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CONTENTS

Vascular

Clinical Application Lower Radiation Doses in IVR Procedures with Trinias —Benefits of the Latest Image Processing Engine in Arrhythmia Ablation— Department of Radiology, The University of Tokyo Hospital Toshihiro Hayashi, Hideyuki Iwanaga

M inimally Invasive Procedures in Practice —New 3D Workstation Features for Shorter Procedure Times—

With COVID-19 — Shimadzu Initiatives—

Customer Communication in the DX Age

RAD

Clinical Application Experience Using RADspeed Pro for Dynamic Radiography Department of Radiology, Kyorin University Hospital Koji Yamashita

R/F

Technical Report Development of FLEXAVISION™ F4 package Medical Systems Division, Shimadzu Corporation Masahiro Uehara

Stories of Kyoto-born Masterpieces

Vascular

Lower Radiation Doses in IVR Procedures with Trinias —Benefits of the Latest Image Processing Engine in Arrhythmia Ablation—



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1. Introducing the Hospital

The University of Tokyo Hospital (Fig. 1), located in the Bunkyo Ward of Tokyo, has 1,226 beds (including 48 psychiatric care beds), 7 medical divisions with 38 medical departments, and treats all types of diseases. Every year, the hospital provides medical care to 580,000 outpatients (2,374 per day on average) and 320,000 inpatients (880 per day on average). The hospital also performs around 10,000 surgical procedures each year, the most of any national university hospital in Japan¹⁾.



Fig.1 The University of Tokyo Hospital

The hospital is a designated "advanced treatment hospital," "core hospital for cancer genomic medicine," and "core hospital for clinical research," as well as a "Tokyo disaster base hospital," and provides regional medical care as a "base hospital for coordination of regional cancer care." The University of Tokyo Hospital is also a designated "emergency medical care center," receiving 10,000 emergency patients each year and providing care for acutely ill patients in all fields of medicine. The angiography section of the Department of Radiology has 6 systems (including a hybrid angiography system in the operating room) and performs around 3,200 cases for diagnostic catheterizations and IVR procedures each year.

In total, the hospital has around 4,000 employees, and all medical staff including physicians, nurses, and radiological technologists coordinate across medical disciplines and are dedicated to providing advanced medical care on a routine basis.

The unchecked spread of COVID-19 from the beginning of 2020 had a major impact on normal medical practice at the hospital, resulting in a significant drop in cases across the board compared to previous years.

A feature of cardiology care at this hospital is that, as a heart transplant facility, the hospital performs more investigations and procedures specifically related to heart failure than other facilities. The hospital also performs diagnostic and IVR procedures for ischemic heart disease, arrhythmia, valvular disease, pulmonary hypertension, and other cardiac disorders.

2. Background to System Acquisition and System Features

In April 2007, the hospital acquired Shimadzu's BRANSIST safire VB9 bi-plane system, which was used for coronary angiography by the Department of Cardiovascular Medicine and for diagnostic and IVR procedures in the head region by the Department of Neurosurgery. The first FPD system acquired by the angiography section of the Department of Radiology was a direct conversion FPD system. This system was used for 12 years and was updated into a Trinias system, which is currently used, in January 2019. This update included the installation of a large format monitor with the capacity for simultaneous signal input/output on up to 27 channels, allowing

Clinical Application



Fig.2 Photograph of Main System Unit and Large Format Monitor



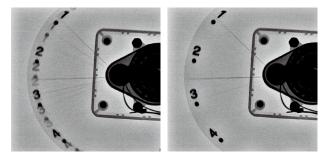
Fig.3 Comparison of RCA Images (Left: Old, Right: New)

each clinical group at the hospital to use a different screen layout on the monitor. Touch panel consoles in the examination room and control room can be used to select and display electronic patient records, PACS images, results from workstation analysis, and other information as required, which aids diagnostic and IVR procedures (Fig. 2).

Another major benefit of updating to the latest Trinias system has been a simultaneous reduction in X-ray doses to patients and improvement in image quality (Fig. 3).

3. Impact of New SCORE PRO Advance X-Ray Image Processing Technology

IVR is now being performed on increasingly difficult cases and operators are employing ever more demanding techniques. Because of this trend, physicians now demand both higher levels of expertise for radiological technologists and improved image quality and lower X-ray doses for the equipment itself. The hospital's Trinias system is equipped with SCORE PRO Advance X-ray image processing technology with state-of-the-art motion tracking noise reduction technology that reduces noise without afterimages due to object movement, an extremely useful feature for IVR procedures (Fig. 4).



(a) Recursive Filter Processing (b) SCORE PRO Advance Processing

Fig.4 Example Noise Reduction Processing in Fluoroscopic Image of Rotating Phantom (Excerpt from Kazuhiro Mori, MEDICAL NOW, No. 76 2014)

4. Hospital Experience with Shimadzu's Angiography System

Our Shimadzu angiography system is 70 % used to perform ablation (ABL) for arrhythmia and 30 % to perform coronary angiography, percutaneous coronary intervention (PCI), and other procedures for ischemic heart disease. More arrhythmia procedures, including cardiac pacemaker implantation procedures, are being performed every year, with around 320 ABL procedures annually and a four-fold increase over the past 10 years. The most common ABL procedure performed at the hospital is pulmonary vein isolation for atrial fibrillation, a procedure that aims to block signal conduction between the pulmonary vein and the left atrium. This procedure can be performed by two main methods: by applying radiofrequency energy with a catheter, or by balloon ablation with a cryoballoon, radiofrequency hot balloon, or laser balloon. ABL procedures are safely performed using intracardiac echography and 3D mapping systems such as CARTO, EnSite, and Rhythmia to construct a 3D view of the cardiac chamber and display sources of arrhythmia, reentry circuits, and the ablation catheter (Fig. 5).

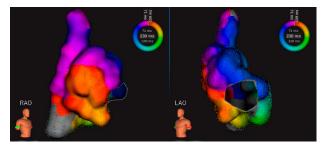


Fig.5 3D Mapping of a Common Type Atrial Flutter

Clinical Application

In general, magnetic fields created by these 3D mapping systems cause stripe-shaped noise in fluoroscopy and radiography images, and imaging programs of angiographic system must be modified to reduce this noise, which is unique to each 3D mapping system (CARTO, EnSite, and Rhythmia). However, Trinias is protected physically by magnetic shielding on the sensor sides that reduces image noise to a level acceptable for clinical use. This ability to reduce image noise without special image processing or modifications to the imaging program is a great benefit of Trinias.

Trinias also allows us to download cardiac CT data to the 3D workstation and display roadmap fluoroscopy images on the 3D workstation during procedures, which helps procedures (optional feature).

5. Our Efforts in Reducing X-Ray Doses

Upon acquiring Trinias, imaging protocols were changed through consultation with physicians to match the resulting improvements in image quality. For ABL, the fluoroscopy pulse rate was changed from 3.75 pulse/sec to 3 pulse/sec and the radiography acquisition frame rate was changed from 15 frame/sec to 5 frame/sec.

Fig. 6 shows where our use of Trinias places among fluoroscopic dose rates for pulmonary vein isolation as reported in "Multicenter Survey on Radiation Dose of Cardiac Intervention," published in the Japanese Journal of Radiological Technology (Vol. 76, No. 7, 2020)²⁾. The graph shows this hospital uses relatively low fluoroscopic dose rates for pulmonary vein isolation compared to the 98 facilities surveyed throughout Japan.



Fig.7 Pulmonary Venogram of Cryoballoon Pulmonary Vein Isolation

The fluoroscopic dose per minute was lowered by around 65 % at the patient entrance reference point (PERP) and the radiography dose was reduced by around 62 %. **Fig. 7** shows a pulmonary venogram acquired with Trinias during pulmonary vein isolation by cryoballoon ablation.

The image is a contrast-enhanced image obtained by manually injecting contrast medium and shows the cryoballoon placed in the upper left pulmonary vein. The contrast of the image is good and contrast medium injected from the catheter lumen has pooled in the pulmonary vein, indicating complete succesful occlusion of the pulmonary vein by the balloon.

Fig. 8 compares fluoroscopic time and air kerma (Ka,r) clinical data from ABL procedures for arrhythmia performed before and after the Trinias update in January 2019. Although fluoroscopic times increased significantly after the update, air kerma (Ka,r) values displayed by the system reduced significantly. The increase in fluoroscopic times may be explained by a change in physicians soon after the update and because the younger physicians were less experienced with the procedure.

We also compared fluoroscopic times and air kerma (Ka,r) values with data from 90 facilities throughout Japan that perform ABL (**Fig. 9**). The graphs show

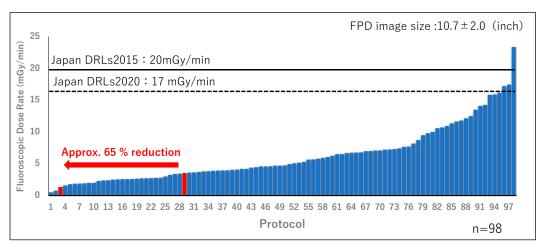


Fig.6 Fluoroscopic Dose Rate for Catheter Ablation

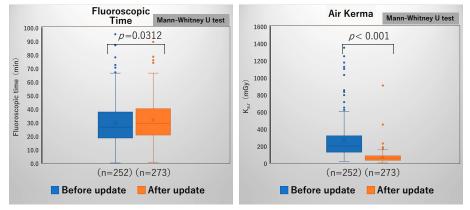


Fig.8 Fluoroscopic Time and Air Kerma (Ka,r) for ABL before and after Update

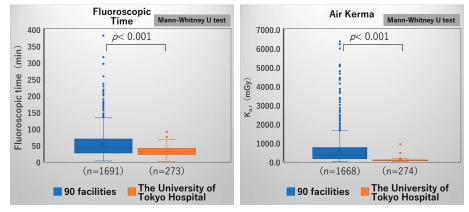


Fig.9 Comparison with 90 Facilities and the University of Tokyo Hospital

that fluoroscopic times and air kerma values displayed by the system are significantly lower at this hospital compared to the 90 facilities. These findings indicate the system update had a meaningful impact in reducing radiation doses for arrhythmia procedures.

6. Conclusion

This article presented our experiences with angiography systems procured by our hospital and used in arrhythmia procedures. In Japan, foreign equipment manufacturers have long dominated this area of medicine, but we believe this article shows the excellent results that can now be obtained with equipment from Japanese manufacturers. Clinical needs will continue to increase, and we look forward to further technological improvements and new developments from Shimadzu.

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M inimally Invasive Procedures in Practice

—New 3D Workstation Features for Shorter Procedure Times—

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IVR procedures are becoming increasingly complex and sophisticated, and require angiography systems that can achieve lower radiation doses, less contrast media use, and shorter examination times. Shimadzu's latest Trinias™ series angiography system comes with various features that support minimally invasive procedures.

This article presents new features* added to Shimadzu's SCORE 3D Workstation, a workstation used for 3D image analysis.

* New features are available to customers who upgrade to the paid version of SCORE 3D Workstation.

1 Improved Automated Path Creation Function

3D images are often used to measure distance and degree of stenosis during procedures, but simpler procedures are needed for these measurements.

VR (volume rendering) Tracking was an essential function for taking measurements with the SCORE 3D Workstation that has now been relaunched as Vessel Tracking. As the name suggests, VR Tracking generated a path along a blood vessel of interest from a user-specified start point and end point on a VR image of that blood vessel. Although VR Tracking was simple to use, there were also some limitations, such as not generating satisfactory paths along branched vessels and being unsuitable for CTO (chronic total occluded) lesions, which VR Tracking had difficulty showing on the VR image. The new function, called Vessel Tracking, resolves these limitations. Vessel Tracking now (1) generates paths from any type of view (VR, axial, coronal, and sagittal), (2) tracks based on pixel values in cross-section views, allowing it to track objects not visible on VR images (such as blood vessels), and (3) allows the user to set not only a start and end point, but also multiple intermediate tracking points if needed. Tracking points are also displayed correctly across the different views, hence tracking point positions can be verified across four image views (VR, axial, coronal, and sagittal) (Fig. 1). Fig. 2 shows examples of this function being used with a branched vessel and a CTO lesion.

Vessel Tracking can reduce the time spent on measuring blood vessels during a variety of procedures.

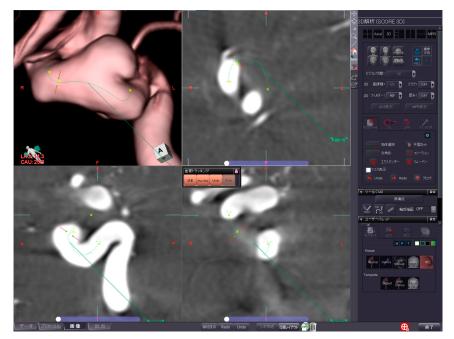


Fig. 1 Operation Screen after Applying Vessel Tracking to Axial Section View (Yellow squares are tracking points. Tracking points are also displayed correctly across VR, coronal, and sagittal images.)



Fig. 2-a Path Generation on Branched Vessel

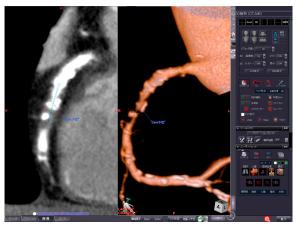


Fig. 2-b Path Generation at CTO Lesion

2 C-Arm Range of Motion Displayed on VR Image

3D-reconstructed VR images can display the complete vessel and a target region from any direction, making them an essential tool when determining the C-arm working angle for intervention. Nevertheless, users often evaluate a target region only to arrive at a C-arm working angle that is physically incompatible with the actual system C-arm, prompting the need for a way of showing this incompatibility earlier in the process.

A newly added feature shows when the current VR image angle is inside or outside the range of motion of the actual C-arm (Fig. 3). The user can confirm at any time whether a given view is within the C-arm range of motion without having to navigate to a separate pop-up screen that transmits the angle to the C-arm. This allows the C-arm working angle to be determined quickly while simply rotating the VR image and observing the target region *.

(* An icon displayed on an image may not show the actual range of motion depending on table height, position, and peripheral equipment.)





Fig. 3 Software Feature Showing C-Arm Range of Motion Left: Angle within range of motion (green icon) Right: Angle not within range of motion (red icon)

3 Additional Features to Improve Ease of Use

3.1 MRI Image Support

As well as including support for MRI images, support has been added for roadmap images created by superimposing MRI images and fluoroscopy images**. When a preoperative CT is not feasible or is not performed, existing MRI images can be used in IVR procedures.

3.2 Support for Shortcut Keys

Frequently used features can now be summoned with ease via shortcut keys on the keyboard. It is possible to summon frequently used features such as creating cyclic movie images, rotating the VR image (in 8 directions vertically/laterally/longitudinally), and measuring 2D distances with a single key press.

** Optional feature

4 Final Comments

Shimadzu has been developing image-guided applications that offer real-time performance and unique procedure-supporting features to assist minimally invasive procedures. Shimadzu continues to value the viewpoints of all stakeholders in the interventional radiology field and strives to achieve increasingly minimally invasive procedures.

Customer Communication in the DX Age

1. Introduction

In January 2022, the Trinias angiography system area in the Medical Center showroom at Shimadzu's Head Office (Nakagyo-ku, Kyoto) reopened after renovations. The renovations included a new digital platform and create a space that will be used for value co-creation and to support improvements in medical technology for customers around the world. After this reopening, the Trinias area can now be visited both in person and also remotely via the Internet (Fig. 1).

The COVID-19 pandemic created an unprecedented disaster experienced on a global scale and has triggered a dramatic acceleration in digitalization and IT modernization across all fields. Online interactions have begun to enter every part of our lives and form a new normal in the with-COVID era, with online gatherings becoming a feature of not only our private lives but also business lives or various academic meetings. These changes exactly mirror digital transformation (DX), a process defined as "IT that permeates to change every aspect of peoples' lives for the better."

Shimadzu is also working proactively to introduce support to be able to describe products and their clinical usefulness to customers remotely. Shimadzu intends to integrate these new activities with a communication space built in the showroom with greater online connectivity, helping its customers improve their quality of medical care and creating new value.



2. Overview of Trinias Room

An examination room has been created in an area 7 m by 6.7 m, similar in size to a common cath lab, that will be used as a showroom for parties of several people to view a system, to perform simulated procedures for up to 10 people, and other uses. The room is also equipped for activities involving X-ray radiation, with X-ray protection measures on the system as well as radiation protective apron, neck guards, and protective glasses used by operators. Network cameras are also installed on the ceiling (three in the examination room and one in the control room) to share images of operators and their manual operations online.

Live images, reference images, and other images output by the angiography system are also networked and sent to a streaming PC together with the video camera images mentioned above. Remote meeting software such as Zoom and Microsoft Teams installed on the streaming PC can then be used to distribute these images over the Internet (Fig. 2).

Presented below are several ways of using this setup along with specific case examples.

3. System Viewing

- Case 1: A customer wishes to verify system features but is unable to visit in person.
- Case 2: Several people are unable to attend a system demonstration in person.

System operation and manual manipulation of tableside modules are streamed via images from video cameras, and viewers are given the same explanations as an in-person demonstration (Fig. 3). Because system viewings can be simultaneously streamed online, in-person and online activities can be combined to offer a versatile range of viewing plans.

Fig.1 Trinias Area in Concept

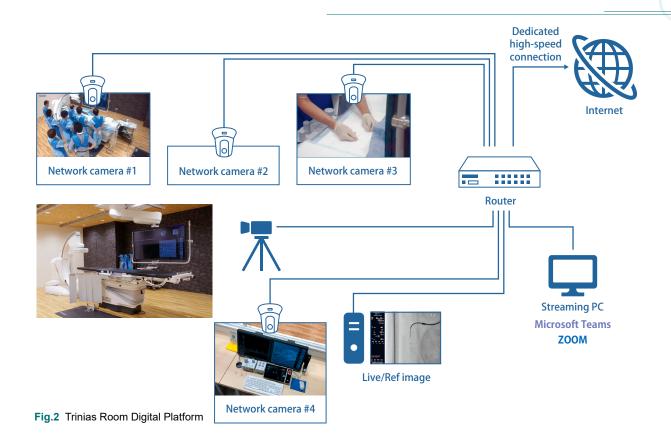




Fig.3 Online Streaming Screen

4. Workshops and Training Sessions (Paid Plan)

• Case 3: A customer wants to receive immediate training in an unused feature.

Customers can be trained over the Internet. The Trinias room can be used for expedited training to show customers actual working system interfaces and how to operate the system (Fig. 4). Training sessions streamed online can also be presented to the client as screen recordings to reference at a later date.



Fig.4 Joint Workshop with Device Manufacturers to Train Customers in Correct Use of Medical Devices

• Case 4: A customer wants to conduct training workshops to be attended by a wide selection of team members of multiple facilities.

Shimadzu offers the Trinias room and also meeting rooms and can organize experiments and workshops involving X-ray irradiation upon request. Team members unable to attend in person can participate online or be sent screen recordings of the workshop.

5. Value Creation

• Potential case 5: Promote new technologies or ideas to improve medical practice.

Shimadzu will assemble various manufacturers of peripheral equipment used in catheterization procedures to distribute new technical information. Shimadzu is planning events that can be attended both online and in person.

• Potential case 6: Events that create ideas for new features.

Shimadzu will create new value by holding "ideathons" with customers to exchange ideas on product and application development.

Shimadzu is always taking on new challenges and working to improve the quality of healthcare for its customers.

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RAD

Experience Using RADspeed Pro for Dynamic Radiography



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1. Introducing the Hospital

Located in Mitaka City, Tokyo, Kyorin University Hospital is an "advanced treatment hospital" providing advanced medical care, an "advanced emergency and critical care center" operating on a 24-hour basis, is the only university hospital in the Tama region, and has 1,153 beds and 64 radiological technologists. Kyorin University Hospital is a core hospital in the Tama area, a large region that comprises the western half of Tokyo and contains one-third of the population of the Tokyo Metropolis. The hospital is responsible for providing medical care not only in the Tama area but also in the western Wards of Tokyo, including neighboring Setagaya and Suginami Cities (Fig. 1).



Fig.1 View of Kyorin University Hospital

2. System Setup and Characteristic Features of Radiography Room

In June 2020, the hospital procured a Shimadzu RADspeed Pro digital general radiography system (hereinafter, "RADspeed Pro") alongside a Konica Minolta AeroDR fine digital radiography system during renovations to the radiography room and started to perform dynamic chest radiography in clinical practice (Fig. 2). The radiography room is



Fig.2 RADspeed Pro System

a multipurpose space in which a system must offer high levels of imaging accuracy and also versatility, and perform not just dynamic radiography, but imaging of all parts of the body in various patient positions. In terms of imaging modalities other than dynamic radiography, RADspeed Pro integrates a combination of equipment, functions, and applications and flexibly meets the various needs of the hospital.

3. Setup and Features of Dynamic Radiography System

The dynamic radiography system uses an X-ray generator capable of sequential pulse irradiation and a flat panel detector (FPD) that supports dynamic imaging. The system also supports imaging in various body positions, including standing, siting, and supine positions. Conventionally, chest radiography has only acquired static images that offer partial insights such as images during the maximal inspiration phase or maximal expiration phase, but dynamic radiography can acquire sequential data during respiratory movement

Clinical Application

that spans from maximal inspiration to maximal expiration. Images are acquired on an FPD with a 400 \times 400 μ m pixel pitch, 16-bit depth, and image area of 17 × 17 inch (42.5 × 42.5 cm) allowing imaging of a variety of large and small sites in the chest, neck, and extremities. The X-ray generator can also be set to generate sequentially pulsed X-rays with irradiation times of any duration up to 20 seconds. The only frame rate available when RADspeed Pro was first procured was 15 frames per second (fps), but 6 fps can also be used today. By suitably combining these irradiation times and frame rates, we can perform dynamic radiography of various sites of interest in respiratory, cardiovascular, and orthopedic areas with due consideration to radiation doses (Fig. 3). As post-image processing, we use the image processing technology in Konica Minolta's KINOSIS dynamic image analysis workstation (not RADspeed Pro) to visualize structures in the chest area, automatically calculate the lung area,

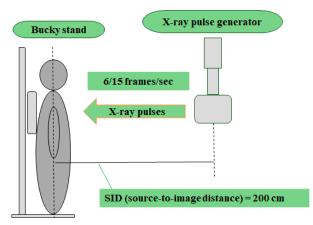


Fig.3 Dynamic Radiography System Setup

Requesting Department	Department of Respiratory Surgery			Department of Respiratory Medicine	Department of Cardiology	Radiation therapy	Department of Thyroid Surgery
Clinical Diagnosis	Pneumothorax Other Mediastinum		All cases	All cases		Thyroid/vocal cord area	
Imaging Protocol			PL: Deep breathing (Standing + Supine)	PH: Breath-hold + PL: Deep breathing	PL (Standing + Supine)		Vocal cords A: Enunciation \rightarrow P PL
Small	200mA 80			30mA †	80mA †		
X-ray techniques	PH (90kV	250mA 5msec)	PL (120kV 1	25mA 2msec)	100kV 125	mA 4.0msec	90kV 200mA 2.5msec
Large	↓ 100kV	JOOKV 2		↓ 50mA	↓ 160mA		↓ 4.0msec
Source-to- ImageDistance	200 cm (40/12:1)				150cm (40/10:1)		150cm (40/8:1)
Voice Instruction System		PH: Each breath-he PL: Respiratory reg			As per PL	Natural breathing (around 10 seconds)	Thyroid (English-Voice (4))
	PL (<u>Original</u> · PL · FE · BS · BsXFE)						
Image Processing	Before Ope :PH2+LM After Ope :PH2			PL (<u>Original</u> • FE)	<u>Original</u>	<u>Original</u>	Original + FE (Enlarge and send)
			+ Supine <u>original</u>				

Table 1 Dynamic Radiography by Department

quantitatively evaluate diaphragm movement, and visualize function in the respiratory and cardiovascular regions (Fig. 4).

4. Dynamic Radiography Techniques in Kyorin University Hospital

At our hospital, requests for dynamic chest radiography are mostly received from the department of respiratory medicine, department of respiratory surgery, department of cardiology, department of thyroid surgery, and department of radiology, and routine dynamic radiography procedures have been established and are followed for each requesting department. For dynamic chest radiography, we acquire original images that combine three to five different image processing steps applied to each imaging protocol, including breath-hold, forced respiration, and dynamic neck radiography (Table 1).

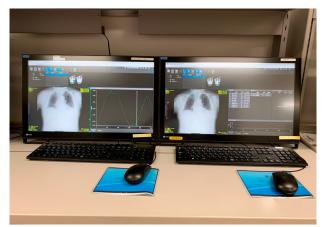


Fig.4 KINOSIS

During dynamic chest radiography, breath-hold imaging is performed for approx. 7 seconds in a standing or supine position, and a voice instruction system is utilized in forced respiration imaging for approx. 14 seconds, which includes maximal inspiratory position, expiratory phase, maximal expiratory position, and inspiratory phase imaging. Patients are provided instructions in order to prevent disparities arising due to patient motion and differences in breathing, and examinations are performed as the patient performs breathing exercises that follow the directions of the voice instruction system as close as possible (Fig. 5).



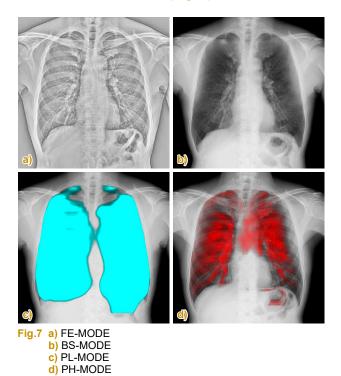
Fig.5 Positioning for Dynamic Chest Radiography

Patients are seated during dynamic neck radiography to limit body movement and ensure examination reproducibility. The patient's mandible is elevated and the head immobilized so radiography is performed with the anthropological baseline at 25 degrees to the FPD. A total imaging time of approx. 7 seconds includes both breathing and vocalization, and patients are instructed to maintain a steady tone during vocalization due to the impact of unstable tones on vocal cord movement (Fig. 6).



Fig.6 Positioning for Dynamic Neck Radiography

Upon acquisition, dynamic images are analyzed automatically by KINOSIS to create images that display quantitative data and functional information. The different types of image processing available are frequency enhanced processing (FE-MODE) that enhances specific frequency bands; bone suppression processing (BS-MODE) that reduces signals from the ribs and clavicle area within the lung field; diaphragm motion processing (DM-MODE) that performs specific component tracking to measure maximum and minimum lung field area, change, and diaphragm movement; pixel value change-low frequency processing (PL-MODE) that performs reference frame ratio processing to enhance and visualize breathing-associated signal changes in lung field tissue (changes in X-ray transmission); and pixel value change-high frequency processing (PH-MODE) that visualizes signal changes related to the heartbeat in lung field tissue when imaging a breath-hold for 7 seconds (Fig. 7).



The maximum size of dynamic image files sent for viewing by physicians, including processed images, is around 5 GB. Based on the number of images acquired, this is equivalent to approx. 30 % of the total file size of all hospital images transferred in 1 month. Although the sequential images acquired by dynamic radiography make it a clinically useful technique, the nature of these sequential images makes the image file sizes much larger than static images. As well as a main server dedicated to viewing dynamic images, many facilities also install client terminals in each department.

Clinical Application

Our hospital does not send all images to the main PACS server because server capacity would become overwhelmed. Since images could not be viewed in departments where there are no client terminals, the hospital built a viewing environment that utilizes a general image viewing system. By linking this viewing system to all dynamic images, the system can be used to instantaneously view dynamic images and images processed by KINOSIS from approx. 2.000 medical record systems held at our hospital (Fig. 8).

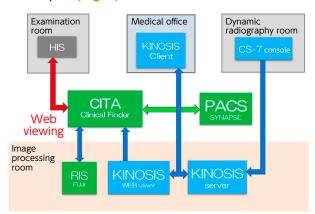


Fig.8 Network Diagram

5. Clinical Images

Pneumothorax

Here is presented a case diagnosed with pneumothorax by dynamic chest radiography.

Determining pulmonary collapse, identifying blebs and bullae, and determining air leaks are important for pneumothorax diagnosis, and dynamic radiography can be used to evaluate the status of a collapsed lung based on associated respiratory motion and mediastinal shifts requiring urgent attention (Fig. 9). BS × FE-MODE image processing also improves the visibility of blebs and bullae that overlap costal shadows (Fig. 10).

Bronchial Stenosis

Here is presented a case of right bronchial stenosis caused by lung cancer in which the airway was secured with a stent (Fig. 11). Breath-hold imaging was performed in addition to deep breathing imaging, revealing compression of pulmonary vessels and bronchi by a tumor at the hilus of the left lung, reduced signal levels in PH-MDOE and PL-MDOE in the left lung (Fig. 12), and left phrenic nerve paralysis and mediastinal shift (Fig. 13). Dynamic radiographs allow us to determine the effectiveness of treatment and check the course of recovery.



Fig.9 Pneumothorax Case a) Original image at Maximal Inspiration b) Original image at Expiration



Fig.10 Pneumothorax Case a) BS × FE-MODE at Maximal Inspiration b) BS × FE-MODE at Expiration



Fig.11 Right Bronchial Stenosis Case a) Original image at Maximal Inspiration b) Original image at Expiration

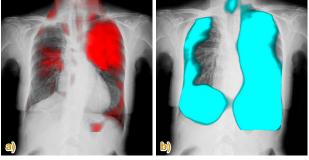


Fig.12 Right Bronchial Stenosis Case a) PH-MODE b) PL-MODE



Fig.13 Right Bronchial Stenosis Case a) BS × FE-MODE at Inspiration b) BS x FE-MODE at Expiration

Recurrent Nerve Paralysis

Here is presented a case of left recurrent nerve paralysis diagnosed by dynamic vocal cord radiography (Fig. 14, 15).

Dynamic neck radiography is used to examine the vocal cords. Recurrent nerve paralysis is normally diagnosed by laryngoscopy, but this procedure causes pain and places a significant physical burden on the patient, hence can only evaluate vocal cord movement in the upper part of the vocal cords. Dynamic radiography with deep breathing and vocalization offers a minimally invasive evaluation of the entire neck region and also allows us to extract minute vocal cord movements. Dynamic neck radiography is also useful in cases of post-surgical non-symptomatic transient recurrent nerve paralysis, including cases with hoarseness or dysphonia as a postoperative evaluation. Also, while laryngoscopy now carries the risk of COVID-19 transmission, dynamic radiography can be used to examine patients safely with no similar transmission risk.



Fig.14 Recurrent Nerve Paralysis Case a) Original image at Inspiration b) Original image at Vocalization



Fig .15 Recurrent Nerve Paralysis Case a) FE-MODE at Inspiration b) FE-MODE at Vocalization

6. Conclusion

Dynamic radiography can perform quantitative evaluation of diaphragm and chest movement in the thoracic region and acquire ventilation weighted images and blood flow weighted images without the use of contrast medium. Furthermore, dynamic radiography can acquire not only morphological information but also functional information through an examination that places a lower burden on the patient and poses a lower risk of disease transmission. For these reasons, dynamic radiography is expected to become a new reference in lung function testing. We look forward to dynamic radiography being developed to target more sites and disease indications, and more analytical tools being developed in tandem with this expansion. Finally, in the near future, we hope these techniques can be used not only to understand current pathologies but also to predict possible future pathologies, and will become established and widely adopted as a new imaging modality alongside existing general chest examinations.

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R/F Development of FLEXAVISION™ F4 package

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1. Introduction

Shimadzu has released the FLEXAVISION F3 package R/F system (hereinafter, "F3 package") combined with a removable 14 × 17-inch FPD (Flat Panel Detector) that can perform fluoroscopy and radiography while docked in the R/F table and radiography (wired) when removed from the table. The F3 package has highly acclaimed for supporting various examinations in a single apparatus including fluoroscopy and radiography in gastrointestinal or urological examinations, and general radiography in orthopedic examinations with the FPD undocked from the table.

Shimadzu has now developed and launched the FLEXAVISION F4 package R/F system (hereinafter, "F4 package"), which inherits the design philosophy of the FLEXAVISION series of systems while incorporating significant practical improvements such as a new wireless 17-inch FPD, a new 600 kHU X-ray tube unit, DSA (Digital Subtraction Angiography) functions, and support for DICOM RDSR (Fig. 1). This article introduces the features of the F4 package.



Fig.1 FLEXAVISION™ F4 package Main Unit

2. Standout Features of F4 package

2.1 New FPD

(1) Supports Maximum 17-Inch and Minimum 6-Inch Field of View

The 17 \times 17-inch large field FPD (**Fig. 2**) can provide a single view of the kidneys and bladder in urological examinations, the whole large intestine in lower gastrointestinal examinations, and the entire lung field in chest imaging. The F4 package also introduces support for a new 6-inch field of view, making it possible to observe the area of interest in enlarged images during endoscopic procedures and other examinations.





(2) Support for Wireless Radiography

While the removable FPD in the F3 package is wired to the R/F table when undocked for radiography, the new removable FPD in the F4 package can perform wireless radiography. The wireless FPD is useful for close contact radiography on the R/F table, or for imaging a patient on a stretcher using X-ray tube rotation function* or in combination with a ceilingmounted X-ray tube (Fig. 3, 4). In examination rooms where chest imaging is mainly performed by combining a removable FPD with a Bucky stand, you can also choose to operate the removable FPD for wired imaging upon request, which does not require battery replacement.

* X-ray tube rotation function is an optional feature.





Fig.3 Patient Positioned Directly against FPD

Fig.4 Imaging a Patient on a Stretcher

(3) Improved SNR (signal to noise ratio)

The SNR of the new FPD is significantly improved compared to that of the previous FPD (Fig. 5). The new FPD produces highly visible fluoroscopy images with reduced noise, even for thicker patients.

The F4 package also retains image processing engine, including multi-frequency processing, which has highly acclaimed in the F3 package,and contributes to reduce halation in direct X-ray irradiation area and enhance the contrast and edges of devices.

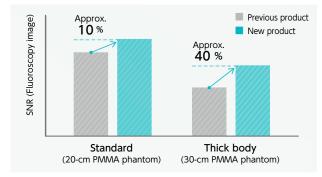


Fig.5 SNR Comparison between Previous and New FPD

2.2 New 600 kHU X-Ray Tube Unit

A new 600 kHU X-ray tube unit is also available for the F4 package. It allows for shorter F-R times* (as short as 0.9 sec). The new 600 kHU X-ray tube unit helps with examinations of the upper gastrointestinal region and other areas where exposure timing is important for diagnosis imaging.

* Time from pressing the image acquisition button to X-ray exposure under fluoroscopic conditions.

2.3 Space-Saving Design

The F4 package, equipped with a large field FPD, retains the space-saving design of the previous FLEXAVISION series. In addition to the compact design of its R/F table, its control cabinet is

contained within a single unit, ensuring ample working space in the examination room, easy placing of other equipment around the system, and smooth entry and exit of patients on wheelchairs or stretchers (Fig. 6).

The control room is equipped with a single remote control console, you can perform all operations, including control of the fluoroscopy table and X-rays, and digital image processing. A single PC system and no additional image processing control cabinet also keep the area under the control console clear and make efficient use of the limited space available in the control room (Fig. 6, 7).

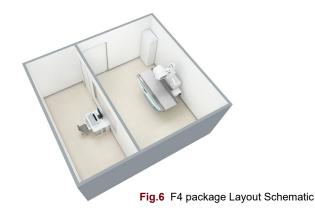




Fig.7 Remote Control Console

2.4 Universal Design (1) Smart STEP

A soft-start/soft-stop function is used to raise and lower the bed (Fig. 8) to alleviate patient anxiety caused by sudden movements. In addition, the lowest position of the foot rest is as low as 10 cm from the floor, making it easier for patients to get on and off and to be assisted by medical staff. In addition, a sensor is equipped at the table end, and automatically stops the table tilting if any obstacles happens to get trapped.

Technical Report



Fig.8 Table Tilt for Standing Imaging

(2) Smart FACE

The bedside controller is equipped on the front of the table as standard that allows the operator to tilt the table, elevate the table, move the imaging unit longitudinally, and move the tabletop laterally (Fig. 9). This allows the operator to move the table while also providing medical attention alongside the patient. The bedside controller is also recessed into the table to avoid accidental button presses by a nearby stretcher or bed.



Fig.9 Bedside Controller

The collimator controller is equipped on the front of the collimator unit as standard, allowing the operator to move the imaging unit longitudinally with ease even when the table is lowered (Fig. 10). Also, in consideration of interference between the collimator and the operator's head when the bed is lowered, soft rubber is configured at the bottom of the collimator unit.



Fig.10 Collimator Controller

2.5 X-Ray Dose Reduction and Dose Management

A new virtual collimator setting has been added that can be used to check the collimator position on the last image hold without X-ray irradiation. Six different fluoroscopy frame rate settings are also available from a maximum rate of 15 fps down to 2 fps, and the operator can switch frame rates from the remote control console during ongoing procedures according to the requirements of the examination.

The F4 package also now supports the DICOM RDSR for dosage management. Depending on the requirements of the facility, reports can also be output as CSV files.

2.6 DSA Function

The F4 package now supports DSA* at up to 15 fps. A roadmap function is also available that superimposes fluoroscopy images or DSA images acquired during a procedure over live fluoroscopy images.

* DSA is an optional feature.

3. System Specifications

Table 1 is a summary of major specifications.

Table 1

Component	Specification	
R/F Unit	Table size: 792 × 2100 mm (Between side grooves: 650 mm) Longitudinal stroke of imaging unit: 900 mm Lateral movement of Table top: 220 mm Table height: 690 to 950 mm Tilting angle: -30° to +90° SID: 1100 mm, 1500 mm (standing position) Oblique Angle (Patient's head to foot): -30° to +30° (system with oblique projection) X-ray tube swing-out: 37° or 90° (option) X-ray tube rotation: 90°, 180° (option)	
X-Ray Flat Panel Detector (FPD)	X-ray conversion material: Csl Pixel pitch: 160 μm Field of view: 17x17, 14x14, 12x12, 9x9, 6x6 inch Bit depth: 16 bits	
Image Processing Unit	OS: Windows 10 Fluoroscopy: Pulse fluoroscopy (15, 12.5, 7.5, 5, 3, 2 fps) * Sequential fluoroscopy is also available. Radiography: SPOT radiography, sub-divisional radiography, serial radiography, DSA imaging (optional) External devices: DICOM MWM/MPPS, RDSR PRONT, STORAGE (RF/CR/DX) card reader, barcode reader (option)	
X-ray high- voltage generator	Maximum rated output: 50 kW Generation method: Inverter method	
X-Ray Tube Unit		

Technical Report

4. Summary

The FLEXAVISION F4 package is a high performance system with significantly improved capabilities that can perform general radiography examinations as well as fluoroscopic examinations (Fig. 11). Under the tagline "Fits all your needs with 17×17 inch wireless FPD". Shimadzu continues to develop flexibly examination environments that meet the needs of clinical fields.



Fig.11 Example Examination Room/Control Room Layout



A sample seal. In addition to characters, detailed patterns are also engraved onto the face. A traditional boat shape, the case has been hand-carved and covered in cloth, and is the work of a craftsman from the Kanto region.

Kyo-insho Seals

Insho, or seals, are thought to have first crossed over to Japan from China during the Asuka period, later inspiring the creation of *Gyoji* (the emperor's imperial seal) and other official seals in the former Heian-kyo capital in Kyoto. Japan's first *inbanshi*, or official seal engraver, was active in Kyoto during the Edo period. From then onwards, Kyoto developed into Japan's central *insho*-producing region, and in 1874, Kyoto's *inbanshi* spent a year creating the emperor's *Gyoji* seal and the national *Kokuji* seal. The *Gyoji* and *Kokuji* seals used in official national documents today are *Kyo-insho*—that is, *insho* from Kyoto.

In Japan, *insho* seals are also known as *hanko*, and typically these *hanko* are engraved with an old seal script called *tensho*. *Kyo-insho*, however, mainly use a *tensho* script from the Han Dynasty called *Kan inten*, which is characteristic for its use of straight lines. Meanwhile, while *hanko* are predominantly 60 mm in length, *Kyo-insho* are often shorter at 45 mm, and registered seals tend to be favored with an accompanying case. In the old days, even shorter 30 mm *Kyo-insho* were created for geiko and maiko to conceal in their kimono. This modest, Kyoto-like sizing is perhaps another unique characteristic of *Kyo-insho*.

Accurately Reproducing the Design onto the Face of the Seal

After determining the size and material to be used, the face of

the seal is levelled out and red ink is applied to the surface. The design of the seal engraving is done in black, and so the red ensures it can be reproduced in finer detail. The next step is to draw a grid on the surface of the seal to aid the reproduction of the design. As the material used is often not perfectly round, finding the center can be a challenge, and many craftsmen will draw three lines and find the approximate center from where the lines intersect. However, Daisei Tanaka, the fifth-generation head of Tanaka-Bunshoudou—a seal store founded in 1860—uses a self-made tool to find the center using a cross and draws a 1 mm grid on the surface of the seal. This grid makes a huge difference in the accuracy of the design reproduction.

Once the base of the seal is complete, the next step is to create the design. Alongside the customer's requests, the craftsman selects the type of script, the thickness of the characters, and the overall style. Seal stores have differing policies on whether to show the design to the customer beforehand, but having customers agree to the design is said to enhance their degree of satisfaction with the finished product. When the design has been finalized, next is to draw the design onto the face of the seal with an ink brush, the key being to reverse the characters. This is said to be the most difficult process, and many stores have switched to use of scanners and machine-based engraving instead. On occasion, a



A handmade tool that holds the seal material, locates the center, and allows the craftsman to draw a grid without damaging the face.

A tool used to hold the seal material in place during the initial rough carving. It has been custom-painted black to ensure that it doesn't reflect any light.





The red sample impressions (top right and bottom right) are used to help customers select the type of script. On the left are impressions from rubber seals used between 1904 and 1908. Previously, seal stores were required to register seals with local police stations—a similar idea to the seal certificates used in Japan today.



After the rough carving, the seal is removed from the holder and the craftsman switches to the finishing knife.



The final carving. Carving the face at an angle from the edge increases toughness and flexibility and makes the seal more durable.

The knives at the front are for finishing, and those at the back are for the rough carving. Fine, sharp knife edges enable the carving of detailed patterns.



mirror is used to check how the characters look, while the grid also helps to ensure the design is on track. On a small seal, this process takes around an hour to complete.

Next the craftsman takes an engraving knife to roughly carve out the red sections around the characters, before switching to a finishing knife and carving the outline. Failing to complete this process correctly prevents the creation of sharp lines and makes for a blurry outcome when the seal is stamped. Once the outline is carved, sandpaper is used to remove the red ink, before black ink is applied in its place to clarify any uncarved sections. Black ink has coarser particles than red ink, and so when it has been polished down smoothly using a tool made of boar tusk, the craftsman moves onto the final carving. This process involves fine adjustments—the seal is repeatedly stamped onto paper to check the outcome of the impression.

Enhancing Technique and Speed with Reliable Tools

Today there are only a few *Kyo-insho* stores remaining where the seals are completely hand-carved. Some stores entrust machines to draw the design onto the seal and undertake the initial rough carving, only applying the finishing touches by hand. Perhaps the reason for this shift is the precise technical skill required and the relatively low level of productivity.

Despite these drawbacks, Tanaka still insists on completely hand carving his seals, even redesigning his tools for the process. Tanaka studied engineering at university, and before taking over Tanaka-Bunshoudou, he worked in the automotive department of a heavy industries company. Using his expertise, he did away with standard steel carving knives, creating his own high-speed steel knives instead. "High-speed steel is much sharper and doesn't chip, and so it means I can proceed with carving ivory and other hard materials in one go," says Tanaka. He has also made an improved grid divider that takes into account the red ink components to use when applying the design to the seal surface. "I started somewhat later than other seal craftsmen, but I've used my expertise and experience to create some reliable tools, and so Tanaka-Bunshoudou products will always be hand-carved." Standout Kyo-insho continue to be produced today thanks to the outstanding techniques of inbanshi like Tanaka and their carefully designed tools.

> Special thanks to: Tanaka-Bunshoudou https://www.bunnshoudou.jp/english.html

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