

# Radiology Japan

Japan Industries Association of Radiological Systems October 2006 No. 53

## Review of the Japanese Market for Diagnostic Imaging and Therapeutic Systems in the Year 2005

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

From January through December 2005 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>123,270</b>	<b>+5</b>	<b>42,914</b>	<b>+11</b>	<b>29,202</b>	<b>+27</b>	-	-	<b>109,558</b>	<b>+8</b>
· General-purpose R/F		31,733	+5	5,020	-21	54	-	1,534	-1	26,767	+12
· Cardio & angio		13,488	0	6,636	+17	16,419	+32	288	-4	23,270	+15
· General-purpose radiography		16,300	-20	9,329	+11	1,621	+45	5,153	+28	8,591	-35
· Mobile		3,785	+49	1,953	+71	159	-19	802	+30	1,991	+25
· Dental		6,514	+2	2,041	+17	0	-	4,114	0	4,473	-3
· Others		51,450	+17	17,933	+18	10,950	+18	-	-	44,466	+17
<b>2 CT</b>		<b>114,477</b>	<b>+46</b>	<b>72,653</b>	<b>+69</b>	<b>18,666</b>	<b>+12</b>	<b>1,436</b>	<b>+7</b>	<b>60,490</b>	<b>+16</b>
<b>3 Nuclear medicine</b>		<b>4,684</b>	<b>-20</b>	<b>0</b>	<b>0</b>	<b>21,259</b>	<b>+46</b>	<b>263</b>	<b>-14</b>	<b>25,943</b>	<b>+28</b>
<b>4 MRI</b>		<b>34,737</b>	<b>-9</b>	<b>18,220</b>	<b>-26</b>	<b>40,034</b>	<b>+37</b>	<b>508</b>	<b>24</b>	<b>56,551</b>	<b>+33</b>
<b>5 Image processing systems</b>		<b>15,203</b>	<b>+9</b>	<b>3,139</b>	<b>+7</b>	<b>6,316</b>	<b>+13</b>	-	-	<b>18,381</b>	<b>+11</b>
<b>6 Related items &amp; accessories</b>		<b>29,151</b>	<b>+8</b>	<b>12,581</b>	<b>+15</b>	<b>1,901</b>	<b>-42</b>	-	-	<b>18,471</b>	<b>-4</b>
<b>7 Diagnostic ultrasound</b>		<b>88,929</b>	<b>+8</b>	<b>59,575</b>	<b>+10</b>	<b>9,425</b>	<b>-9</b>	<b>7,613</b>	<b>+1</b>	<b>38,780</b>	<b>0</b>
<b>8 Therapeutic systems</b>		<b>6,902</b>	<b>-9</b>	<b>1,968</b>	<b>-28</b>	<b>5,390</b>	<b>+49</b>	<b>529</b>	<b>-15</b>	<b>10,324</b>	<b>+21</b>
<b>Total</b>		<b>417,354</b>	<b>+13</b>	<b>211,049</b>	<b>+19</b>	<b>132,193</b>	<b>+24</b>	-	-	<b>338,498</b>	<b>+13</b>

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

### Review of the Results for 2005

( ): changed from the previous year.

1. The total count of medical imaging system in the year 2005 showed an increase in the domestic market.

- Production 417.4 billion yen (+13%)
- Export 211.0 billion yen (+19%)
- Import 132.2 billion yen (+24%)
- Domestic Market 338.5 billion yen (+13%)

2. The domestic market by major medical equipment showed:

- X-ray 109.6 billion yen (+8%)  
Mobile X-ray increased to 2 billion yen (+25%) and other X-ray to 44.5 billion yen (+17%) of which Mammography increased to 8.9 billion yen (+34%).

While the sales of General-purpose radiography has been continuously declining since the year 2003 with 8.6 billion yen (-35%) in 2005, that of X-ray data processing systems has been continuously improving since the year 2003 with 26.3 billion yen (+19%) in 2005.

- CT 60.5 billion yen (+16%)  
1,436 sets (+7%)
- Nuclear medicine 25.9 billion yen (+28%)  
263 sets (-14%)  
PET has shown 20.5 billion yen (+49%).
- MRI 56.6 billion yen (+33%)  
508 sets (+24%)
- Image processing systems 18.4 billion yen (+11%)

All of the above contributed to the increase of the total diagnostic equipment sales to 328.2 billion yen (+13%).

3. The production output in the year 2005 increased to 417.4 billion yen (+13%).

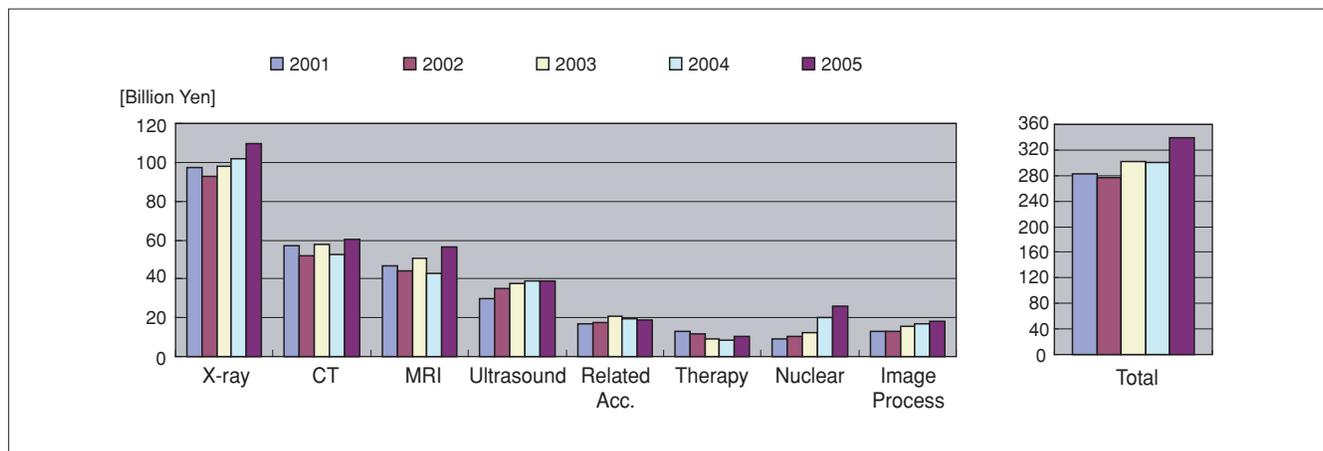
- X-ray 123.3 billion yen (+5%)  
Both Mobile and other X-ray showed an increase to 3.8 billion yen (+49%) and 51.5 billion yen (+17%) respectively, while General-purpose radiography decreased with 16.3 billion yen (-20%).

- CT 114.5 billion yen (+46%)  
The significant increase was helped by the increase in export.
  - Image processing systems 15.2 billion yen (+9%),
  - Diagnostic ultrasound 88.9 billion yen (+8%).
  - Nuclear medicine 4.7 billion yen (-20%).
4. The export increased to 211 billion yen (+19%).
- CT 72.7 billion yen (+69%)
  - X-ray 42.9 billion yen (+11%)
    - Mobile 2 billion yen (+71%)
    - Others 17.9 billion yen (+18%)
    - Cardio & angio 6.6 billion yen (+17%)
    - Dental 2 billion yen (+17%)
    - General-purpose radiography 5 billion yen (-21%)
  - MRI 18.2 billion yen (-26%)
  - Therapeutic systems 2.0 billion yen (-28%).
5. The import increased to 132.2 billion yen (+24%) contributing to boost up the domestic market.
- X-ray 29.2 billion yen (+27%)  
The import of General-purpose radiography increased to 1.6 billion yen (+45%), Cardio & angio to 16.4 billion yen (+32%), and Others to 11.0 billion yen (+18%).
  - CT 18.7 billion yen (+12%)

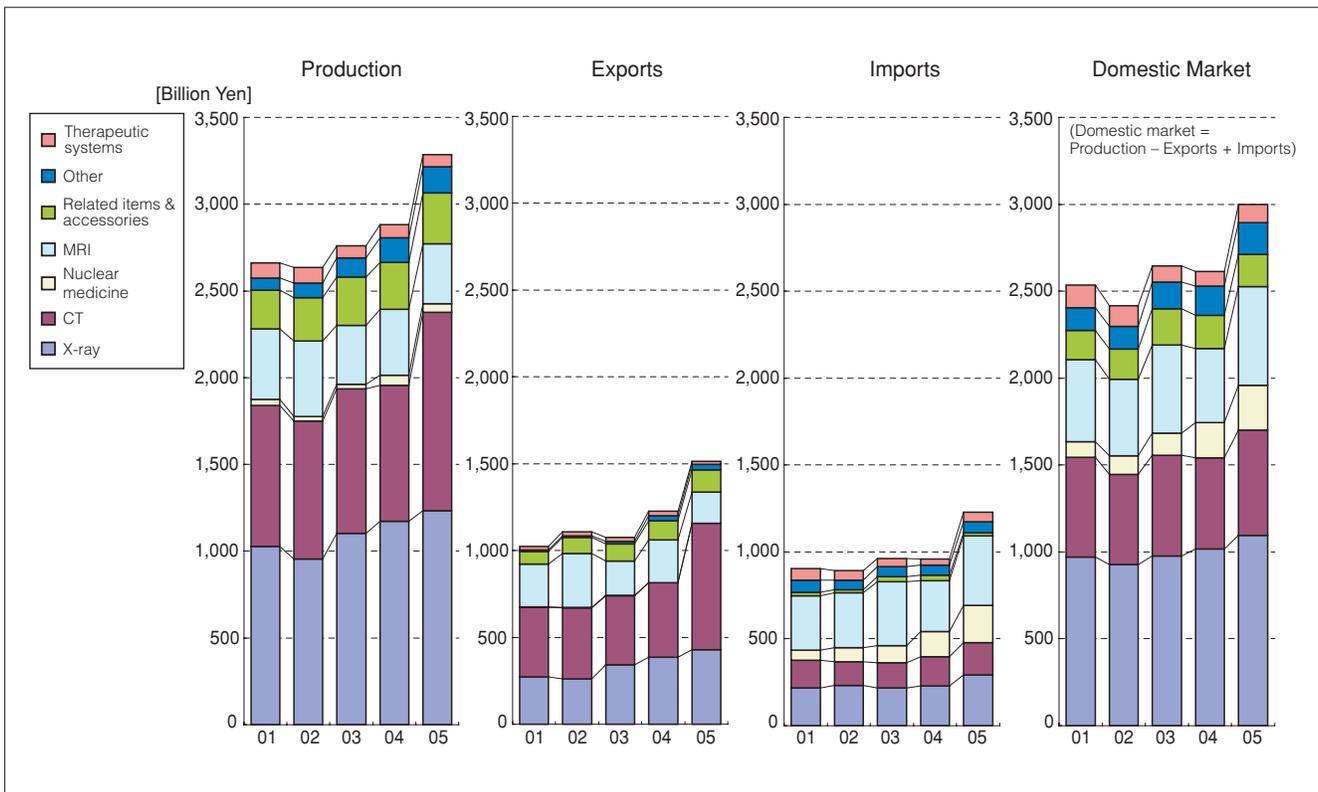
- Nuclear medicine 21.3 billion yen (+46%)  
PET import of 17.6 billion yen was the main factor of the growth.
- MRI 40 billion yen (+37%)
- Image processing systems 6.3 billion yen (+13%)
- Therapeutic systems 5.4 billion yen (+49 %)
- Related items & accessories 1.9 billion yen (-42%).

6. Overall, PET, MRI, Mobile X-ray, Therapeutic systems, other X-ray, CT and Cardio & angio showed a growth in the domestic market in 2005, which resulted in the market increase (+13%) on the whole. Looking at the shift from 2001 through 2005 by major equipment, the sales of X-ray has been increasing every year since 2001 (the market of each equipment has expanded with the progress of digitalization as the background, and the market of Mammography has expanded with the application since 2004 of mammography examination to those aged 40 and up as the background). Both CT and MRI increased and decreased by rotation every other year and showed an increase in 2005, while Nuclear medicine has continuously increased with PET as its central increase factor. Both Diagnostic ultrasound and Related items & accessories have leveled off, and Therapeutic systems have shown a slight decrease year by year.

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



**Trends in Production, Exports, Imports, and Japanese Market for Medical Imaging and Therapeutic Systems**  
 [Actual January-December figures for years 2001 to 2005] \* Excluding diagnostic ultrasound systems



# New Chairman Mr. Inomata's message (June 1, 2006)



**Hiroshi Inomata**  
Chairman

**Japan Industries Association of Radiological Systems**

---

*It is my greatest honor to succeed the past chairman Mr. Masamichi Katsurada, as the current chairman of the Japan Industries Association of Radiological Systems (JIRA). JIRA is an association of enterprises that are engaged in activities making social contributions in the medical field through developing, manufacturing and marketing X-ray, ultrasound, CT, MR, PET and other diagnostic imaging devices; radiotherapeutic equipment; and medical information systems. With aging of our society, that is a demand also in medical care for greater efforts toward providing better quality and safer instruments, with greater consideration for quality of life.*

*In Japan, these medical imaging systems will play three major roles.*

*The first role is the creation of “new value of medical imaging”. Following the recent advent of new diagnostic imaging devices such as CT and MR, the diagnostic sensitivity of diseases such as cancer, cerebral infarction and cardiac disease has improved spectacularly. Further to these developments, imaging technologies including PET and optical topography which provide new diagnostic information have become available in the market. More advanced medical imaging systems that combine the above instruments or integrate diagnosis and treatment, which allow even earlier diagnosis and treatment are expected to be developed in the future.*

*The second role is the strengthening of “value from the patient’s standpoint”. The industries are searching to develop medical imaging systems that pose little burden on the patients. In addition to*

*making efforts to reduce radiation exposure, development of medical imaging systems that realize safer and less invasive surgeries is required. Furthermore, strengthening of safety management and maintenance is important to assure safety and quality after marketing, so that patients may receive medical care without safety concern.*

*The third role is to make further “social contributions”. For those of us who are engaged in the medical imaging system industries, our greatest pride is to be able to contribute to the people’s health. Especially, it is our great pleasure to be able to participate in the realization of high technological medicine. However, under the current situation of reduced revenue and increased medical expenditure in the medical insurance system, medical care operations are becoming more difficult. Under such situation, it is important that persons in need of care will receive medical care at the level needed. In the field of medical care, we shall continue to improve the social values that medical imaging systems can contribute, such as patients’ quality of life, care efficiency, and cost-effectiveness.*

*JIRA will participate actively to fulfill the above three roles. In order to realize these roles, we are working to foster closer collaboration between the administration, academy and industry, as well as collaboration between medicine and engineering; and to submit recommendations on various policies as an attempt to speed up the responses from all parties concerned. These activities are being expanded to a global scale.*

*We sincerely hope for your interest and continuous support of the JIRA activities.*

# Report on JRC 2006

JRC 2006, the joint meeting of the 65<sup>th</sup> Congress of the Japan Radiological Society (JRS), the 62<sup>nd</sup> Congress of the Japanese Society of Radiological Technology (JSRT) and the 91<sup>st</sup> Congress of the Japan Society of Medical Physics (JSMP), was held at Pacifico Yokohama from April 7<sup>th</sup> (Fri) to 9<sup>th</sup> (Sun).

JIRA managed ITEM 2006 (The 2006 International Technical Exhibition of Medical Imaging) at this JRC meeting, and organized the opening ceremony at the entrance of the Main Exhibition Hall on the first day. At the opening ceremony, Yokohama City Fire Band played a splendid musical performance.

This year's main theme was "Radiology Tomorrow". Many kinds of systems equipped with the latest technologies were

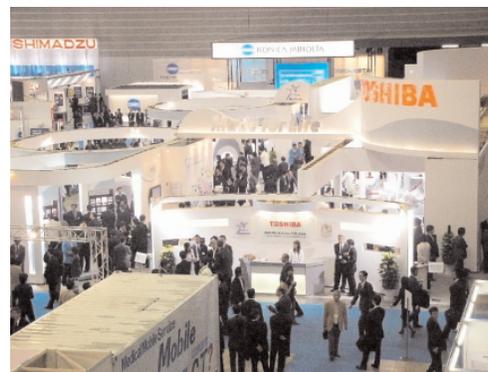
showcased in the venue. Among them, a wide variety of the digital technology appeared in the exhibition.

A total of 129 companies and 1 organization joined the exhibition, which occupied a total of 8,287 square meters floor space of the Pacifico Yokohama Exhibition Hall B, C and D. Although the first day was a weekday, many visitors participated from the beginning, and the actual number of visitors scored 20,576 persons, which was the first time to exceed 20,000 persons for the exhibition.

Next year, ITEM 2007 will be held at Pacifico Yokohama from April 13<sup>th</sup> (Fri) to 15<sup>th</sup> (Sun), 2007. It is expected that this exhibition will take even more a major role as a stage of development in the rapidly changing medical field.

Type of visitors	Total number of visitors (*)		Actual number of visitors	
	Y2005	Y2006	Y2005	Y2006
Congress registered numbers				
JRS members	4,073	4,076	2,393	2,553
JSRT members	7,739	8,378	3,102	3,409
JSMP members	422	550	199	275
Non members	1,862	1,998	773	826
Visitors				
Radiologist	705	786	496	546
Radiological Technologist	6,351	6,631	3,748	3,870
Medical related	1,205	1,300	780	768
Exhibitors	12,315	15,998	4,746	6,551
Others	5,707	3,315	2,976	1,778
<b>TOTAL</b>	<b>40,379</b>	<b>43,032</b>	<b>19,213</b>	<b>20,576</b>

Note (\*) The number of visitors include repeat visitors.



ITEM 2006

# JIRA Activity Reports

## Introducing “JIRA Annual Report on Medical Imaging Devices & Systems 2006”

“JIRA Annual Report on Medical Imaging Devices & Systems 2006” was launched in April 2006 as part of social activities of Japan Industries Association of Radiological Systems (JIRA). It reviews administrative trends surrounding diagnostic imaging device related industry and reports JIRA activities as well as suggestions for administration and society as an industry’s white paper. (Only the Japanese version was published this time.)

The report will be published every year, for concerned ministries, groups, research institutes and mass media, with the following matters incorporated. It consists of some articles and statistics and data, and the source materials include various data justified by figures including, health expenditure medical care facilities, and market estimates derived from JIRA’s independent statistics, as the social background of the medical device related industry.

1. Summary of medical diagnostic imaging device industry
2. Opinions from the industry about government administration of medical affairs, industrial measures, health insurance and reimbursement system, etc.
3. Business plan and activity report by JIRA



The following is the brief introduction of some opinions from the industry described in the report.

The report introduces the “Visions of medical device industries” which was developed in 2003 based on the request by Ministry of Health, Labor and Welfare. The industry and the government administration cooperatively followed up the action plan of the vision from 2004 through 2005 to steadily advance the vision on the whole. The revision of Pharmaceutical Affairs Law in 2005 as well as the entry of designated medical devices for maintenance and management into the subject of maintenance in Medical Service Law can be considered as milestones in the promotion of the vision, which also has significance to the industry.

In the vision, the following three requests are presented from the industry to the administration.

The first request is to recognize and evaluate the role of medical device system fairly.

When a medical device which the industry has developed is fairly evaluated and the compensation is made appropriately, both the evaluation and the compensation can be applied to the next development. Then, this contributes to the improvement of medical care standard as well as healthcare efficiency. The scheme and the process of this cycle are more important than anything else. We believe that this eventually leads to the development of the medical device industry and to the enforcement of international competitiveness.

Medical device system can contribute to early and more accurate diagnosis to improve patients’ QOL as well as healthcare efficiency. However, rationales for adding cost have not yet been clarified in its compensation, the medical service remunerations.

We believe it is important to reflect technical as well as socioeconomic evaluation of medical devices into medical service remunerations in a visible form from the viewpoint of the effectiveness and safety of diagnosis, imaging technology, upgrading functions and performances, etc. In other words, fair evaluation of medical equipment eventually leads to the development of the medical device industry.

In terms of the development of new medical technology, we request the development of legislation which can be used in actual medical treatments and in the development of new technology, or the management of clinical trial system, so that a medical device system, where diagnosis and treatments grow together with pharmaceuticals and medical equipments, will be promptly introduced into the market.

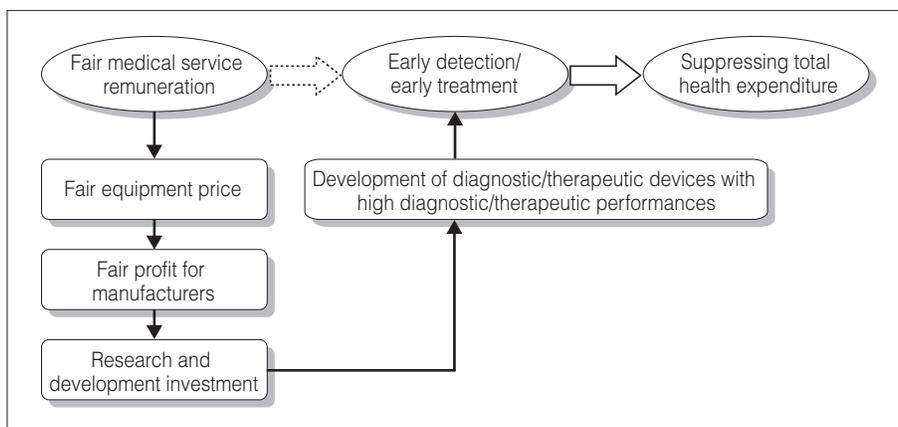
The second request is about the whole concept of the industrial development and restriction, which correspond to the diversification and advancement of medical device system. As an example is shown, one of the most significant issues is placing application software embedded in medical devices in the legal system in the same manner as medical devices. An application software creates new diagnostic function as well as value to improve the safety of diagnostic function. These software have come to be increasingly diversified.

The third request is about proper use of medical devices in medical care institutions. As the infrastructure in medical care institutions, it is required to establish a medical device managing unit to promote safety in using devices, secure human resources and strengthen the training system. Moreover, to ensure the safety from the viewpoint of using medical devices in accordance with their characteristics, a scheme which ensures the safety in all phases of development, distribution, use and disposal is required. Such scheme has different focus depending on respective med-

ical device, material, etc. For example, identification codes need to be systematized, but we believe how the codes are displayed and how they are linked to a safety traceability securing system would vary greatly among medical devices or their materials accordingly. So, we speculate that it is necessary, for securing safety traceability of medical devices, to explore measures including a uniform management by a medical device managing unit and description in package inserts.

Lastly in order to shorten approval time for medical device, we, JIRA, strongly request continuous employment of engineering-oriented resources.

We aimed to compile “Medical Diagnostic Imaging Device (Related) Industries 2006” to introduce JIRA’s suggestions and activities in a manner which is easy for outside people to understand. However, there may be some unsatisfactory parts as this is the first publication. Your comments will be highly appreciated.



Source: Excerpt from Material ① (p.30) of the “Visions of Medical Device Industries”

Figure 2 Development of high diagnostic and therapeutic performance devices by fair medical service remuneration, and according total medical cost suppression

Table 1 Hurdles and requested measures

<p><b>Research</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• Environment for industry-government-academia cooperation has not yet been established.</li> <li>• Diagnostic device field is evaluated by insurance only vaguely.</li> <li>• There exists no organization to function as data pool upon research and development.</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Establishment of flexible management structure for government subsidy</li> <li>• Introduction of the ratio against “total” in tax reduction for research and development</li> <li>• Launch of the Japanese version of BECON</li> <li>• Appropriation of national defense related budget</li> <li>• Effective utilization of NEDO subsidy</li> <li>• Accreditation of hospitals designated for research and development for each field</li> </ul>	<p><b>Production</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• Excessive time span for PAL approval</li> <li>• Opaque introduction of C2 (equipment which is not applied medical fee on reimbursement system) insurance</li> <li>• Insufficient activities of Japan Association for the Advancement of Medical Equipment.</li> <li>• Uncertainty of market size due to the fluctuating insurance evaluation</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Reorganizing functions of Japan Association for the Advancement of Medical Equipment and Pharmaceuticals and Medical Devices Evaluation Center</li> <li>• Fostering examiners from biomedical engineering field</li> <li>• Development of standardized SCM with government initiative</li> <li>• Establishment of the total supply network of equipments and components</li> </ul>
<p><b>Development</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• More excessive time and cost for clinical trial than the U.S.</li> <li>• The number of clinical imaging data analysis is limited.</li> <li>• Technology development is insufficient from the current healthcare trend.</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Active inducement of advanced analysis technology development</li> <li>• Development support of special medical devices for pediatric and ER</li> <li>• Support for development of CAD by human body region</li> <li>• Support for cross industries R &amp; D for micro medical device</li> <li>• Support for the specialized implementation systems for advanced clinical practice</li> </ul>	<p><b>Retail</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• CRM system shortage in a series of processes</li> <li>• Unclear regulations on used medical device retail</li> <li>• Limited comprehensive evaluation for procurement</li> <li>• Putting a brake to market introduction based on insufficient insurance evaluation</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Expanding medical device quota in ODA</li> <li>• Fostering medical physicists for equipment purchase, etc.</li> <li>• Establishment of FDG (for PET) distribution station</li> <li>• Fair evaluation of equipments in insurance system</li> </ul>
<p><b>Recycling</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• Lack of understanding about wastes and environment</li> <li>• Insufficient lifecycle cost awareness</li> <li>• No understanding about cost appropriation</li> <li>• Reluctant in adopting of recyclable and reusable components</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Setting target value of recyclable and reusable materials composition</li> <li>• Government’s active inducement of introduction of the environmental products</li> <li>• Support for making up remanufacturing system</li> <li>• Apply medical devices quota in saving-energy preferential tax system.</li> </ul>	<p><b>Maintenance</b></p> <p><b>【Hurdles】</b></p> <ul style="list-style-type: none"> <li>• Inconsistent measure of Pharmaceutical Affairs Law (repair) and Medical Service Law (maintenance) are questionable</li> <li>• Unclear criteria on the breach of Medical Service Law</li> <li>• Complication caused by the number of remote maintenance and multi vendor intervention</li> <li>• Ambiguous stand of display-type measurements of physical property such as CRT</li> <li>• Fostering of security system vendors and accreditation system are ill-prepared.</li> </ul> <p><b>【Requested measure】</b></p> <ul style="list-style-type: none"> <li>• Introduction of tax exemption in maintenance cost</li> <li>• Establishment of evaluation system for preventative maintenance</li> <li>• Standardization of safety criteria for parts and components supply</li> <li>• Clear positioning of maintenance cost in medical fee</li> </ul>

Source: Prepared by JIRA

## Table of Contents

Upon launching “JIRA Annual Report on Medical Imaging Devices & Systems 2006”

### 1. JIRA

- 1.1 Mission of Japan Industries Association of Radiological Systems
  1. Changes in medical imaging system environment and the crisis of the industries
  2. JIRA philosophy
  3. Basic principles and activity guidelines
  4. Summary
- 1.2 Priority activities policy in 2006
  1. Promotion of the visions of medical device industries and realization of cooperation (Proposals to and cooperation with the administration)
  2. Promotion of responses to Revised Pharmaceutical Affairs Law
  3. Responses to medical service remunerations (Evaluation of technology, human resources, and materials as well as maintenance and operation cost)
  4. Improvement of industrial and business environments (Maintenance service business, safety readiness)
  5. Activation of international activities (Interactions with related organizations overseas)
  6. Proposals to the outside and activation of PR activities
  7. Enforcement of compliance and law-abiding
  8. Fundamental services to member companies
  9. Summary
2. Overview of medical diagnostic imaging device industries
  - 2.1 Diagnostic imaging devices and their market trends
    1. What is diagnostic imaging device among medical devices?
    2. Classification of medical devices
    3. Domestic market trends of diagnostic imaging devices in 2005 (JIRA’s independent statistics)
    4. International market trends of diagnostic imaging devices
  - 2.2 Visions of medical device industries
    1. Regarding the formulation of the visions of medical device industries
    2. JIRA proposals in 2002 upon formulation of the visions of medical device industries
    3. Follow up of the visions of medical device industries
  - 2.3 Healthcare system in Japan
    1. Healthcare insurance system in Japan
    2. Healthcare system in Japan
    3. Medical service remunerations system

- 2.4 Summary of Revised Pharmaceutical Affairs Law and efforts of JIRA
  1. Classification of medical devices
  2. Authorization and certification
  3. Post-marketing safety
  4. Providing information
  5. Partial revision of the enforcement regulations of Medical Care Law
3. Overview and organization of JIRA
  - History of JIRA
  - JIRA organization
  - JIRA related groups
4. JIRA activity report
  - 4.1 JIRA priority activities guidelines and the results in 2005
    1. Compliance Committee
    2. Commendation Committee
    3. Trade Modernization Committee
    4. JIS Drafting Committee (JIRA Standard Committee)
    5. IEC/SC Expert Committee
    6. Medical Radiation Facilities Safety Administration Center (MRC)
    7. Public Relations Committee
    8. Survey and Research Committee
    9. Academia Relations Committee
    10. Exhibition Committee
    11. Education/Training Committee
    12. Medical Imaging System Division
    13. Standardization Division
    14. Regulation and Economy Divisions
    15. International Division
    16. Related Apparatus and Accessory Division
  - 4.2 List of publications in 2005
    1. JIRA publications
    2. JIS drafts

### Index

### Source materials

## Report of Korean Medical Regulations Investigation & Regular Interaction with Medical Devices Related Institutions in Korea

JIRA delegation visited Korean Food and Drug Administration (KFDA), Korea Testing Laboratory (KTL), Korea Medical Devices Industry Association (KMDIA), and Korea Medical Devices Industrial Cooperative Association (KMDICA) from March 5 through 9, 2006, in order to make an additional investigation of detailed regulations regarding Korean Medical Equipment Law, asking questions regarding the law, investigating the trends of Korean medical equipment market and holding a regular exchange with medical devices related institutions.

### 1. Korean Food and Drug Administration (KFDA)

- (1) The Department of Medical Devices was spun off from the Department of Pharmaceuticals, and it employed a teamwork formation with a general manager as its head, under which the following teams were included.
  - a. Medical Devices Safety Measures Team
  - b. Medical Devices Managing Team
  - c. Medical Devices Evaluation Department
- (2) As of March 2006, about 350 out of approximately 1700 medical device manufacturers have already obtained Korean GMP (KGMP). KFDA estimates that 60 to 70% of the manufacturers will be able to obtain KGMP.
- (3) "Preliminary examination system of advertisement" targeted on August, 2006 would be delayed. This operation supposed by KMDIA is under restudying.
- (4) It was revealed that the following three matters had been revised among the detailed regulations of Korean Medical Devices Laws:
  - a. Criteria for medical devices manufacturing, import and quality control
  - b. Provisions regarding medical devices classification and designation
  - c. Provisions regarding medical devices approval, etc.
- (5) The number of names assigned to medical devices for sale is limited to one name per one model.
- (6) Certificate for export products is issued by KFDA.
- (7) Medical device must be registered as SYSTEM.
- (8) EMI testing presently is required, however EMS method may be acquired by the end of this year.



Medical Devices Safety Measures/Management Teams



Evaluation Department

## 2. Korean Testing Laboratory (KTL)

- (1) JIRA received 10 subsidiary rules of the Medical Equipment Law.
- (2) KTL informed 342 companies (191 manufacturers and 151 importers) obtained KGMP as of March 2, 2006.
- (3) As for electrical and electronics system, MOU concludes with 58 organizations from 33 countries, but MOU/MRA of medical devices has not yet been concluded.
- (4) Sensor and/or software are not regarded as medical devices. System with PC and software is regarded as medical device.



KTL



KTL members

## 3. Korea Medical Devices Industry Association (KMDIA)

- (1) As of March 7, 2006, the number of member companies is approximately 240.
- (2) Regarding "Preliminary examination system of advertisement," legal provisions are now being prepared and the prospect timing for its implementation has not yet been established.
- (3) JIRA was provided with the import and export statistics of the fiscal year 2003 as a medical devices market data in Korea.
- (4) The Department of Welfare announced the ceiling of medical treatment materials, which KMDIA is looking for, as a transparent and rational standards on March 1.
- (5) PACS has already been introduced into most hospitals in Korea, but electronic medical record is going to be introduced now.



KMDIA



KMDIA Executives

#### 4. Korea Medical Devices Industrial Cooperative Association (KMDICA)

- (1) KMDICA member companies are approximately 300.
- (2) 150 member companies obtained KGMP (out of which 122 companies obtained KGMP newly.)
- (3) JIRA received the fiscal year 2004 medical devices market data of Korea.
- (4) Insurance reimbursement for medical technology has come to be applied to new medical technology since 2005.
- (5) KMDICA requests to participate in educational trainings by related organizations in Japan (including corporate seminars) were given to JIRA.



KMDICA



KMDICA

#### 5. Others

- (1) KFDA is conducting studies to introduce EMS.
- (2) Korea has an intention of participating in GHTF as a member.

### DITTA TC Conference & COCIR Opening Event Conference, March in Brussels

#### 1. DITTA TC Conference

On the March 27<sup>th</sup> DITTA TC Conference was held. JIRA chaired this year's DITTA conference.

At the DITTA TC Conference, discussions were held on agendas including environmental issues (WEEE/RoHS/EuP), the third party certification system, GHTF-related matters, and promotion of IT introduction.

##### (1) Environmental issues (WEEE/RoHS/EuP)

The chairperson of COCIR environmental committee made a report which included topics related to WEEE, RoHS, EuP in EU and RoHS in China. The position paper regarding RoHS compiled by COCIR was submitted to the consultant in charge on March 21.

It was also reported that RoHS practice in China is scheduled to start on March 1, 2007. It was agreed that sub groups to share information and perform investigation would be formed within DITTA so that more correct information would be obtained.

##### (2) Third party certification

The representative of NEMA made an update on 510k. Last year, 250 to 300 applications were handled by third-party certification organizations, which resulted in approximately 10% of the total number of applications. The reviewing period by FDA for third-party certifications is 20 days on average. MDUFMA (medical device user fee & modernization act) enacted by FDA in 2002 is supposed to be reviewed next year.

The representative of JIRA made an update on the current situation of the third-party certification system in Japan. For the third party certification, 372 criteria for the certification have been established. Among Class II equipments for which certificate criteria have been established, there was a case in which it took as long as 4 weeks before the certification was finally issued.

#### 2. COCIR Opening Event - Seminar eHealth : Challenges and Opportunities

On March 28<sup>th</sup>, COCIR organized a seminar on eHealth to celebrate the opening of its Brussels office.

At the seminar, the promotion of eHealth in EU for the following 15 years was discussed as the central topic. Deployment of eHealth (healthcare IT) in the EU and Regulation in China for Medical Devices are two major issues concerned and put stress on by COCIR.

#### 3. Open Session of the COCIR General Assembly

On 29<sup>th</sup>, the Open Session of the COCIR General Assembly was held with the attendance of COCIR members, physicians of Radiological Congress, representatives of the industry and representatives of JIRA/NEMA. Representatives of each group made an update on their activities.

##### (1) Recent activity report by COCIR

- a. Response to environmental issues: RoHS/WEEE/EuP

Efforts for environmental issues are getting on track towards the achievement of international standards based on restrictions which each nation should practice and on requests by markets. These efforts will probably develop into the lifecycle assessment (Product Standard IEC-60601-1-9), and disclosure of the information regarding the impacts on the environment during the lifecycle after the start of product commercial operation which is requested by users. COCIR focuses on medical devices responses to environmental issues, opinion exchange for standard establishment, and organizing information to give accurate feedback to members.

b. Contribution to infrastructure building for healthcare management

Medical expense in Europe (15 countries) occupies 8.6% of GDP, while the number of healthcare workers reaches up to 10% of the total workers. In addition, lengthening of average life expectancy by 10% means the increase of GDP by 0.35% per year. COCIR regards infrastructure building for healthcare as an important economic factor, and therefore, it has earnestly geared up infrastructure building for healthcare in EU area. COCIR continuously plans to set up and manage workshops depending on needs in order to place the full weight on the best practice sharing selectively. There are several challenging issues because laws and restrictions vary among countries, but COCIR will make a plan through the year 2013 and implement it.

(2) Interaction with Radiological Congress

The representative of European Society of Radiology (ESR) made an update on its activities. ESR is a newly established organization to bundle European Congress of Radiology (ECR) and European Association of Radiology (EAR) together. The society was established in 2005 and aims to unite the two existing organizations into one by 2008. So far, ECR has hosted and managed annual academic conference, while EAR has promoted interaction with each country through committee activities and hosting academic conferences in the fields of education, special technology and research. Moreover, it has been engaged in WG activities regarding safety confirmation on X-ray equipment, MRI and contrast agent, hospital management, and Teleradiology.

ESR strives to organize opinions from the academia and the industry, and to realize requests through lobbying the European Commission (EC), so that radiology in Europe will be strengthened and improved.

Currently, ESR is engaged in the following activities: creation of guidelines for technology, quality and safety man-

agement which will be indispensable for equipment users; research on new fields such as molecule imaging; and promotion of training for healthcare workers.

(3) Interaction with other industries

ORGALIME (European Engineering Industry Association), which is the largest organization related to electrical/electronics, machinery, metal and manufacturing fields, consists of 34 organizations from 23 countries in EU. The representative of the association made an update on their activities. The association not only provides its members with EU restriction information quickly, but also lobbies energetically. It also lobbies regarding globally common issues as well as issues in EU area. Issues such as EMC/WEEE/RoHS/EuP share the common field with COCIR, and thus, information exchange through deepened interaction is expected.

(4) Impact of the U.S. Deficit Reduction Act on medical service remunerations by diagnostic imaging

The representative of NEMA reported about the affects followed by the Deficit Reduction Act enforced in 2005. The act forces the reduction of US\$ 8 billion in 10 years. Specifically, the medical service remunerations by MRI, CT, PET, Ultrasound, etc. are reduced by as much as 20 to 70%, which will result, for patients, in the increase of diagnostic imaging cost and the prolonged waiting days before medical examinations. It was reported that 31 organizations had submitted the request to the Senate so far for re-investigation of the act.

(5) Report by Japan

The representative of JIRA made a report of the domestic market, production, export and import trends of medical imaging systems in Japan. The assessment of the New Pharmaceutical Affairs Law, which had been revised one year earlier, and the situation following the revision of medical service remunerations were reported as well.

## Participation in the 10<sup>th</sup> GHTF Conference, June in Lubeck

From June 28 through 30, 2006, the 10<sup>th</sup> Global Harmonization Task Force (GHTF) was held in Lubeck, Germany. Three members of the International Division of JIRA joined this meeting. In addition to the announcement of this year's GHTF activity accomplishments, a number of lectures based on actual examples and panel discussions were given as to the theme "Design for Patient Safety" of the 10<sup>th</sup> conference. The theme-related topics included the following: the importance of designing medical devices by taking into account human factors and workflow. Moreover, 8 workshops were held with themes such as each country's situation of STED.

# Development of Japanese Radiological Equipment in the Post-World War II (18)

## Development of charged particle accelerator therapy equipment Popularization of linear accelerator therapy equipment

Sumio Makino  
Advisor, JIRA



### 1. Brief outline of the last issue

Radiotherapy in Japan was performed by X-ray equipment before and immediately after the war. It was followed by RI (cobalt-60 and cesium-137), i.e. high-energy radiotherapy. Based on this experience, it further developed into a smaller radiation source (focus) and a higher energy, i.e. betatron therapy equipment.

Betatron did achieve high-energy radiotherapy. However, the low level of its radiation dose became a problem. In the next stage, therefore, a linear accelerator (briefly called Linac) became a promising radiotherapy system.

This article describes the history of development of “radiotherapy in Japan and its equipment in the post world war II” based on the experience of the author (Sumio Makino) who were involved in the birth and up to full development of Linac.

### 2. Emergence of Linac radiotherapy equipment

The excerpt from “Progress of radiotherapy equipment” by Yoshio Onai (Toshiba Medical Review, January 1985) is as follows.

*In 1925, Ising announced the theory of linear acceleration of progressive wave for electron acceleration. In 1947, Fry and others used microwaves developed for radar during the war, accelerating electrons successfully. In 1952, the medical linear accelerator (Linac) was installed for the first time in the world at Hammersmith Hospital in London. This was an 8-MeV unit. Then, 4-MeV units were mass-produced and installed in major therapy centers in the United Kingdom. ---The rest is omitted.---*

*In our country, actual installation took place in 1963. Different types of Linac were imported by the Cancer Institute (U.K. Mullard, 4.3 MeV: figure 1), the National Cancer Center (U.S. Varian, 6 MeV: figure 2) and the National Institute of Radiological Sciences (U.K. Vickers Armstrong, 6 MeV: figure 3), respectively. In 1964, they started actual application for therapy. Every type has a magnetron which emits the microwave (progressive wave) to accelerate electrons. The type installed at the National Institute of Radiological Sciences used X-band whose wavelength is 3 cm. The other two*

*types used S-band whose wavelength is 10 cm. Use of X-band could shorten an accelerating tube and a new system was expected. But, further development was not realized. ---Text partly omitted.---*

*NEC collaborated technically with Varian and manufactured a semi-national 6-MeV system (and delivered it to Aichi Cancer Center) in 1965. Mitsubishi Electric developed a 6-MeV system (and delivered it to National Kanazawa Hospital) in 1966. Toshiba developed a 13-MeV system (and delivered it to Kurume University). ---The rest is omitted.---*

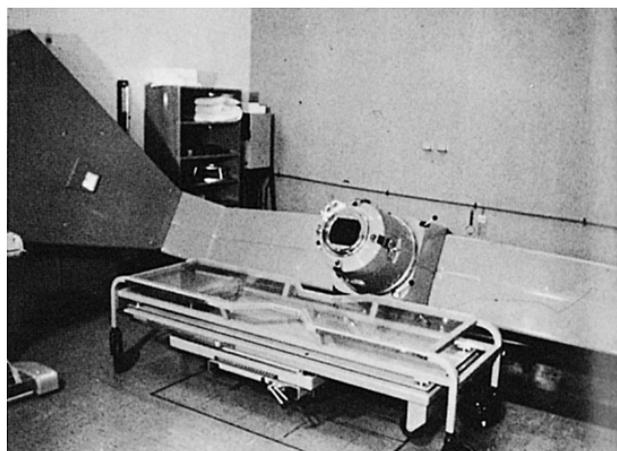
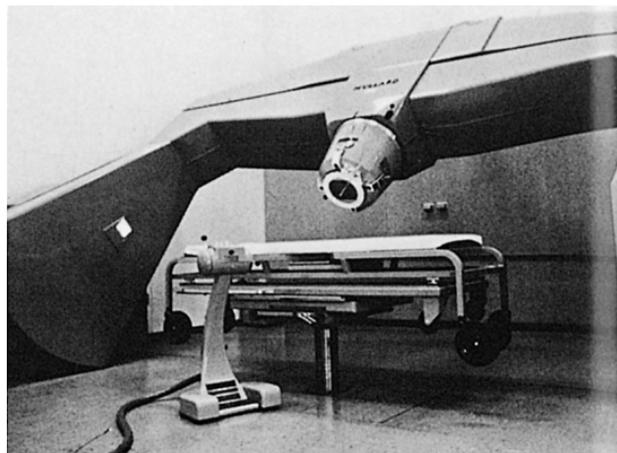


Figure 1. 4.3-MeV Mullard Linac installed at the Cancer Institute in 1963

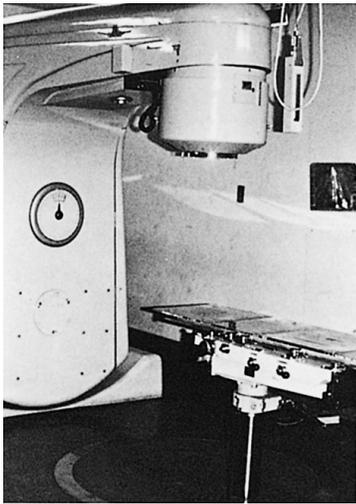


Figure 2.  
6-MeV Varian Linac  
installed at the National  
Cancer Center

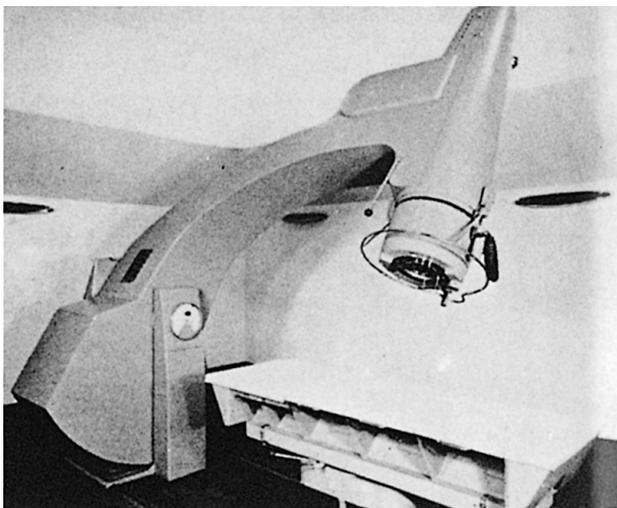


Figure 3. 6-MeV Vickers Armstrong Linac, the same type as  
installation at the National Institute of Radiological  
Sciences

### 3. Development of therapeutic Linac: Experience, background and episodes

As mentioned above, the betatron seemed excellent among the charged particle accelerator therapy systems because of its small X-ray focus of high-energy radiation used for therapy. Unfortunately, it had rather insufficient X-ray output and was limited to high-energy electron therapy. As mentioned in the last issue, the betatron had also some problems in manufacturing technology. We did not find a definite theory for the manufacturing process, including adjustment that is required to obtain the stable X-ray output. Finally, the medical (therapeutic) betatron did not come into wide use as expected.

#### *A. Is the output of 6 MeV optimal, necessary and sufficient for Linac?*

Here, the author would like to make an excuse and gain the understanding of readers.

From the very beginning, our development aimed at “a 15-MeV Linac”. At that time, a common-sense level of energy was 6 MeV or so. We found, however, that it was not “a necessary and sufficient” output. This was proved on the basis of the experience in the betatron electron therapy. We attempted to develop a new Linac.

The author fears that this article is based on the author’s private experience alone and is not appropriate for this public news brochure. But, the development of Linac of the then dramatically high energy, 15 MeV, is considered to be worth recording as an epoch-making event in the history. It is hoped that this article will be read and accepted as such.

Toshiba Corporation had manufactured many units of therapeutic betatron. As mentioned above, betatron had many problems. From an objective standpoint, it became necessary to rapidly shift from betatron to Linac. Toshiba Central Laboratory started its research on a medical Linac (6 MeV) using the X-band.

Before completion of that research, it became necessary to promptly supply Linac to the market instead of betatron. Apart from the research by Central Laboratory, Medical System Division was forced to actively start development of a product. The author was instructed to be a chief of development project team.

Unfortunately, the author was quite ignorant of the technical knowledge of microwave and incapable of discussing the theoretical structure of Linac. It was natural to seek assistance and guidance from Central Laboratory. One of the competent researchers was Naoshi Shigemura, who was also an active member of JIRA.

#### *(A-1) What level (MeV) of energy is optimal and the most effective for therapy?*

The first idea that the author came up with was a great achievement by Tadayoshi Matsuda, radiotherapist, the then chief of Department of Radiology, Toyohashi Municipal Hospital, who used a Siemens betatron and had his own “theory” as an expert of radiotherapy.

His “theory, i.e. principle”, which he told me whenever he met me, was as follows. “I am a radiotherapist who must cure any cancer as long as it is curable. (In other words, unsuccessful treatment of incurable cancer will only increase pain of patients.) First of all, I use the electron beam (15 to 16 MeV) of this betatron (Siemens 18 MeV) to cure visible cancer at the upper and lower jaw. The electron beam is remarkable effective.”

His “theory” and Siemens equipment impressed the author very much. The author wanted to make by all means radiotherapy equipment which can realize effectiveness of 15-MeV elec-

tron beam, and considered it a future mission.

#### *(A-2) How to make a 15-MeV Linac?*

We had to develop a therapeutic Linac all on our own. The author's initial concept was "to use S-band at the present stage and to aim at 15 MeV instead of 6 MeV".

As mentioned above, the accelerator research team of Central Laboratory was testing and researching a 6-MeV X-band Linac. Its advantage was a short accelerating tube, whereas its disadvantage was excessive height of equipment and unstable emission. Thus, their development was making slow progress. Therefore, the above-mentioned initial concept was determined.

However, every manufacturer was making a Linac of output of 6 MeV or less, and enjoying a widespread use. We wondered how we could make a 15-MeV Linac which is as practical (with competitive price) as a 6-MeV Linac. We consulted the researcher, Shigemura, about technical possibility of S-band. After several days, he reported the result of calculation as follows. Depending on structure of an accelerating tube, we can obtain the output of 15-MeV even when we use the same magnetron (5 MW).



Figure 4. A prototype accelerating tube of 15-MeV Linac

#### *(A-3) Steady progress for development of 15-MeV Linac, sale of number one unit and colossal effort toward completion*

It started in 1965. It was naturally a joint project with Central Laboratory, which was represented by Shigemura. Figure 4 shows senior managers of Medical System Division taking a close look at a prototype accelerating tube.

Before a prototype system was completed, advanced advertising of "high-energy Linac" attracted much attention from the market.

In April 1966, the Congress of Japan Radiological Society was held in Kagoshima. After attendance there, the author returned to Tokyo and received an inquiry from the late professor Kiichiro Ozeki, Kurume University requesting us to explain "the high-energy Linac". It was for the first time that we explained the concept of Linac under development to a radiotherapist. As a result, we were convinced that we were on the right track of 15-MeV electron beam radiotherapy and that its future was promising.

The number one unit was delivered to Kurume University. Our factory was dedicated to manufacture X-ray equipment. Manufacture of Linac, a kind of microwave equipment, was our first experience. We had much difficulty in the manufacturing process. Although we postponed the delivery date, we had to install the equipment before we were sure of stable performance. It took much time before the equipment was put into clinical use. The late Yoo Ono (the then assistant professor of Kurume University, later professor of Fukuoka University) was involved in the whole process from the commercial negotiation to the installation of equipment. When Fukuoka University selected an X-ray CT for installation there, he was kind enough to remember the author as an engineer friend of his. It was a grateful and pleasant experience.

The Linac room of Kurume University became like our workshop. It was full of workers and materials for a long time. The inns nearby were like laborer's lodging at construction site.

The magnetron was rated 5 MW and very expensive. How many magnetrons were airlifted from the tube factory via Fukuoka Airport?---

Some people said jokingly as follows: At the Airport whenever they received a heavy wooden box whose edge was as long as 1.6 m, a porter used to say instantly without seeing any record, "Well, the destination is Kurume". Figure 5 shows the Linac delivered to Kurume University. The equipment was manufactured originally for the output of 15 MeV. But, it was downgraded later to 13 MeV because of immature electronic circuitry.

Some time after this equipment was put into clinical use, we received an inquiry from a doctor in the U.S., saying, "I want to know more about a 15-MeV high-energy Linac." He was professor Charry, MD, at Department of Radiology, Faculty of Medicine, Minnesota University.

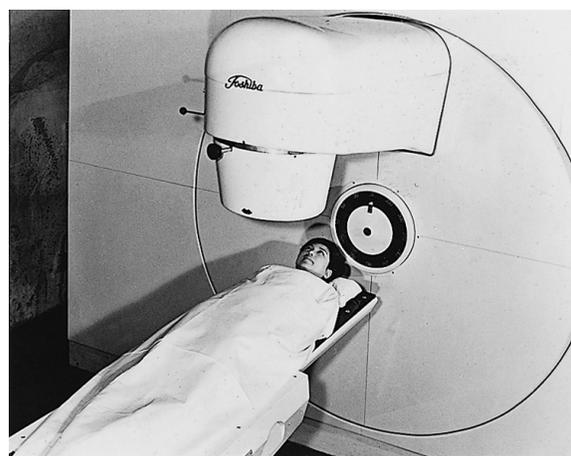


Figure 5. The number one unit of 13-MeV Linac delivered to Kurume University

*(A-4) A true story of a proverb "A little learning is a dangerous thing"*

Just as in the usual case of the author, I addressed this inquiry (recklessly without hesitation). Dr. Charry visited Japan in June 1968, if I remember correctly. He wanted to inspect a high-energy Linac in actual operation. It was a matter of course that he was welcome. He was accompanied by a physicist (the so-called PhD) at Chicago University, who acted as a consultant to Dr. Charry. In the U.S., when medical doctors purchase medical equipment, they are always accompanied, by convention, by PhD, who assumes technical responsibility. We were so informed, and that was our first experience of that convention.

They inspected the Linac room of Kurume University.

First of all, the author explained, in broken English, the principle, structure, function and design concept, by drawing sketches on the blackboard. One of the visitors, an old PhD, who listened attentively, said to me, "I see. You had a good idea to make a high-energy Linac."

Then, he presented me some documents, saying, "Well, Mr. Makino, this is my papers for your information. I hope that you read them".

"Thank you very much." This is a present from a customer, which we should receive with thanks. The author received three papers and was surprised to find that the papers were written by Dr. Skaggs. That is because Dr. Skaggs was an authoritative physicist and his papers were like our textbooks. The author, a layman of Linac, was shocked to have met him and lectured on Linac. It was a very embarrassing experience even to the author who had guts to do everything possible.

He stayed for several days. The author apologized to him profusely, but he only smiled and nodded.

We delivered a Linac to Minnesota University. Afterward, we had many chances of reunion. Dr. and Mrs. Skaggs visited Japan and had a good time, while the author visited Chicago, and exchange of experience continues. Figure 6 shows Dr. Charry taking care of his first patient to be treated by the Linac.

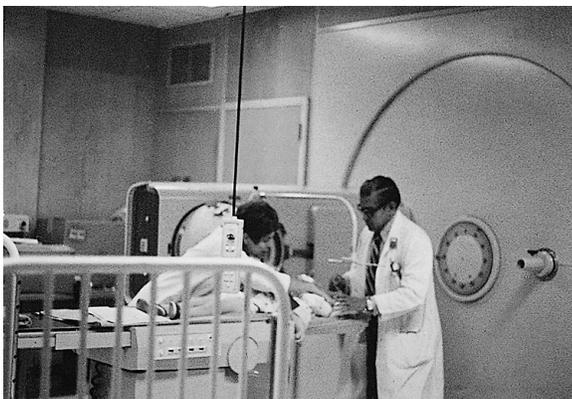


Figure 6. Treatment of the first patient at Minnesota University

*(A-5) Mass production of Linac*

We had much difficulty in developing a 15-MeV Linac. According as electron beam radiotherapy became popular, the number of orders for the Linac increased. Figure 7 shows the mass production line of Linac at the factory.

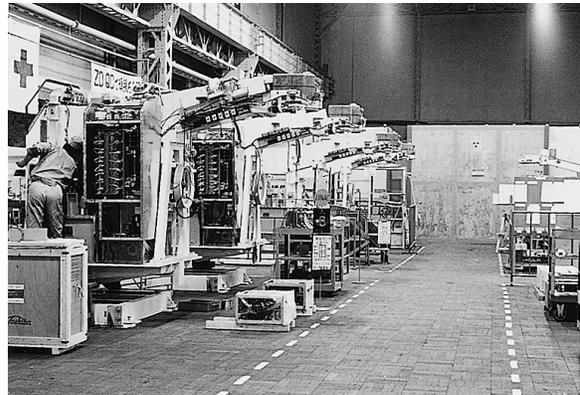


Figure 7. Mass production of 15-MeV Linac. Linac is rarely mass-produced.

Finally, high-energy, at least 12 MeV or higher, was confirmed to be useful for electron beam radiotherapy. On the other hand, for X-ray radiotherapy, compact equipment of low energy of 6 MeV or 4 MeV was preferred.

The market trend is shown in figure 8 (excerpted from Onai's paper mentioned above).

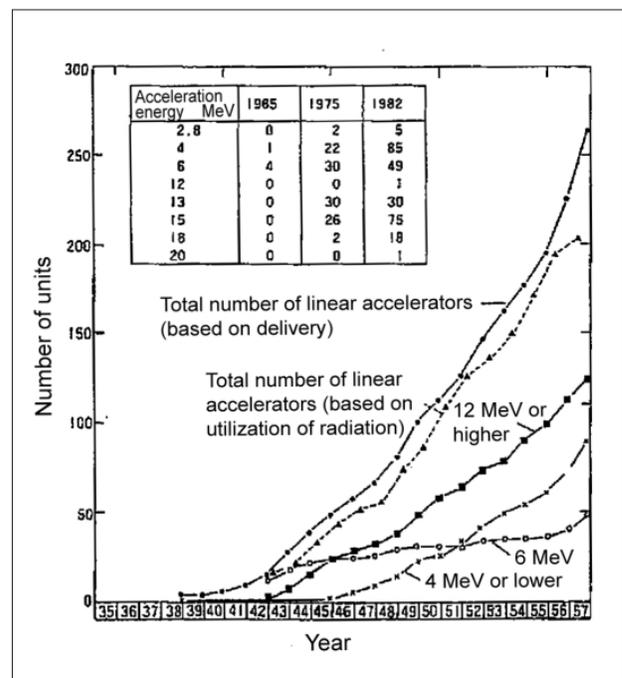


Figure 8. Annual trend of number of linear accelerator installed in our country

(The data since 1974 was provided by Radiotherapy System Study Group.)