# Radiology Japan

Japan Industries Association of Radiological Systems February 2004 No. 48

### Review of the Japanese Market for Diagnostic Imaging and Therapeutic Systems, the First Half Year 2003

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

|                               |            |                          |         |                          |         | From Janua               | ry through         | June 2003                | Unit: Mil | lions of yen             |
|-------------------------------|------------|--------------------------|---------|--------------------------|---------|--------------------------|--------------------|--------------------------|-----------|--------------------------|
| Category                      | Production |                          | Exports |                          | Imports |                          | Domestic Market    |                          |           |                          |
| Item                          | Amount     | % to<br>Previous<br>Year | Amount  | % to<br>Previous<br>Year | Amount  | % to<br>Previous<br>Year | Number<br>of Units | % to<br>Previous<br>Year | Amount    | % to<br>Previous<br>Year |
| 1 X-ray                       | 54,051     | 108                      | 16,762  | 135                      | 8,627   | 75                       | 9,688              | 110                      | 45,916    | 93                       |
| • General-purpose R/F         | 14,630     | 94                       | 2,962   | 106                      | 25      | 16                       | 751                | 95                       | 11,693    | 90                       |
| • Cardio & angio              | 5,235      | 103                      | 2,741   | 138                      | 4,777   | 60                       | 125                | 64                       | 7,271     | 66                       |
| • General-purpose radopgraphy | 12,527     | 113                      | 3,561   | 177                      | 431     | 101                      | 2,227              | 121                      | 9,396     | 99                       |
| • Mobile                      | 2,331      | 154                      | 1,446   | 271                      | 158     | 100                      | 369                | 86                       | 1,043     | 92                       |
| • Dental                      | 3,347      | 101                      | 630     | 143                      | 0       | -                        | 2,839              | 103                      | 2,716     | 95                       |
| • Others                      | 15,981     | 118                      | 5,422   | 117                      | 3,236   | 115                      | 3,377              | 121                      | 13,796    | 117                      |
| 2 CT                          | 42,176     | 113                      | 19,738  | 104                      | 6,504   | 234                      | 637                | 123                      | 28,942    | 137                      |
| 3 Nuclear medicine            | 1,553      | 84                       | 38      | 48                       | 3,366   | 94                       | 104                | 139                      | 4,880     | 91                       |
| 4 MRI                         | 17,780     | 78                       | 9,439   | 59                       | 12,881  | 137                      | 230                | 127                      | 21,222    | 131                      |
| 5 Image processing systems    | 5,733      | 106                      | 522     | 159                      | 1,661   | 281                      | 1,915              | 82                       | 6,872     | 121                      |
| 6 Related items & accessories | 13,983     | 101                      | 5,213   | 108                      | 1,071   | 109                      | -                  | _                        | 9,841     | 98                       |
| 7 Diagnostic ultrasound       | 34,129     | 105                      | 24,048  | 117                      | 2,970   | 172                      | 1,772              | 57                       | 13,050    | 95                       |
| 8 Therapeutic systems         | 4,158      | 68                       | 1,068   | 105                      | 2,855   | 85                       | 284                | 100                      | 5,945     | 70                       |
| Total                         | 173,562    | 102                      | 76,828  | 103                      | 39,935  | 118                      | -                  | -                        | 136,668   | 105                      |

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

### Review of the first half year 2003

Approximate percentages in comparison with the previous first half year are shown in parentheses.

The performance of the entire medical device industry from January through June 2003 was 173.6 billion yen (102%) in production, 76.8 billion yen (103%) in exports, and 39.9 billion yen (118%) in imports, amounting to 136.7 billion yen (105%) in the domestic market.

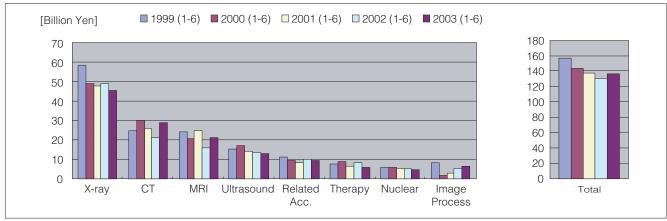
In the domestic market, computed tomography (CT) systems and magnetic resonance imaging (MRI) systems in particular showed strong growth at the 30% level compared with the same 6-month term of the previous year: 28.9 billion yen (137%) for CT and 21.2 billion yen (131%) for MRI. This growth, however, does not indicate a recovery in the market. In April 2002, a reimbursement program was revised, resulting in a reduction in reimbursement points of approximately 6% for CT and approximately 31% for MRI. Consequently, hospitals took a wait-and see position concerning the purchase of these systems, and same 6-month sales for 2002/2001 fell to the 60% level. In 2003, although such purchasing restraint showed some relaxation, both modalities have yet to reach the levels of several years ago and are still exhibiting a downward trend.

Overall sales of diagnostic X-ray systems were 45.9 billion yen (93%), showing a continuing decline. In particular, a big drop was seen in cardio & angio systems, with figures of 64% for the number of units and 66% for sales value. This is thought to reflect the lack of growth in the number of medical specialists who use such systems as well as the trend to employ these systems only for definitive diagnosis, which has led to a significant fall in demand.

Data concerning diagnostic ultrasound systems has only recently begun to be collected from JIRA member companies. This early data showed a decrease to 13.1 billion yen (95%). In particular, the trend from April to June showed a decline in unit prices.

For your information, trends in the last five first-half years are shown in the next page.

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



# **JIRA Activity Reports**

### Reports on Korean Medical Device Regulations

Representatives from the JIRA International Division visited Korea from September 17 to 19, 2003, and exchanged information with the Korea Food & Drug Administration (KFDA), Korea Medical Devices Industry Association (KMDIA), Korea Testing Laboratory (KTL), and Korea Medical Instrument Industrial Cooperative (KMIC).

### 1. Korea Food & Drug Administration (KFDA)

The JIRA members visited the Medical Devices & Radiation Health Department of the KFDA to meet with Mr. Lee Geon Ho, Manager of the Department. The similar approach to regulatory reform shared by Korea and Japan assisted a productive exchange. The outline of ongoing reform of the Pharmaceutical Affairs Law in Japan was presented from the JIRA side. KFDA described the outline of the Korean Medical Device Law as follows:

- The Korean Medical Devices Law was enacted on May 29, 2003. A working group comprising members from the academic society, industry, and KFDA is currently preparing the related ordinances and regulations for enforcement.
- Classification in the Medical Device Law is being reviewed with reference to the Global Harmonization Task Force (GHTF) documents. However, the classification route is likely to include more mandatory features, unlike self-classification in Europe. (It was explained that JIRA classification is based on GHTF's four classes, but is partially different from Europe. KFDA commented that it serves as a useful reference.)

 As for the quality system, GMP is not yet compulsory, but is scheduled to become so in two or three years. ISO13485 is likely to be the applicable standard.

# 2. Korea Medical Devices Industry Association (KMDIA)

A meeting was held with Mr. Kim Suk Jae, General Manager, Mr. Na Heung Bok, Manager, and representatives from the member and affiliate companies.

- JIRA explained that KFDA and the Japanese authority were holding discussions on GMP mutual recognition between Korea and Japan, and the use of the globally recognized ISO13485 as a common base. JIRA recommended that private organizations participate in ongoing GHTF discussions on ISO13485 or quality system auditing.
- On-site GMP audits, which will be required with the reformed Pharmaceutical Affairs Law (PAL) by the Ministry of Health, Labour and Welfare of Japan, are not required for overseas manufacturers by the Korean authority. Meanwhile, Korean manufacturers are subjected to very strict on-site audits by China.
- PACS is a Class 2 device in Korea. The situation in Japan was explained as follows. Currently, PACS is not regarded as a medical device. The workstation will become a Class 2 medical device under the revised Pharmaceutical Affairs Law, although it is not yet certain that all PACS products will become Class 2 devices.
- At the moment, application software is not treated as a medical device in Korea, but is intended to be included in the scope of medical devices in the future.
- The adoption of Risk Management requirements in GHTF has yet to be considered in Korea.

### 3. Korea Testing Laboratory (KTL)

Mr. Ko Chang Ho, Director General of the Medical Device Center, and Mr. Kim Soon Chang, Manager of the Medical Radiological Device Team, participated in a meeting for the exchange of information.

- The Medical Device Center functions as a certification body for KFDA approval. Its operations include quality system auditing at manufacturing sites and importers, type test, and medical device testing and inspection. Since this year, medical device testing and inspection has been transferred from KFDA to the private sector. The Center is also engaged in supporting industry and medical device policies as well as conducting research.
- For medical device testing and inspection, the specifications and safety of Class 2 devices (except for radiological equipment) can now be reviewed by four private organizations including KTL. KFDA also continues to undertake reviews. KFDA charges a testing fee of 30,000 won, while private companies charge 300,000 won, 10 times as much. However, the certification process is faster with a private company: usually one month or less, and only 2 weeks in the case of KTL. The KFDA testing standards are IEC-60601-1 and other special standards. These standards are available at the KFDA website. Some products need to meet special requirements unique to Korea.
- Questions and answers regarding the Medical Device Law are shown below. Enforcement ordinances and regulations are currently under preparation, and may be subject to changes in the future.

1) Article 3. Classification

The current three-class system will change to a four-class system in accordance with the GHTF recommendation. The present Class 3 will be divided into 3A and 3B to make four classes: Class 1, Class 2, Class 3A, and Class 3B. Classification rules will be established and the class specified on a product basis.

2) Article 6. Medical Device approval

The enactment of the new Medical Device Law will lead to the establishment of a new importer approval system, in addition to the existing manufacturing and distribution approval systems. A transitional measure will be introduced to allow importers currently holding product approvals to obtain approvals through a declaration.

3) Article 14. Quality Testing Facilities

Quality testing facilities and the quality management system will not be changed from the current practice. GMP is recommended, but is not mandatory.

4) Article 41. Updating

There will be no updating system at present. Quality system review will be performed every 2 years.

5) Others

Type testing has not changed from now. The same standards are employed for the quality management system, but the requirements of qualification systems for manufacturing and importing managers will be deleted.

### 4. Korea Medical Instrument Industrial Cooperative (KMIC)

Mr. Pak Chung Nam, Managing Director, and Mr. Ahn Byung Chul, Manager of the Operation Team met with the JIRA delegates.

KMIC gave a briefing on the progress of the establishment of a joint committee of related organizations in China, Korea, and Japan. Bilateral discussions with the China Association for Medical Devices Industry (CAMDI) in China are scheduled for October 2003. KMIC proposes that the information exchange with JIRA should take place when the 20th Korea International Medical, Clinical Laboratories & Hospital Equipment Show (KIMES 2004) is held in March 2004.

The market trend data presented from KMIC is shown in Table 1.

### 5. Seminar on the reform of the Japanese Pharmaceutical Affairs Law

Delegates from JIRA gave a presentation on the recent movements related to the Japanese Pharmaceutical Affairs Law reform in a seminar hosted by KTL in which 120 interested people participated. A detailed explanation was given and a lively discussion was conducted regarding the background of the legal reforms, the modifications to the system, classification, third-party certification, and changes in import control systems.

One of the issues that came to light was the difficulty concerning welfare equipment. Welfare equipment is regarded as a medical device in Korea, while it is not in Japan. Therefore, when such equipment is shipped from Japan to Korea, it cannot obtain a manufacturing and distribution certificate.

|                     |                               | 2000 | 2001 | 2002  |
|---------------------|-------------------------------|------|------|-------|
| Domostio production | Overall medical devices       | 690  | 995  | 1,123 |
| Domestic production | Diagnostic X-ray systems      | 155  | 230  | 245   |
| Euro ante           | Overall medical devices       | 415  | 445  | 461   |
| Exports             | Diagnostic ultrasound systems | 156  | 131  | 101   |
| Imports             | Overall medical devices       | 730  | 884  | 1,028 |
|                     | MRI                           | 33   | 34   | 37    |
|                     | X-ray systems                 | 21   | 17   | 31    |
|                     | Diagnostic ultrasound systems | 23   | 24   | 29    |

#### Table 1. Korea's market trends (Unit: million US\$)

### Medical Imaging System Division Report on the International Modern Hospital Show 2003

The Japan Hospital Association and the Nippon Omni-Management Association (NOMA) organized the International Modern Hospital Show 2003, which was held from July 16th to 18th at Tokyo Big Sight under the theme "Pursuing Peace of Mind and Trust in Health, Medical Care, and Welfare in the 21st Century". There were 59,700 visitors and 316 exhibitors - the largest number ever.

A detailed report on this show can be viewed at NOMA's website (http://www.noma.or.jp/hs/index-e.html). The following is a report on the exhibition themes and the seminar held by the Integrating the Healthcare Enterprise-Japan (IHE-J) Project, which aims to promote the integration of medical information. These events were organized mainly by the JIRA Medical Imaging System Division.

In the corner "Medical Care Support Utilizing Imaging and Information Networks", which was one of the exhibition themes of the show organizers, the IHE-J Project introduced its basic principles and activities using exhibition panels, while also demonstrating some of the multi-vendor connections that were shown at CyberRad2003 with the cooperation of the participating vendors. On the adjacent IT Solution Stage, the IHE-J Project presented a lecture entitled "IHE-J: The Actualization of Medical Imaging Systems through a New Standardization", which attracted capacity audiences every day. On the first day of the exhibition, the IHE-J Project also conducted its own "IHE-J Seminar" in the adjacent hall, with lecturers invited from many fields. This seminar was also a great success and was attended by an enthusiastic audience.

### **IHE-J Seminar Program**

Coordinator: Hidenori Shinoda,

Chairman, IHE-J Technology Examination Committee

1. "The Efforts of the Ministry of Economy, Trade and Industry toward Information-oriented Healthcare Service"

Masafumi Ohki, Assistant Director, Service Industries Division, Commerce and Information Policy Bureau, Ministry of Economy, Trade and Industry

2. "IHE from the Viewpoint of the Ministry of Health, Labour and Welfare"

Fumio Takesue, Assistant Director, Medical Technology and Information Promotion Department, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare

 "IHE Specifications that can reduce Introduction Costs" Nobuo Okazaki, Visiting Professor, The University of Arizona

- 4. "The Standardization to be realized by IHE" Minoru Hosoba, Chairman, JIRA Medical Imaging System Division, and General Manager, Medical Information System Division, Shimadzu Corporation (Professor, Kyoto College of Medical Technology)
- 5. "A New Approach to Standardization the IHE-J Project"

Takeo Ishigaki, Professor, Department of Radiology, Nagoya University School of Medicine

6. "IHE and the Standardization of Medical Information" Michio Kimura, Professor, Department of Medical Informatics, Hamamatsu University

School of Medicine

IT in the medical field is represented by electronic charts and regional alliances, and the corner "Medical Care Support Utilizing Imaging and Information Networks" presented advanced cases and new technologies, exciting a great deal of interest. In this environment, the introduction of IHE-J activities provided an opportunity for administrators of medical institutions to recognize its achievements in the field of radiology, where standardization among multiple vendors has been moving forward.

As IT gains further acceptance in the field of medicine, it is clear that the IHE-J Project will play a greater role and face higher expectations at future International Modern Hospital Shows. The IHE-J Project will continue its activities in order to meet these expectations.

### Report on the 31st Scientific Meeting and Exhibition of the Japanese Society for Magnetic Resonance in Medicine

The 31st Scientific Meeting of the Japanese Society for Magnetic Resonance in Medicine was held at Highland Resort in the Fujikyu Highlands from September 25 through 27, and the concurrent technical exhibition was held at Fujikyu Highland Conifer Forest (second floor). Professor Tsutomu Araki (Department of Radiology, School of Medicine, University of Yamanashi) served as the president of the scientific meeting. Nearly 350 papers were presented. One meeting hall was dedicated to the Categorical Course throughout the threeday event. The meetings consisted of programs allowing participants to obtain a clear overall understanding of MRI, and lively discussions were held during the session. The number of participants was 1,021 (see table), slightly fewer than the 1,385 who participated last year. However, taking into consideration the relatively remote location of Highland Resort and the limited transportation access, this number suggests that magnetic resonance imaging is a very active academic discipline today.

Eighteen companies participated in the concurrent technical exhibition, displaying state-of-the-art equipment and related products as well as giving software demonstrations. The venue for the exhibition was the second floor of Conifer Forest, facing Mt. Fuji. The exhibits were set up and removed smoothly thanks to the careful planning of the secretariat and also due to the fact that no large-scale equipment was shown. The exhibition site was located some distance from the scientific meeting, in a quiet forested area. Following the opening of the exhibition, however, a shuttle bus ran every 20 to 30 minutes from the scientific meeting at Highland Resort to provide convenient transportation. In general, physicians who viewed the poster presentations on the first floor then moved to the second floor to visit the exhibits and listen attentively to descriptions of the latest equipment. The scientific meeting was elegantly presented, allowing participants to keep up with advances in diagnostic medicine while creating an atmosphere of relaxation and peace of mind.

Next year's meeting is scheduled to take place under the presidency of Professor Toshiro Inubushi (Molecular Neurobiology Research Center, Shiga University of Medical Science) at Otsu Prince Hotel from September 16 (Thursday) through 18 (Saturday). It is expected that a large number of companies will participate in the exhibition.

### Exhibitors (in alphabetical order)

Asahi Kasei Information Systems Co., Ltd. Eiken Chemical Co., Ltd. Eisai Co., Ltd.



View of the site

GE Yokogawa Medical Systems, Inc. Goodman Co., Ltd. Hitachi Medical Corporation KGT Inc. L.A. Systems Inc. Nemoto Kyorindo Co., Ltd. Nihon Medrad K.K. Nihon Schering K.K. Philips Medical Systems Corporation Physio-Tech Co., Ltd. Riko Trading Co., Ltd. Siemens-Asahi Medical Technologies Ltd. Too Corporation Toshiba Medical Systems Corporation Varian Technologies Japan Ltd.



Exhibition booths in the hall

### Number of participants in the 31st Scientific Meeting and Exhibition of the Japanese Society for Magnetic Resonance in Medicine

|  | Full members | Student members | General participants | Students | International students | Total |
|--|--------------|-----------------|----------------------|----------|------------------------|-------|
| Registration on the day (September 25) | 372          | 34              | 249                  | 4        | 0                      | 659   |
| Registration on the day (September 26) | 68           | 10              | 45                   | 1        | 0                      | 124   |
| Registration on the day (September 27) | 8            | 0               | 7                    | 4        | 0                      | 19    |
| Subtotal                               | 448          | 44              | 301                  | 9        | 0                      | 802   |
| Advance registration                   | 205          | 14              | -                    | -        | -                      | 219   |
| Total                                  | 653          | 58              | 301                  | 9        | 0                      | 1020  |

\* Excluding 50 participants who were exempted from registration fees, including honorary members of the Society and those associated with the technical exhibition and luncheon/evening seminars.

# Development of Japanese Radiological Equipment in the Post-World War II Period (13)



Sumio Makino Advisor, JIRA



### Outline of the story up to the last issue

The history of tomography systems has been traced in this series of articles. First, so-called planar tomography, in which the X-ray tube is shifted in either an arc or the horizontal direction, suffered from blurred images of structures located away from the target lesion. To overcome this problem, circular-shift tomography (referred to as "Circus Tomo") was introduced. The previous issue outlined the research and development work of Dr. Akira Matsukawa of Fukushima Medical University starting from around the early 1950s.

Following Japan's total defeat in the Second World War, we Japanese had to start over from square one. We had to develop and produce everything we needed all by ourselves. The people of that time were full of vitality under such challenging circumstances.

The initial success of Circus Tomo led to further conceptual advances and the development of multiorbital tomography or spiral tomography, referred to as "Roulette Tomo". The present issue describes the development of such multiorbital tomography systems as the closing phase in the history of tomography system development.

# Evolution to multiorbital tomography (Roulette Tomo)

Dr. Kazue Kimura of Fukushima Medical University (cited in the previous issue) delivered a special lecture at the Japanese Association of Tomography, and the contents of that lecture were published in detail in the Association's journal, the Japanese Journal of Tomography (Volume 18, No. 2), in 1992. Excerpts from Dr. Kimura's lecture are quoted below.

"We felt that a spiral orbit should be even better than a circular orbit, and again asked the Hattori Factory, which produced a prototype for research and development of circular orbit tomography [as introduced in the previous issue], to make a tomography system permitting spiral movement. This was in 1958. The basic structure of the system was the same as the previous prototype with four supports, with the only difference being the mechanism by which the X-ray tube was suspended in the horizontally extended arm support, and this transverse arm was slowly rotated by a motor while the point of support to suspend the X-ray tube was gradually moved from the center of rotation toward the edges. In this way, the X-ray tube moved in a spiral orbit during rotation.

In spiral tomography, X-rays are emitted continuously starting from the area immediately above the subject to the surrounding areas where the effects of blurring are strong in order to obtain a single image. Good results were achieved in the field of ENT. Based on these studies, a system supporting movement in multiple orbits was designed and named "Roulette Tomo". The prototype was completed in 1959 and placed on the market in 1960 (\*1) as a multiorbital tomography system. Dr. Matsukawa reflected that the system was designed in cooperation with the late Mr. Iwai, B.Eng., of Tohoku University. Systems of the same type were soon introduced by different companies. In July 1960, Dr. Matsukawa presented a report of his work at the General Assembly of the Japan Radiological Society in Sapporo (\*2).

Thirty years later, multiorbital tomography seems to have been eclipsed by X-ray CT, but it is still frequently employed for the visualization of bones, the spine, and joints in ENT as well as for the primary evaluation of lung shadows to determine the appropriate approach in further work-up. Before the emergence of X-ray CT, many studies on X-ray tomography were conducted to evaluate a variety of ideas such as multilayer, enlarged, high-voltage, oblique, stereoscopic, and TV techniques."

- \*1 Dr. Akira Matsukawa et. al. Nippon Acta Radiologica (Journal of the Japan Radiological Society) 1962;21(10):947-953.
- \*2 Dr. Akira Matsukawa, et. al. Nippon Acta Radiologica (Journal of the Japan Radiological Society) 1960;20(10):2167-2190.

# Practical application of a multiorbital tomography system

A paper describing the practical application of this new multiorbital tomography system was jointly prepared by researchers in the medical and engineering fields, including Dr. Kazue Kimura of Fukushima Medical University and Mr. Katsumi Nagai of Toshiba. A paper entitled "A study on pluridirectional tomography: Images of the skull obtained with various X-ray tube shifts" was published in Nippon Acta Radiologica (Journal of the Japan Radiological Society) No. 3, March 1974.

The following quotes are taken from section II of this paper.

### "II. Outline of System Performance

The multiorbital tomography system employed was the LGM-1 system (Toshiba Corporation) (Fig. 1). Table 1 shows a summary of the major functions of the system, including the tube shift method, the tube tilt angle relative to vertical  $(\theta)$ , and the time required to shift the tube (in seconds).

- 1. The tube shift method can be set in five different modes and can be selected by pressing a single button (one-touch operation).
- 2. Images can be acquired with the tube set at any desired location, including the location immediately above the subject where  $\theta$  equals 0° (i.e., support of general radiography).
- 3. For the linear-shift method, the direction of tube shift can be arbitrarily selected in relation to the long axis of the body. In addition,  $\theta$  can be set at any desired angle in the range from 5° to 25°. The time required for tube shift is reduced as  $\theta$  becomes smaller.
- 4. For the circular-shift method,  $\theta$  can be arbitrarily selected up to  $\theta=25^{\circ}$  and the tube can be rotated in a circular pattern. The time required for one rotation is constant and is not affected by the value of  $\theta$ .
- 5. For the elliptical-shift method, the long axis of the ellipse can be set in two directions, perpendicular or parallel to the long axis of the subject.  $\theta$  is 20° for the long axis and 10° for the short axis.
- 6. For the hypocycloid-shift method,  $\theta$  is set to 12° at minimum and 20° at maximum. Technically, it is possible to adjust  $\theta$  to 10° at minimum and 30° at maximum.
- 7. For the spiral-shift method, the number of tube rotations is  $6\pi$  (i.e., three rotations). In the first rotation (2 $\pi$ ),  $\theta$  remains at 25°, after which  $\theta$  is continuously reduced, finally reaching 4° at  $6\pi$ , where one spiral shift is completed. The direction of rotation is set to be clockwise.

8. The system is provided with two options for the tube rotating radiation angle ( $\Psi$ ): 360° for total exposure and 90° for selective exposure on the right and left sides of the circular shift."

Following the completion of the prototype, researchers started clinical studies to obtain images of the head. Generally, a phantom is used for such experiments, but the research team at Fukushima Medical University used a cadaver head that was free of pathology. The materials and methods of the study were described in section III, portions of which are extracted below.

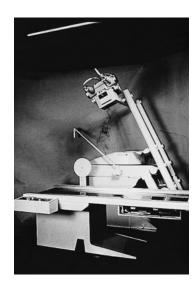


Figure 1. Overall view of the tomography system (Model LGM-1, Toshiba).

### Table1 Forms of Trajectories of the Tomograph

| TUBE-SHIFT TYPE  |            | $\theta$ min. $\theta$ max. | SHIFTTING<br>TIME   |
|------------------|------------|-----------------------------|---------------------|
| LINEAR S.        | *          | 5° — 25°                    | 0.5 sec.<br>10 sec. |
| CIRCULAR S.      | ۲          | 0° — 25°                    | 3 sec.              |
| ELLIPTICAL S.    | $\bigcirc$ | 10° 20°                     | 4 SEC.              |
| HYPOCYOLOIDAL S. | Ô          | 12°∼ 20°                    | 6 SEC.              |
| SPIRAL S.        | 0          | 4° ~ 25°                    | 9 sec.              |

### "III. Study Methods

Study specimen. The specimen used in this study was a fresh cadaver head that was free of pathology as confirmed in X-ray images. The head was amputated at the level of the 5th cervical vertebra and was placed in the vertical position for one to two weeks. Following X-ray confirmation that the cerebral ventricles were filled with air, tomography was performed (Figs. 2A and 2B).

Imaging and observation methods. The head was placed face-up in a fixed position with both the median plane and the orbitomeatal plane oriented vertically. Images were acquired in a tomographic plane passing through the external acoustic meatus bilaterally (standard plane) (Fig. 2B)."

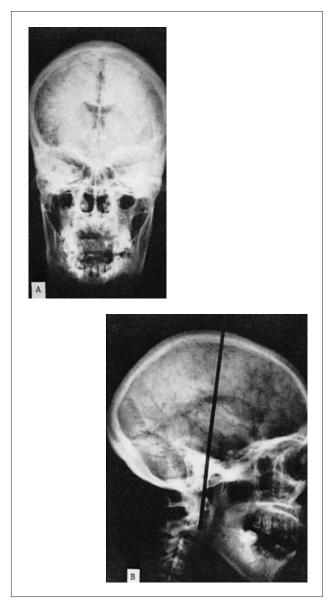


Figure 2. Radiographs of the cadaver head A: Frontal view. B: Lateral view. The black line indicates the standard plane (tomographic plane)

A section of the cadaver head was generated along this standard plane and compared against the previously acquired film images to evaluate the performance of the system.

### "IV. Results

#### 1. Anatomical structures in the section

A section obtained in the standard plane of the head is shown in Figs. 3A and 3B.

The section therefore corresponds to a frontal image of the plane passing through the long axes of the external and internal auditory meatus on both sides. The bony structures shown in this section include the region from the external auditory meatus to the epitympanum, the middle ear, the area from the internal auditory meatus to the vestibule and to the semicircular ducts, and a part of the cochlea (posterior portion). The portion of the clivus protruding toward the great foramen is also seen. As for the cervical vertebrae, the plane corresponds to the level of the atlas and the odontoid process.

2. Comparison of images obtained using different shift methods

(A) Circular-shift tomography."

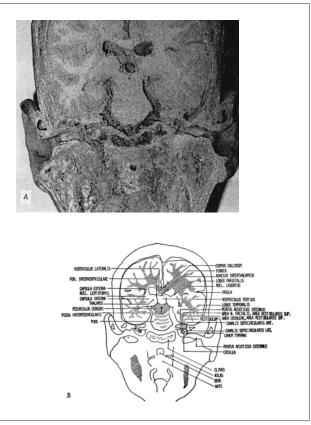


Figure 3. A: Anatomical findings of the section at the tomographic plane (standard plane). B: Diagram of the frontal section.

Here, the author would like to omit the description of circular-shift tomography and present only the conditions for image acquisition as shown below.

- "(i) Image obtained with  $\theta$ =5° and  $\Psi$ =360° (Fig. 4)
- (ii) Image obtained with  $\theta$ =25° (Fig. 5)
- (B) Hypocycloid-shift-method tomography

The plane obtained is comparatively thick and the findings are similar to those obtained by circular-shift tomography using  $\theta=5^\circ$ . However, the image has much fewer interfering shadows. In other words, the obtained tomogram has less blur even though the thickness of the plane is large (Fig. 6).

(C) Spiral-shift-method tomography

The tomogram obtained can be regarded as the integral of images obtained using circular-shift tomography with  $\theta$  varied continuously from 4° to 25°. This method seems to provide a slightly thinner imaging plane and fewer interfering shadows than the hypocycloid-shift method (Fig. 7)."

### Table 2 Comparison of tomographic images obtained using various tube-shifting methods in LGM-1

|   | Circulars.<br>s. $\theta = 5^{\circ}$ | Circulars.<br>s. $\theta = 25^{\circ}$ | Hypocy-<br>cloidals. | Spiral s. |
|---|---------------------------------------|--|----------------------|-----------|
| Meatus Acusticus<br>Internus Canales<br>Semicirculares<br>Vestibulum, Cochlea | 0                                     | ۲                                      | Δ                    | Δ         |
| Cavum Tympani   | 0                                     | ۲                                      | Δ                    | Δ         |
| Meatus Acusticus<br>Externus  | 0                                     | ۲                                      | Δ                    | Δ         |
| Atlas, Axis   | 0                                     |  | 0                    | ۲         |
| Clivus  | 0                                     |  | 0                    | ۲         |
| Pons  | 0                                     | Δ                                      | ۲                    | ۲         |
| Pedunculus Cerebri  | 0                                     | Δ                                      | ۲                    | ۲         |
| Hemispherium  | 0                                     | Δ                                      | ۲                    | ۲         |
| Ventricle   | 0                                     | Δ                                      | ۲                    | ۲         |
| Sulcus, Incisura,<br>Gyrus  | 0                                     | Δ                                      | ۲                    | ۲         |

Note:

- △ The tomographic image of the organ is clearest, with little distortion. (Excellent for clinical applications)
- The tomographic image of the organ is clearer, but with some obstructive shadows. (Useful for clinical applications)
- O The tomographic image of the organ shows less sharpness, with considerable obstructive shadows.

Then, the paper goes on to present a summary of the results as quoted below.

### *"Summary*

We compared tomographic images of the same section of the cadaver head obtained using different tube-shift methods and assessed each method from the clinical viewpoint. The results of our assessment are summarized in Table 2."

In the present article, the author would like to omit the remainder of the summary and proceed directly to the "Conclusion" section.

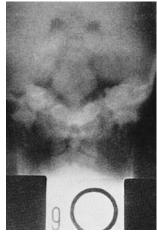


Figure 4. Tomogram of the cadaver head obtained at the same level (standard plane) with circular-shift tomography.  $\Psi$ 360°,  $\theta$ =5°

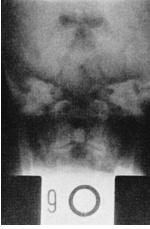


Figure 5. Tomogram of the cadaver head obtained at the same level (standard plane) with circular-shift tomography.  $\Psi$ 360°,  $\theta$ =25°



Figure 6. Tomogram of the cadaver head obtained at the same level (standard plane) with hypocycloid-shift tomography.  $\Psi$ 360°,  $\theta$ =12° min to 20° max



Figure 7. Tomogram of the cadaver head obtained at the same level (standard plane) with spiral-shift tomography.  $\Psi$ 360°,  $\theta$ =4° min to 25° max

### "IV. Conclusion

Using a multiorbital tomography system, we have obtained tomographic images of the cadaver head with the tube shifted in various modes: circular shift with  $\theta=5^{\circ}$  or  $\theta=25^{\circ}$ , hypocycloid shift, and spiral shift. The images obtained were compared from the clinical viewpoint, leading to the following conclusions.

- 1. For the examination of small bony structures in the skull, circular-shift tomography with  $\theta=25^{\circ}$  (i.e., thin-section tomography) can accurately depict the morphological characteristics of these structures.
- 2. The hypocycloid-shift and spiral-shift methods have fewer interfering shadows and are therefore effective for comparing the images of bony regions.
- 3. Thin-section tomography, such as circular-shift tomography with  $\theta=25^\circ$ , is suitable for demonstrating the cerebral ventricles and parenchyma within the skull. However, if the regional anatomy is clearly understood, the hypocycloid-shift and spiral-shift methods can also be employed.
- 4. Circular-shift tomography with  $\theta=5^{\circ}$  is characterized by thick-section imaging and a number of interfering shadows. Future studies to evaluate the value of this method are eagerly awaited, as well as research concerning the generation of stereoscopic views."

### Summary of Development of X-ray Tomography Systems

The author has described the history of development of X-ray tomography systems, from conventional planar tomography systems to fairly sophisticated hypocycloidshift-method tomography systems, by quoting the literature. At that time, chest disease was considered to be the "national disease" of Japan, and researchers worked hard to develop an effective radiographic method to clearly demonstrate lung lesions surrounded by the ribs. Perhaps such efforts simply reflected the natural aspirations of scientists and researchers, but looking back on their passionate pursuit of this goal, one cannot help but think that it was based on an even deeper sense of devotion as healthcare professionals fighting to conquer a national disease.

The author would also like to remind the reader of the efforts of Dr. Shinji Takahashi, who identified the drawbacks of overlapped images in general radiography and contributed to the development of an axial transverse tomography system. His work reflected a personal mission to try to improve treatment accuracy in radiotherapy by obtaining cross-sectional radiographic images in order to identify the size and location of structures in the body.

Following these efforts in the development of tomography, the focus of research shifted to the development and establishment of modern diagnostic imaging technologies such as X-ray computed tomography, ultrasonography, endoscopy, magnetic resonance imaging, and nuclear medicine. The actual systems developed at that time may appear to have lost their relevance, but it could also be argued that the objectives of earlier medical researchers and healthcare professionals were simply realized in a different form.

Today, there have been amazing advances in electronic technologies, and medical professionals and engineers, such as the author, no longer wrestle with building large timber frameworks to create new "hardware", as was the case for our predecessors. In a way, the author misses those simpler times. Is this feeling merely nostalgia for the "good old days" on the part of the person writing these retrospective articles?

### Japan Radiology Congress (JRC) 2004 – -Radiology: Its Standardization and Its Individualization –

### International Technical Exhibition of Medical Imaging 2004 (ITEM 2004)

The Japan Industries Association of Radiological Systems (JIRA) will hold ITEM 2004 in conjunction with the 63rd Annual Meeting of the Japan Radiological Society (JRS) and the 60th Annual Meeting of the Japanese Society of Radiological Technology (JSRT).

| Chairman: | Masamichi Katsurada                          |
|-----------|--|
| Dates:    | April 8 (Thu.) through April 10 (Sat.), 2004 |
| Venue:    | Pacifico Yokohama Exhibition Hall,           |
|           | 1-1-1 Minato Mirai, Nishi-ku, Yokohama       |
|           | 220-0012, Japan                              |

#### From the Chairman,

The next International Technical Exhibition of Medical Imaging (ITEM 2004) will be held for three days from Thursday April 8 to Saturday April 10, 2004, at Pacifico Yokohama Exhibition Hall, the same venue as in 2003. 2004 will mark the 17th year in which ITEM is held. In recent years, ITEM has expanded globally and grown to become the largestscale comprehensive exhibition in Asia related to medical radiology. ITEM 2003 was held here in Yokohama after a two-year absence, and was the largest exhibition ever in terms of both the number of companies exhibiting and total exhibition area. The actual number of visitors (the number of registered visitors) has also grown by about 4,500 since the exhibition held in Kobe in 2002. Not only is the exhibition area larger, but I also believe that this exhibition will be the greatest ever in terms of increased interest by the general public in health and medical issues, combined with the enthusiasm of physicians and technicians working in the healthcare field and the efforts of various companies in the medical industry in response to their enthusiasm. Reform of the Pharmaceutical Affairs Law has advanced to reflect the trend toward international conformity of medical device regulations, and the environment surrounding medical care will change significantly, including reformation of the medical service systems that will serve as the basis for healthcare, revision of reimbursement systems, and greater consciousness of safety issues related to medical equipment. At the Japan Industries Association of Radiological Systems (JIRA), we are making the greatest possible efforts to ensure that ITEM 2004 will be an even more comprehensive exhibition in which industry, governments, and academia can unite to address the diversifying needs in the changing environment surrounding medical care.

#### 63<sup>rd</sup> Annual Meeting of JRS

| President: | Tatsuo Kumazaki, M.D., Ph.D.                 |
|------------|--|
| Dates:     | April 8 (Thu.) through April 10 (Sat.), 2004 |
| Venue:     | Pacifico Yokohama, 1-1-1 Minato Mirai,       |
|            | Nishi-ku, Yokohama 220-0012, Japan           |

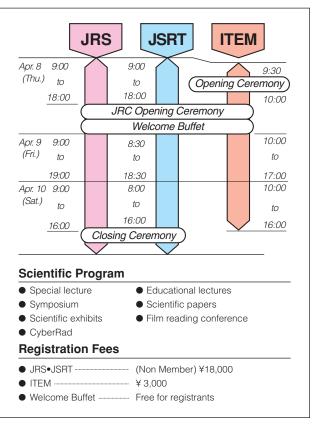
From the President,

The joint theme for JRC 2004 is "Radiology: Its Standardization and Its Individualization".

### 60<sup>th</sup> Annual Meeting of JSRT

| President: | Katsuhiko Mori                               |
|------------|--|
| Dates:     | April 8 (Thu.) through April 10 (Sat.), 2004 |
| Venue:     | Pacifico Yokohama, 1-1-1 Minato Mirai,       |
|            | Nishi-ku, Yokohama 220-0012, Japan           |

The theme of the Congress is "Further Research in Radiological Technology Science".



#### JRC 2004 Schedule



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