Medical Center	Quincy, Calif.	U.S.A. June 1969
Göteborgs Universitet	Washington D.C.	U.S.A. Dec. 1969
Dickson	Dickson	Sweden Oct. 1970
Cancer Center	Cancer Center	U.S.S.R. Dec. 1970
William Beaumont Hospital	Canton, Mich.	U.S.A. Jan. 1971
University of Amsterdam	Amsterdam	Netherlands Mar. 1971
University of Wisconsin	Madison, Wis.	U.S.A. Aug. 1971
Lund	Lund	Sweden Sept. 1971
Jackson Memorial Hospital	Miami, Fla.	U.S.A. Oct. 1971
Washington Hospital Center	Washington D.C.	U.S.A. Oct. 1971
Mt. Sinai Hospital	Miami, Fla.	U.S.A. Oct. 1971
Mary Hitchcock	Manchester, N.H.	U.S.A. Feb. 1972
Marshall Hospital	Quincy, Mich.	U.S.A. Apr. 1972
Corpus Christi Hospital	Tucson, Ariz.	U.S.A. Apr. 1972
University of Arizona Medical Center	Tucson, Ariz.	U.S.A. May 1972
University of Amsterdam	Amsterdam	Netherlands Sept. 1972

Figure 13.

Summary

The author has reviewed the early research in the development of axial transverse tomography and was very impressed by the fact that a lone researcher was helping to lay the groundwork for CT amid the ruins of post-war Japan. Dr. Shinji Takahashi was a Japanese radiologist who asked himself, “Why can’t it be done?” The author is deeply gratified to have been a part of this project as an engineer in the later stages when Dr. Takahashi’s ideas were reaching their fruition.

In fact, immediately after the events described here, X-ray CT was introduced, demonstrating the soundness of Dr. Takahashi’s ideas. The importance of Dr. Takahashi’s early research into axial transverse tomography systems in laying the groundwork for the revolution that was to lead to the development of X-ray CT cannot be overestimated.

JRC 2003 (Japan Radiology Congress)

– Radiology: Translating Life Science into Patient Care –

– ITEM 2003 “Medical Imaging: The Key to the New Healthcare World” –

International Technical Exhibition of Medical Imaging 2003 (ITEM 2003)

The Japan Industries Association of Radiological Systems (JIRA) will hold ITEM 2003 in conjunction with the 62nd Annual Meeting of the Japan Radiological Society (JRS) and the 59th Annual Meeting of the Japanese Society of Radiological Technology (JSRT).

Chairman: Masamichi Katsurada
Dates: April 11 (Fri.) through April 13 (Sun.), 2003
Venue: Pacifico Yokohama Exhibition Hall,
 1-1-1 Minato Mirai, Nishi-ku, Yokohama
 220-0012, Japan

From the Chairman,

ITEM 2003 will be held at Pacifico Yokohama Exhibition Hall. It has been three years since ITEM 2000 was held in Yokohama. This city reminds us of the final match of the 2002 FIFA World Cup jointly hosted by Korea and Japan, the first soccer World Cup series held in Asia. This ITEM, although on a far smaller scale than the FIFA World Cup, has a history of 16 years since its beginnings in 1988 and is gaining increasing recognition throughout the world as Asia's largest comprehensive exhibition in the field of medical radiology. ITEM 2002, held in Kobe, involved approximately 40,000 participants during its 3 days. With the expanded booth area of the Yokohama site, we anticipate that an even greater number of people will take part in ITEM 2003. The medical equipment industry strives to develop patient-friendly devices that are easy for physicians to use and contribute to effective diagnosis. JIRA is holding this international exhibition to provide an opportunity for healthcare professionals and managers to see the results of the efforts made by individual manufacturers and vendors. In addition, our objective is to help healthcare professionals and managers find solutions to practical problems by means of a more active exchange of information.



Pacifico Yokohama

62nd Annual Meeting of the Japan Radiological Society

President: Junji Konishi, M.D.
Dates: April 11 (Fri.) through April 13 (Sun.), 2003
Venue: Pacifico Yokohama Conference Center,
 1-1-1 Minato Mirai, Nishi-ku, Yokohama
 220-0012, Japan

From the President,

Considering the recent progresses in life science, I have chosen “Radiology: Translating Life Science into Patient Care” as the main theme for the meeting.

59th Annual Meeting of the Japanese Society of Radiological Technology

President: Kazutaka Masuda
 Chief Radiological Technologist
Dates: April 11 (Fri.) through April 13 (Sun.), 2003
Venue: Pacifico Yokohama Conference Center,
 1-1-1 Minato Mirai, Nishi-ku, Yokohama
 220-0012, Japan

The theme of the congress is “Standardization of Radiological Technology”

● JRC 2003 Schedule ●

	JRS	JSRT	ITEM	
Opening Ceremony				
Apr. 11 (Fri.)	9:00	9:00		10:00
to	to	to		to
	18:00	18:00		17:45
Welcome Buffet				
Apr. 12 (Sat.)	8:30	8:30		10:00
to	to	to		to
	19:20	18:30		17:00
Apr. 13 (Sun.)	8:30	8:30		10:00
to	to	to		to
	16:00	15:30		16:00
Closing Ceremony				
Scientific Program				
● Special lecture	● Educational lectures			
● Symposium	● Scientific papers			
● Scientific exhibits	● Film reading conference			
● CyberRad	● International Symposium			
Registration Fees				
● JRS•JSRT	¥12,000			
● ITEM	¥ 3,000			
● Welcome Buffet	Free (registrants)			

Commendation by JIRA Chairman's Award for Year 2002

The persons who have offered distinguished service to JIRA division and committee activities for many years were commended by the Chairman prior to the reporting session of JIRA on September 26, 2002. Certificates of commendation and

memorabilia were presented by Chairman Katsurada. The seven persons that were commended and their achievements are listed below. We would like to congratulate them and thank them for their continuous cooperation regarding JIRA activities.



Mr. Hiroshi Aradate
(Toshiba Corporation)

Achievements: Contributed to JIRA activities for many years, including his service as Chairman of the SC-4209 Expert Committee of the Standardization Division.



Mr. Hiroshi Ishihara (Shimadzu Medical System Nishinihon Corporation)

Achievements: Contributed to JIRA activities for many years, including his service as Chairman of the Engineering Division and Assistant Center Manager at the Medical Radiation Facilities Safety Administration Center.



Mr. Takayoshi Izumi
(CMI, Inc.)

Achievements: Contributed to JIRA activities for many years, including his service as Chairman of the PL and Safety Measures Committee of the Regulations and Economy Division.



Mr. Katsushi Takayama
(Seikosha Co., Ltd.)

Achievements: Contributed to JIRA activities for many years, including his service as Vice Chairman of the Inter-Company Information Committee of Related Apparatus and Accessory Division and Chairman of the JIS Z4918 (Film Observation Device) Committee.



Mr. Minoru Hosoba
(Shimadzu Corporation)

Achievements: Contributed to JIRA activities for many years, including his service as Chairman of the Medical Imaging System Division.



Mr. Tomoyuki Honno
(Hitachi Medical Corporation)

Achievements: Contributed to JIRA activities for many years, including his service as Chairman of the Industry and Academia Cooperation Division and Chairman of the Exhibition Committee.



Mr. Shigetaka Miura
(GE Yokogawa Medical Systems, Ltd.)

Achievements: Contributed to JIRA activities for many years, including his service as Vice Chairman of the International Division and Chairman of the GHF-ISO/TC210 Committee.

JIRA

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