2002 Annual Meetings of JRS, JSRT & Technical Exhibition

-New Horizons of Radiology in the 21st Century-

JIRA will hold the International Technical Exhibition of Medical Imaging, ITEM 2002, during the period April 4 - 6, 2002, in conjunction with the 61st Annual Meeting of the Japan Radiological Society (JRS) and the 58th Annual Meeting of the Japanese Society of Radiological Technology (JSRT).

Chairman: Masamichi Katsurada
Dates: April 4 (Thu.) through April 6 (Sat.), 2002
Venue: Kobe International Exhibition Hall, 6-11-1 Minatojima, Nakamachi, Chuo-ku, Kobe

A total of 120 companies and one institution (CAR) will have exhibition booths in the 5,721 m² area of the Kobe International Exhibition Hall at Port Island. The exhibition will cover a wide range of technological advances from new developments in diagnostic imaging to the rapid expansion of IT in medicine.

61st Annual Meeting of the Japan Radiological Society (JRS)

President: Professor Ryusaku Yamada, M.D.
Dates: April 4 (Thu.) through April 6 (Sat.), 2002
Venue: Portopia Hotel at Port Island, 6-10-1 Minatojima, Nakamachi, Chuo-ku, Kobe

At the 61st Annual Meeting, JRS looks forward to exploring advances in radiology in the new century with the main theme 'New Horizons of Radiology in the 21st Century' together with JSRT and JIRA. JRS has scheduled many interesting and exciting programs, including the International Symposium. JRS 2002 will give all participants the opportunity to learn about the most recent technological advances and to discuss future developments in the field of radiology.

Contacts:
- Exhibition: Japan Industries Association of Radiological Systems (JIRA)
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58th Annual Meeting of the Japanese Society of Radiological Technology (JSRT)

President: Shozo Nakanishi, Chief Radiological Technologist
Dates: April 4 (Thu.) through April 7 (Sun.), 2002
Venue: Portopia Hotel at Port Island, 6-10-1 Minatojima, Nakamachi, Chuo-ku, Kobe

In the words of the President, "New trends such as overthrowing stereotypes and changing our values and views are expressed in the main theme of this conference for the year 2002, 'New Horizons of Radiology in the 21st Century'. In addition, the subtitle 'Seeking for Harmonious Life of Technology and Humanity' is the expression of our hopes."

A joint reception buffet will be held from 6:30 to 8:30 P.M. on Thursday, April 4, in the Ohwada Room of the Portopia Hotel.

2002 Schedule

Scientific Program
- Special lecture
- Symposium
- Scientific exhibits
- CyberRad
- Educational lectures
- Scientific papers
- Film reading conference

Registration fee
- JRS+JSRT ¥12,000 (on site)
- JIRA ¥3,000
Three delegates from JIRA visited Beijing, China, from December 13 to 15 to promote communication with the State Drug Administration of China (SDA) and the JIRA China Working Group (China WG), and made significant progress.

1. Meeting with SDA
Three SDA members from the Department of Medical Devices (Beijing) and the Liaoning Medical Device Quality Supervision and Testing Institute (Shenyang) attended the meeting. The attendees from JIRA were the three delegates from Japan and eight members from local offices/subsidiaries of JIRA member companies.

JIRA presented a report to the SDA concerning the establishment of the China WG in the International Division and the holding of a seminar on Chinese "Regulations for Supervision and Administration of Medical Devices". The SDA members expressed a very favorable response, stating that the actions taken by JIRA to promote JIRA-SDA interaction, to establish the China WG, and to translate the relevant laws and regulations into Japanese were extremely valuable and greatly appreciated. They also stated that they hoped to continue working in close cooperation with JIRA and to exchange information. This meeting led to significant advances in a number of areas, including partial modification of the Chinese National Standards (GB), posting of additional bylaw information at the website (http://www.cmdi.gov.cn), further consideration of the bylaws concerning "regulations for the administration of medical software" and the "certification system of the Medical Device Quality Supervision and Testing Institute", and the information that it is now possible to directly contact SDA personnel by e-mail for product registration.

2. Meeting with the JIRA China WG
Nine members from five companies attended from the China WG and participated in enthusiastic discussions and information exchange. The information presented by the JIRA International Division focused on the organization of JIRA, the activities of the International Division, the establishment of the China WG, and the anticipated activities and membership of this WG. The WG reported the information presented at the SDA seminar and related materials. In addition, requests and comments to JIRA headquarters were presented. It is virtually impossible for a single company to negotiate with the organizations of the Chinese government, and the participants acknowledged their appreciation and high expectations for the establishment of the China WG and the support of the JIRA International Division.

The Overseas Regulations Committee of the JIRA International Division is planning to maintain close communication with the SDA and to continue its strong support for the China WG, as well as to organize and translate the large amount of information obtained during the visit to China at this time. Such information is scheduled to be presented to the members of JIRA through seminars and so forth.

In closing, we would like to express our deep appreciation to the members of the China WG for their cooperation and our hopes for the further development of the China WG.

International Division Activity Report
1. Study on Pharmaceutical Affairs Laws in neighboring countries in Asia
The International Division has recently been involved in studying the pharmaceutical affairs law systems in Asian countries. Information concerning the medical device laws and regulations in Korea and China has been obtained and presented at internal JIRA seminars. In particular, China is now focusing on its participation in WTO and GHTF.

1-1 Medical Device Regulations in China
The International Division has been studying the Regulations for the Supervision and Administration of Medical Devices of China (effective April 10, 2000) to obtain a clear understanding of these regula-
1. Announcement of JIS drafts: see JIS draft preparation work above.
2. JIRA announcement of four publications at the 29th Autumn Scientific Meeting of the Japanese Society of Radiological Technology (JSRT): (1) Q & A manuals for protection of the X-ray room, (2) manuals for the calculation of shielding of the X-ray examination room, (3) standards for X-ray equipment for medical use – standard testing methods for radiation protection, and (4) approval criteria for X-ray equipment for medical use – standard testing methods for electrical/mechanical safety.

3. JESRA briefing

A briefing was held for member companies on September 28, 2001, with regard to the above standard testing methods for radiation protection, electrical/mechanical safety, and CT systems.

Medical Imaging System Division Activity Report

Integrating Healthcare Enterprise (IHE), The Japanese View

In the US and Europe, HIS/RIS/PACS standardization is moving forward under the name IHE. In Japan, however, it is necessary to develop a Japanese version of IHE because of Japan's unique environment, including the privacy act, public key infrastructure (security communication infrastructure based on public key cryptography), and electronic image data archiving guidelines. To this end, we are, as an industrial association, expressing to the Ministry of Economy, Trade and Industry (METI) and academia the need for a technical approach to standards and connection demonstrations by gathering all relevant vendors in a hall. We believe that this is the best approach for promoting the establishment of a framework for the Japanese system.

In practical terms, we have formed a committee called IHE Japan, in which JRS, JSRT, JAMI, JAHIS and other related organizations participate in order to determine future directions. METI has approved this movement, and a supplementary budget has been provided for this fiscal year. It was decided that this project will be conducted under the auspices of JIRA, and we are urgently working to prepare a vendor demonstration at ITEM 2002 as our immediate objective.

Regulations and Economy Division Activity Report

1. Submission of comments from the industry regarding fiscal 2002 reimbursement reform (Economy Committee)

Following the relocation of personnel in the Ministry of Health, Labour and Welfare in June 2001, the comments were submitted again on July 23. In particular, the following three points were identified as requiring special attention:

1) To position and evaluate maintenance administration expenses based on a cost structure.
2) To evaluate monitor-based diagnosis technologies.
3) To introduce functional software units in reimbursement rules.

2. Pharmaceutical Affairs Law (PAL) reform (Regulations Committee)

The Ministry of Health, Labour and Welfare presented a proposal to The Japan Federation of Medical Devices Associations (JFMDA) on issues concerning medical device administration in July 2001.
The International Congress of the Diagnostic Imaging and Therapy Systems Trade Association (DITTA), which includes members from NEMA in the US, EFC in Canada, COCIR in Europe, and JIRA in Japan, was held in Chicago on November 28, 2001. At this Congress, domestic market trends in diagnostic imaging systems in Japan, based on a voluntary survey conducted by JIRA, were presented (see graph). In 1999 and 2000, a level of 100% (compared with each previous year) was not achieved, and a falling trend was observed again for the first half of 2001, with a figure of 97% in comparison with the same time period of the previous year 2000.

The following graph shows more precise movements of the market values of the major modalities (except for ultrasonography) for the first half of 2001 compared with the same period of the previous year.

3. Public comments on documents attached to medical devices (Safety Committee)

Following the announcement of draft guidelines for attached documents at this time, comments concerning clear specifications for the contents of attached documents and operation manuals, as well as a request for postponement of the transition period, were collected and submitted.

4. JESRA standards for protective clothing (Safety Committee)

This committee promotes activities to standardize the labeling methods for specifying the manufacturing date, maintenance procedures, and service life as JESRA standards.

5. Safety of MRI systems (Safety Committee)

An accident involving the death of a patient occurred in an MRI imaging room in August, 2001 in the US when an oxygen cylinder made of a magnetic material was brought into the room. The Committee sent an urgent written warning to the Japanese Society of Magnetic Resonance in Medicine (JMRM) and also published a warning statement on the JIRA homepage. The response from JMRM was that it would provide systematic and continuous training and promote education regarding this potential hazard.

6. Matters related to the Education/Training Committee

1) A joint seminar of the Regulations and Economy Division and the International Division was held in Ikakikai-Kaikan, Tokyo, on September 19, 2001.
2) A seminar concerning the reimbursement application manual was held under the joint auspices of the Japan Electronics and Information Technology Industries Association (JEITA) at Ikenoshata Bunka Center, Tokyo, on November 16, 2001.

7. Future projects

A risk management symposium focusing on safety issues is planned for the joint annual meetings in 2002, and a request was submitted to solicit participation as panelists. To promote safety as listed in the PAL reform, a seminar is scheduled to improve understanding of ISO 13485 and risk management.
Summary up to the previous issue

Since gastric cancer is considered to be a "national disease" in Japan, medical research concerning the early detection of gastric cancer has been actively pursued, resulting in the practical application of "X-ray indirect radiography" in mass screening programs.

Development of a prototype "X-ray indirect radiography system" for stomach mass screening (excerpts from Hitachi source materials)

Sequence of events up to prototype development:

In around 1955, Dr. Toshio Kurokawa (then president of Tohoku University), Dr. Masaharu Nishiyama, and Dr. Shoei Hasegawa reported the prevalence of gastric cancer in Japan and proposed the idea of mass screening programs for the early detection of gastric cancer.

Agreeing with this concept, in 1957, Hitachi started to collaborate in a project to develop X-ray equipment for stomach mass screening from the technological standpoint and developed a pilot system for basic research. Using this system, the value of X-ray indirect radiography in stomach mass screening was confirmed, leading to further collaborative research and the completion of a prototype system. The course of events is outlined below.

Pilot system for basic research

(1) Standing-type stomach indirect "snapshot" system

This system was initially developed for the purpose of basic research. A snapshot mechanism for indirect imaging was placed in front of the fluorescent screen of a standard direct radiographic/fluoroscopic system for the examination of the stomach, resulting in a standing-type indirect snapshot system.

In fluoroscopy, the fluorescent screen is viewed directly. On the other hand, radiographic examinations are performed using a camera mechanism mounted to a semitransparent mirror that is moved into position. Such a mechanism is shown in Fig. 1.

(2) Prone-type stomach indirect snapshot system

Based on the results of studies conducted using the above pilot system, it was found to be more effective to examine patients in the prone, supine, and oblique (with the patient's body positioned obliquely) positions than in the standing position alone.

As discussed above, a stationary-type system for basic research was developed, clinical trials were conducted, and the usefulness of X-ray indirect radiography for stomach mass screening was established. The next step was to produce a prototype vehicle-mounted system.

The last phase, i.e., the development of a vehicle-mounted system, continued to involve trial-and-error methods, particularly with regard to the improvement of the fluorescent screen and fluoroscopic/radiographic components, until the installation of a Canon mirror camera for gastric imaging.

Vehicle-mounted stomach mass screening X-ray equipment

The radiographic examination vehicle was fitted with shielding for X-ray protection (Fig. 2).

The prototype fluorography system that was developed had the following features.

The X-ray generator employed a high-voltage (125 kV, 1 µF, wave-tail cutting-type) capacitor. The snapshot mechanism was remotely controlled and a 35-mm roll-film camera was employed. Vertical, horizontal, pivoting, and oblique movements of the table (from the supine position to 45° tilt) were all electrically controlled.

Using a vehicle in which this prototype was installed, mass screening was performed in the Tohoku district (in the northern part of Japan) to determine the system requirements for more widespread use.
Improved mass screening X-ray equipment

Consequently, following the pilot and prototype tests described in the previous section, a number of modifications and improvements were made, including the adoption of a brighter fluorescent screen (for special cine imaging), an expanded exposure field, an electrical snapshot mechanism, a 70-mm roll-film camera, a fixed high-tension voltage circuit for the X-ray tube, and a wider table movement range.

Final prototype X-ray system for stomach mass screening

After the above-mentioned trial production in four phases and based on the results of prototype tests and related basic research, the final prototype was completed, providing higher image quality and improved ease of operation.

The records of the development processes state that modifications were performed for the fluoroscopy system to achieve brighter images and more comfortable examination by adopting a design permitting a 70-mm roll-film camera for radiography to be combined with a skull Odelca camera modified for snapshot imaging so as to achieve even higher image quality.

"In the meantime, Dr. Masaharu Nishiyama devoted virtually all of his efforts to providing guidance in system design and clinical applications", recalls an engineer who was with Hitachi at that time.

The main areas for modification were the fluoroscopy and radiography mechanisms, a summary of which is shown in Fig. 3.

Figure 4 shows the first completed vehicle used for stomach mass screening at that time.

Development of the mirror camera

At around the same time as the completion of the Kurokawa-Nishiyama indirect radiography system at Hitachi, Canon Inc. made significant progress in overcoming the problems with the Odelca camera, as shown in Fig. 3. Yuichiro Koizumi, the design engineer responsible for the Canon mirror camera for gastric fluoroscopy/radiography, recalls the situation at that time.

(1) Kurokawa-Nishiyama system (1960)

"In 1960, the so-called 'Kurokawa-Nishiyama' vehicle-mounted stomach mass screening system was developed by Hitachi and put to practical use. In this system, a roll-film camera with a refractor was employed for miniaturizing the images projected on the fluorescent screen. However, compared with the mirror lens system developed later, the images provided by the optical system were too dark, and the system also suffered from the disadvantages of excessive exposure dose for stomach imaging and long exposure times. As a result, image quality was poor and tended to be affected by gastric movement."

(2) Modified system employing a camera designed specifically for the head (1962)

"In order to overcome these drawbacks, the hood of the skull Odelca camera manufactured by Oldelft Limited was modified and the camera was then used in a vehicle-mounted stomach mass screening system. This product was placed on the market in 1962. It had superior image quality, but because a mirror lens system intended for head imaging was employed, it had a small field of view and was not really suitable for widespread application in stomach mass screening."

(3) Modified system employing a camera designed for the chest (1963)

"In 1963, Canon developed a mirror camera for chest imaging, and a stomach mass screening system incorporating this camera was introduced in clinical practice. In contrast to the head mirror lens system, the fluorescent screen measured 40 cm x 40 cm. As a result, images of the stomach appeared too small on the film. This system was therefore judged to be unsuitable for stomach mass screening."

(4) Demand for a camera designed specifically for the stomach

"At that time, gastric cancer became one of the leading causes of death in Japan, and there was strong demand for the development of a mirror camera optimized for stomach mass screening."

(5) Development of the "Magen-mirror"

"In response to this demand, Canon began development work to produce a mirror camera for stomach mass screening in 1963. First, a fluorescent screen measuring 30 x 30 cm was determined to..."
be ideal. Then, as the next most important design factor, it was necessary to determine the optimal overall length of the mirror camera. When this system was used in combination with an over-table tube system, if the total length exceeded a certain limit, floor excavation work was required at the time of installation. To avoid this problem, Canon held individual consultations with three X-ray equipment manufacturers and concluded that the camera could be mounted to existing equipment without floor excavation if the overall length did not exceed 1 m."

"Engineers specializing in optical design did their utmost to meet this requirement in a practical product. Mechanical engineers focused on the durability of the drive system for the plane mirror, which reciprocated in the same manner as the mirror in a single lens reflex camera each time the system was switched between fluorescent screen fluoroscopy and mirror lens radiography. Over time, this mirror camera acquired a nickname within the company, the "Magen-mirror.""

"For your reference, Oldelft Ltd. subsequently developed a mirror camera for stomach mass screening and exhibited it at the annual meeting of the Japan Radiological Society (JRS). This camera, however, had an overall length exceeding 1 m and thus could not be used in combination with examination tables produced by X-ray equipment manufacturers."

(6) Basic research and clinical trials of the Magen-mirror

Upon completion of the prototype Magen-mirror, clinical trials were required in order to evaluate this camera. However, it was difficult to decide which medical institution would be the most suitable for conducting such trials. We then heard about Dr. Hiroshi Horikoshi (1931-1975) at the National Cancer Center, who was performing medical examinations once a week at a hospital where one of our company physicians, Dr. Fumio Otsuka, was working. Dr. Horikoshi later moved to Doshisha University to assume a professorship in the Faculty of Medicine. We consulted with Dr. Otsuka and learned that Dr. Horikoshi was a widely recognized as one of the leading authorities working at the cutting edge of double-contrast imaging of the stomach, together with Dr. Ichikawa of the National Cancer Center. Consequently, the Magen-mirror, which was completed in September 1965, was brought to the Department of Radiology of the National Cancer Center, and under the guidance of these distinguished physicians, basic research and clinical trials were conducted by a number of outstanding radiographers and radiologists.

(7) Debut in 1966

At the end of February 1966, the Magen-mirror, combined with a radiographic/fluoroscopic table produced by an X-ray equipment manufacturer, was publicly unveiled to medical professionals and the press at the Akasaka Prince Hotel. Leading newspapers ran headlines and published photographs, hailing this system as the world's first camera for stomach mass screening and predicting that it would prove to be a very useful tool in the fight against cancer. A similar introduction was held at the Osaka Shin-Hankyu Building ten days later.

(8) Market launch

In April 1966, Mr. Koizumi delivered presentations on the Magen-mirror at the annual meetings of the JRS and the Japanese Society of Radiological Technology (JRT) in Kagoshima. (At that time, it was possible for manufacturers to deliver presentations at the JRS meeting.) These presentations were prepared based on the data obtained from basic research and clinical trials conducted at the National Cancer Center. The presentations were well received, and I felt that the medical community had given its blessing to the birth of this camera. At the end of that month, the camera was launched in the market.

(9) The "Magen-Mirror with TV" system

At that time, there was also increasing interest in so-called image intensifier (I.I.) indirect technology, in which the output image of a 9-inch I.I. was recorded on 70-mm film. However, the resolution of the I.I. at that time was insufficient. After carefully evaluating these technologies, we investigated the feasibility of a method combining TV fluoroscopy of the stomach and mirror camera radiography. This method was confirmed to be practicable when the brightest possible lens was used, the fluorescent image from the Magen-mirror fluorescent screen was projected onto the photoelectric surface of a 2-inch Image Orthicon pickup tube (IO tube), and the image was observed on a TV monitor. With regard to the image pickup lens employed in this system, the brightest possible refractor (60-mm, 1:0.65) was developed. These components were combined to obtain a system that was developed and launched under the name "Magen-M mirror with TV", the CX-M S70TV. This system made it possible to significantly reduce the fluoroscopic exposure dose. It was also designed for ease of use by radiologists and radiographers, substantially improving operating efficiency in the clinical setting. The Magen-mirror systems that had previously been placed on the market were gradually superceded by systems employing this new TV imaging method.

In October 1967, the first Magen-M mirror with TV system was installed at the National Cancer Center. Subsequently, a 100-mm Magen-M mirror with TV system, the CX-M S100TV, was developed and placed on the market. This system employed a combination of 100-mm film imaging and a 2-inch IO tube.

(10) Shift towards I.I. indirect imaging

Following the development of a high-resolution I.I. with a CsI (rather than multi-alkali) photoelectric surface, a high-resolution I.I. with a 12-inch input size, and a 100-mm spot camera, the standard method for stomach mass screening gradually shifted from the combination of a Magen-mirror and an IO tube to the I.I. indirect imaging method using a 100-mm spot camera, which eventually became the mainstream.

Popularization of vehicle-mounted stomach mass screening systems and the emergence of under-table tube systems

Hitachi's success in developing the stomach mass screening system described above had a significant impact on other manufacturers.

X-ray mass screening of the stomach was, and continues to be, an important healthcare concern, and radiology equipment manufacturers at that time were naturally interested in developing X-ray TV systems for stomach mass screening. In the Kansai region, Shimadzu Corporation succeeded in developing the ring-stand

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