

# Radiology Japan

Japan Industries Association of Radiological Systems

October 2007 No. 56

## Review of the Japanese Market for Diagnostic Imaging and Therapeutic Systems in the Year 2006

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

From January through December 2006 Unit: Millions of yen

Item	Category	Production		Exports		Imports		Domestic Market			
		Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Number of Units	% Δ from Previous Year	Amount	% Δ from Previous Year
<b>1 X-ray</b>		<b>135,713</b>	<b>+12</b>	<b>48,637</b>	<b>+13</b>	<b>27,156</b>	<b>-7</b>			<b>114,232</b>	<b>+4</b>
· General-purpose R/F		30,923	-3	5,342	+6	29	-46	1,517	-1	25,610	-4
· Cardio & angio		13,219	-2	6,822	+3	14,266	-13	265	-8	20,663	-11
· General-purpose radiography		22,356	+37	10,135	+9	1,210	-25	5,356	+4	13,432	+56
· Mammography		2,637	-2	23	-42	6,004	-3	723	-3	8,618	-3
· Mobile		3,393	-10	1,601	-18	144	-9	741	-8	1,936	-3
· Dental		6,990	+7	2,146	+5	0	-	4,260	+4	4,844	+8
· Others		56,195	+9	22,568	+25	5,503	-50			39,129	-13
<b>2 CT</b>		<b>124,186</b>	<b>+8</b>	<b>82,958</b>	<b>+14</b>	<b>29,319</b>	<b>+57</b>			<b>70,546</b>	<b>+17</b>
<b>3 Nuclear medicine</b>		<b>10,054</b>	<b>+115</b>	<b>943</b>	<b>-</b>	<b>13,776</b>	<b>-35</b>			<b>22,887</b>	<b>-12</b>
<b>4 MRI</b>		<b>35,254</b>	<b>+1</b>	<b>15,549</b>	<b>-15</b>	<b>40,263</b>	<b>+1</b>			<b>59,968</b>	<b>+6</b>
<b>5 Image processing systems</b>		<b>23,416</b>	<b>+54</b>	<b>3,837</b>	<b>+22</b>	<b>7,401</b>	<b>+17</b>			<b>26,980</b>	<b>+47</b>
<b>6 Related items &amp; accessories</b>		<b>32,740</b>	<b>+12</b>	<b>16,335</b>	<b>+30</b>	<b>2,549</b>	<b>+34</b>			<b>18,955</b>	<b>+3</b>
<b>7 Diagnostic ultrasound</b>		<b>91,841</b>	<b>+3</b>	<b>58,270</b>	<b>-2</b>	<b>10,203</b>	<b>+8</b>			<b>43,775</b>	<b>+13</b>
<b>8 Therapeutic systems</b>		<b>5,515</b>	<b>-20</b>	<b>2,435</b>	<b>+24</b>	<b>8,868</b>	<b>+65</b>			<b>11,948</b>	<b>+16</b>
<b>Total</b>		<b>458,719</b>	<b>+10</b>	<b>228,964</b>	<b>+8</b>	<b>139,537</b>	<b>+6</b>			<b>369,292</b>	<b>+9</b>

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

### Review of the Results for 2006

( ) refers to increase or decline of percentage over the previous year.

- The total count of medical imaging system was as follows:
  - Production 458.7 billion yen (+10%)
  - Export 229.0 billion yen (+8%)
  - Import 139.5 billion yen (+6%)
  - Total domestic market 369.3 billion yen (+9%) including the amount reported by new companies 8.9 billion yen
  - 4.6 billion yen out of 8.9 billion yen belonged to Other diagnostic image processing systems.

- The domestic market of major equipment was as follows:
  - X-ray 114.2 billion yen (+4%)
  - CT 70.5 billion yen (+17%)

- Nuclear medicine 22.9 billion yen (-12%)
  - MRI 60.0 billion yen (+6%)
  - Image processing systems 27.0 billion yen (+47%)
  - Diagnostic ultrasound 43.8 billion yen (+13%)
- Total diagnostic equipment increased to

357.3 billion yen (+9%)

For diagnostic X-ray system, the following increased:

- General-purpose radiography 13.4 billion yen (+56%)
- Dental 4.8 billion yen (+8%)

whereas, the following decreased:

- Cardio and angio 20.7 billion yen (-11%)
- General-purpose R/F 25.6 billion yen (-4%)

Total X-ray finally increased to 114.2 billion yen (+4%)

- The total production output increased to 458.7 billion yen (+10%), in which the amount reported by new companies reached 10.1 billion yen.

Especially,

– Nuclear medicine increased to 10.0 billion yen (+115%)

For diagnostic X-ray system, the following increased:

– General-purpose radiography 22.4 billion yen (+37%)

– Dental 7.0 billion yen (+7%)

whereas, the following decreased:

– Mobile 3.4 billion yen (-10%)

– General-purpose R/F 30.9 billion yen (-3%)

As a result, total X-ray system 135.7 billion yen (+12%)

Also, the following increased:

– Image processing systems 23.4 billion yen (+54%)

– CT 124.2 billion yen (+8%)

4. The total exports increased to 229.0 billion yen (+8%), in which the amount reported by new companies reached 22 billion yen.

Especially, the following increased:

– Image processing systems 3.8 billion yen (+22%)

– CT 83.0 billion yen (+14%)

For diagnostic X-ray system,

– General-purpose radiography increased to 10.1 billion yen (+9%)

whereas,

– Mammography decreased to 0.02 billion yen (-42%)

– Mobile decreased to 1.6 billion yen (-18%)

Total X-ray amounted to 48.6 billion yen (+13%)

Also,

– MRI decreased to 15.5 billion yen (-15%)

5. The total imports increased to 139.5 billion yen (+6%), in which the amount reported by new companies reached 1.0 billion yen.

Especially,

– CT increased to 29.3 billion yen (+57%)

For diagnostic X-ray system, the following decreased:

– General-purpose R/F 0.03 billion yen (-46%)

– General-purpose radiography 1.2 billion yen (-25%)

– Cardio and angio 14.3 billion yen (-13%)

Total X-ray amounted to 27.2 billion yen (-7%)

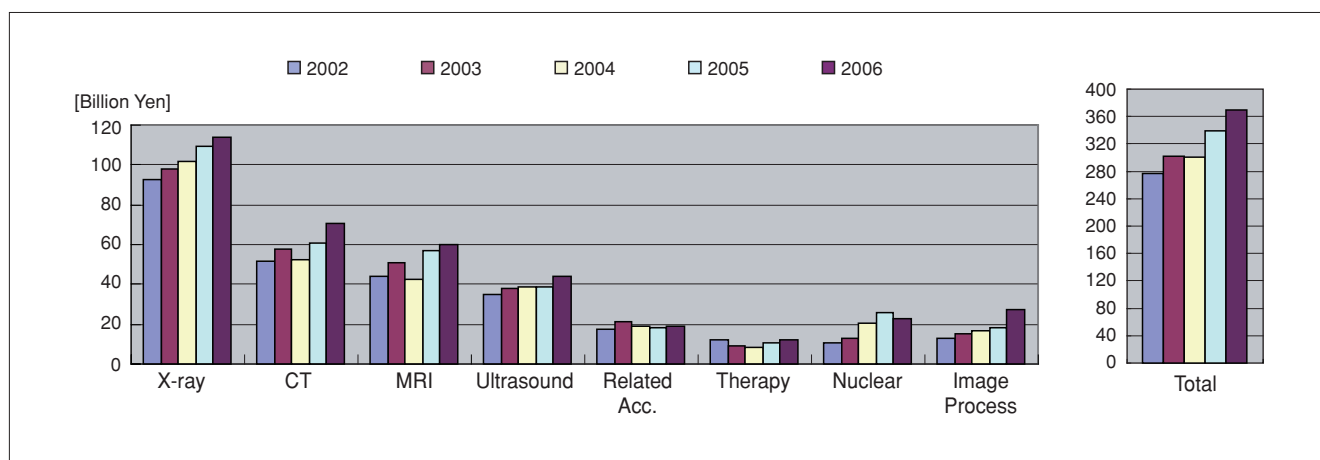
also,

– Nuclear medicine decreased to 13.8 billion yen (-35%)

6. As stated above, the count for CT, diagnostic X-ray systems in which especially include General-purpose radiography, Image processing systems and Diagnostic ultrasound equipment increased. Therefore, the overall sales in the domestic market in 2006 increased by 9%.

According to the variation from 2002 to 2006 for every major system, diagnostic X-ray systems increase annually from 2002. (In 2006, General-purpose radiographic equipment increased markedly because of a tendency toward digitalization, whereas Mammography decreased although it had increased rapidly in 2004, decreased.) CT and MRI increased from 2004, but Nuclear medicine equipment, which increased mainly with PET continuously from 2002, decreased with a peak in 2005. Related items and accessories remained unchanged and Image processing systems, Diagnostic ultrasound and Therapeutic systems tended to increase.

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



## 10-years change of medical systems market in Japan from 1997 to 2006

### Diagnostic Imaging and Therapeutic Systems: Production

(Unit: Hundred million yen)

Year	X-ray	CT	Nuclear medicine	MRI	Related items & accessories	Image processing systems	Therapeutic systems	Sub-total	Diagnostic ultrasound	Total
1997	1,027 (106)	869 (106)	49 (73)	446 (109)	186 (113)	91 (827)	89 (131)	2,757 (110)	- -	2,757 (110)
1998	947 (92)	850 (98)	59 (120)	490 (110)	198 (106)	82 (91)	102 (114)	2,728 (99)	- -	2,728 (99)
1999	961 (101)	821 (97)	50 (84)	407 (83)	224 (113)	100 (121)	89 (88)	2,652 (97)	- -	2,652 (97)
2000	980 (102)	733 (89)	46 (92)	336 (83)	208 (93)	39 (40)	88 (99)	2,431 (92)	- -	2,431 (92)
2001	1,027 (105)	814 (111)	35 (76)	404 (120)	224 (107)	71 (180)	85 (97)	2,660 (109)	- -	2,660 (109)
2002	954 (93)	796 (98)	27 (78)	434 (107)	251 (112)	82 (115)	90 (105)	2,633 (99)	751 -	3,384 -
2003	1,103 (116)	832 (105)	27 (97)	338 (78)	279 (111)	111 (136)	69 (77)	2,759 (105)	764 (102)	3,523 (104)
2004	1,172 (106)	785 (94)	58 (220)	380 (113)	270 (97)	140 (126)	76 (110)	2,882 (104)	825 (108)	3,706 (105)
2005	1,233 (105)	1,145 (146)	47 (80)	347 (91)	292 (108)	152 (109)	69 (91)	3,284 (114)	889 (108)	4,174 (113)
2006	1,353 (110)	1,242 (108)	101 (215)	353 (101)	327 (112)	234 (154)	55 (80)	3,664 (112)	918 (103)	4,587 (110)

### Diagnostic Imaging and Therapeutic Systems: Exports

(Unit: Hundred million yen)

Year	X-ray	CT	Nuclear medicine	MRI	Related items & accessories	Image processing systems	Therapeutic systems	Sub-total	Diagnostic ultrasound	Total
1997	254 (111)	349 (105)	13 (100)	190 (130)	47 (102)	23 (1,150)	14 (108)	890 (114)	- -	890 (114)
1998	178 (70)	359 (103)	11 (85)	240 (126)	49 (104)	19 (83)	20 (140)	876 (98)	- -	876 (98)
1999	241 (135)	345 (96)	7 (65)	201 (84)	47 (96)	10 (51)	18 (87)	869 (99)	- -	869 (99)
2000	268 (111)	368 (107)	6 (89)	215 (107)	59 (126)	5 (52)	16 (92)	938 (108)	- -	938 (108)
2001	274 (102)	398 (108)	3 (44)	247 (115)	73 (125)	8 (157)	21 (131)	1,025 (109)	- -	1,025 (109)
2002	260 (95)	411 (103)	2 (60)	309 (125)	95 (129)	7 (94)	23 (108)	1,107 (108)	470 -	1,577 -
2003	343 (132)	397 (97)	1 (40)	198 (64)	98 (103)	16 (215)	23 (100)	1,077 (97)	496 (106)	1,572 (100)
2004	385 (112)	429 (108)	1 (74)	247 (124)	109 (111)	29 (185)	27 (119)	1,228 (114)	542 (109)	1,769 (113)
2005	429 (111)	727 (169)	0 (0)	182 (74)	126 (115)	31 (107)	20 (72)	1,515 (123)	596 (110)	2,110 (119)
2006	485 (113)	830 (114)	9 (0)	155 (85)	163 (130)	38 (122)	24 (124)	1,706 (113)	583 (98)	2,289 (108)

Diagnostic Imaging and Therapeutic Systems: Imports

(Unit: Hundred million yen)

Year	X-ray	CT	Nuclear medicine	MRI	Related items & accessories	Image processing systems	Therapeutic systems	Sub-total	Diagnostic ultrasound	Total
1997	164 (92)	84 (88)	40 (55)	183 (60)	39 (156)	8 -	41 (123)	559 (79)	- -	559 (79)
1998	206 (126)	74 (88)	84 (210)	258 (141)	52 (133)	3 (38)	42 (102)	719 (129)	- -	719 (129)
1999	196 (95)	102 (138)	64 (75)	264 (102)	33 (63)	9 (328)	48 (113)	715 (99)	- -	715 (99)
2000	234 (119)	221 (216)	54 (85)	368 (140)	30 (92)	54 (616)	61 (127)	1,022 (143)	- -	1,022 (143)
2001	217 (93)	159 (72)	59 (108)	313 (85)	19 (62)	69 (127)	67 (110)	901 (88)	- -	901 (88)
2002	232 (107)	135 (85)	81 (138)	317 (102)	17 (93)	56 (81)	53 (79)	892 (99)	69 -	961 -
2003	217 (94)	145 (107)	100 (125)	366 (115)	29 (171)	60 (107)	44 (83)	962 (108)	107 (155)	1,070 (111)
2004	230 (106)	167 (115)	145 (145)	292 (80)	33 (112)	56 (93)	36 (82)	960 (100)	104 (97)	1,064 (99)
2005	292 (127)	187 (112)	213 (146)	400 (137)	19 (58)	63 (113)	54 (149)	1,228 (128)	94 (91)	1,322 (124)
2006	272 (93)	293 (157)	138 (65)	403 (101)	25 (134)	74 (117)	89 (165)	1,293 (105)	102 (108)	1,395 (106)

Diagnostic Imaging and Therapeutic Systems: Domestic Market

(Unit: Hundred million yen)

Year	X-ray	CT	Nuclear medicine	MRI	Related items & accessories	Image processing systems	Therapeutic systems	Sub-total	Diagnostic ultrasound	Total
1997	937 (103)	604 (103)	76 (60)	439 (77)	178 (134)	76 (844)	116 (132)	2,426 (100)	- -	2,426 (100)
1998	973 (104)	565 (93)	133 (175)	509 (116)	202 (113)	66 (87)	124 (106)	2,572 (106)	- -	2,572 (106)
1999	917 (94)	578 (102)	107 (80)	469 (92)	210 (104)	99 (149)	119 (96)	2,499 (97)	- -	2,499 (97)
2000	946 (103)	585 (101)	94 (88)	489 (104)	179 (85)	89 (90)	133 (112)	2,515 (101)	- -	2,515 (101)
2001	970 (103)	574 (98)	91 (96)	470 (96)	168 (94)	132 (149)	131 (99)	2,536 (101)	- -	2,536 (101)
2002	926 (95)	520 (91)	106 (117)	442 (94)	173 (103)	130 (99)	120 (92)	2,418 (95)	350 -	2,768 -
2003	977 (106)	580 (111)	126 (119)	506 (114)	210 (122)	155 (119)	90 (75)	2,645 (109)	376 (107)	3,021 (109)
2004	1,017 (104)	523 (90)	203 (161)	426 (84)	193 (92)	166 (107)	85 (94)	2,613 (99)	387 (103)	3,000 (99)
2005	1,096 (108)	605 (116)	259 (128)	566 (133)	185 (96)	184 (111)	103 (121)	2,997 (115)	388 (100)	3,385 (113)
2006	1,139 (104)	705 (117)	229 (88)	600 (106)	190 (103)	270 (147)	119 (116)	3,252 (108)	438 (113)	3,693 (109)

The performance in the year 2006 (January through December), according to the statistics of Japan Industries Association of Radiological Systems, have been summarized. These have been added to the results of the 10-year (1997-2006) variation in the production, export, and import and domestic market of medical systems and are summarized here along with tables and bar graphs.

As for the sales in the domestic market over the 10 year period (excluding Diagnostic ultrasound), sales in the first half, from 1997 to 2002, remained unchanged but sales from 2003 increased, resulting in an increase of overall sales to 82.6 billion yen (+34%). The introduction of new technologies (DR/CR, MDCT, MRI enhancement of field strength, PET and PET/CT and state-of-the-art Therapeutic systems) is considered to have contributed to the growth in the domestic market. In addition, sales of CT and MRI in the domestic market decreased when the medical service remunerations was revised in 2002 and 2004, whereas it increased in 2006 when the medical service remunerations was also revised. As for the 10-years change in domestic market, growth was seen in X-ray system with 20.2 billion yen (+22%), CT with 10.1 billion yen (+17%), Nuclear medicine with 15.3 billion yen (+201%), MRI with 16.1 billion yen (+37%), and Image processing systems with 19.4 billion yen (+255%). Sales of Related items & accessories and Therapeutic systems remained unchanged with 1.2 billion yen (+7%) and 0.3 billion yen (+3%), respectively. The greatest growth was seen in the amount in X-ray (20.2 billion yen) and in the ratio in Image processing systems (+255%). Sales of Diagnostic ultrasound, for which full-year statistics started in 2002, increased to 8.8 billion yen (+25%).

Production during the 10 years increased by 90.7 billion yen (+33%), in which growth was seen in CT with 37.3 billion yen (+43%), X-ray with 32.6 billion yen (+32%) and Image processing systems with 14.3 billion yen (+157%) and a drop was seen in MRI with 9.3 billion yen (-21%) and Therapeutic systems with 3.4 billion yen (-38%).

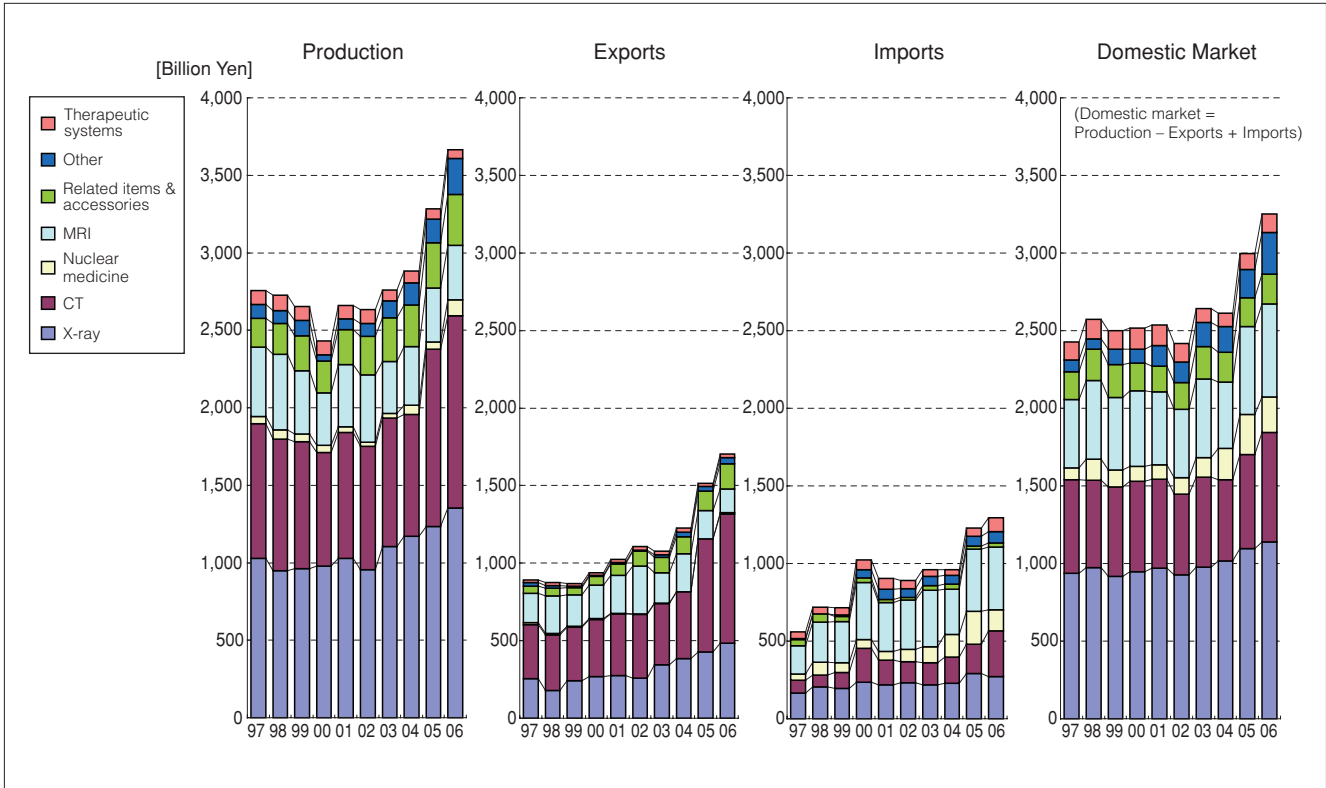
The export amount over the 10 years increased by 81.6 billion yen (+92%). The greatest growth was seen in the amount of CT (48.1 billion yen) and in the ratio of Related items & accessories (+248%). On the other hand, sales of MRI decreased by 3.5 billion yen (-18%).

The import amount during the period increased by 73.4 billion yen (+131%). A large growth was seen in MRI with 22.0 billion yen (+120%), CT with 20.9 billion yen (+249%), and X-ray with 10.8 billion yen (+66%). While sales of Related items & accessories decreased by 1.4 billion yen (-36%).

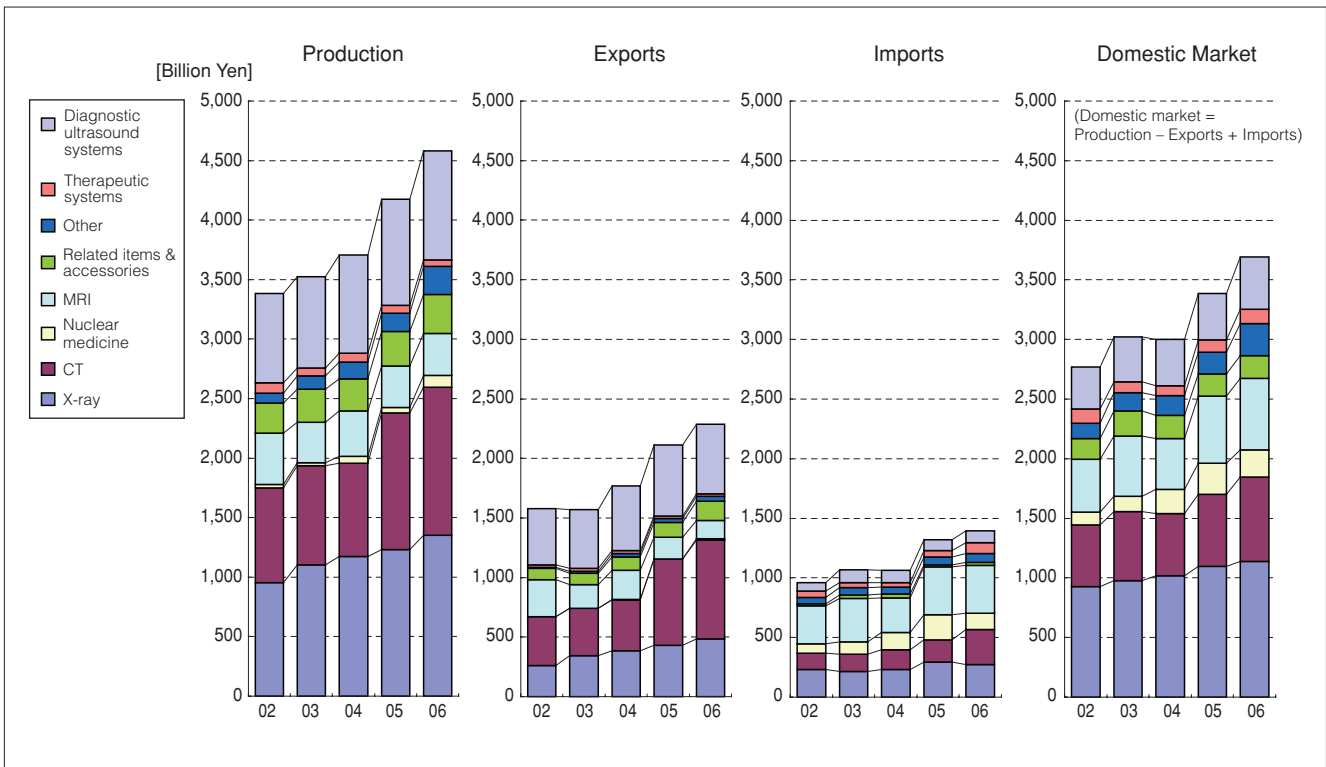
When the changes in percentage distribution for all major system were investigated in the production and domestic market, based on the performance in 2002 when Diagnostic ultrasound was included in the full-year statistics, production increased for CT (23.5% → 27.1%), Image processing systems (2.4% → 5.1%), and Nuclear medicine (0.8% → 2.2%), but decreased for MRI (12.8% → 7.7%) and Therapeutic systems (2.7% → 1.2%).

Similarly, sales in the domestic market increased for Image processing systems (4.7% → 7.3%), and Nuclear medicine (3.8% → 6.2%) CT (18.8% → 19.1%), but decreased for X-ray (33.4% → 30.8%) and Therapeutic systems (4.3% → 3.2%).

**Trends in Production, Exports, Imports, and Japanese Market for Medical Imaging and Therapeutic Systems**  
 [Actual January-December figures for years 1997 to 2006] \* Excluding diagnostic ultrasound systems



**Trends in Production, Exports, Imports, and Japanese Market for Medical Imaging and Therapeutic Systems**  
 [Actual January-December figures for years 2002 to 2006]



# Report on JRC 2007

JRC2007, the joint meeting of the 66<sup>th</sup> Congress of the Japan Radiological Society (JRS), the 63<sup>rd</sup> Congress of the Japanese Society of Radiological Technology (JSRT) and the 92<sup>nd</sup> Congress of the Japan Society of Medical Physics (JSMP), was held at Pacifico Yokohama from April 13<sup>th</sup> (Fri) to 15<sup>th</sup> (Sun).

JIRA managed ITEM2007 (The 2007 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 "Challenge without limits". 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 143 companies and 1 organization joined the exhibition, which occupied a total of 8,759 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 22,148 persons, which was much more than last year.

Next year, ITEM 2008 will be held at Pacifico Yokohama from April 3<sup>rd</sup> (Fri) to 5<sup>th</sup> (Sun), 2008. 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	
		Y2006	Y2007	Y2006	Y2007
Congress registered numbers					
	JRS members	4,076	4,502	2,553	2,700
	JSRT members	8,378	9,714	3,409	3,677
	JSMP members	550	717	275	355
	Non members	1,998	2,128	826	845
Visitors					
	Radiologist	786	948	546	592
	Radiological Technologist	6,631	7,600	3,870	4,247
	Medical related	1,300	1,486	768	819
	Exhibitors	15,998	19,191	6,551	6,834
	Others	3,315	4,044	1,778	2,079
<b>TOTAL</b>		<b>43,032</b>	<b>50,330</b>	<b>20,576</b>	<b>22,148</b>

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



ITEM 2007



# JIRA Activity Reports

A view point at “JIRA Annual Report on Medical Imaging Devices & Systems 2007”

## 1. The present situation of the Japanese medical care system

An aging society with a decreasing population of young people aggravates and exhausts the financial conditions of the health insurance system, which is intended to ensure social security benefits, etc. In this situation, the government plans to suppress the total medical expenditures of the nation, to extensively review the medical practice system, and to drastically reform the medical practice system itself. To suppress rising medical expenditure, the government is decreasing the medical service remunerations to a large extent (for example, it was decreased by 3.16% in the 2006 fiscal year). In addition, the government plans to do the following. To promote preventive care and home medical care. To apply the Diagnosis Procedure Combination (DPC) to patients to be hospitalized because of acute diseases, in which hospital reimbursement is subject to the blanket payment of hospital reimbursement as specified by a combination of diagnosis-related groups and procedures. To assess the seriousness of a disease by medical practice classification and the classification of Activities of Daily Living (ADL). To shift the less serious patients from hospitals to rehabilitation/welfare facilities based on this assessment. To drastically review the plans of medical practice. To promote the collaboration of local community medical practice. To establish a social medical corporation and to implement other various policies.

Especially, the concrete policies for medical facilities include the following. To decrease the number of beds per population and the average number of days of hospitalization, which are said to be higher than in Europe and the USA. To address the medical practice system under the blanket payment of reimbursement. To modify medical service remunerations for easy implementation of government policies. To classify facilities according to the functions specified by the Medical Service Law criteria. To review the criteria of deployment of nursing personnel. If these policies were implemented as planned, then the number of beds now available at the facilities would be almost halved in five or six years. The 900,000 beds for acute and general patients would decrease by half. The 380,000 beds for the patients of chronic disease would decrease to about 150,000.

The Organization for Economic Cooperation and Development (OECD) announced the data related to the population and medical care system in 2005.

The comparison data of UK, USA and Japan is illustrated with the table on Figure 1.

As shown above, the number of beds is almost twice but the nurses are only one quarter in Japan compared with UK/USA.

However, when the number of nurses per population of 1000 is compared on the other hand, then the difference is not large. Namely, the Japanese nurses cannot provide better care because they must take care of more beds than UK as well as USA.

To decrease the number of beds to the level of Europe and USA, the Ministry of Health, Labour and Welfare plans to review the medical reimbursement system and Medical Service Law, and to envisage various policies to decrease the number of days of hospitalization. It is important for each medical facility to play a unique role in the diversification of functions. It is likely that the medical facility that fails to do so will not be able to survive in the loop of collaboration.

Namely, such a medical facility will have less reimbursement under the suppression of medical expenditures and will be unable to have a favorable balance of profit and loss. To survive in this severe and unfavorable environment, a medical facility must address the following. To play a unique role in medical practice in the local community. To decrease the number of days of hospitalization. To increase the number of hospitals to which patients are referred. To improve patient satisfaction. To participate in DPC. To be assessed by the hospital evaluation system. To implement risk management, privacy protection and electronic management methods, etc.

Comparison with UK and USA

(unit: people)

	No. of beds per 1000 people	No. of doctors per 100 beds	No. of nurse per 100 beds	No. of nurse per 1000 people
Japan	7.2	13.7	54.0	7.8
UK	3.7	49.7	322.4	9.7
USA	2.8	66.8	233.0	7.9

(Source: OECD data 2005)

Figure1. Medical care system comparison data as of year 2002.

Although the economical circumstance around Medicare service is so serious in Japan, the political measures should have the positive adoption of the state-of-the-art medical technology to improve the patient outcome and comfort which will naturally bring the similar situation of UK and USA.



## 2. Outlines of the major revision of reimbursement system related with the diagnostic imaging system in FY 2006

FY 2006 revision introduces the following major contents.

- The diagnostic imaging control addition is dislocated from DPC blanket category.
- The image processing addition of CT is newly adopted.
- The separate classification for MDCT and SSCT is adopted. The scan region rating is no more existing.
- MRI is divided with 1.5T over and others. The regional rating is no more existing.
- No more measure to evaluate the skill of radiological technologists as far as CT and MRI are concerned.
- When the same region of head, trunk and limb are examined twice or more in a month, no additional fee is admitted.
- PET/CT is newly admitted.
- The mammography is admitted as an individual item separated from X-ray radiography.

At a glance of this revision, the decrease seems to be insignificant. However, the decrease is obvious in several categories.

The following examples will explain how to address the revision of medical service reimbursement in the future.

### 1) Evaluation of diagnostic imaging management addition, and its separation from DPC blanket category

The revision of the medical service reimbursement in FY 2006 made the diagnostic imaging control addition apart from the DPC, and includes it in the category of fee-for-service. This means that diagnostic imaging service is now admitted to the radiologist as the doctor fee. Formerly, the addition was included in "the function evaluation coefficients" in "the medical facility-specific coefficients" of the blanket evaluation. Now, the addition is outside the blanket evaluation. However, this change is said to be insignificant for such medical organizations that participated in DPC, although they formerly counted the addition of diagnostic imaging control fee.

### 2) Conformity of computer image processing evaluation in diagnostic imaging with the Pharmaceutical Affairs Law

In FY 2006 revision, the addition of a fee was approved for a computed image processing procedure. However, if the film is charged, this image processing fee is not counted as a score. The medical facilities that request this addition cannot submit a charge for the film. Therefore, they must implement the electronic storage of image data and go for film-less. It is necessary to pay attention here to the devices used for diagnosis. JIRA emphasizes the necessity of diagnosis by using the medical devices that comply with the Pharmaceutical Affairs Law. If such devices are used, they are subject to compulsory recalls at the time of serious nonconformity of devices, preventing secondary and tertiary damage, thus securing the safety of patients.

### 3) The change of CT and MRI evaluation

CT evaluation is now changed to the performance oriented thought. The MDCT becomes distinguished position and on the other hand SSCT has low score. All the procedures for the second time onward will have low scores. For MRI, evaluation by the performance of the device is thought as important. MRI of at least 1.5T and MRI less than 1.5T are distinguished by scores. The conventional distinction for procedures by medical doctors and radiological technologists is now withdrawn.

### 4) Separation of mammography from general X-ray radiography

Evaluation of mammography as an individual technique separated from general X-ray radiography is considered to greatly affect future market development. When an addition of digital image processing is made, mammography is given independent scores. Eventually, the position of mammography has been clearly defined by this revision. Mammography is now taken as a separate category to have a new evaluation system. This is big progress.

## 3. The results of study by JIRA and the issues to be addressed in the future

JIRA considers that the diagnostic imaging devices should be evaluated not only by the performance of the device but also by other various evaluation factors. Against this consideration, the multi-slice CT is now distinguished only by the number of slices. MRI is now distinguished only by the magnetic intensity. Such evaluation by a single factor is not appropriate. Devices should be evaluated by the whole life stage of the medical device, starting from research and development, through clinical application, maintenance and check, and to the disposal. The evaluation shall be consistent and systematic. JIRA considers that the technical evaluation of medical devices should be distinguished into the following three categories.

### (1) The category involved in the medical devices

They should be studied mainly by the medical device industries (JIRA) to determine the evaluation criteria, such as the operational cost, necessary resources, and the medical economics analysis.

### (2) The category involved in the examination technique

They should be studied mainly by the society of diagnostic radiological technologists to determine the examination criteria, such as the technical operational conditions, the social QOL and etc.

### (3) The category involved in the diagnosis

They should be studied mainly by the specialized medical societies to determine the clinical needs, clinical capabilities, and etc.

These three factors should be the basis of total evaluation. It is very important that the medical devices and technologies should be evaluated appropriately, and should be used to contribute to the efficient medical practice and to provide reliable medical care to patients. Formerly, the reimbursement for medical devices was determined mainly by “the devices” and “the personnel cost”. In the future, it is necessary that the element of “examination technique” and “the clinical efficacy” is to be added for the proper evaluation of a medical device. Accordingly, JIRA clarifies the calculation base of reimbursement, shifting from devices and personnel to the medical economic approach, and studying the evaluation based on medical economic values.

JIRA will work out the examples of new diagnostic techniques to clarify the economic evaluation. The “MRI diffusion enhancement images for cerebral infarction” and the “CT perfusion images” are the cases to be enumerated.

Among the three major fatal diseases, especially the acute cerebral infarction requires early diagnosis for patients. The MRI diffusion enhancement images can visualize the cystic edema, which is considered very helpful to the doctor. The CT perfusion images can visualize the affected region accurately, also considered very helpful. For the cerebral infarction, JIRA will plan to make “the relative evaluation to compare the MRI with the diffusion enhancement images with the conventional MRI”, and “the relative evaluation to compare CT with the perfusion images with the conventional CT”.

JIRA intends to cooperate with related organizations and address the appropriate evaluation of medical devices.

## About the revision of the Medical Service Law .....

### 1. Introduction

#### 1-1 Development until establishment of the Medical Service Law

In Japan, the modern medical service system started in 1874 (the 7th year of the Meiji era). Under this system, the installation of medical facilities required permission from regulatory authorities. Afterwards, in 1933 (the 8th year of the Showa era), the regulating rule for clinics and dental clinics were established based on the authorization rules of the Medical Practitioners Law and Dental Practitioners Law, respectively. Then, in 1942 (the 17th year of the Showa era), the National Medical Service Law was enacted. Under this National Medical Service Law, medical facilities were clearly classified in the hospitals and clinics, and when doctors established their clinics, it was required that they received permission from the regulatory authorities.

After World War II, the National Medical Service Law was divided into several related laws. As far as the medical facilities were concerned, it was urgently necessary to increase the number of facilities immediately after the War, resulting in the establishment of the Medical Service Law in 1948 (the 23rd year of the Showa era). From that time up to the present, the Medical Service Law has been revised several times.

#### 1-2 Sequence of revisions of the Medical Service Law

The Medical Service Law was intended to secure a certain level of medical practices, to establish the standard in these medical facilities and to increase the number of facilities. It was promulgated as Law No. 205 on July 30, 1948 (the 23rd year of the Showa era), and enacted from October 27 of the same year. The sequence of important revisions in the past is as follows.

- 1) First revision in 1985
  - Limitation of the total number of hospitals and beds
  - Stratification of medical services by specifying medical service areas
- 2) Second revision in 1992
  - Provision of medical service to meet an aging society and change of disease structure
  - Systemization of functions of medical facilities
- 3) Third revision in December 1997
  - Creation of hospitals that supporting community care
- 4) Fourth revision in December 2000
  - Institutionalization of the new classification of beds (Establishment of medical services by hospitalization)
- 5) Fifth revision in June 2006
  - Provision of medical service that is high-quality, easy and reliable

### 2. Outline of revision in 2006

The revised law was promulgated on June 21, 2006 and partially enacted in advance. The following rules were enacted from April 1, 2007.

- Rule for provision of information about medical service functions
- Rule for the hospital admission plans and hospital discharge/convalence plans
- Rule for the advertisement of medical services, dental services or midwife facilities, etc.
- Rule to secure the safety of medical service
- Rule for hospitals, clinics and midwife facilities
- Rule for basic policy to secure the provision system of medical service

Among these rules, the most important one to use is “the rule to secure the safety of medical service”. It is detailed as follows.

#### 2-1 How to secure the safety of medical service

Administrators of hospitals, e.g. hospitals, clinics or midwife facilities have obligations to establish the following organization to secure the safety of medical service.

- 1) Providing guidelines for safety control of medical services
- 2) Holding Safety Control Committee meetings for safety control of medical service
- 3) Implement staff training for safety control of medical service

- 4) Scheme to improve administrative system, e.g. accident report at hospital in order to secure the safety of medical service

#### 2-2 Maintenance and safety use system for medical devices

- 1) Deploy Medical Device Safety Control Manager for safety use of medical devices
- 2) Implement staff training for safety use of medical devices
- 3) Planning and implementation of maintenance of medical devices
- 4) Information collection required for safety use of medical devices and other means for improvement with the purpose of safety use of medical devices

### 3. Demand of the times

Medical device industries are required, as the basic stance, to comply with the laws and regulations, and to substantiate exchange and provision of information.

Hospitals are required to maintain, check and safety use of medical devices. In concrete terms, the industries are expected to assist and cooperate with them as follows.

- 1) Training for safety use of medical devices
  - To substantiate the contents of explanation of medical devices at the delivery time
  - To assist the periodic training to develop operators skill level
- 2) Planning for maintenance of medical devices
  - To clarify the maintenance contents and check. To implement retention and control of maintenance records
  - To promote the importance of maintenance and the preventive maintenance
  - To correspond to outsourcing of maintenance task
- 3) Provision and collection of information
  - To update package inserts and to assist its digitalization
  - To collect information of accident at hospital, e.g. periodic information exchange meeting
  - To clarify the service life of medical devices

### 4. Conclusion

This revised law is named “The Law to partially revise Medical Service Law, etc. to establish a system for provision of high-quality medical service.” As the name suggests, hospitals are required to “establish a system for provision of high-quality medical service”. Hospitals are required to implement a safety control system for all medical devices. From this viewpoint, our industries which provide hospitals with medical devices should recognize their important duties (such as assurance of security and safety, collection and provision of information).

### JIRA debut the China International Medical Equipment Fair, Spring Exhibition

JIRA exhibited at the China International Medical Equipment Fair (CMEF) Spring Exhibition (Dalian), which is the largest in scale of this kind in China. For the first time the purpose of participation is to fully help the JIRA member companies manufacturing/selling medical devices and related products to advance to the Chinese market of medical devices, and to show the activities of JIRA, which is the Japan Industries Association of medical devices. The ten member companies displayed their equipments or catalogs.

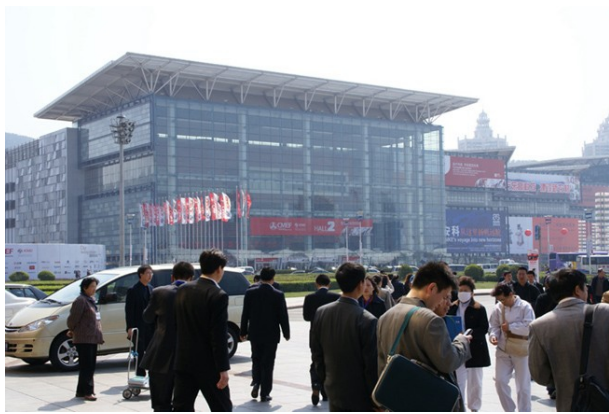
Apart from regional or local exhibitions, the following four main exhibitions are being held in China this year.

- (1) The China International Exhibition and Technical Exchange of Hospital Equipment (CHINA HOSPEQ 2007) organized by the Chinese Ministry of Health, at Beijing in September
- (2) The 19th International Medical Instruments and Equipment Exhibition (CHINA MED 2007) organized by the Chinese Military, at Beijing in April
- (3) The 57th CMEF International Medical Equipment Fair, Spring Exhibition, at Dalian in April
- (4) The 58th CMEF International Medical Equipment Fair, Autumn Exhibition, at Chengdu in October

In particular, the largest fair is the CMEF International Medical Equipment Fair, (Spring/Autumn) Exhibition, in which JIRA exhibited for the first time this year, because its scale (the number of participating companies and the display floor space) and the number of visitors are the greatest. The exhibits include medical devices, health equipment, welfare equipment, nursing care equipment, rehabilitation equipment and tools, sanitary supplies, hospital equipment and medical technologies.

The 57th CMEF International Medical Equipment Fair, Spring Exhibition, was comprised of 1925 companies (including 126 companies from 17 countries, which displayed their products in the International Display Zone). The exhibit floor space was about 85,000 square meters. The number of pre-registered visitors was about 28,000 from within China and about 1,200 from foreign countries. During the period of the exhibition, the total number of visitors was about 50,000 from 77 countries.





Main exhibition site, the second hall



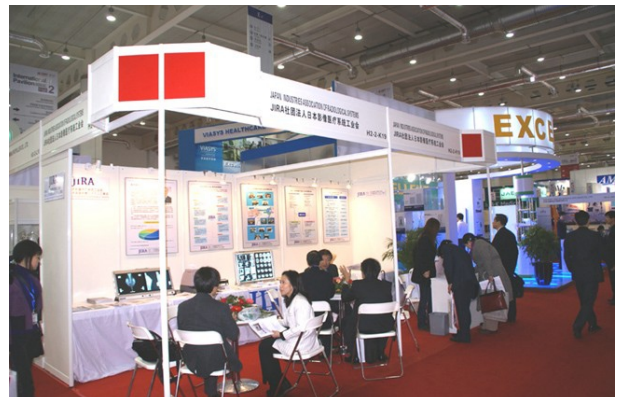
The opening ceremony

The following companies exhibited in the JIRA booth.

- (1) IKEN ENGINEERING Co., Ltd.: X-ray shielding and protection (panel & catalogs)
- (2) SANKYO MEDICAL CO., LTD.: Film Imager (panel & catalogs)
- (3) ELK CORPORATION: Dry Imager (panel & catalogs)
- (4) ORION ELECTRIC CO., LTD.: X-ray film viewer
- (5) TORECK CO., LTD.: Patient dose meter
- (6) OKAMOTO MANUFACTURING CO., LTD.: ID camera, X-ray cassette
- (7) KASEI OPTONIX, LTD.: Intensifying screen
- (8) MITAYA MANUFACTURING CO., LTD.: X-ray grid
- (9) KYOTOKAGAKU CO., LTD.: Chest phantom
- (10) MORIYAMA X-RAY EQUIPMENTS CO., LTD.: Mammo Schaukasten



Exhibits in JIRA booth



Panoramic view of JIRA booth



Receptionists at JIRA booth



Demonstration at JIRA booth





Korean booth



French booth

We displayed equipment and catalogs translated into Chinese, which were well received by the visitors to the JIRA booth. We had many enquiries from visitors. A large number of visitors pointed to the portrait of Mr. Inomata, Chairman of JIRA, saying, "I know him." To increase our shipment of products to China, it is essential to increase familiarity of Japanese companies and the reliability and safety of our products. In this exhibition, participating member companies directly contacted the visitors, resulting in successful business negotiations.

### Visit to Toshiba Dalian Co., Ltd.

On the occasion of our participation in the 57th CMEF International Medical Equipment Fair, Spring Exhibition, held in Dalian, China, we visited Toshiba Dalian Co., Ltd. This company is a local manufacture affiliated company of Toshiba Medical Systems Corporation, which is one of the JIRA member companies.

Toshiba Dalian Co., Ltd. is located about 40 minutes drive from the city area of Dalian, at the center of the Dalian Economic and Technical Development Zone. The profile of this company is as follows. In 1991, it was established by four Toshiba affiliated companies on its own capital. In 2002, it started the manufacture of medical devices. The main products include motors, TV transmitters, IC boards, CT, probes for

diagnostic ultrasound systems, diagnostic X-ray TV fluoroscopic systems, clinical laboratory systems, tuners for PC and so on.

The company is certified under ISO-14001 and ISO-9002, manufacturing mainly those products for Chinese market.

Workers are recruited from the neighborhood of the company, and engineers are recruited for the design and development division from excellent human resources nationwide.

Moreover, the company is active in social contribution and close relations with the local community, for example, by donating the buildings of an elementary school. That school was named Toshiba Hope Elementary School as a token of gratitude to Toshiba.



Toshiba Dalian Co., Ltd. front



The inside of medical equipment factory



President Kashii and the visitors from JIRA

## Report of Business Trip to Korea

JIRA delegation made a business trip to Korea from March 12 to 17 for the purpose of an additional investigation of the Korean Medical Equipment Law, a survey of the Korean medical equipment market trend, an investigation of Korean RoHS and an inspection of KIMES2007. We visited the Korean Food and Drug Administration (KFDA), the Korean Testing Laboratory (KTL), the Korean Medical Devices Industry Association (KMDIA) and the Korean Medical Devices Industrial Cooperative Association (KMDICA) and obtained much new information.

### 1. Results of additional investigation about the Korean Medical Equipment Law and related regulations

#### 1-1 Revision of the Medical Equipment Law

(1) The revision bill of the Medical Equipment Law promulgated in September 2006 is under discussion. Although the revision is planned to be enacted in June 2007, it was found that many revised versions of the Law and related regulations had been issued.

- At this moment, it is required to obtain the approval item by item individually. However, as for medical devices in which the safety hazard is so slight and the patient's or operator's life and health are hardly threatened, it can be applied upon item group by item group. (A part of Classes I and II are subjected.)
- A designation system to the organization of quality management and inspection of medical devices, clinical trial facilities (hospitals) is introduced.

(2) Revision of the regulations of the enforcement of the Medical Equipment Law

- Among the declaration items which were conventionally necessary, as for items with a minor change, the procedure was simplified only by notifying the content of the change to KFDA.
- Partial flaws in the management of the current system related to manufacturing medical devices were improved and supplemented, and the range of consigned manufactures was expanded. Although the entire consignment of the manufacture was restricted previously, those countermeasures enabled it.
- The regulations of the enforcement will be revised in September, 2007 and notified in April, 2008. The transition period will be set for six months to one year as a renewal period.
- Whenever a problem is found in the safety / efficacy of a medical device, the manufacturer / importer / distributor / lease agency shall immediately recall the concerned products distributed or shall take necessary countermeasures for the recall.

(3) The certification of manufacture and sales is required in the inspection of medical devices, however, the European MDD certificate is not accepted in Korea.

(4) Private import of a medical device that has not been approved for manufacture or import in Korea is not allowed.

(5) At present, there is no regulation on maintenance and inspection.

(6) Revision of the related regulations of the Medical Equipment Law

KMDIA summarized and submitted the requests by manufacturers about the standard of self-tests that are excessively strict. Consequently, some requests, which were considered reasonable, were allowed to be introduced. The pressure proof test required by an internal guidance for the self-test was also exempted.

Manufacturers in Japan can substitute it by the submission of a test record which NB in Japan conducts, and those can save the expenses.

#### 1-2 K-GMP

(1) As of March 2007, about 1,000 companies obtained K-GMP, which was planned to be enforced on May 30, 2007. Among the top 300 companies, 60% already acquired it, 20% are waiting for inspection and 20% have not applied yet.

(2) Because companies can neither manufacture nor sell medical devices without K-GMP after the enforcement, rushed applications are expected to increase.

(3) KMDIA consigned by the administration is conducting GMP education for member companies without charge, covering 1,800 companies in 2007.

#### 1-3 Revision of EMC regulations

(1) EMS method is applied to the following 11 items of medical devices from July 1, 2007, and IEC60601-1-2 (Ed.2) Annex 1 is applied; artificial respirators, patient monitors, cardiographs, electric wheel chairs, cardio-impact equipment, medical endoscopes (capsule type), fetal cardio-sound meters, medical oxygen saturation meters, acoustic aid, apnea meters, drug-infusion pumps

#### 1-4 Inspection of software for PACS

(1) Requirements for the medical device designation of PACS are applied for all medical devices with which medical images are telecommunicated. PACS are designated as Class II of medical devices. Thus, software used for PACS are categorized as Class II. Telecommunication systems only with character information are not categorized as medical devices.

(2) The standards of PACS are classified with hardware and software and technical files are shared each other. The standards of software are referred to those of FDA in the



U.S.A. IEC62304 which is the process standard of software has not been adopted yet. The guideline for the application of PACS can be seen on KFDA's homepage.

- (3) The software version up shall be conducted after acquisition of an approval for the partial change.
  - If the change does not influence the main functions, the version up can be done voluntarily.
  - Only persons who have been permitted by KFDA can execute the field version up after obtaining the approval for changes. (Unauthorized service company is not allowed to do that.)
- (4) Although the registration of software alone has been allowed in the current system since the end of 2005, there has been no case.

#### 1-5 Preliminary examination system of advertisement

- (1) KMDIA was consigned by KFDA to the right for the preliminary examination system of advertisement. Accordingly, they are planning to make a working team for the preliminary examination. The related regulations were notified on October 4, 2006 and it is planned to be enforced on April 5, 2007.
  - Newspapers specialized for medical industry and product catalogues are excluded from the subjects.
  - Expressions like "The best" are regarded as a transgression.
  - The inspection expense is set at ₩100,000/case.
  - Details of regulations are under discussion at present.

## 2. Results of surveys about the trend of the Korean medical equipment market

- (1) In 2005, the number of manufacturers of medical devices increased to about 1,800 companies and the number of importers increased to about 1,200 companies.
- (2) The amount of domestic production was USD1,635 million (+10.6% compared with the previous year's), the export was USD699 million (+22.8%), the import was USD1,509 million (+17.58%), and the resulted domestic market in Korea was USD2,445 million (+11.5%). As such, the market of medical devices in Korea is increasing steadily.

## 3. Korean RoHS

Although the enforcement was planned to start on July 1, 2007 at the beginning, it has been postponed to 2008. It was found that the Division of Environment as the main body proceeded to arrange the laws. At present, household electric appliances are expected to be subjected, however, medical devices are unknown.

## 4. KIMES 2007 International Medical, Clinical, Laboratories & Hospital Equipment Show

- (1) KIMES 2007 is the largest scale international exhibition for Korean healthcare industries, exhibiting not only diagnostic imaging equipment, but also the whole medical products including healthcare products. The exhibition space was 32,382 m<sup>2</sup>, which was 11% larger than the previous year's. In 2007, the number of exhibitors was about 1,000, increasing by about 10% compared with the previous year's, and about 300 overseas buyers participated. The number of visitors was 53,729, including more than 1,000 overseas visitors from 60 foreign countries.
- (2) Manufacturers in Korea strive to improve the design of diagnostic imaging equipment. A large number of FPD-DR systems and CR systems were exhibited as new products. The exhibition of mammography equipment is tending to increase. The number of Japanese companies who participated alone was not many, on the other hands, the exhibition of Chinese manufacturers increased. KIMES 2008 will be held at the COEX International Exhibition Space during the period of March 13 – 16, 2008. JIRA is now studying the participation in KIMES 2008.

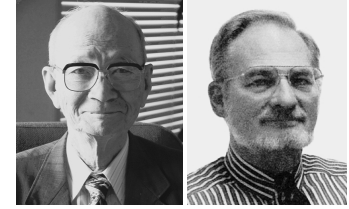


Medical Devices Safety Policy Team, KFDA



Medical Devices & Radiation Health Department, KFDA

# Development of Japanese Radiological Equipment in the Post-World War II Period (21)



Sumio Makino (Advisor, JIRA) John F. Moore PhD (BIR)

## Origin of X-ray CT, Part II. --- Change of generations, Beginning of continuous full-rotation X-ray CT

### 1. Preface ...Reaching the idea of ultimate X-ray CT

In 1972, X-ray CT started. Later, it developed into high-speed rotation, helical system, three-dimension image and CT angiography. It reached the ultimate stage of progress to establish reliability of diagnostic imaging in hospitals and to bring about great benefits to patients.

The foundation of this progress was “continuous full-rotation” X-ray CT. The beginning of this research dates back to around 1976 or 1977. The author participated in that research and wants to record the detailed process of research in JIRA's documents. This is the reason why the author contributed this article.

### 2. Initial introduction of CT into market

Although X-ray CT was installed for the first time in Japan at Tokyo Women's Medical University in the spring of 1976, it had already been surprisingly popular worldwide from 1973. Figure 1 shows orders received and advance orders as of 1973 by EMI the developer of CT.

In 1976 when CT diagnosis began in Japan, about 20 companies in the world had already joined or planned to join the CT industry.

The following are companies that entered (or planned to enter) the CT market in 1976.

Siemens, Philips, CGR (France), GE (USA), Picker (USA, UK), EMI (UK), Varian (USA), HITACHI (Japan), Toshiba (Japan), Shimadzu (Japan), Pfizer (USA; ACTA Scanner), Neuroscan (USA), Elscint (Israel), Syntex (USA), AS&E (USA), Ohio Nuclear (USA), Artronix (USA), Litton (USA), and Searle (USA).

### 3. Rapid growth and sudden decline of EMI Medical (UK)

Immediately after EMI announced the availability of X-ray CT in 1972, it received many orders in the international market (see Figure 1), enjoying a prosperous business. In Japan, Toshiba became the “distributor” under a sales contract with

EMI and installed the first X-ray CT at Tokyo Women's Medical University as mentioned above. The import was funded by the surplus of damage insurance. As a result, a large quantity of CT scanners (it was called a bulk order) was imported at a stretch and installed in the brain surgery departments of medical schools of national and public universities. Toshiba was very busy with the related installations from 1975.

However, the prosperous business of EMI CT did not last long. As shown in Figure 2, the business experienced typically a rapid growth and sudden end.

John F. Moore PhD, who was the technical director of EMI (USA) in those days, recently (in 2003) sent to the author (Makino, formerly Toshiba) a detailed report about the decline of business, the reasons and countermeasures taken. The countermeasures themselves led to the development of “full rotation CT.”

This article quotes his report and explains how the new type of CT was developed.

#### ORDERS ACCEPTED FOR EMI-SCANNER

01	ATKINSON NORLEYS , WIMBLEDON , U.K.	(DELIVERED)
02	THE NATIONAL HOSPITAL , LONDON , U.K.	(DELIVERED)
03	MANCHESTER ROYAL INFIRMARY , MANCHESTER , U.K.	(DELIVERED)
1.	MAYO CLINIC , ROCHESTER Minnesota.	(DELIVERED)
2.	MASSACHUSETTS GENERAL HOSPITAL , BOSTON.	(DELIVERED)
3.	MONTREAL NEUROLOGICAL INSTITUTE , CANADA.	(DELIVERED)
4.	PRESBYTERIAN ST. LUKE, CHICAGO.	(DELIVERED)
5.	SOUTHERN GENERAL HOSPITAL , GLASGO , U.K.	(DELIVERED)
6.	MILLARD FILLMORE , BUFFALO.	
7.	UNIVERSITY OF IONA , IONA.	(DELIVERED)
8.	CLEVELAND CLINIC , CLEVELAND.	(DELIVERED VIA CHICAGO)
9.	KANTONSPITAL , BASEL, SWITZERLAND.	(DELIVERED)
10.	SOCIETY OF NEW YORK HOSPITAL , NEW YORK.	(DELIVERED)
11.	UNIVERSITY HOSPITAL, AUGUSTA.	
12.	KAROLINSKA, STOCKHOLM.	
13.	METHODIST HOSPITAL, HOUSTON.	
14.	OCHSNER FOUNDATION HOSPITAL , NEW ORLEANS.	
15.	HAMILTON CIVIC , ONTARIO , CANADA.	
16.	GEORGE WASHINGTON , WASHINGTON.	(DELIVERED)
17.	NEW YORK UNIVERSITY , ST. LOUIS.	
18.	WASHINGTON UNIVERSITY , ST. LOUIS.	
19.	FRANKLIN HOSPITAL , SAN FRANCISCO.	
20.	UNIVERSITY OF TORONTO CANADA.	
21.	OSPEDALI DI BOLOGNA , BOLOGNA.	
22.	PALO ALTO MEDICAL CLINIC.	
23.	NEUROSURGICAL SCIENCES BUILDING , PORT LAUDERDALE , FLORIDA.	
24.	ATLANTA NEUROLOGICAL CLINIC , ATLANTA , GEOGIA.	
25.	HAHNEMANN MEDICAL COLLEGE , PHILADELPHIA.	
26.	EPISOPAL HOSPITAL , PHILADELPHIA.	
27.	UNIVERSITY OF CALIFORNIA , SAN FRANCISCO.	
28.	STANFORD UNIVERSITY MEDICAL CENTER , STANFORD , CALIFORNIA.	
29.	VENTURA HOSPITAL , CALIFORNIA.	
30.	HENRY FORD HOSPITAL , DETROIT , MICHIGAN.	
31.	FORT SAUNDERS PRESBYTERIAN HOSPITAL , TENNESSEE.	

Figure 1. Famous hospitals in the US that ordered or planned to order EMI X-ray CT

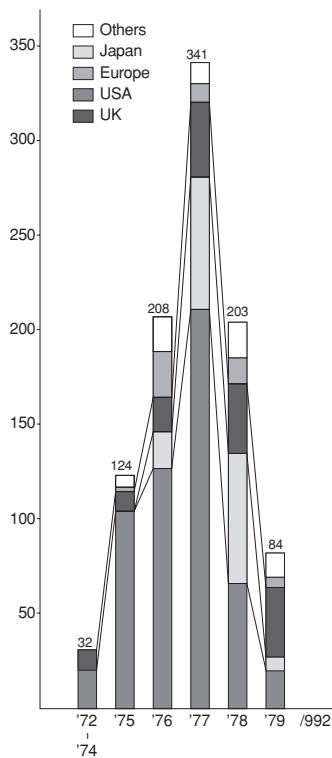


Figure 2. Shipment statistics of EMI X-ray CT: rapid growth and sudden end

### (1) EMI Medical (UK) decline and EMI (USA) awareness of the business crisis led to development of CT-7070.

In 1976, EMI still retained the largest market share in the international X-ray-CT market. However, several competitive companies were attacking EMI with new products featuring new designs.

EMI scanner adopted the “translate-rotate” system for the first time, shifting from the first-generation scanner to the second-generation scanner. In spite of this development, the required scan speed was still 18 seconds, and this was the basic problem to solve.

Many of other companies avoided the “translate-rotate” system, which stops a motion intermittently. A typical example was the GE 7800 scanner. In this scanner, a fan-beam from an X-ray tube is combined with an arc-shaped array detector. This combined unit makes a full rotation at a stretch. The speed was 4.8/9.6 seconds for fast/slow modes respectively. This “rotate-rotate” system was called by GE the third-generation scanner. Another example was a scanner of AS&E (American Science and Engineering). Detectors were placed on the entire circumference of the fixing ring, and an X-ray tube rotated within the ring in less than five seconds. This system was called “rotate-stationary” or the fourth generation.

However, GE 7800 had a weak point in the third generation scanner. Artifacts appeared, for example, at the edge of bones where there is much tissue density fluctuation from region to region. This type of artifact was difficult to remove. (In fact, GE

did not sell this scanner for three years after announcement.)

In this situation, the management of EMI (UK) thought that their 1010 brain scanner and 5005 whole-body scanner could still compete favorably with the third-generation GE scanner and the fourth-generation AS&E scanner in the market. Besides, the EMI management forgot an important fact. GE and other companies new in the CT market were strenuously developing original image reconstruction software. The Engineering Department members of EMI (USA group located in Northbrook outside Chicago) found out this fact and thought it necessary to take action. However, EMI (UK) was busy with producing scanners to meet the increasing demand from the market, neglecting the business crisis warning indicated by EMI (USA), and disapproving the action plan proposed by EMI (USA) group.

### (2) Why was development on model 7070 (full rotation, nutating system) started?

In the meantime, the rise of GE caused EMI Medical to rapidly lose their market. This was because American hospitals were demanding quick scan speed. Engineers at Northbrook conceived to design a CT with the scan speed quicker than that of GE. The trouble was that they did not know an algorithm of image reconstruction. Fortunately, late in 1976, an American invented software comparable to the UK software, making development of a new CT possible.

Early in 1977, the management of EMI (UK) noticed that GE was increasing their market share in the U.S., and finally permitted a development plan proposed by EMI (USA) Northbrook.

The development team had four goals

- To increase the scan speed
- To increase the spatial resolution of image
- To reduce the patient exposure to radiation
- To eliminate artifacts from images

To realize these goals, the movement or motion of a scanner would have to be simple. The detector would have to be compact and efficient. It should not be like a GE third-generation CT. These were the basic design concepts.

The engineers at Northbrook studied how to satisfy these requirements. The EMI 5005 whole-body CT was available at that time. However, the engineers concluded that it was not feasible to use this model as a basis of a new design. Then, after an extensive study of related factors, they finally gave up using the second-generation CT as a basis.

The engineers started brainstorming. They presented many ideas. For example, moving an X-ray tube on a complicated curvilinear orbital, separating the motion of an X-ray tube and that of the detector, using two or more X-ray tubes and others. More than thirty ideas were presented and they finally were discounted.

On the other hand, the management (EMI Medical UK) noticed that the current model (5005) was unable to keep its

market share as before, and realized the necessity of a new scanner. This was reflected in a statement by President Bob Hagglund of EMI America. He started to support the engineers at Northbrook. In UK, they started a development project in 1976 and established the Central Research Lab. under the name of "DIAMOND." They invented a special anode of X-ray tube to eliminate artifacts peculiar to the third-generation scanner. But, in the end they failed. Eventually, research and development were converged with EMI America Northbrook to produce the new model 7070.

### (3) Appearance and fate of nutating

The research team presented the idea of installing a detector ring inside an X-ray tube orbit. If realized, this idea could decrease the size of scanner, the size of the detector and consequently the price of scanner. The invention was the "nutating detector ring." The ring had an inclination of two degrees against an orbital plane of an X-ray tube. The ring part near the X-ray tube is outside the X-ray beam. The opposite part of ring is inside an X-ray beam that penetrated a patient. As the X-ray tube moves, the inclination angle of the ring changes, with the X-ray tube remaining stationary. Figure 3 illustrates the principle of the nutating system.

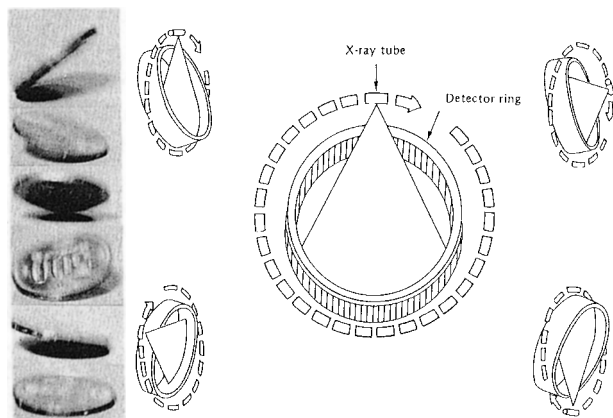


Figure 3. A coin moves as shown at the left panel when its rotation is about to end. The detector ring moves like this coin, and it avoids an X-ray beam coming from outside. This explanation was by Dr. Moore.

The first scanner of the nutating system was exhibited at RSNA in 1977. Many competitors said that the structure was too complicated and problematical. In fact, however, the structure was fairly simple. It resembled two large ball bearings that perform nutation twice. The nutating CT, CT -7070, was a solid-state CT produced for the first time in the world. It was featured with the scan speed of only three seconds and the highest spatial resolution available in the market. The first unit of CT-7070 was installed at Mallinckrodt Institute, St. Louis, where it was well accepted by researchers. Then, EMI Medical obtained 80 sets of advance orders.

However, the time was too late. THORN Electrical Industries merged with EMI, and THORN did not inherit EMI Medical division but separated it. EMI Medical division became the target of M&A. Toshiba was one of the possibilities. Finally, GE inherited EMI Medical division.

### (4) Establishment of BIR and development of TCT-900

Although Toshiba did not inherit EMI Medical division, Toshiba paid attention to an idea of ultimate CT reached by Dr. Moore and some twenty Northbrook engineers. Before they were involved in the organizational confusion of EMI, Toshiba helped them to establish a new company. They established "Bio-Image Research Inc. (BIR)" at Northbrook to improve CT-7070 and to develop a full-rotation CT, model TCT-900, for Toshiba. BIR improved the performance of CT-7070 and at the same time promoted direct overseas investment from Toshiba.

CT-7070 has mechanically cumbersome high-voltage cables that connect to a high-voltage generator outside the gantry and an X-ray tube rotating inside the gantry. To eliminate this mechanism, BIR invented a high-voltage slip ring, applying it to Toshiba TCT-900, and producing a complete, continuous full-rotation CT.

Toshiba engineers joined this development in typical "international cooperation", and experienced the frontier spirit in development with their American counterparts.

More than 400 sets of TCT-900 have been sold in the market. Not only that fact, the success of continuous rotation technology has led to the subsequent evolution of CT.

That includes a helical CT, 3D scan, volume scan, multi-slice scan, and angio CT. This evolution has contributed much to improve diagnostic accuracy.

## 4. Summary

Before the continuous full-rotation CT was completed, there were twists and turns in the path of development. A new idea was born around 1977 and bore fruit through cooperation between Japanese and American researchers. The design of a new CT required a new concept for research. This is the impression still fresh in my memory.

Ushering in a new age of technical innovation, we should carry out research and development in the future from a global viewpoint without shutting ourselves up into isolation and insularity.