

# Radiology Japan

Japan Industries Association of Radiological Systems

March 2007 No. 55

## Review of the Japanese Market for Diagnostic Imaging and Therapeutic Systems from April to September 2006

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

From April through September 2006 Unit: Millions of yen

Item	Category	Production		Exports		Imports		Domestic Market			
		Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Number of Units	% Δ from Previous Year	Amount	% Δ from Previous Year
<b>1 X-ray</b>		<b>63,348</b>	<b>+8</b>	<b>24,159</b>	<b>+12</b>	<b>10,919</b>	<b>0</b>			<b>50,109</b>	<b>+4</b>
· General-purpose R/F		13,527	-8	2,497	+7	0	0	745	+1	11,030	-11
· Cardio & angio		5,962	-9	3,170	-7	6,049	+6	118	+1	8,841	0
· General-purpose radiography		10,868	+32	4,828	-2	280	-36	2,537	-5	6,321	+67
· Mammography		1,079	-26	4	-58	1,999	-28	303	-20	3,074	-28
· Mobile		1,530	-14	775	-8	51	-22	305	-25	807	-20
· Dental		3,770	+12	1,115	0	0	-	2,272	+16	2,655	+19
· Others		26,612	+10	11,770	+30	2,540	-47			17,381	-13
<b>2 CT</b>		<b>57,703</b>	<b>+11</b>	<b>37,973</b>	<b>+14</b>	<b>14,070</b>	<b>+78</b>			<b>33,800</b>	<b>+26</b>
<b>3 Nuclear medicine</b>		<b>4,783</b>	<b>+425</b>	<b>408</b>	<b>-</b>	<b>5,326</b>	<b>-39</b>			<b>9,702</b>	<b>+1</b>
<b>4 MRI</b>		<b>16,916</b>	<b>+1</b>	<b>8,826</b>	<b>-6</b>	<b>17,328</b>	<b>+23</b>			<b>25,417</b>	<b>+18</b>
<b>5 Image processing systems</b>		<b>11,661</b>	<b>+65</b>	<b>2,133</b>	<b>+46</b>	<b>2,985</b>	<b>+13</b>			<b>12,512</b>	<b>+52</b>
<b>6 Related items &amp; accessories</b>		<b>16,445</b>	<b>+12</b>	<b>8,523</b>	<b>+34</b>	<b>1,325</b>	<b>+26</b>			<b>9,247</b>	<b>-1</b>
<b>7 Diagnostic ultrasound</b>		<b>44,550</b>	<b>+7</b>	<b>28,619</b>	<b>+8</b>	<b>4,845</b>	<b>+14</b>			<b>20,777</b>	<b>+8</b>
<b>8 Therapeutic systems</b>		<b>2,166</b>	<b>+37</b>	<b>1,236</b>	<b>+53</b>	<b>4,317</b>	<b>+83</b>			<b>5,248</b>	<b>+68</b>
<b>Total</b>		<b>217,572</b>	<b>+12</b>	<b>111,877</b>	<b>+12</b>	<b>61,115</b>	<b>+18</b>			<b>166,812</b>	<b>+14</b>

(Note) Domestic Market: Calculated by the formula (Production – Exports + Imports).

### Review of April to September 2006

The percentage in ( ) refers to the increase or decline over the previous year. The data includes new companies that reported their results.

- The total count of medical imaging systems was as follows.
  - Production 217.6 billion yen (+12%)
  - Export 111.9 billion yen (+12%)
  - Import 61.1 billion yen (+18%)
  - Total domestic market 166.8 billion yen (+14%)
- The domestic market of major equipment was as follows:
  - X-ray 50.1 billion yen (+6%)
  - CT 33.8 billion yen (+26%)
  - Nuclear medicine 9.7 billion yen (+1%)
  - including PET-related products 6.0 billion yen

- MRI 25.4 billion yen (+18%)
  - Image processing systems 12.5 billion yen (+52%)
  - Diagnostic ultrasound 20.8 billion yen (+8%)
- Total diagnostic equipment increased to 161.6 billion yen (+13%)

Some diagnostic X-ray systems were as follows.

- General-purpose radiography 6.3 billion yen (+67%)
- It increased successively since the 4th quarter of 2005 fiscal year.
- Dental 2.7 billion yen (+19%)
- On the other hand, the following decreased.
- General-purpose R/F 11.0 billion yen (– 11%)
  - Mammography 3.1 billion yen (– 28%)
  - Mobile 0.8 billion yen (– 20%)
- Total X-ray 50.1 billion yen (+6%)

3. The total production output increased to 217.6 billion yen (+12%).

(This data includes 6.7 billion yen by new companies.)

Especially,

– Nuclear medicine increased to 4.8 billion yen (+425%)

Some diagnostic X-ray systems were as follows. The following increased:

– General-purpose radiography 10.9 billion yen (+32%)

– Dental 3.8 billion yen (+12%)

On the other hand, the following decreased:

– Mammography 1.1 billion yen (– 26%)

Total X-ray 63.3 billion yen (+8%)

4. The total exports increased to 111.9 billion yen (+12%).

(The data includes 1.7 billion yen by new companies.)

Some diagnostic X-ray systems decreased as follows.

– Mammography 4.0 million yen (– 58%)

– Mobile 0.8 billion yen (– 8%)

– Cardio & angio X-ray R/F 3.2 billion yen (– 7%)

– General-purpose radiography 4.8 billion yen (– 2%)

But, the exports of system components were 9.3 billion yen.

So, the total of diagnostic X-ray systems was 24.2 billion yen (+11%).

On the other hand,

– MRI decreased to 8.8 billion yen (– 6%)

5. The total imports increased to 61.1 billion yen (+18%).

It contributed to the increase of sales in the domestic market.

(The data includes 0.9 billion yen by new companies.)

Especially, the following increased.

– CT 14.1 billion yen (+78%)

– MRI 17.3 billion yen (+23%)

– Image processing systems 3.0 billion yen (+13%)

– Related items & accessories 1.3 billion yen (+26%)

– Diagnostic ultrasound 4.8 billion yen (+14%)

– Therapeutic systems 4.3 billion yen (+83%)

On the other hand, some diagnostic X-ray systems decreased.

– General-purpose radiography 0.3 billion yen (– 36%)

– Mammography 2.0 billion yen (– 28%)

– Mobile 0.05 billion yen (– 22%)

The total diagnostic X-ray system was 10.9 billion yen (0%).

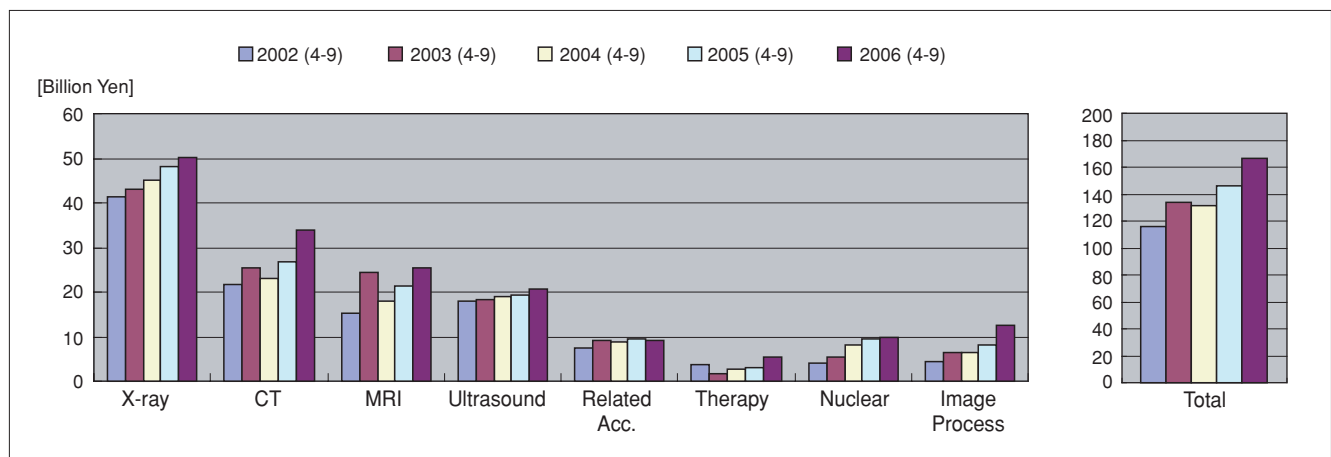
Although PET import was 4 billion yen, the total nuclear medicine system decreased to 5.3 billion yen (– 39%).

6. The total domestic market increased to 166.8 billion yen (+14%).

Although Related items & accessories decreased to 9.3 billion yen (– 1%), the total major systems increased and the total reached 166.8 billion yen (+14%).

This data includes 5.9 billion yen by new companies. The 2.7 billion yen out of 5.9 billion yen was Image processing systems.

### Diagnostic Imaging and Therapeutic Systems Market in Japan Trends in the Last Five Years by Modality



# Message for the year 2007



**Hiroshi Inomata**  
Chairman

**Japan Industries Association of Radiological Systems**

The latest situation surrounding medical care is very severe by the medical-expenses restrictive policy, because a balance is required between the medical level desired and the medical expenses afforded.

In Japan, we are in an aging society with fewer children. The total population is leveling off. The labor force that supports society is decreasing. In such a situation, medical care is required to be of higher quality, safer, and more patient-friendly. In April 2005 the Pharmaceutical Affairs Law (PAL) was revised to make regulations more strict and detailed. Furthermore, in April 2006, the medical treatment fee was amended with decrease of medical expense on average of minus 3.16%.

Under such circumstances, the domestic market of medical imaging system, especially MR and CT, showed a solid growth in the first half of 2006 fiscal year. But, the market has shrank or leveled off for general-purpose R/F, mammography systems and accessories. In addition, the tendency in recent years is that equipment is being used for more years before replacing. The issue for safety and maintenance of equipment has become important. Now, three years have passed since the revision of PAL. Several problems still remain unsolved. For example, it takes much time to acquire approval. An application costs much money. Above all, reimbursement fee of medical imaging system in the medical treatment fee is not clear yet. No incentives are available for development of safe and efficient imaging system and its clinical application. In order to make medical care more efficient and "patient-friendly", the whole medical system must be reformed. JIRA intends to solve these problems, to cooperate with related academic and industrial bodies from the viewpoint of patients, and make practical proposals to administrative authorities. In order to obtain understanding of all related parties, we are intensifying public relation activities. As one example, we published "JIRA Annual Report on Medical Imaging Devices & Systems 2006" in April 2006. Subsequent editions will follow.

To cope with remarkable change in our business circumstances, we have made our major action plan for 2007 as follows.

1. Proposal for appropriate evaluation of medical equipment and clarification of fee in the reimbursement
  - 1) Systemization of total evaluation technique of medical imaging system
  - 2) Clarification of safety measures and maintenance cost
  - 3) Establishment of evaluation of medical IT

2. Promotion of conformity to medical care-related laws and regulation, as well as a proposal for improvement/harmonization
3. Proposal and cooperation toward the next Vision for Medical Device Industries
4. Promotion of international activity
5. Promotion of proposal to Administrative Authorities and public relation activity
6. Compliance implementation within JIRA members
7. Reinforcement of cooperation between member companies and development of JIRA services to members

The details of these policies are as follows.

## 1. Proposal for appropriate evaluation of medical equipment and clarification of fee in the reimbursement

We have emphasized this subject on every occasion, and we intend to continue this stance with the following activities for this year.

- (1) Systemization of total evaluation technique of medical system  
In the past, evaluation was based on the cost of equipment and the related personnel expenses. From now on, it must be based on social and economic needs. Such evaluation should include the cost of maintenance of equipment, technology and skill for imaging, improvement of patient's QOL, early detection of disease, efficient medical care and sharing of information. We propose that such a total evaluation should be implemented.
- (2) Clarification of safety measures and maintenance cost  
Medical system replacement is taking longer. Users should understand: "Safety and maintenance cost should be correlated". It is defined that "The maintenance cost is one of the important expenses", recognized by "Study Group of Cost of Medical Facilities" of the Central Social Insurance Medical Council. We promote clarification of maintenance cost that is essential for the safety of patients.
- (3) Establishment of evaluation of medical equipment based on IT promotion  
The Cabinet Secretariat announced its "New IT reform strategy". The No. 1 item of the six important policies is "a reform of the medical care system through IT". Medical sys-

tem and IT will be fused, for example, in the form of telemedicine, networking, and efficient medical care in local communities. We contribute to the Medicare activity for clinical efficiency and Medicare efficiency.

## 2. Promotion of conformity to medical care-related law and regulations, as well as proposal for improvement/harmonization

There are two main laws related to medical care. One is the Medical Service Law for medical institutions. The other is PAL for manufacturers and sellers of medical device. PAL was revised in April 2005. Enforcement regulations of the Medical Service Law were partially revised in April 2006. Further partial revision of the Medical Service Law is scheduled. The new provisions affecting JIRA are as follows.

- (1) The revised PAL newly specified "specially designated maintenance management required medical device". Its contents were incorporated into "the partial revision of enforcement regulations of the Medical Service Law". The device in this category is to be maintained more carefully than before.
- (2) "The partial revision of the Medical Services Law" requires medical institutions to have an organization that receives from Marketing Approval Holders information of security, modification, and etc. of "specially designated maintenance management required medical device", etc. At the same time, it requires them to record maintenance activity. This revision adopts JIRA's long-standing request that medical institutions should have such an organization to meet the new regulations.

These regulations are all based on patient's rights to receive "safe/secure medical care." JIRA should comply with them positively. JIRA intends to expand the scope of medical device that is subject to new regulations.

This is the third year since the enactment of the revised PAL. The following issues remain unsolved.

- (1) The revised PAL required a shift to a new form of business. Most companies are still under the grace period. We request a smooth and simple procedure for renewal of registration.
- (2) The transition procedure for manufacture/sale of the products approved under the old PAL is unclear and complicated.
- (3) The industrial standards such as JIS are referred to as the essential requirement for medical devices. When these standards are revised, a new application is necessary. The procedure for the application and setting of a transition period is unclear.

We request the related bodies to clarify and simplify the procedure.

## 3. Proposal and cooperation toward the next Vision for Medical Device Industries

In March 2003, the Ministry of Health, Labour and Welfare announced "the Vision for Medical Device Industries", indicating major policies. In response to this vision to vitalize industries, JIRA revealed the present situation and problems found in each phase: research, development, production, sales and further maintenance/repair and disposal. Last year, JIRA proposed the following matters.

- (1) Appropriate recognition and evaluation of roles to be played by the medical imaging system
- (2) Appropriate vitalization and regulation of the medical imaging system that is suitable for their diversification and sophistication
- (3) Further arrangement of the system, human resources and infrastructure that aims at the appropriate use of the medical imaging system
- (4) Request related to assessment and approval

We continue to make efforts to realize this vision based on these proposals.

In 2008, five years after the release of "the Vision for Medical Device Industries", the Ministry will revise "the vision" based on the progress of the current vision. JIRA intends to make proposals for various policies and cooperate in drafting "the new vision" based on the present situation and future prospect.

## 4. Promotion of international activity

As cooperating with foreign industrial associations (Europe: COCIR, U.S.: NEMA, Canada: EFC-MIISC), JIRA will perform various international activities, including the trade of medical device, reimbursement, international standardization and international harmonization, thus promoting the presence of JIRA. It will survey the laws and regulations for medical device in the growing Asian markets, especially China and Korea, and provide information for members.

In 2006, JIRA served as the chairman of the DITTA, which consists of four associations: COCIR, NEMA, EFC-MIISC and JIRA, and led global activity. JIRA submitted the position paper to GHTF. The paper is reflected in GHTF documents and declarations. On the other hand, JIRA participates in AHWP and supports their activity positively.

Last year, JIRA collected information and exchanged information with COCIR about European environmental regulations, especially the RoHS regulation of medical equipment. China adopted similar regulations in March 2007. In response to this, JIRA cooperated with DITTA and submitted a position paper. Environmental regulations will be increasingly globalized. For example, the REACH (Registration, Evaluation and Authorization of Chemicals) directive will be issued in Europe. In order to cope with this trend, JIRA and member companies will make efforts to comply with global environmental regulations.

## **5. Promotion of proposal to Administrative Authorities and public relation activity**

JIRA will promote affiliation and cooperation with medical and industrial associations: the Japan Radiological Society (JRS), Japanese Society of Radiological Technology (JRST), Japanese Federation of Medical Devices Associations (JFMDA), Japan Electronics and Information Technology Industries Association (JEITA), and Japanese Association of Healthcare Information Systems Industry (JAHIS), etc. JIRA will submit proposals about reimbursement and laws related to medical equipment to governmental agencies, the Cabinet Office, the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of Education, Culture, Sports, Science and Technology. In addition, JIRA promote public relations activity through its web site and publications. In April last year, additionally JIRA published "JIRA Annual Report on Medical Imaging Devices & Systems 2006". A 2007 edition will follow.

## **6. Compliance implementation within JIRA members**

Last year, we established a contact point for consultations on compliance in the JIRA secretariat. Each division and committee in JIRA performed the self-audit of compliance in order to have better understanding of compliance and promote specific measures.

Further, JIRA cooperated with JFMDA's corporate ethics committee in issuing "Guidelines for promotion code" and "Guidelines for donations to academic associations". JIRA also cooperated with the Fair Trade Council in drafting "Certificate test criteria".

This year we continue activities such as holding of seminars to make JIRA and JIRA members more conscious of compliance.

## **7. Reinforcement of cooperation between member companies and development of JIRA services to members**

In 2006, the revised PAL imposed "continual training". JIRA cooperated with three other bodies and held training courses ten times at 7 sites, which many trainees participated in. JIRA will continue training courses mainly for member companies. In April last year, we introduced "JIRA market statistics" into the statistic system to make it more accurate and useful for member companies.

JIRA has been operating the International Technical Exhibition of Medical Imaging (ITEM). ITEM is held with an increasing number of participating companies, exhibition floor space and number of visitors year by year. In April this year, ITEM 2007 at Pacifico Yokohama will be sponsored by the Japan Radiology Congress (JRC) and operated by JIRA.

In order to enable members to share information quickly, JIRA will continue also this year to utilize its web site and to publish "JIRA News" and "JIRA Bulletin" and reinforce cooperation between member companies.

In order to promote these activities and make them successful, it is essential to have a closer relationship with Administrative Authorities, related academic societies, related industrial associations, etc., and develop global and speedy activities. JIRA intends to make concerted efforts to play its role and contribute to improve the health and QOL of people.

# JIRA Activity Reports

## Activities of Regulation and Safety Division

### I Outline of the Division

#### 1. Introduction

In April 2006, the then Regulation and Economy Division was reorganized. Its Economy Committee was separated and became independently the Economy Division. The rest of the division became “the Regulation and Safety Division”, consisting of the following four committees.

- (1) Regulation Committee: deal with general legal matters such as the Pharmaceutical Affairs Law (PAL) and other laws related to medical imaging system
- (2) Safety Committee: mainly cope with quality assurance and post-market safety of medical imaging system
- (3) QMS Committee: handle the quality management system for manufacturing procedure
- (4) Software Committee: aim to address incorporation of application software for medical imaging system

#### 2. Basic policies

The basic concept of this Division is “to enhance JIRA’s activity to the level where it is possible to make proposals for medical device policy to government offices.” As a means to achieve this goal, we disseminate information of activity to members, convey information and technology to other associations and academic circles, and promote public relations activity on every occasion.

The three basic policies in FY 2006

- (1) Promotion of response to legal matters,
- (2) Ensure of further safety of medical devices,
- (3) Promotion and realization of The Vision of Medical Device Industry.

#### 3. Collaboration with external bodies

In order to achieve our objective as the Regulation and Safety Division, we collaborate with the following academic parties and industrial bodies,

- (1) Japan Federation of Medical Devices Association
- (2) Japan Electronics and Information Technology Industries Association’s Electronics Business Committee
- (3) Japanese Association of Healthcare Information Systems Industry
- (4) Japan Radiological Society
- (5) Japanese Society of Radiological Technology
- (6) Japan Association of Radiological Technologists
- (7) Diagnostic Imaging Consortium.

### II Activities of its committees

#### 1. Regulation Committee

At present, the Regulation Committee has six working groups (WGs) on these individual themes.

- (1) PAL WG
- (2) Approval/Certification Criteria Drafting WG
- (3) Classification WG
- (4) Good Clinical Practice (GCP) WG
- (5) RoHS-WEEE WG
- (6) Animal-Use Medical Device PAL WG

Two years have passed since the enactment of the revised PAL. We are performing improvements to address the issues that still remain unsolved.

- Clarification of transition procedures from old forms of marketing business at the time of renewal of registration
- Clarification of transition of revision and withdrawal of criteria
- Clarification of transition of Approval/Certification
- Preparation for the further revision of PAL.

#### 2. Safety Committee

The revised PAL requires severe post-market obligations of the Marketing Approval Holder, when it is a newly established business. For this reason, this committee performs activity mainly addressing the post-market surveillance of medical devices.

This committee has Post-Market Safety Control subcommittee (Good Vigilance Practice (GVP) committee) and Mammography Equipment Delivery GL-WG.

In order to address the post-market safety control, we participate in the Japanese Society of Radiological Technology (JSRT)’s “Medical Safety Subcommittee” as well as “Medical Safety Control Guidelines Drafting Committee”, which consists of JSRT, Japan Association of Radiological Technologists, and JIRA. (JIRA is in charge of a part of medical device control.)

#### 3. QMS Committee

QMS stands for Quality Management System, which covers all the aspects of manufacturing procedure. JIRA QMS committee has the following three important policies.

- (1) Study of the revised PAL in relation to QMS, and deployment of dissemination activity
- (2) Study of international standards and deployment of dissemination activity
- (3) Addressing GHTF and studying foreign regulations.

#### 4. Software Committee

The Software Committee consists of two WGs.

- (1) Software WG1; to draft the approval criteria for universal diagnostic imaging work station.
- (2) Software WG2; to clarify the present situation and problems of software and to incorporate software into medical imaging system.

At present, the revised PAL defines clearly the articles for universal diagnostic imaging work station. WG1 and WG2 acts jointly to clarify applicability (HIS, RIS, PACS for medical information, radiography, diagnostic imaging, informed consent, electronic health records, etc. for administration).

#### International harmonization of JIS standards related to X-ray apparatuses

A "Standardization Committee" has been set up as the principal business of Japan Industries Association of Radiological Systems (JIRA) and is promoting "Standardization of industrial standards based on international harmonization". JIRA provided a quick response in the deliberation of the IEC standard draft in cooperation with "IEC/SC related Technical Committee". It established a "JIS draft preparation Sub-Committee" for the preparation of a draft of JIS and is positively promoting the establishment of JIS with incorporating IEC translated standard. The activities for standardization of JIS based on the international harmonization are as follows:

A SC (Sub Committee) belonging to a standardization committee of an X-ray systems Gr. was re-organized in July, 2006. The new and old corresponding list of SC is shown in table 1. This re-organization aimed to make a system corresponding to the review of policies of IEC standards relating to X-ray devices under IEC/SC 62B' charge. The Steering Group X-ray was adopted in order to review the construction of relevant IEC standards for X-rays at the meeting of IEC/SC 62B held in Williamsburg in U.S.A. in April, 2004.

Based on the above decision, a temporary member group gathered in Dublin, Ireland in Sept. 2005, and proposed a practical plan to review the said standards about the following main discussion points:

- (1) Harmonization with new standard IEC60601-1, 3rd edition shall be achieved.
- (2) IEC standards shall be arranged into 3 divisions of product safety standards, quality assurance and performance assessment criteria.
- (3) The standards shall become international standards to be employed in the regulations of each country based on the trends of the EU and Japan (JIS referred in the revised Japanese Pharmaceutical Affairs Law), etc.

One of these proposals is re-construction of individual safety standards for X-rays based on system units being used in clinical practices.

**Table 1 Standardization Committee: reorganization of X-ray equipment Gr.**

Past organization		JIS	After July 2006		IEC
SC-2102	Machinery safety	Z4703	SC-2102	Abolition (a missing number)	60601-2-32
SC-2201	X-ray tube, tube assembly	Z4704, Z4102 Z4751-2-28	SC-2201	X-ray tube, tube assembly	60336, 60522, 60806, 60613, 60601-2-28
SC-2202	X-ray high-voltage equipment	Z4702	SC-2202	Abolition (a missing number)	60601-2-7
SC-2203	X-ray equipment protection	T0601-1-3	SC-2203	X-ray equipment protection	60601-1-3
SC-2204	X-ray equipment for animal	—	SC-2204	X-ray equipment for animal	—
SC-2205	Mammographic X-ray equipment	Z4751-2-45	SC-2205	Mammographic X-ray equipment	60601-2-45: The safety of mamma- graphic X-ray equipment  61223-3-2: Acceptance tests-Imaging performance of mamma- graphic X-ray equipment
SC-2206	Dental X-ray equipment	X4711	SC-2206	Dental X-ray equipment	60601-2-5: Particular requirements for basic safety and essential performance of dental X-ray equipment  61223-3-4: Acceptance tests-Imaging performance of dental X-ray equipment
SC-2207	X-ray field restriction equipment	Z4712	SC-2207	Abolition (a missing number)	
/			New SC-2208	X-ray equipment for radiography and radioscopy	60601-2-54: Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy  61223-3-1: Acceptance tests-Imaging performance of X-ray equipment for radiographic and radioscopic systems
/			New SC-2209	X-ray equipment for IVR	60601-2-43: Particular requirements for the safety of X-ray equipment for interventional procedures  61223-3-3: Acceptance tests-Imaging performance of X-ray equipment for digital subtraction angiography (DSA)
RC1102	Bone mineral analyzer	—	New SC-2210	X-ray bone mineral analyzer	60601-2-**



## Report on the Chinese visit (International Division)

A visiting group was sent to China from September 4 to 14 for regular meeting with Chinese Medical bodies and to join in the exhibition CHINA- HOSPEQ2006.

### 1. Ministry of Health (MOH) in China

- (1) The investment plan of the following three types in rural districts will be enforced to improve healthcare service and medical facilities of the agricultural communities in China.
  - People's hospitals: 400 beds or less (an average of 300 beds)
  - Hygiene hospitals: about 40,000 institutions, each with 50 beds (mid-western district: 27,000 and eastern district: 13,000)
  - Hygiene clinics: Clinics for outpatients

A bulk purchase system will be adopted from fiscal 2006 and will be enforced.

Target products at present are three kinds: X-ray equipment, Ultrasonic system and Electrocardiograph.

The technical committee of Chinese Medicine Facilities Association evaluates the medical equipment for the selection of models and inform each institution of the results. Some medical doctors in universities, and engineers from manufacturers and service organizations are included in the member of the committee. The results are approved by the Ministry of Health and made available to the public. Their expiration date shall be three years. The approved products are displayed in CHINA-HOSPEQ and showed to prospective purchasers for deep understanding of them. Thereafter, the Ministry of Health wants to buy them en bloc.

- (2) A new joint medical insurance system for agricultural committees

A new insurance system was adopted from fiscal 2006 with an annual premium of 50 RMB of which 40 RMB is born by the government and 10 RMB by the farmer. The district office shall give support when the farmer cannot afford it. Achievement is aimed at 40% in 2006, 80% in 2007 and 100% in 2010.



### 2. State Food and Drug Administration of China (SFDA)

In the medical field in China, SFDA evaluates technical levels of distributors; manages product registration, approval and certification of medical device, and MOH evaluates technical levels of purchasers; evaluates technical levels of hospitals and certificate these grades, and assigns and manages items to be purchased according to the size of the institutes.

- (1) SFDA Notification No. 205 was published on May 10, 2006 to accomplish thorough compliance to the requirements specified in GB9706.1-1995 (IEC60601-1) standards for electric safety confirmation examination of medical electric devices. SFDA is working on and putting pressure on the industries to complete the scope of all test items, including currently registered products, within 2007.
- (2) The concept of SFDA on the certificate of manufacture by the Japan Ministry of Health, Labour and Welfare (an English version is now available for the evidence to overseas product registration) for the attachment of application is just an informative reference and the case of re-registration application is similarly dealt with. Also, the written certificate issued by a third-party certification body is similarly dealt with. SFDA always demands a faithful report in accordance with the said safety standards.
- (3) A design change of a registered product shall be in accordance with detailed rules (a SFDA16 notification) and the product shall be re-applied even for one increase in the specifications or performance. In addition, re-application is also required in the case that the manufacturer changes its registered address.
- (4) The adoption of standardization for EMC test has been already decided, and SFDA looks forward the timing of making its effective. The postponement of the original plan was announced.
- (5) Procedures for the report of accidents are similar with that in Japan and the accidents shall be reported to the provincial State Drug Administration Center.

In China, a period required for product registration is said to become longer than ever before. In addition, the gap between IEC standards and China GB standards is still remain in some part and needed to be urgently revised. It seems SFDA has still facing such time consuming task to be taken.



### 3. Certification and Accreditation Administration of the People's Republic of China (CNCA) and the China Quality Certification Center (CQC)

- (1) The detailed rules of Chinese Compulsory Certification (CCC) is now under preparation, meetings for an exchange of opinions between CQC and related business companies have been held and CQC said to have got requirements from the industries.
- (2) When the design change of listed products in the CCC controlled product list is required, or when a manufacturer has determined that the change may involve the change of products safety even if they are not listed in the same controlled list, re-application is required.
- (3) Ministry of Information Industry (MII) covers the Chinese RoHS matter. CNCA/CQC are not directly involved in it, but intend to be involved in it at the stage of actual practice.



### 4. China Association of Medical Devices Industry (CAMDI)

- (1) This organization's role is said to have expanded to be a consultant for the product registration as well as that for the clinical trials and adviser to the administration. Approximately 11,700 companies have become members of the association.
- (2) International trade of Chinese medical devices resulted in exports of 3.2 billion dollars, imports of 1.8 billion dollars from January to July in 2006, and exports exceeded imports in actual achievement.
- (3) JIRA was requested to participate in CMEF exhibition that will be held in Dalian city from April 10 to 13 in 2007.



### 5. The 15<sup>th</sup> China International Medical Equipment & Facilities Exposition and Symposia (CHINA-HOSPEQ2006)

JIRA joined the exhibition held in Beijing on September 7 to 9 for the first time by the request of MOH in China. Many persons relating to hospitals, manufacturers, business firms, news agents and publishers visited the exhibition.



## Report on the DITTA TC Meeting Chicago 2006

As it has been every year, the meeting was held in line with opening of the RSNA on November 28<sup>th</sup> in Chicago, on the preceding day of the DITTA main meeting in 2006. NEMA, COCIR, MIISC and JIRA participated in, and this year, JIRA acted as the chairperson. At this meeting, we discussed many issues, which include some remaining issues from the previous March meeting. The important issues from the TC meeting were also reported to the DITTA main meeting.

### 1. Response to Chinese RoHS

We decided that DITTA would submit the position paper on the Chinese RoHS in December to the Chinese Government by a combination of nine associations including other industrial associations in Europe and USA. In the future, the reinforcement of environmental regulations in every country will become very important for DITTA. Therefore, we agreed in continuous information exchange in order to acquire mutual understanding.

### 2. Information exchange on a third-party certification program

Following the preceding meeting, JIRA updated the content of certification criteria utilized in a third-party certification system. Assessment by a third-party certification body is important in view of the "Approved once, Accepted everywhere" of GHTF, and no additional information was exchanged.

### 3. Development of GHTF STED in each country

Using a cross-comparison of STED status, JIRA raised the problem that every country applies STED in a different way. Now, AHWP(Asian Harmonization Working Party) is trying to summarize CSDT(Common Submission Dossier Template) and gathering the comments from the public. This time, we explained and discussed the positioning and difference on STED and CSDT. In conclusion, it was recognized that we still need more time to have mutual understanding. When JIRA will have completed a draft of comment to CSDT, the draft will be circulated to other DITTA members, and if the consensus is achieved among the members, DITTA will make a position paper based on that in the future.

### 4. Discussion of UDI (Unique Device Identification)

NEMA submitted a counterproposal for UDI under FDA examination. In Japan, there is a issue of "Bar-code labeling on medical devices" as well. It was discussed whether or not stationary type medical devices such as diagnostic imaging system require particular labeling in medical institutes in view of the safety of patients. NEMA will establish a Task Force team in the next fiscal year to adjust and settle such problems including the cost matter, and make any proposal on the presupposition that particular labeling is unnecessary.



# Development of Japanese Radiological Equipment in Post-World War II Period (20)



Sumio Makino  
(Advisor, JIRA)



Shigenobu Yanaka  
(formerly Hitachi  
Medical Corporation)

## Origin of X-ray CT — Revolution of radiology —

### 1. Introduction (Makino)

The year of 1972 was really the revolutionary year of radiology. EMI (U.K.) announced CT at RSNA in Chicago that year. It attracted much attention from brain surgeons in the world. The first CT in Japan (U.K. EMI-Scanner) was installed in 1976 at Tokyo Women's Medical University as a result of effort of the late Professor Koichi Kitamura of the department of brain surgery. In August of that year, he scanned the head of the first patient in Japan and detected six tumors. The clinical significance was great and the doctors were all impressed. I had a chance of witnessing this situation 27 years ago.

Subsequently, the then Professor Minoru Inaba of the department of brain surgery at Tokyo Medical and Dental University, as a specialist, explained the decisive effectiveness of EMI-Scanner. The necessity of CT scanner for brain surgery was emphasized and the Ministry of Finance was persuaded to provide the fund from the surplus of damage insurance. As a result, 37 brain CT scanners were imported at a stretch and installed at the department of brain surgery of medical school of national and public universities. Among them, 30 sets came from U.K. EMI, and 7 sets came from ACTA, being imported by Shimadzu Corporation.

Such a rapid introduction of CT by Japan became the target of envy of the medical community of many countries. The era of CT in Japan began with the dramatic development mentioned above.

The so-called CT technology, or CT study, or "Computer Tomography" became suddenly the subject of research for many research laboratories in the world. This trend resulted in the application of IT for medical imaging equipment, and in the revolutionary change of radiology.

As mentioned above, U.K. EMI scanner appeared in Japan. Under the guidance of Professor Inaba, the scanners were purchased with the surplus of damage insurance and installed at universities (whose department of brain surgery requires CT). This effort surprised the foreign medical community with the unique method and "speed" of introduction. Toshiba Corporation took charge of these import activities, and began to manufacture its own CT soon afterward. [For details, please refer to "Key words

for enterprise success: Case study of X-ray CT business" that was authored by Sumio Makino and published in 1987.]

Why is it that such a big deal involving the government proceeded so rapidly and smoothly? It was unprecedented. People thought of many reasons for that. But, it was a special business that was driven by the absolute effectiveness of new medical technology.

On the other hand, Hitachi Group developed its own CT technology from the very beginning, overcoming many difficulties and starting manufacture. It was only Hitachi that did so in Japan. Their efforts should be recorded in this series "Development of Japanese Radiological Equipment in the Post-World War II Period". So, I asked Mr. Shigenobu Yanaka, the then development manager, for his contribution. He willingly contributed the following precious article.

### 2. Development of X-ray CT (the first national product) by Hitachi (Shigenobu Yanaka, former senior director of Hitachi Medical Corporation)

#### 1. Introduction

Development of X-ray CT (hereafter CT) is a great achievement comparable to the discovery of X-ray (in 1895). Initially, 19 manufacturers participated in competitive development in the world. At present, however, business is limited only to several integrated manufacturers of medical equipment. In Japan, Toshiba Corporation and Shimadzu Corporation imported foreign products at the early stage, shifting to their own production, whereas Hitachi Medical Corporation (hereafter our company) developed CT independently with home ground technology.

Mr. Sumio Makino asked me to contribute an article about development of the first national CT, which will be published in JIRA journal. I accepted his request because I think that record-keeping is a duty of one of developers. Your forgiveness would be much for my poor memory after the lapse of 28 years.

## 2. The birth of development theme

A big event in the history of introduction of CT in Japan was the import of 37 sets of CTs. On the occasion of the visit by the Queen Elizabeth to Japan on May 7, 1975, the decision was made by the Ministry of Finance and the Marine and Fire Insurance Association of Japan, Inc. They allocated the investment yield of compulsory automobile liability insurance in order to donate the imported CTs to national and public university hospitals throughout Japan.

U.K. was then experiencing an unfavorable balance of payment in the trade with Japan. U.K. EMI succeeded in development of CT for the first time, and announced this new technology with 3-year clinical results on April 29. It was a timely coincidence.

Note (Makino):

Introduction of X-ray CT into Japan was a "dramatic" event. The total price was five billion yen, which was unprecedented for the purchase of medical equipment. It caused a furor and speculation. But in fact, "That was the way how CT was introduced," and "EMI-Scanner was well-received." This fact is worth recording.

We wanted to know more about the future prospect of CT in terms of technology, medicine and business. We read several papers in foreign journals and started preliminary survey and experiment in the period between November 1974 and January 1975. It was several months before the visit by the Queen Elizabeth.

The December 1973 issue of British Journal of Radiology carried three CT-related papers, which we probably noticed in the middle of the following year. We had been engaged in development of X-ray diagnostic imaging and in the issue of images themselves for a long time. So, these papers were quite new to us and seemed to predict the era of new imaging technology.

The 80 × 80 CT image was mosaic and the spatial resolution was as poor as the early scintiscanner image. However, the significance of image was very different. I thought that our company should develop such a device as a manufacturer of medical imaging equipment. But, our knowledge and information were insufficient, so we were unable to make a formal proposal for development. The expected scale of potential market was unknown, either.

Foreign journals were the main source of information available. We formed a study team to read them in turn in order to know more about the principle and the reconstruction and algorithm and to start preliminary experiments. The team was joined by Koike (presently, Technical research center, Regeneration medicine development division manager) and Takagi (presently, Kashiwa Office, CT business strategy manager). Both of them and the author belonged to the research group

of Kashiwa Factory.

In the first experiment, we used a phantom having small X-ray contrast, which was a Mylar sheet sandwiched between thick acrylic plates. We scanned it with a narrow X-ray beam, and measured the penetrated X-ray intensity by using a detector consisting of NaI crystal and photomultiplier tubes. We converted the measurement data into digital data and measured the distribution of intensity. This experiment was nothing new, which was the so-called "evaluation of detectability in the scanning type X-ray imaging system." But, we noticed several advantages, that the detection system was very efficient, the dynamic range was wide, the scattered ray was effectively eliminated with a narrow beam scanning, and then the contrast resolution was much higher than the conventional X-ray imaging system using the two-dimensional sensor.

In the next stage of experiment, we attempted to "reconstruct cross-sectional images by using the measurement values of X-ray beam projected from multiple directions." To our regret, however, it was difficult to perform this immediately in our research environment of those days.

Fortunately, Division No. 4 of Hitachi Central Research Laboratory took charge of medical equipment, and they were our old colleagues. We were helped by Senior Researcher Yamamoto (presently, Professor at Toyohashi University of Technology), who had already started to investigate the reconstruction algorithm of CT. Then, we built the measurement system by combining an X-ray generator and a detector at the laboratory of Kashiwa Factory of Hitachi Medical Corporation and sent the data to Central research laboratory for reconstruction calculation.

We placed an X-ray source and a detector face-to-face for horizontal scan. We placed a phantom in between. The phantom was acrylic structures (of several kinds) immersed in a water tank, being rotated once for each horizontal scan. An example of an experimental device and a phantom are shown in Figures 1 and 2.

We used a seamenstar-like phantom, because it enabled us to measure resolution of reconstructed images and to detect directional artifact if any.

It took 45 minutes to obtain measurement data required for one slice of cross-sectional image, and took tremendous time to record the data on the punch tape. Measurement data of one slice required several rolls of the tape. They were transported almost every night from Kashiwa Works to Central research laboratory located in Kokubunji City, which was 50 km away from Kashiwa, and took one more night to obtain the reconstructed image. Such collaboration had not been well performed in the beginning. Data from Kashiwa were sometimes incomplete. Parameters were not compatible between the measurement system (Kashiwa) and the calculation system (Central research laboratory) and reconstruction of image was impossible. Trouble was due to mutual misunderstanding and poor communication. Although the image quality was poor, everyone began to feel the

feasibility of CT. Figure 3 shows the reconstructed image of the phantom shown in Figure 2.

Such a situation continued till around February 1975. This development theme was not yet authorized, but approved only “implicitly”.

Now, let us look back upon the status of development in the world about CT of those days. U.K. EMI developed CT in 1971 began to be introduced by U.S., Canada and Switzerland around 1973. It showed epoch-making effectiveness to diagnosis of a head disease. Furthermore, in U.S., a whole-body scanner (ACTA scanner) was developed in March 1974. Moreover, EMI scanner was displayed at U.K. Medical Equipment Exhibition in Tokyo in April 1974, which was later informed the author.

Japanese cerebral neurosurgeons and radiologists gradually became aware of CT, and keenly realized the necessity for this equipment. We were informed that they recommended “domestic production of CT” to the management of our company. At that time, X-ray TV was called high-priced equipment. CT was 10 times more expensive than X-ray TV. Given high risk of development of CT, it was difficult for us to reach a quick conclusion.

With this situation as a background, “Development Committee” of our company was held in March 1975 in a time-

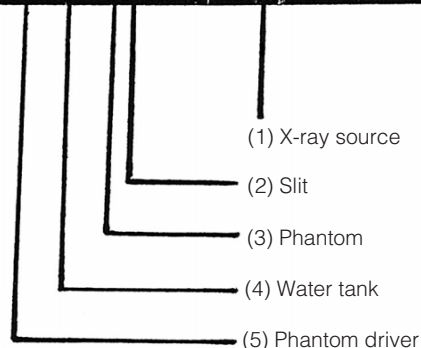
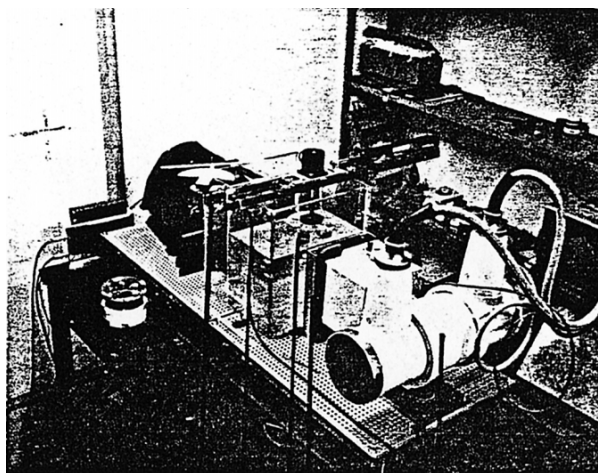


Figure 1 Measurement system to obtain CT image (around February 1975)

ly manner. It was a good chance for us to report the result of experiment and propose further development. This committee was the highest decision-making body about the product development. The committee members included president, senior managers in charge of design, research in the factories and planning and sales. It was periodically held once in a month.

The then president Goto’s decision opened the path to “development of domestic CT”. He instructed us to make a prototype in 6 months and to ship a product by March 1976, just one year from then.

President Goto used to be General Manager of Instrumentation Division of Hitachi, Ltd. He already noticed advantage of quantitative imaging information obtained by CT, instead of analog information obtained by X-ray film. This was a big factor of his decision. We also foresaw the future where the definite diagnosis is possible with CT value. Our foresight was right. The subsequent development was in high-speed measure-

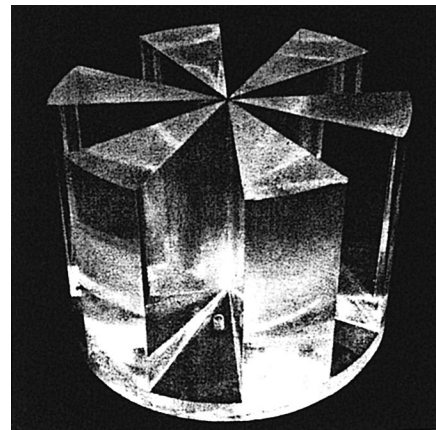


Figure 2 An example of phantom used to evaluate reconstruction calculation

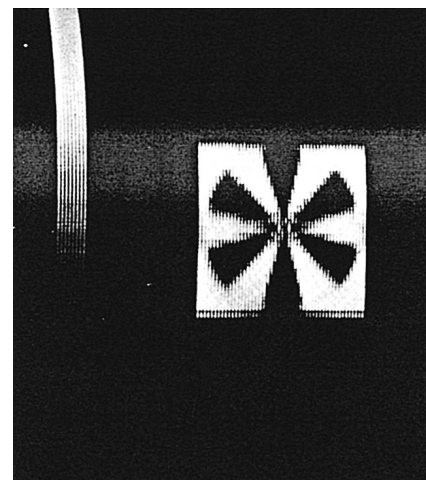


Figure 3 The reconstructed image of the phantom shown in Figure 2 (February 1975). The measurement data obtained at Kashiwa Factory was reconstructed at Hitachi central research laboratory.

ment with spiral and multislice scan, fast reconstruction, high image quality and three-dimensional image. CT aimed at the direction with detailed anatomical information of “diagnostic imaging.” The three-dimensional image of high image quality now available reminds us of the history of painstaking development.

### 3. Toward completion of prototype

The project was immediately inaugurated in response to the decision by Development Committee. We started the project with 11 elites of the research group as well as engineers from the design department of factory. However, none of them have ever seen CT. The first step of their work was to share information. At that time, Kashiwa Factory was organized to have two design departments. One was Roentgen department in charge of X-ray equipment, and the other was ME department in charge medical electronics department. As the technical field of CT extended over these two departments, both departments cooperated each other to develop a single system. This was our first case for integration of our technical capabilities.

We considered the following points in deciding the specification for the prototype.

- (1) The system shall be dedicated to brain scan. The scan time shall be within 4 to 5 minutes.
- (2) The system shall be easy to use.
- (3) The system shall be highly reliable.
- (4) The system shall incorporate the existing technology as much as possible.
- (5) The image-processing component shall consist of micro-computer control and dedicated calculator.

We opted for a brain scanner because the necessity for CT was higher for diagnosis of brain, and early commercialization was anticipated. The target patients include many emergency patients, such as apoplexy and trauma. Doctors and technologists are unfamiliar with key-in operation. In order to allow them to operate the system easily and quickly, we adopted the push-button input like the conventional X-ray equipment.

We designed the system to facilitate the patient setting and the slice determination.

As for the image processor, other companies adopted a standard minicomputer. We attempted to shorten the reconstruction time, to reduce cost and to increase the added value. So, our company adopted a microcomputer, and developed a separate calculator. This was strongly recommended by Design Department as a new concept of image processor for the coming era of digital medical imaging. That was a hardware-oriented system. At the product introduction meetings, other companies criticized that our system is more difficult to expand than minicomputer-base system. But, we thought that our system had necessary and sufficient functions, and our choice was right.

The late Tomita designed a scanning mechanism. He used to work for Machinery Research Laboratory of Hitachi, Ltd.,

who designed a driving mechanism for X-ray multiple orbit tomography and was called “an expert of mechanism”. So, he took care of designing mechanism also in this project. Once the specification and performance required for a scanner are known, he devised a very unique mechanism. A scanner must run at constant speed during horizontal scan, and at the end, it must turn back quickly and smoothly with a large displacement of angle. The gravitational effect varies with the rotation angle. In order to meet this specification, he combined a cylindrical cam with a spring-index device.

At the same time when the project was started, the members in charge of scanner design moved to a design office located in Yotsukaido City, Chiba Prefecture and concentrated on the design work. The members had designed the mechanism that repeatedly moved for X-ray fluorographic table and tomographic equipment. However, they had never design such a mechanism that must repeat scanning and rotation for more than four minutes to cover a single slice of image, and repeat the same sequence several times (to cover several slices of image). One designer complained, saying “This is just like a life-test of mechanism.”

The members in charge of image processor were working day and night to design both hardware and software. Especially, they were behind a schedule in deciding the algorithm of reconstruction.

Thanks to their efforts, design of hardware was completed by the end of June, including X-ray system, measurement system, and scanner and image processor. About three months passed since the start of project.

Around this time, the market situation began to change affecting the morale of project members. The EMI scanner was scheduled to work in August at Tokyo Women’s Medical University as the first equipment in Japan. The government intended to allocate the investment yield of compulsory automobile liability insurance and to install the imported CTs to national and public university hospitals throughout Japan. The market began to move rapidly.

The most shocking news was our management’s decision to install our prototype CT at Fujita Gakuen Nagoya Health University in October. We felt as if “we were attacked from both sides by the enemy”.

The decision was made when the equipment was not completed and images were not obtained. The local salespersons obtained the CT installation plan of Nagoya Health University, got an approval from the top management, and negotiated with the university. The decision was made whether Development Department accepted it or not.

We said, “The prototype is not complete enough for clinical use in a hospital.” Our request was rejected at once. “Hitachi’s heavy electric machines, even if they are gigantic, have no prototype at all. The first machine is to be delivered to a customer.”

We felt the summer of 1975 especially hot. A scanner traveled the stroke of 240 mm in 0.77 seconds. A single horizontal

scan required 1.15 seconds as expected. It was a good start.

However, once we completed the basic configuration of equipment and produced images, we faced many problems one after another. Every component passed the test. But, the whole sequence from measurement to reconstruction calculation did not work normally. The equipment operated but it did not produce images. This was the first bottleneck on the path to success.

The ultimate output of diagnostic imaging equipment is defined as “an image with the outstanding diagnostic capability”. Initial image produced by the prototype was far from this definition. The phantom image should be a ring. But, we obtained two semicircles coupled and displaced. We found the cause of this trouble at once. It was due to the mechanical displacement of positions during scanning.

The most serious problem was “excessive noise in the image and low contrast resolution”. We had many suspicious causes, such as vibration of a scanner during scanning, insufficient SN ratio of a detector, accuracy of AD converter, calculation algorithm, number of bits, external noise.

We used a single machine in turn and continued experiment until 22:00 everyday. After a quick night meal, we had discussion about the progress of the day. During the discussion, the atmosphere became depressing. Everybody wanted that the trouble was not due to his own fault. Even when the cause of trouble was found out, solution was more difficult. The countermeasures produced a new trouble. Especially, software engineers had a difficult time in cleaning up after others' mistakes.

Some engineers continued to work even after the night meal at 22:00 and discussion meeting. Next morning, they transferred the result to the members of next shift.

Although it was very trying time, problems were solved one by one and the quality CT image became better and better. We were encouraged. The quality of reconstructed image of the phantom (Figure 2 seamenstar) reached the level as shown in Figure 4 by the real-time calculation.

Around this period, many people of Kashiwa Factory became interested in development of this new equipment. Especially, workers in charge of material procurement and machining were cooperative. Early in the morning, they were ready to respond to our quick request. The members of research group felt the factory-wide cooperativeness and became tense.

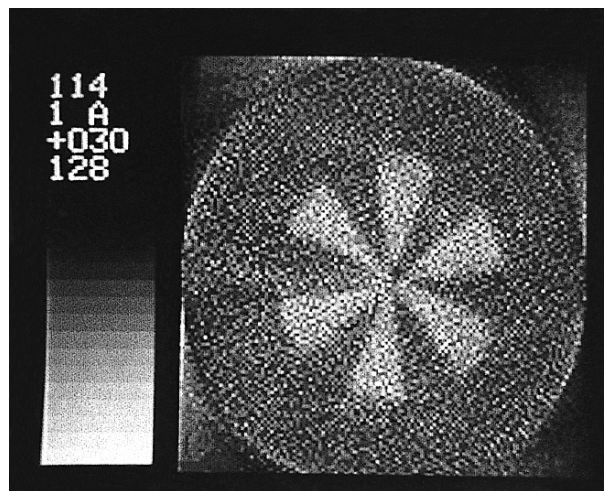


Figure 4 The reconstructed image of phantom (Figure 2) (September 1975)  
Real-time measurement and calculation by a prototype

In September, we were informed of the news that EMI CT was installed in Tokyo Women's Medical University and it began to work. The first patient's CT image showed more clinical information than doctors expected in advance, again demonstrating the effectiveness of CT.

We were not sure whether we could deliver the prototype to Nagoya Health University in October. But, we invited Professor Koga (Department of Radiology) and Lecturer Jinno (presently, professor of cerebral neurosurgery) to the certificate test on September 30. We made every effort to improve the image quality into late at night on the previous day. We wondered whether the image would be acceptable to clinicians.

On the day of test, we saw the brain of a volunteer on CRT screen. But, we could not find any cerebral ventricles that should have been seen. They were barely seen in the noisy image. Doctors who operate the brain and see the inside everyday must have been disappointed. When we began to feel despair, one of the doctors said, “Any way, bring the machine to us. We shall try to use it.” Thus, clinical operation of the first domestic machine started.

The machine was installed on the first basement level of Nagoya Health University (Figure 5). The first patient, a young man with intracranial hypertension, was scanned on October 16. Scanning required 4 minutes and 45 seconds. The picture elements were  $128 \times 128$ . The image (Figure 6) showed the cerebral ventricle expanded by hydrocephalus, although the image was upside down. It was only one month behind after the EMI CT in Tokyo Women's Medical University started to work. (Refer to the Nihon Kogyo Shimibun report on October 18 that reported domestic CT production by Hitachi Medical Corporation.)

Immediately after this installation, we received guidance from university doctors and made on-site improvement. They were enthusiastic and just like trying to grow a premature baby who was born at last.



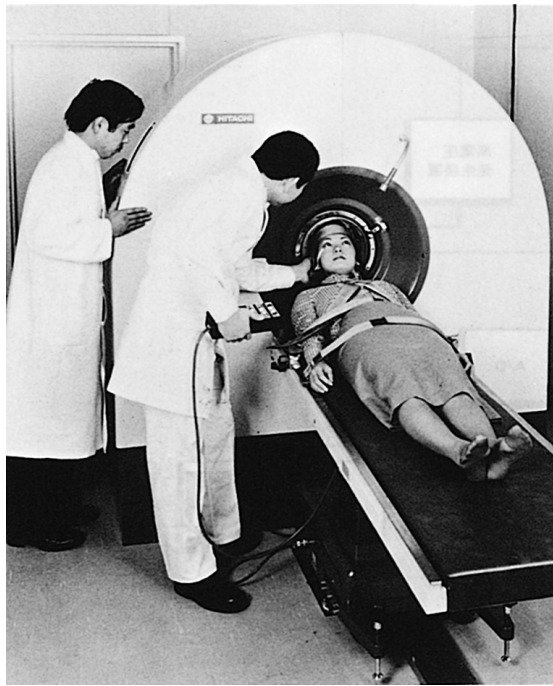


Figure 5 The first CT of domestic production installed in Nagoya Health University.

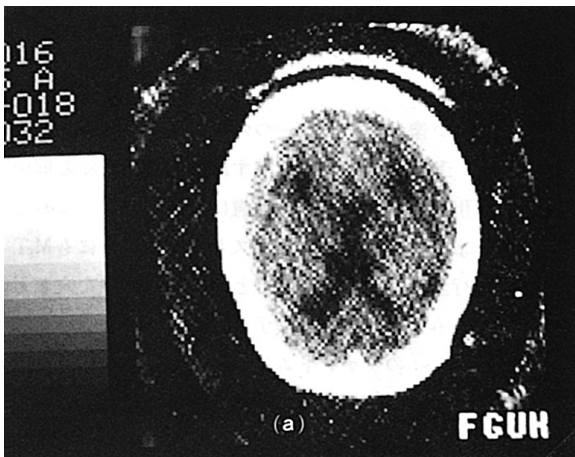


Figure 6 The first clinical image obtained by the first CT of domestic production (October 16, 1975) (Reproduced from Medics Vol.2/No.2)



The newspaper that reported the first CT of domestic production (The Nihon Kogyo Shimibun dated October 18, 1975)

Dr. Katada (presently, professor of radiology) and Mr. Sawada, Chief Engineer, who were in charge of this equipment devoted all their time to CT, giving us complaints and new ideas. It was really industrial and academic cooperation, with both trouble and pleasure.

In May of the following year (1976), we announced the clinical result and displayed our machine at the 35th Japan Radiological Society Congress attracting much attention. The first commercial CT was installed in March of the same year at Kobayashi Cerebral Neurosurgery Clinic located in Ueda City, Nagano Prefecture.

After these many twists and turns, Japan now ranks the fourth in terms of development and production of CT.

### 3. Summary (Makino)

The CT technology has revolutionized the medical practice since the late 1970s. It has changed all the JIRA-related matters, including what diagnostic imaging equipment should be, medical equipment manufacturers, organization of production factories and so on. The reform motivated exploitation of new business.

The introduction of CT in Japan was quite different from other countries. Hitachi Group developed its own technology. On the other hand, EMI scanners were introduced at a stretch at the governmental level.

In that sense, this article is worth recording.