



Fujifilm Digital Mammography System

ASPIRE Cristalle

FDR MS-3500 (FDR-3500DRLH)

FDR MS-3500 Option

Tomosynthesis Exposure

Tomosynthesis Exposure Software

Operation Manual

1st Edition: January 2017

**Tomosynthesis
Exposure Software
Overview of the
Optional Product**

**Tomosynthesis
Exposure Software
Operation Procedures**

This Operation Manual describes details on how to operate FUJIFILM Tomosynthesis exposure software and cautions to be observed when operating it. Please read the Operation Manual thoroughly before actually operating the Tomosynthesis exposure software.

Also, please read "FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide" and the related operation manuals. After reading this manual, store the manual nearby for easy reference.

FUJIFILM Corporation

Introduction

[INDICATIONS FOR USE]

The Fujifilm ASPIRE Cristalle with Digital Breast Tomosynthesis (DBT) Option acquires and generates FFDM and DBT images, and is intended for use in the screening and diagnosis of breast cancer.

A screening examination may consist of sets of CC and MLO images acquired in:

- the FFDM mode only, or
- an FFDM image set and a DBT image set acquired in the ST (standard) mode. The FFDM image set and the DBT image set must be acquired with N-mode dose setting, and may be acquired in one compression (Tomo Set mode) or separate compressions (FFDM and DBT modes).

[DEVICE DESCRIPTION]

The Fujifilm ASPIRE Cristalle system (Model: FDR MS-3500) is an integrated digital mammography system. It consists of two main subsystems and has three operating modes.

A. Main subsystems

- 1) The FDR-3500DRLH X-ray Stand (Exposure Unit) is an integrated x-ray delivery system consisting of the FDR-3500H (exposure stand) and FDR-3000DRL (flat panel detector and control cabinet).
- 2) The FDR-3000AWS Acquisition Workstation (AWS) controls the exposure unit to acquire and process mammographic images. With it, the operator registers patient identifying information, selects exposure condition, displays study information, edits patient identifying information, displays studies and confirms image quality. The FDR-3000AWS is configurable with several monitor options.

B. Operation modes

The FDR MS-3500 has three selectable modes of operation. A single common detector and x-ray tube are used for all of the modes. The 1) full-field digital mammography (FFDM) mode is FDA-cleared (K133972) and is standard. This PMA is for two additional modes to be enabled upon FDA approval by a software upgrade and comprise the DBT Option: 2) the DBT mode and 3) the Tomosynthesis Set menu (Tomo Set menu) mode.

- 1) The standard FFDM mode produces conventional two-dimensional FFDM images of the breast. Both CC and MLO screening views and diagnostic views may be acquired at either the L- (Low), N- (Normal) or H- (High) mode dose setting.
- 2) The optional DBT mode captures the three-dimensional (3D) DBT images of the breast by taking multiple low-dose images per view along an arc over the breast. All images are acquired in the ST (standard) DBT mode with N-mode dose setting only. During acquisition, the x-ray tube moves approximately 1 degree for each image in a 15° arc (-7.5° to +7.5°) above the compressed breast, acquiring 15 images in approximately four (4) seconds. These acquired projection images are reconstructed for interpretation as cross-sectional “slices” of the breast, with each slice typically 1-mm thick. The DBT image set may be acquired for the CC, MLO and other views of the breast.
- 3) The optional Tomosynthesis Set menu (Tomo Set menu) mode combines the FFDM and DBT modes during a single compression of the breast, acquiring the DBT images in ST mode and N-mode dose and FFDM image with N-mode dose.

This Operation Manual provides necessary information for using the tomosynthesis exposure software, such as the overview, operation procedures and precautions to observe, as well as daily inspections and maintenance.

📖 For details on the exposure unit and X-ray exposure, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

This Operation Manual applies to the following software.

- FDR-3500H Application Software V3.0 or later
- FDR-3000DRL Application Software V1.0 or later
- AWS Application Software (referred to as “AWS” hereafter) V6.0 or later

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 9. When performing exposures in FFDM and DBT modes individually, make sure that the dose level is set to “N-mode” for DBT mode.
-

This system is classified as a medical device under EC Directive 93/42/EEC.

It has been designed for operation by medical personnel who have undergone the proper training and under whose direction patients will come in contact with it.

Process waste correctly, as stipulated by local law or any regulations that apply.

Caution : Rx Only in the United States (Federal law restricts this device to sale by or on the order of a physician.)

Open-Source Software Used in This Product

This product uses third party's software that is made available as open source software or free software. SUCH SOFTWARE IS PROVIDED “AS IS” WITH NO WARRANTY OF ANY KIND AS TO ITS MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

For information on open source software used in this product, please see the attached CD (114Y2286002B) and DVD (114Y2286003B). Source codes for certain type of open source software used in this product are available at delivery cost. If you would like to receive such source codes, please contact FUJIFILM dealer or the service representatives at the agency from which you purchased this product.

(Please be noted that any inquiries concerning the contents of source codes should be directed to original licensors of open source software.)

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FUJIFILM Digital Mammography System Operation Manuals

Manage and store all the Operation Manuals of the devices constituting the system together as a set.

FUJIFILM Digital Mammography System FDR MS-3500 Operation Manual

FDR MS-3500 Option Tomosynthesis Exposure Tomosynthesis Exposure Software Operation Manual

- ▶ For details on the exposure unit and X-ray exposure, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

FUJIFILM Mammography Workstation FDR-3000AWS Operation Manual

- ▶ See “Workstation FDR-3000AWS Reference Guide” for optional items for the AWS.

The following FDR MS-2500 options are usable.

Biopsy Positioner Kit FDR-2000BPY Operation Manual

FDR-2000BPY Option Lateral Approach Kit Operation Manual

Contents at a Glance

Chapter 1

Tomosynthesis exposure software Overview of the Optional Product

This chapter describes the product overview and the precautions of the optional Tomosynthesis exposure software.

Chapter 2

Tomosynthesis exposure software

Operation Procedures of the FDR MS-3500 for Using the Tomosynthesis exposure software (Optional)

This chapter describes the operation procedures of the optional Tomosynthesis exposure software.

How to Read This Manual

Basic page layout

Please have a good grasp of the basic page configuration of this Operation Manual, as illustrated below, for you to use it more efficiently.

Section title
Shows the title of an operation procedure described in the section.

Lead
Describes information we wish you to know in advance of your operating the system or information that may help you to operate it.

Item title
Indicates the operation that is covered under the item.

Operation procedure
Describes an operation procedure according to sequential numbers.

Index
A caption that facilitates you to open a desired [Chapter] quickly.

Page number
Displayed in conjunction with the chapter number.

2.3.2 Basic Operation Procedures
The operation procedures are described below.

2.3.2.1 Starting up the FDR MS-3500
1 Start up the FDR MS-3500.
For details of how to start up the FDR MS-3500, see "FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide".

2.3.2.2 Inputting Patient Information
There are two methods to enter the patient information. One is inputting newly, and the other is inputting automatically by searching information on the database.
For details, see "FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide" or "Workstation FDR-3000AWS Reference Guide".
1 Input the patient information in the "Patient Information Input window".



"Patient Information Input window"

2 Select **Next**.

2.3.2.3 Selecting Exposure Menu Items
To carry out Tomosynthesis imaging, use the Tomosynthesis Exposure menu.
1 Select "Tomosynthesis" from the display group list in the "Exposure Menu Selection window".
The "Exposure Menu Panel" shows the Tomosynthesis imaging exposure menu items.
If imaging by the Tomosynthesis menu fails, specify the image as the mis-exposed, register it with the Tomosynthesis menu again, and then try again.
When changing the name of an exposure menu for Tomosynthesis imaging or Tomosynthesis setting menu item, set it so that it is intended for Tomosynthesis imaging.
To newly create an exposure menu for Tomosynthesis imaging, create it based on the factory-installed Tomosynthesis imaging menus.



"Exposure Menu Selection window"

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2 Tomosynthesis Exposure Software Operation Procedures

Indicators

Information items to be observed when you are operating this system and the supplementary remarks are described in this manual with the respective marks. For the safe system operation, be sure to observe **Warning/Caution**.



Indicates hazardous situations that may lead to serious injuries or even death if the precaution is not or cannot be followed.



Indicates a potentially hazardous situation which may result in slight or moderate degree of injury or property damage if the CAUTION is ignored or could not be followed.



Indicates procedures requiring special attention, instructions that must be followed, supplementary explanations, etc.



Shows an item helpful for further effective system operation.



Shows a more detailed operation method or an item that describes additional information.

Expressions

Messages appear on the display panel and the buttons are shown as below.

- **Buttons (example)**



Select .

The button to operate is shown.

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Chapter 1

Tomosynthesis Exposure Software

Overview of the Optional Product

This chapter describes necessary information for using the optional tomosynthesis exposure software, such as the product overview, operation procedures and precautions to observe, as well as daily inspections and maintenance.

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1.1 For Safe Operation

1.1.1 Precautions Before Operating This Equipment

Before using this equipment, please read “Precautions Before Operating This Equipment” carefully so that you can operate it correctly. Whenever you operate this equipment, be sure to observe those precautions. Failure to do so may cause injury or damage to property.

The institution where the equipment is installed is responsible for its use and maintenance.

In addition, this equipment should not be used by persons other than doctors or suitably trained staff.

This system is classified as a medical device under EC Directive 93/42/EEC.

This equipment has been designed on the assumption that the patient would not come into direct contact with it or for operation by appropriately trained operator.

Process waste correctly, as stipulated by local law or any regulations that apply.

The correlation applicable between related devices and their constituent subassemblies and components does not affect the safety of the operation of this equipment.

1.1.2 Precautions to be Observed When Using the Electric Medical Equipment

We ask that you heed these usage precautions and use the equipment correctly.

1. This equipment should only be used by trained individuals.
2. Observe the following precautions before beginning to use the device.
 - 2-1. Inspect the switch contacts, polarities, dial settings and meters and confirm that the equipment is functioning properly.
 - 2-2. Confirm that the ground wire has been completely connected.
 - 2-3. Make sure that all cords have been connected properly and safely.
 - 2-4. Be aware that correct diagnosis can be hindered and danger can result from using different pieces of equipment together.
3. Heed the following precautions after using the equipment.
 - 3-1. Using the established procedure, restore the operation switches, dials, etc., to what they were prior to use and then turn the power off.
 - 3-2. When unplugging cords, do not pull on the body of the cord itself or apply unnecessary force.
 - 3-3. Store accessories safely to avoid damage.
4. If there is trouble with the equipment, do not attempt to fix it randomly. Instead, do what is indicated and entrust repairs to a professional.
5. Do not remodel the equipment.
6. Maintenance and Inspection
 - 6-1. Inspect the equipment and parts periodically.
 - 6-2. If the equipment has not been used for a long time, confirm that it operates normally and safely prior to using it again.
7. Other Items
 - 7-1. When subjecting patients (particularly infants and pregnant women) to radiation, make sure not to exceed the necessary time and dose. Also, ensure that radiation is contained within the region for exposure.
 - 7-2. For cleaning and disinfecting the parts that patients come in contact with in a normal usage environment, slightly moisten a soft cloth (non-woven cloth: Kimwipe®) in neutral detergent or ethanol for disinfection and wipe away any dirt. Do not use any other cleansers or disinfectants.
Also, do not scrub the equipment's surface vigorously.
 - 7-3. Follow the Operation Manual and operate the equipment correctly.

1.1.3 Safety

Read this section before using the equipment to ensure proper handling.

Preventing explosion



WARNING

- Because this equipment is not explosion-proof, do not use combustible and explosive gases near the equipment.
- Flammable gasses may stay in the study room after disinfection. Ventilate the room well before powering on the system following disinfection.

Preventing electrical shock



WARNING

- To prevent electrical shock, observe the following cautions.
 - Never open any covers of the equipment. Do not touch a high-voltage unit of the equipment with your hand, otherwise you may receive an electrical shock.
 - Do not install the equipment in a location where the equipment might be exposed to water.
 - Ensure that the equipment is fully grounded.
 - Ensure that all cables are connected correctly and safely.
- If you find an incorrect connection, stop using the system and contact a designated contractor.
- Do not use the equipment where the equipment may be exposed to any liquids. Never allow any liquid to spill on over or into the equipment. Otherwise, electrical shock may occur. Should you suspect any liquid has penetrated into the equipment, immediately stop using it and contact our official dealer.
- Do not use the equipment in a location where metal particles could come into the equipment. This may cause an electrical shock.
- Make sure to turn off the equipment before cleaning or disinfecting parts other than the compression plate, exposure table, armrests, and face guard. Otherwise, you may receive an electrical shock.
- During cleaning or disinfecting of the equipment, keep the temperature of the study room 15°C to 35°C to ensure proper performance of the exposure unit.
- Do not use a multiple tap connector or extension cable for powering the equipment constituting the AWS. Otherwise, fire or electrical shock may occur due to the electrical load exceeding the allowable limit.
- Always use optional items and supplied items recommended by Fujifilm. Using optional items and supplied items other than those recommended by Fujifilm may cause electrical shock or damage to occur.



CAUTIONS

- Follow the specified procedure when turning off the equipment. Otherwise, the flat panel sensor could be damaged by thermal shock.
- Do not store magnetic media near the exposure stand or control cabinet of the exposure unit. Otherwise, magnetism generated by the equipment may cause the data to be lost.

Preventing radiation damage



CAUTIONS

When breast thickness is 45mm, if 20 exposures or more are made in total or if an exposure is continued for one minute or more*, the health of the patient may be compromised.

* When breast thickness is 100mm : 8 exposures or more in total or an exposure continued for 20 seconds or more. US (Type B), EU (Type C)

* When breast thickness is 75mm : 14 exposures or more in total or an exposure continued for 40 seconds or more. Japan (Type A)

Connection instructions



WARNING

Make sure that the devices to be connected to the equipment are authorized for connection.

Technologist' s and patient' s safety instructions



WARNING

- Make sure that no patient is around the equipment before powering on it after an electrical outage.
- Inspect the equipment before leading a patient to the equipment. Should you find any failure, contact our official dealer.
- Before exposure with X-ray, check that the patient has been positioned appropriately. Technologists or patients must operate the exposure equipment from a safe position. Check that there are no other people within the exposure area or around the device.
- Before leading a patient to the equipment, make sure that the foot switch is away from the path to the equipment and outside of the movable region of the swivel arm. Otherwise, the patient or technologists may accidentally touch the foot switch in the way to the equipment, resulting in an unintended operation.
- Make sure to keep observing movements of both equipment and patient while positioning the movable parts at the patient's body.
- When the patient is inspected, sitting on a chair, use a height-adjustable chair and set it to the lowest position so that the patient is not caught in the exposure unit.
- Make sure that a patient's hand or foot does not touch the swivel arm control panel, control pad or foot switch.
- Exposure should be made in an environment where the technologist can visually and aurally determine the patient' s condition.
- If the equipment malfunctions while adjusting the movable parts or performing a study, immediately press the emergency stop button and contact our official dealer.
- Do not operate the AWS installed in a study room while touching the patient's body. Otherwise, the patient may receive an electrical shock.

System isolation instructions



WARNING

- To ensure complete system isolation, never install any unauthorized accessories or other such items. When it is necessary to install authorized accessories or optional items, contact our official dealer.
- Keep equipment other than the exposure stand out of reach of patients to ensure appropriate system isolation.
- To prevent the system from colliding with other equipment and getting faulty, do not change the location of the installation of the system and do not place any other equipment or article within the range of the motions of the system.
- Do not move the AWS from where it is installed.

Radiation safety instructions

X-ray exposure time in a study is controlled as follows.

- In auto mode
The auto-specified exposure conditions control the maximum exposure dose (time).
- In manual mode
The manual mAs setting controls the X-ray exposure time.

X-ray exposure time in an abnormal situation can be controlled by the following.

- Early release of the exposure switch
- Hardware backup timer of the high voltage generator
- Detection of abnormality in the generator

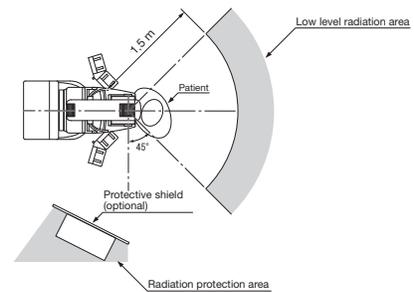


WARNING

- Operate the device by following the instructions given in the Operation Manual and supplied documentation. Wrong operations could expose a technologist or patient to unnecessary X-ray exposure.
- Make sure that no one other than a technologist or patient is in the study room when making X-ray exposures. If it is necessary for a care assistant or other person to remain in the room, provide sufficient radiation protection when using the remote exposure switch or remote exposure foot switch.
- Use the longest possible focal spot to skin distance to minimize the absorbed dose.
- Reduce the radiation field size to the minimum necessary size for the exposure. If X-rays are unavoidably radiated to areas outside of the subject region, take other protective measures such as readjusting the collimator or wearing a Pb apron.

Radiation protection area

The manager of the facility must specify the radiation protection area, in which minimum radiation is present, where a doctor or technologist can make an exposure safely, using the figure below as a guide.



WARNING

- Only qualified technologists are allowed to make X-ray exposures.
- Before making an X-ray exposure in the study room, the technologist must retreat to the radiation protection area secured by the protective shield (optional).
- When making an X-ray exposure remotely from a room next to the study room, install the protective shield (optional) or protective window, or take other measures to protect the adjacent room from radiation.
- When making an X-ray exposure in the study room with the remote exposure switch or remote exposure foot switch but without using the protective shield (optional), wear protective clothing. If not wearing protective clothing, make an X-ray exposure while staying in the low level radiation area 1.5 m or more away at the rear of the patient back.
- Technologists must wear a film badge or pen dosimeter to monitor exposure doses they receive.

Mechanical safety instructions

Danger of hitting or being caught between the parts

The technologist or patient can only come into contact with the armrests when the patient is being positioned.

Do not grab the armrests, but place the hands lightly on them.

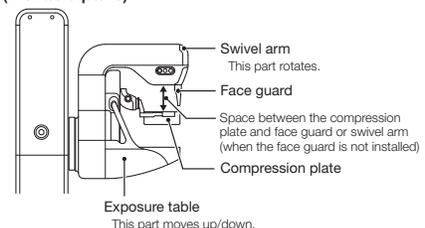
The technologist must remove all the dangers that could harm the patient or third party before operating the system. Potentially dangerous parts are indicated by arrows in the figure below.



WARNING

- A patient's or technologist's hand, foot or other body parts may hit or be caught by the potentially dangerous parts. Eliminate all dangers completely.
- When operating the equipment by the foot switch, swivel arm control panel or control pad, make sure that no hand, foot, or other part of the technologist's or patient's body is caught between the movable parts.

Dangerous parts on the exposure stand (Movable parts)



Emergency stop button



WARNING

Press the emergency stop button to immediately turn off the equipment in an emergency. This cuts off the power to the exposure stand and stop it forcibly.
The equipment has the three buttons: two on the exposure stand and one on the control pad.

Software use instructions



CAUTIONS

Do not install any software in addition to the preinstalled software. Do not uninstall the preinstalled software. The system is preinstalled with the appropriate software. If it is deleted or other software is added, various operational errors may result.

Mammography-specific instructions

Only qualified technologists are allowed to operate the equipment. The technologists are required to fully understand the principles of mammography in advance to perform operations described in this Operation Manual.

Protective shield

The protective shield (optional) protects the technologist from exposure to X-rays. This is designed in compliance with the relevant requirements in 21CFR 1020 and IEC 60601-2-45. The shield is 0.5 mm Pb equivalent.



WARNING

When making an exposure by the AWS installed in the study room, the technologist should be where the protective shield (optional) covers and protects all of his/her body from exposure to X-rays.



Inspect the protective shield (optional) before making X-ray exposures.

Face guard

The face guard is designed to prevent the patient's head from entering the radiation field. It is not X-ray proof.



WARNING

When making an X-ray exposure without using the face guard, make sure that the patient's head is physically positioned outside of the X-ray path.

Disinfection instructions



WARNING

- Confirm that the respiratory density of disinfectant including solvent is under legal regulation. Certain disinfectants may damage health. When using a disinfectant, follow instructions supplied by the manufacturers.
- Do not use any of the disinfectants described below as damage to the equipment may result. Quality, performance and safety of the equipment cannot be assured.
 - Chloric disinfectant which is strongly corrosive to metals and rubber parts.
 - Disinfectant whose uses on metals, plastics, and coating are forbidden according to the instructions supplied with the disinfectant.
 - Formalin gas and disinfectant sprays that may get inside the equipment. Disinfectant ethanol is recommended for disinfection. Carefully read the instructions and cautions supplied with the disinfectant before use. Disinfectant ethanol is ethanol of 76.9 to 81.4 vol% without other additives.

Characteristics of the Network



WARNING

Connect to the Ethernet Network of 1000BASE-T, 100BASE-TX, or 10BASE-T prescribed in the IEEE standard 802.3.

Do not connect telephone lines to LAN connector. Only UTP-type straight LAN cables of 4-pair Category 5 cable (CAT 5E) or higher are appropriate for connection to this connector.

Cautions on Network



CAUTIONS

After connecting this system to the network with other systems, confirm that the other systems are not affected. If they are affected, take countermeasures such as network separation.

Precaution on External Network Connection



CAUTIONS

When a setting of the network to which the equipment is connected has been changed, check that the change does not affect the system operation and take measures if necessary.

- Change of connection destination
- Addition of devices
- Removal of devices
- Update of devices
- Upgrade of devices

Other precautions



WARNING

- Be sure to inspect the system periodically. To assure optimum performance of the equipment, it is necessary to systematically perform maintenance and inspection. For information on maintenance and inspection, contact our official dealer.
- Disinfection may be required for the optional items of the system. See the related Operation Manuals for details.
- Clean/disinfect the compression plate using the specified method. Do not sterilize the compression plate. Doing so may cause the compression plate to become deformed or damaged.

Classification

- 1) According to the type of protection against electrical shock
CLASS 1 EQUIPMENT
- 2) According to the degree of protection against electrical shock
Type B applied part
- 3) According to the degree of protection against harmful ingress of water
Main Unit: IPX0
Foot Switch: IPX1
Remote exposure foot switch (optional): IPX8
- 4) According to the degree of safety of application in the presence of a flammable anesthetics mixture with air or with oxygen or nitrous oxide.
Equipment not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or nitrous oxide.
- 5) According to the mode of operation
Continuous operation with intermittent loading

1.1.4 Electromagnetic Compatibility (EMC)

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 Edition 3: 2007-03.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures;

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected. Consult a FUJIFILM dealer for help as necessary.

This Operation Manual contains the names of standards applied in IEC 60601-1-2.

The names of standards applied in EN 60601-1-2 are replaced as follows.

IEC 60601-1-2 (descriptions in this Operation Manual)	Standards applied in EN 60601-1-2
CISPR 11:1997+A1:1999+A2:2002	EN 55011
IEC 61000-3-2:2000+A1:2001+A2:2004	EN 61000-3-2
IEC 61000-3-3:1994+A1:2001+A2:2005	EN 61000-3-3
IEC 61000-4-2:1995+A1:1998+A2:2000	EN 61000-4-2
IEC 61000-4-3:2006	EN 61000-4-3
IEC 61000-4-4:2004	EN 61000-4-4
IEC 61000-4-5:2005	EN 61000-4-5
IEC 61000-4-6:2003+A1:2004+A2:2006	EN 61000-4-6
IEC 61000-4-8:1993+A1:2000	EN 61000-4-8
IEC 61000-4-11:2004	EN 61000-4-11

Further information for IEC 60601-1-2 (EN 60601-1-2)

Model name FUJIFILM Digital Mammography System FDR MS-3500 is referred to as FDR MS-3500 in this section.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Information regarding the cable affecting EMC is as follows.

Name	General Specification
Network Cable (AWS)	Cat5e or more, UTP type and straight cable
Network Cable (Exposure unit)	Cat5e or more, UTP type and straight cable

- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by FUJIFILM Corporation as replacement parts for internal components, may result in increased emissions or decreased immunity of the FDR MS-3500.
- The FDR MS-3500 should not be used adjacent to or stacked with other equipment.
If adjacent or stacked use is necessary, the FDR MS-3500 should be observed to verify normal operation in the configuration in which it will be used.
- Basic performance of equipment and system
Obtains digital images by using the flat panel sensor, and processes, records and outputs the obtained images.
- Test items (Tables 1 to 4)

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The FDR MS-3500 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDR MS-3500 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The FDR MS-3500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. FDR MS-3500 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The FDR MS-3500 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDR MS-3500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FDR MS-3500 requires continued operation during power mains interruptions, it is recommended that the FDR MS-3500 be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
		<5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 5 s
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
The FDR MS-3500 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDR MS-3500 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FDR MS-3500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FDR MS-3500 is used exceeds the applicable RF compliance, the FDR MS-3500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FDR MS-3500. b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

Table 4

Recommended separation distances between Portable and mobile RF communications equipment and the FDR MS-3500			
The FDR MS-3500 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FDR MS-3500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FDR MS-3500 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1.2 Overview of the Optional Product

1.2.1 Overview of Tomosynthesis Exposure Software

This optional software is to generate reconstruction images through a reconstruction process to images taken at various angles.

1.2.1.1 Configuration of Tomosynthesis Exposure Software

The basic configuration of tomosynthesis exposure software is as below:

Components

- Tomosynthesis Exposure Software
- Operation panel

1.2.1.2 Specifications

The specification and processing capacity of tomosynthesis exposure software are described below. They are subject to change without prior notice.

Environmental Requirements

(1) Operating conditions

Temperature	: 20°C to 30°C
Humidity	: 30% RH to 75% RH (No dew condensation)
Air pressure	: 750 hPa to 1060 hPa

(2) Non-operating conditions (including storage)

Temperature	: 15°C to 35°C
Humidity	: 10% RH to 80% RH (No dew condensation)
Air pressure	: 750 hPa to 1060 hPa

Types of the compression plate usable

- 24×30 compression plate (High)
- 24×30 compression plate (Low)
- 24×30 compression plate (Shift)
- 24×30 compression plate (Shift Small)
- 24×30H compression plate (Flex)
- 24×30H comfort paddle (FS)
- 18×24 compression plate (Low)
- 18×24 compression plate (High)
- 18×24 compression plate (Small)
- 18×24L compression plate (Flex)
- 18×24L comfort paddle (FS)
- 18×24 comfort paddle (FS Small)

Other types of the compression plates are not supported.

1.3 Basic Operation

Basic operation procedures of this equipment are described below.

When using the FDR MS-3500 system, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” along with this Operation Manual.

1.3.1 Basic Operation

Attaching/Removing the biopsy compression plate

- ▶ For details on how to attach/remove the compression plate, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” along with this manual.

Attaching/Removing the face guard T

- ▶ For details on how to attach/remove the face guard T, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” along with this manual.

Cleaning/Disinfection

- ▶ For details on cleaning/disinfection, see “2.3.2.13 Cleaning/Disinfection”.

1.3.2 Starting up and Shutting down the System

1.3.2.1 Starting up the System

- ▶ For how to start up the system, refer to “3.1.2 Starting up the System of the FDR MS-3500 Reference Guide.”

1.3.2.2 Shutting down the System

- ▶ For how to shut down the system, refer to “3.1.6 Shutting down the System of the FDR MS-3500 Reference Guide.”

1.4 Maintenance and Inspection

1.4.1 Weekly Inspection and Maintenance

Check images with the phantom. For details, see “Aspire Cristalle Digital Breast Tomosynthesis Option Quality Control Program Manual”.

1.4.2 Periodical Inspection

Make sure to perform the periodical inspections for maintaining the safety.

1.4.2.1 Maintenance and Inspection Items Assigned to Specified Dealer

For periodical inspection of the equipment and necessary arrangements, consult our official dealer or local representative.

Periodical Maintenance

Make sure that the periodical maintenance and inspection assigned to our official dealer are performed as specified.

Maintenance and Inspection Items Assigned to Specified Dealer

Periodical Maintenance and Inspection Items	Frequency
Visual inspection and cleaning of the equipment	Every year
Image quality check	Every year

The cycles of periodical maintenance and inspection or of parts replacement differ depending on the usage and the daily operation time.

For details, contact us directly or our official dealer.

Chapter 2

Tomosynthesis Exposure Software

Operation Procedures of the FDR MS-3500 for Using the Tomosynthesis Exposure Software (Optional)

This chapter describes necessary information for using the optional tomosynthesis exposure software in combination with the FDR MS-3500, such as the system overview, operation procedures and precautions to observe, as well as daily inspections and maintenance.

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2.1 Precautions to be Observed

2.1.1 Precautions Before Use

Before using the tomosynthesis exposure software (optional) in combination with the FDR MS-3500, please read “Chapter 1 For Safe Operation” in “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” and “1.1 For Safe Operation” in “FDR MS-3500 Option Tomosynthesis exposure software Operation Manual” carefully so that you can operate it correctly. Whenever you operate this optional product, be sure to observe those precautions. Failure to do so may cause injury or damage to property.

2.1.2 Safety Precautions

Before using the FDR MS-3500 system, please read this section carefully so that you can operate it correctly. Also, please read “Chapter 1 For Safe Operation” in “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

Preventing explosion

WARNING

- Because this equipment is not explosion-proof, do not use combustible and explosive gases near the equipment.
- Flammable gases may stay in the study room after disinfection. Ventilate the room well before powering on the equipment following disinfection.

Preventing electrical shock

WARNING

- To prevent electrical shock, observe the following cautions.
 - Never open any covers of the equipment. Do not touch a high-voltage unit of the equipment with your hand, otherwise you may receive an electrical shock.
 - Do not install the equipment in a location where the equipment might be exposed to water.
 - Ensure that the equipment is fully grounded.
 - Ensure that all cables are connected correctly and safely.
- Do not use the equipment in a location where the equipment may be exposed to any liquids. Never allow any liquid to spill on or into the equipment. Otherwise, electrical shock may occur. Should you suspect any liquid has penetrated into the equipment, immediately stop using it and contact our official dealer.
- Do not use the equipment in a location where metal particles could come into the equipment. This may cause an electrical shock.
- During cleaning or disinfecting of the equipment, keep the temperature of the study room 15°C to 35°C to ensure proper performance of the exposure unit.
- Follow the specified procedure when turning off the equipment.

CAUTIONS

- Follow the specified procedure when turning off the equipment.
- Do not store magnetic media near the positioner control cabinet. Otherwise, magnetism generated by the equipment may cause the data to be lost.

Connection instructions

WARNING

Make sure that the devices to be connected to the equipment are authorized for connection.

Technologist's and patient's safety instructions

WARNING

- Make sure that no patient is around the equipment before powering on it after an electrical outage.
- Inspect the equipment before leading a patient to the equipment. Should you find any failure, contact our official dealer.
- Before exposure with X-ray, check that the patient has been positioned appropriately. Doctors and technologists must operate the exposure unit from a safe position. Check that there are no other people within the exposure area or around the equipment.
- When guiding the patient to the equipment, place the foot switches from the guiding route and the movable range of the swivel arm. If the patient steps on a foot switch, the system

- Make sure to keep observing movements of both equipment and patient while positioning the movable parts at the patient's body.
- When the patient is inspected, setting on a chair, use a height-adjustable chair and set it to the lowest.
- Do not allow the arms and feet of the patient to touch the foot switches and operation controls.
- Perform exposure with X-ray while doctors and technologists are able to visually and audibly check the status of the patient.
- If the equipment malfunctions while adjusting the movable parts or performing a study immediately stop the equipment and contact our official dealer.

System isolation instructions

! WARNING

- To ensure complete system isolation, never install any unauthorized accessories or other such items. When it is necessary to install authorized accessories or optional items, contact our official dealer.
- Keep equipment other than the exposure stand out of reach of patients to ensure appropriate system isolation.

Radiation safety instructions

X-ray exposure time in a study is controlled as follows.

- In auto mode
The auto-specified exposure conditions control the maximum exposure dose (time).
- In manual mode
The manual mAs setting controls the X-ray exposure time.

X-ray exposure time in an abnormal situation can be controlled by the following.

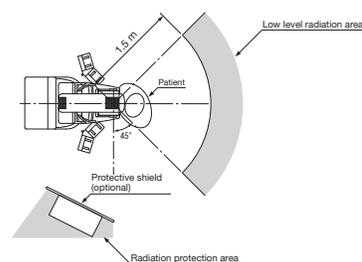
- Early release of the release radiation switch
- Hardware backup timer of the high voltage generator
- Detection of abnormality in the generator

! WARNING

- Operate the device by following the instructions given in the Operation Manual and supplied documentation. Wrong operations could expose a technologist or patient to unnecessary X-ray exposure.
- Make sure that no one other than a technologist or patient is in the study room when making X-ray exposures. If it is necessary for a care assistant or other person to remain in the room, provide sufficient radiation protection.
- Use the longest possible focal spot to skin distance to minimize the absorbed dose.
- Reduce the radiation field size to the minimum necessary size for the exposure. If X-rays are unavoidably radiated to areas outside of the subject region, take other protective measures such as readjusting the collimator or wearing a Pb apron.

Radiation protection area

The manager of the facility must specify the radiation protection area, in which minimum radiation is present, where a doctor or technologist can make an exposure safely, using the figure below as a guide.



! WARNING

- Only qualified technologists are allowed to make X-ray exposures.
- Before making an X-ray exposure in the study room, the technologist must retreat to the radiation protection area secured by the protective shield (optional).
- When making an X-ray exposure remotely from a room next to the study room, install the protective shield (optional) or protective window, or take other measures to protect the

- When making an X-ray exposure in the study room without using the protective shield (optional), wear protective clothing. If not wearing protective clothing, make an X-ray exposure while staying in the low level radiation area 1.5 m (59.05 in.) or more away at the rear of the patient back.
- Technologists must wear a film badge or pen dosimeter to monitor exposure doses they receive.

Mechanical safety instructions

WARNING

- A patient's or technologist's hand, foot or other body parts may hit or be caught by the potentially dangerous parts. Eliminate all dangers completely.
- When operating the equipment by the operation panel, make sure that no hand, foot, or other part of the technologist's or patient's body is caught between the movable parts.

Emergency stop button

WARNING

Press the emergency stop button to immediately turn off the equipment in an emergency. This cuts off the power to the exposure stand and stop it forcibly.

The equipment has the three buttons: two on the exposure stand and one on the control pad.

Mammography-specific instructions

Only qualified technologists are allowed to operate the equipment. The technologists are required to fully understand the principles of mammography in advance to perform operations described in this Operation Manual.

Protective shield

The protective shield (optional) protects the technologist from exposure to X-rays.

This is designed in compliance with the relevant requirements in 21CFR 1020 and IEC 60601-2-45.

The shield is 0.5 mm Pb equivalent.

WARNING

When making an exposure by the AWS installed in the study room, the technologist should be where the protective shield (optional) covers and protects all of his/her body from exposure to X-rays.



Inspect the protective shield (optional) before making X-ray exposures.

Face guard

The face guard is designed to prevent the patient's head from entering the radiation field. It is not X-ray proof.

WARNING

When making an X-ray exposure without using the face guard, make sure that the patient's head is physically positioned outside of the X-ray path.

Tomosynthesis exposure software instructions

CAUTIONS

- While images are taken, the position of the breast may slip off by body motions or another reason, and the precision of reconstruction images may fall.
While images are taken, make the body of the patient stable.
- Use stationary mode mainly to make exposures or acquire taken images for the purpose of the tomosynthesis quality management. The mode cannot be used to make exposures of patients. Only when the dedicated exposure menus are selected, stationary mode can be used. You cannot use the mode in the other exposure menus.

Software use instructions

CAUTIONS

Do not install any software in addition to the preinstalled software. Do not uninstall the preinstalled software. The system is preinstalled with the appropriate software. If it is deleted or other software is added, various operational errors may result.

Disinfection instructions

WARNING

- Confirm that the respiratory density of disinfectant including solvent is under legal regulation. Certain disinfectants may damage health. When using a disinfectant, follow instructions supplied by the manufacturers.
 - Do not use any of the disinfectants described below as damage to the equipment may result. Quality, performance and safety of the equipment cannot be assured.
 - Chloric disinfectant which is strongly corrosive to metals and rubber parts.
 - Disinfectant whose uses on metals, plastics, and coating are forbidden according to the instructions supplied with the disinfectant.
 - Formalin gas and disinfectant sprays that may get inside the equipment.
- Disinfectant ethanol is recommended for disinfection. Carefully read the instructions and cautions supplied with the disinfectant before use.

Other precautions

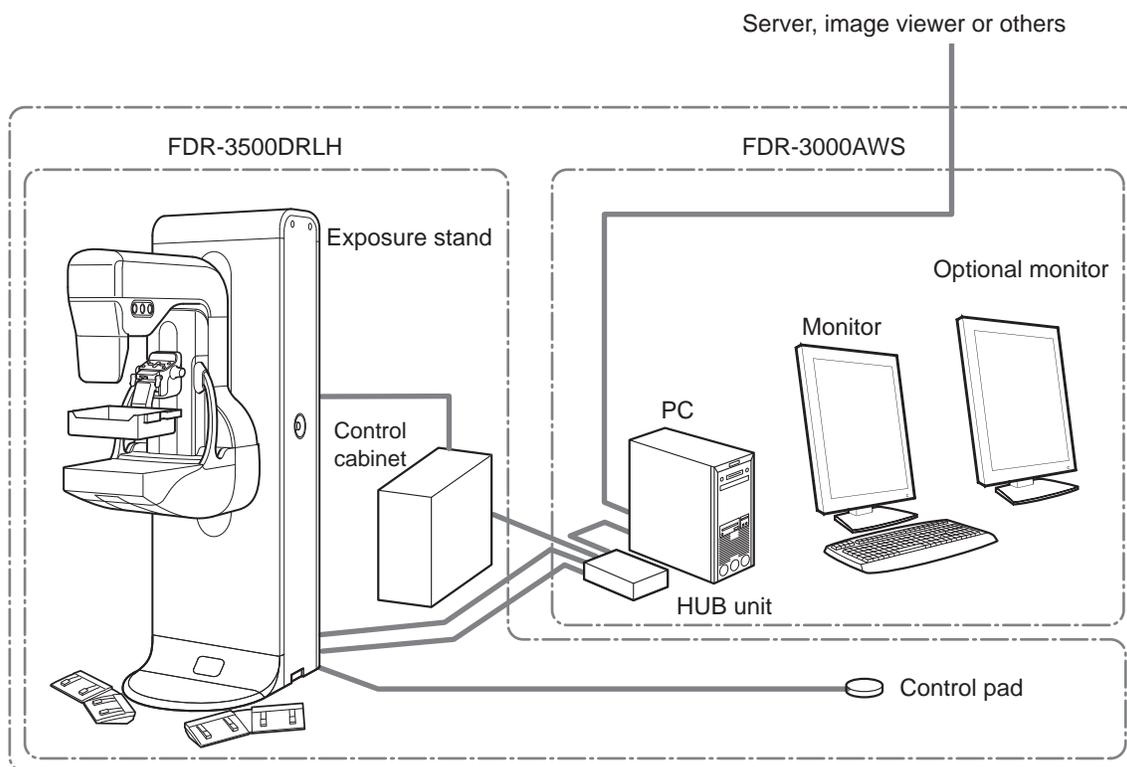
WARNING

- Be sure to inspect the system periodically. To assure optimum performance of the equipment, it is necessary to systematically perform maintenance and inspection. For information on maintenance and inspection, contact our official dealer.
- Disinfection may be required for the optional items of the system. See the related Operation Manuals for details.
- Clean/disinfect the compression plate using the specified method. Do not sterilize the compression plate. Doing so may cause the compression plate to become deformed or damaged.

2.2 Overview of the System for Using the Tomosynthesis Exposure Software (Optional)

2.2.1 Part Names and Functions

For the part names and functions of FDR MS-3500 and tomosynthesis exposure software, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” or “1.2.1.1 Configuration of Tomosynthesis Exposure Software” in this manual.



* AC power with different input voltage is used for each of the devices above.

2.2.2 FDR-3000AWS

“Patient Information Input window”



“Study window”



Exposure menu list

X-ray control panel

On the X-ray control panel, AEC, Target/Filter, kV, mAs, Focus, Grid, and AGD*¹ are configurable.

*1 : It is enabled/disabled according to the setting configured at the time of installation.

X-ray control panel for the Tomosynthesis menu



X-ray control panel for the Tomosynthesis set menu (tomo set menu)



To allow you to choose a Tomo set menu, the X-ray control panel for the Tomo set menu is displayed. By switching between the tabs, you can confirm and configure the exposure conditions of the Tomosynthesis setting menu and 2D (conventional) menu.



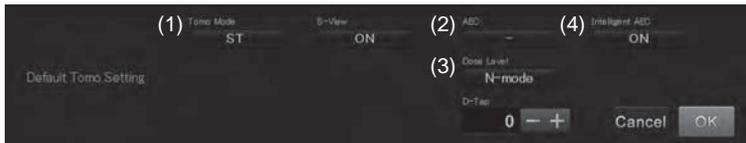
A grey display pane is displayed on the upper right of the exposure conditions of Tomo mode and those other than AEC. The pane shows the exposure conditions of the other menu, which is a tomo set menu.



Configure Tomosynthesis Imaging Default Exposure Conditions button

Click the Configure Tomosynthesis Imaging Default Exposure Conditions button on the “Patient Information Input Screen” to display the “Configure Default Exposure Conditions Screen” shown below. While a study is carried out, the configure default exposure conditions button is not selectable.

Configure Default Exposure Conditions Screen



The screen allows you to configure the AEC and Intelligent AEC. When AWS is activated, calibration ends, and a study is started, the values configured on the screen are automatically applied.

- (1) TomoMode : Only ST mode is available.

 - ▶ See “2.2.3 Specifications” for details.
- (2) AEC : Set “Auto,” “Semi,” “Manu,” or “-” to the default ACE mode.


When AWS is activated, calibration ends, and a study is started, the values configured with this are automatically applied. When “-” is set, “Auto” is automatically set to a study immediately after AWS is activated, and for later studies, AEC mode used for previous studies are automatically applied.
- (3) Dose Level : For the dose level, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”. The value of “Default Dose Level” is automatically set when AWS is activated, calibration ends, AEC mode is changed, and the system recovers from an error. Only “N-mode” is selectable.

- (4) Intelligent AEC : Enable/disable the intelligent modes (iAuto and/or iSemi).


Tomosynthesis View Screen

The “Tomosynthesis View Screen” is displayed on the optional monitor.



▶ For details of operation, see “2.3.2.8 Checking the Images.”

Adjust GA/GS

: Allows you to change the GA/GS of the image.

Register Bookmark

: Allows you to bookmark a reconstruction image.

▶ For details, see “2.3.2.8 Checking the Images.”

(1) Display Images Taken



: Displays images taken.

(2) Display Reconstruction Images



: Displays reconstruction images.

(3) Zoom In/Out



: Allows you to zoom in/out the image.

(4) Move Image



: Allows you to move the image.

(5) Display in Real Scale



: Shows the image in full scale and full magnification.

(6) Display in Pixel-to-Pixel Representation



: Shows the image in pixel-to-pixel representation.

(7) Zoom-to-fit Display



: Selected image is displayed matching the size of the image display area.

(8) Rotate/Reverse Image



: Rotates/reverses the image.

(9) Enable/Disable Overlay



: Enables/disables the overlay to show the information about actual measurements.

(10) Edit Image



: Allows you to edit the information of the image loaded.

(11) Show Cine Imaging



: Shows cine imaging of images taken and reconstruction images displayed in the Tomosynthesis view.

(12) Next Image



: Sets the image selection frame to the next image.

(13) Previous Image



: Sets the image selection frame to the previous image.

- (14) Set Show Cine Imaging Speed  : Sets the Show Cine Imaging speed.
- (15) Configure Display Layout Setting  : Allows you to switch the image display mode of the image display field.
- 1-image display mode: Center:
 - 2-image display mode: Left → Right
 - 4-image display mode: Upper left → Upper right → Lower left → Lower right
- (16) Tile/Stack/Book  : Switches between tile display mode, stack display mode, and bookmark display mode.

Edit Image Screen



- (1) Choose Image to Deliver  : Allows you to select the image to deliver to the printer and storage device.
- (2) Adjust S/L Values  : Allows you to change the S value and L value.
- (3) Adjust Image Processing Parameters  : Allows you to adjust the GP (gradation processing), RP (frequency processing), DRC (dynamic range compression processing), and MFP (multi-frequency processing) values of the image displayed.
- (4) Change Marker Position  : Allows you to change the position of the marker.
- (5) Apply Default Image Parameters  : Applies the image processing parameters pre-configured with the selected exposure menu to the images.
- (6) Confirm Direct X-Ray Field (usable only for reconstruction images.)  : Calculates the direct X-ray field.

CAUTIONS

The masking processing to the displayed image may blacken the shadowed parts (e.g. nipple). After the processing, be sure to check the processed image. Pressing the “Confirm Direct X-Ray Field” button displays the masking processed reconstruction image.

2.2.3 Specifications

• Tomosynthesis exposure conditions

	Range of angles for exposure	Number of images photographable	Pixel size	Image size when output to DICOM	Possible imaging angle	mAs setting range
ST mode (Standard)	±7.5°	15	150µm	100	±172°	16~90mAs

• Reconstruction image field

ST mode

Compression plate	Exposure field	Tomosynthesis image field					
		Depth (mm)	Width for projection image (mm)	Width for reconstruction image on the plate (mm)			
				Height of compression (mm)			
				0	40	70	149
None	24×30	236	295	289	260	239	183
24×30 compression plate (High)	24×30	236	294	289	260	239	183
	18×24 Center	177	237	230	206	187	138
	18×24 Left	177	229	230	206	187	138
	18×24 Right	177	229	230	206	187	138
24×30 compression plate (Low)	24×30	236	294	289	260	239	183
	18×24 Center	177	237	230	206	187	138
	18×24 Left	177	235	230	206	187	138
	18×24 Right	177	235	230	206	187	138
24×30 compression plate (Shift)	18×24 Center	177	237	230	206	187	138
	18×24 Left	177	235	230	206	187	138
	18×24 Right	177	235	230	206	187	138
24×30 compression plate (Shift Small)	18×24 Center	177	237	230	206	187	138
	18×24 Left	177	228	228	206	187	138
	18×24 Right	177	228	228	206	187	138
24×30H compression plate (Flex) 24×30H comfort paddle (FS)	24×30	236	293	289	260	239	183
	18×24 Center	177	237	230	206	187	138
	18×24 Left	177	229	229	206	187	138
	18×24 Right	177	229	229	206	187	138
18×24 compression plate (High)	18×24	177	235	230	206	187	138
18×24 compression plate (Low)	18×24	177	235	230	206	187	138
18×24 compression plate (Small)	18×24	177	235	230	206	187	138
18×24L compression plate (Flex) 18×24L comfort paddle (FS)	18×24	177	234	230	206	187	138
18×24 comfort paddle (FS Small)	18×24	177	235	230	206	187	138

* On a projection image, areas where part of the compression plate are imaged are automatically trimmed before reconstruction.

* After masking processing, be sure to check the processed image. The masking may not be performed well outside of the right and left width of the reconstruction image.

• Image size

24 cm × 30 cm (9.44 × 11.8 in.)

• Breast thickness which tomosynthesis imaging is applicable to

149 mm (5.86 in.) or less (when compressed)

2.2.4 Functions of Which the Operation Method Changes by Using the Tomosynthesis Exposure Software

- **Grid**

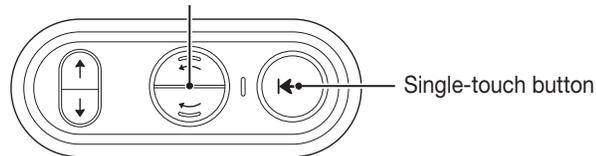
The grid setting is automatically set to “OUT” for the tomosynthesis exposure menus.

- **Rotate button**

If the swivel arm tube stops while Tomosynthesis imaging is carried out, pressing the Single-touch button and Rotate button at the same time rotates only the swivel arm tube. Pressing the Rotate Left button turns it to the left up to 25°, and the Rotate Right button turns it to the right up to 25°. Before conducting an exposure, set the degree to 0°.

Swivel arm clockwise/counterclockwise rotation button

Press this simultaneously with the single-touch button to rotate the tube of the swivel arm clockwise/counterclockwise.



! CAUTIONS

Immediately release the button if the swivel arm may interfere with the tube. Stereo rotation will stop.

2.3 Basic Operation

2.3.1 Features of the Tomosynthesis Exposure Software (Optional)

The features of the tomosynthesis exposure software are as below :

- Projection images are acquired from multi-angles and reconstruction of 3D slice images are automatically generated.
- This software provides a mode (tomosynthesis imaging exposure menu) for performing tomosynthesis imaging only and another mode (tomo set menu) for performing tomosynthesis imaging and 2D imaging sequentially. When performing both tomosynthesis imaging and 2D imaging, they can be performed more efficiently by using the tomo set menu.
- Reconstruction of slice images is automatically generated with the 1-mm pitch, and images taken from multi-angles and/or slice images are viewable on the monitor. Consequently, the image data size at delivery can be reduced.
- You can put a bookmark to slice images and show/output only the bookmarked images. This is useful to find your desired images quickly.
- When you deliver tomosynthesis images and 2D (conventional) images to the same device, 2D images are firstly delivered.

2.3.2 Basic Operation Procedures

Basic operation procedures are described below.

2.3.2.1 Starting up the FDR MS-3500

1 Start up the FDR MS-3500.

- For details of how to start up the FDR MS-3500, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.2.2 Inputting Patient Information

There are two methods to enter the patient information. One is inputting newly, and the other is inputting automatically by searching information on the database.

- For details, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” or “Workstation FDR-3000AWS Reference Guide”.

1 Input the patient information in the “Patient Information Input window”.



“Patient Information Input window”

2 Select .

2.3.2.3 Selecting Exposure Menu Items



To carry out Tomosynthesis imaging, use the Tomosynthesis Exposure menu.

1 Select “Tomosynthesis” from the display group list in the “Exposure Menu Selection window”.

The “Exposure Menu Panel” shows the Tomosynthesis imaging exposure menu items.



- If imaging by the Tomosynthesis menu fails, specify the image as the mis-exposed, register it with the Tomosynthesis menu again, and then try again.
- When changing the name of an exposure menu for Tomosynthesis imaging or Tomosynthesis setting menu item, set it so that it is intended for Tomosynthesis imaging.
- To newly create an exposure menu for Tomosynthesis imaging, create it based on the factory-installed



“Exposure Menu Selection window”

2 Select exposure menu items.

- See “Workstation FDR-3000AWS Reference Guide” for details on the “Exposure Menu Selection window”.

The Tomosynthesis imaging exposure menu items are as shown below.

Menu item name	Abbreviated menu item name
Tomo Right Breast CC	RCC T
Tomo Left Breast CC	LCC T
Tomo Right Breast MLO	RMLO T
Tomo Left Breast MLO	LMLO T
Tomo Right Breast ML	RML T
Tomo Left Breast ML	LML T
Tomo ACR Phantom	ACR T
Tomo MAX4.0 Breast	MAX4 T

The Tomo set menu items are as shown below.

Tomo set menu item name	Exposure menu
Tomo Set Right Breast CC	Tomo Right Breast CC
	Right Breast CC
Tomo Set Left Breast CC	Tomo Left Breast CC
	Left Breast CC
Tomo Set Right Breast MLO	Tomo Right Breast MLO
	Right Breast MLO
Tomo Set Left Breast MLO	Tomo Left Breast MLO
	Left Breast MLO
Tomo Set Right Breast ML	Tomo Right Breast ML
	Right Breast ML
Tomo Set Left Breast ML	Tomo Left Breast ML
	Left Breast ML
Tomo Set ACR Phantom	Tomo ACR Phantom
	ACR Phantom

The Tomosynthesis imaging study menu items are as shown below.

Study menu item name	Exposure menu
Tomo Set Both Breasts 2R	Tomo Set Right Breast CC
	Tomo Set Left Breast CC
	Tomo Set Right Breast MLO
	Tomo Set Left Breast MLO
Tomo Set Right Breast 2R	Tomo Set Right Breast CC
	Tomo Set Right Breast MLO
Tomo Set Left Breast 2R	Tomo Set Left Breast CC
	Tomo Set Left Breast MLO
Tomo Set Both Breasts MLO	Tomo Set Right Breast MLO
	Tomo Set Left Breast MLO
Tomo Both Breasts 2R	Tomo Right Breast CC
	Tomo Left Breast CC
	Tomo Right Breast MLO
	Tomo Left Breast MLO
Tomo Right Breast 2R	Tomo Right Breast CC
	Tomo Right Breast MLO
Tomo Left Breast 2R	Tomo Left Breast CC
	Tomo Left Breast MLO
Tomo Both Breasts MLO	Tomo Right Breast MLO
	Tomo Left Breast MLO

3 Select .

The “Study window” is displayed.

The exposure menu items under a tomo set menu are displayed in the exposure list on the “Study screen”.



- Tomo set menu cannot be changed, and tomosynthesis images cannot be replaced with each other.
- If one of the exposure menu items under a tomo set menu item for tomosynthesis exposure is deleted, all other exposure menu items under the tomo set menu will be deleted.

CAUTIONS

The patient information is displayed at the lower left of the window. Make sure that the information is correct before executing a study.



2.3.2.4 Attaching the Compression Plate

1 Attach the compression plate.

- ▶ For details of how to attach the compression plate, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.2.5 Attaching the Face Guard T

1 Attach the face guard T.

- ▶ For details of how to attach the face guard, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

CAUTIONS

Do not use the face guard T unless the exposure menu is “CC”.

2.3.2.6 Performing Exposures

- ▶ For the detailed exposure procedures, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

1 Perform positioning.



- After positioning, turn on the light field lamp, and make sure that there is no unnecessary shadow or other body parts than the breast in the X-ray exposure field.
- Set the compression force to 60N or more to hold the breast in place.

CAUTIONS

Imaging at 180° may cause the foot of the patient to hit the swivel arm and the patient may fall down; Make sure that the feet of the patient are out of the range where the swivel arm may travel.

2 Perform X-ray photography.

With a tomo set menu, tomosynthesis exposure is performed first, before the 2D (conventional) image. The beep to indicate radiation sounds several times. Keep pressing the exposure button until Tomosynthesis imaging and 2D (conventional) imaging end (until the beep is no longer emitted).



- Do not release the exposure button until the beep stops. When released, the image is treated as mis-exposed and exposure needs to be done again.
- When X-ray exposure results are received from the X-ray exposure unit after performing an exposure with a tomo set menu, the actual tomosynthesis values are displayed on the X-ray control panel and the Total icon is displayed in the mAs value display field.
- Both the decompression button on the exposure stand and the compression foot switch can serve to decompress.
- To ease the discomfort of the patient, add auto decompression setting or decompression button on the exposure stand, or using the foot paddle or manual release, release the compression to the breast(s) by the compression plate immediately after imaging finishes.
- To decompress the compression by the compression plate in a case of emergency, use the decompression button on the exposure stand or emergency stop button. For more information of emergency stop, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.
- If imaging by the Tomosynthesis menu fails, specify the image as the mis-exposed, register it with the Tomosynthesis menu again, and then try again.

CAUTIONS

While Tomosynthesis imaging is carried out, be careful so that the swivel arm does not collide with the patient. If there is possibility of collision between them, press the emergency stop button on the exposure stand or control pad. The swivel arm stops operating.

2.3.2.7 Tomosynthesis View

After taking images, taken images are displayed in the monitor and Tomosynthesis view is displayed in the optional monitor in order in which they are taken.

When all images taken are fully received, the images are automatically reconstruction and the reconstruction images are displayed in the Tomosynthesis view on the optional monitor.

The reconstruction process is conducted according to the conditions configured in the exposure menu.

The reconstruction process is managed as the reconstruction queue, and the status of implementation is displayed in the reconstruction queue.



Switch Type of Image to Display



: Displays images taken.



: Displays reconstruction images.

Change Display Layout Setting

Select from 1 (horizontal) x1 (vertical) to 5 (horizontal) x 6 (vertical).

Tile/Stack/Bookmark mode

Switch between  tile display mode,  stack display mode, and  bookmark display mode.

Display settings for supplementary data items

Configure supplementary data items displayed in the overlay.

Select “Configure supplementary data items” after right-clicking the image.

The following configuration screen is displayed after selection, so select the items you want to be displayed.



The supplementary items you can display are as follows:

- Patient supplementary information : Patient ID, patient’s name, sex, date of birth, and age
- Order information : Accession No., exposure date, exposure time, exposure menu name, image laterality, and patient orientation
- Image supplementary information : Pixel density, tube voltage, tube current, exposure time, mAs value, target/filter, grid, focus spot size, breast thickness, compression force, arm angle, AEC, VCS+VMCS, average glandular dose, entrance skin dose, GA/GS, image area dose product, EI/DI, GPR, trimming size, detector description, detector ID, distance source to detector, tomo angle, tomo time, current image/total images, height of the slice, height of the center slice, slice range, spacing of the slices, image positioning, tomosynthesis mode + reconstruction algorithm, S/L
- Display supplementary information : Magnification ratio (%) compared to the actual size

2.3.2.8 Checking the images

Check for the images taken and reconstruction images in the Tomosynthesis view.



Operations available in the view

The items you can operate are as follows:

- Adjust GA/GS
GA/GS can be adjusted for the displayed reconstruction image with the dragging operation of the mouse.
- Register Bookmark
Right-clicking the mouse on a reconstruction image displayed shows the following items.
 - Register Bookmark
Register a bookmark. Click the first (start) image to bookmark; the image is bookmarked. Then, click the last (final) image to bookmark; the images between the start and final images are bookmarked.
 - Deregister Bookmark
Selecting “Individual” removes the bookmark registered for the displayed image. Select “Collective” removes the bookmarks for all reconstruction images.
 - Cancel
Cancels the bookmark registration.
- Switch Type of Image to Display 
Use this to switch between shot image display mode and reconstruction image display mode.
- Zoom In/Out  
Use this to zoom in/out the image.
- Move Image 
Use this to move the image.
- Display in Real Scale 
Use this to show the image in full scale and full magnification.
- Display in Pixel-to-Pixel Representation 
Use this to show the image in pixel-to-pixel representation.

- Rotate/Reverse Image 

Use this to rotate/reverse the image.

- Enable/Disable Overlay 

Use this to enable/disable the overlay to show the information about actual measurements.

- Show Cine Imaging 

Use this to show cine imaging of images taken and reconstruction images displayed in the Tomosynthesis view.

You can choose either of the following two cine imaging modes:

Long press the Show Cine Imaging button to show the menu to select cine imaging mode.

-  Loop mode: The images are displayed from the first to the last in order, and the first one is displayed after the last one is displayed.
-  Return mode: The images are displayed from the first to the last in order, and then the images are displayed in the opposite order from the last one.
- Set Show Cine Imaging speed: Select Show Cine Imaging speed from five settings. Selecting

 switches between the Next Image button, button to configure slider speed, and the slider. After setting the appropriate speed, select  again.



- Configure Display Layout Setting 

Use this to switch the image display mode of the image display field.

- 1-image display mode: Center 
- 2-image display mode: Left → Right 
- 4-image display mode: Upper left → Upper right → Lower left → Lower right 

- Next Image 

Use this to set the image selection frame to the next image.

- Previous Image 

Use this to set: the image selection frame to the previous image.

2.3.2.9 Editing images

Click  (Edit Image button) to show the Edit Tomosynthesis Image Screen.

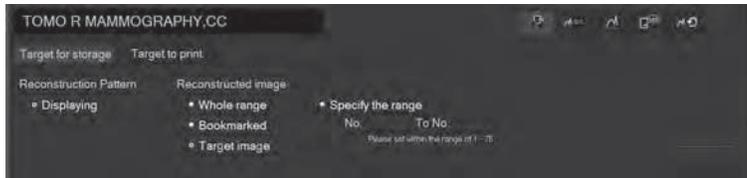
Edit the information of images taken and reconstruction images by using the image edit function of the Tomosynthesis view.

To finish editing, select  or .



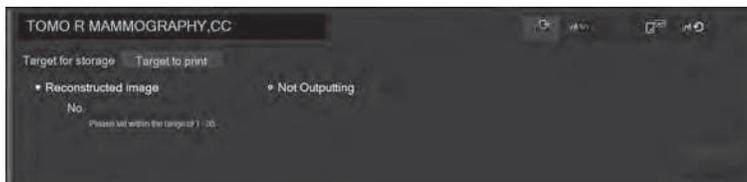
All settings edited are applied to all the images displayed in the Tomosynthesis view.
The items you can edit are as follows:

- Choose Image to Deliver
Use this to select the reconstruction image to deliver to the printer and storage device.
- Target for storage (Displayed items vary with settings at installation.)



(Screen of AWS V6.0)

- Reconstructed Image
Reconstruction images for storage can be selected from “Whole range”, “Specify the range”, “Bookmarked images”, or “Target image”. The target image is the one on which the target marker is saved.
- Target to print (Displayed items vary with settings at installation.)



- Reconstruction image
Input numbers of reconstructed images to be printed.

- Adjust S/L Values
Use this to change the S value and L value.
Select  to save edited results.
- Adjust Image Processing Parameters (usable only for reconstruction images.)
Use this to adjust the GP (gradation processing), RP (frequency processing), DRC (dynamic range compression processing), and MFP (multi-frequency processing) values of the reconstruction image displayed.
Select  to save edited results.
- Change Marker Position
Use this to change the position of the marker.
- Apply Default Image Parameters
Use this to apply the image processing parameters pre-configured with the selected exposure menu to the images.
- Confirm Direct X-Ray Field (usable only for reconstruction images.)
Use this to calculate the direct X-ray field.

Selecting other images or edition items applies the edited settings (Adjust GA/GS, Adjust S/L Values, and/or Change Marker Position) to all reconstruction images of reconstruction process patterns displayed.

2.3.2.10 Functional Comparison of 2D and Reconstruction Images

ID	Item	2D Image	Reconstruction Image
1	Pixel Size	50μ	ST: 100μ*1
2	Display Screen	AWS, Detailed image display	Tomosynthesis view
3	Changing Exposure Menu	✓	✓
4	Modify Image Information	✓	✓
5	Changing Film Annotation Character	✓	✓
6	Image/Study Comments Settings	✓	✓
7	Rotation	✓	✓
8	Flip	✓	✓
9	Adjusting GA/GS	✓	✓
10	Change Image Trimming	✓	-
11	Registering Marker	✓	✓
12	Default Marker	✓	✓
13	Deleting Marker	✓	✓
14	Change Marker Position	✓	✓
15	Inputting Annotations	✓	-
16	Blackening Processing	✓	-
17	Changing Detailed Image Processing Parameters	✓	✓
18	Changing S/L Value	✓	✓
19	Print Settings	✓	✓
20	Delivery Setting	✓	✓
21	Correct Technologist Information	✓	✓
22	MG Positioning	✓	-
23	Positioning of Right/left Image Processing	✓	-
24	Image Laterality	✓	✓
25	Modify Patient Orientation	✓	✓
26	Modify View Code	✓	✓
27	Changing the View Modifier Code Sequence	✓	✓
28	Confirming the Pixel Padding Value	✓	✓
29	ROI Measurement	✓	-
30	QA Measurement	✓	-
31	Saving the Displayed JPEG Image	✓	✓
32	Setting as Mis-exposure Image	✓	✓
33	Print	✓	✓
34	Image Magnification/Reduction	✓	✓
35	1-to-1 pixel-size	✓	✓
36	Actual Size	✓	✓
37	Panning	✓	✓
38	Fit in Window	✓	✓
39	Delivering Study	✓	✓
40	Lock	✓	✓
41	Reset	✓	-
42	Default Image Processing	✓	✓
43	Free Layout Print	✓	-
44	DICOM File Output	✓	✓
45	Changing Patient Information	✓	✓
46	Study Information List	✓	✓
47	Register Bookmark	-	✓
48	Referral Viewing Function	✓	✓*2
49	Network Image Search	✓	-
50	PDI	✓	-
51	Patient ID Auto Convert Software	✓	-

*1 Depending on settings at installation, output is available on the pixel size in parentheses.

*2 Depending on settings at installation, this function is available.

2.3.2.11 Closing the Study

Concerning a study including images by a Tomosynthesis exposure menu, the study is able to be closed only when the reconstruction processes of all Tomosynthesis menus for the study has been completed.

2.3.2.12 Remove the Compression Plate

1 Remove the compression plate.

- ▶ For details of how to detach the compression plate, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.2.13 Remove the Face Guard T

1 Remove the face guard T.

- ▶ For details of how to detach the face guard, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.2.14 Shutting down the FDR MS-3500

1 Shut down the FDR MS-3500.

- ▶ For how to shut down the FDR MS-3500, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.2.15 Cleaning/Disinfection

Turn off the exposure stand before cleaning or disinfection. Note that there is no need to turn off the exposure stand before cleaning the following items that touch patients during studies.

- Compression plate
- Armrests
- Compression plate socket
- Exposure table
- Face guard T

Cleaning

Before studies, make sure to clean parts that touch the patient. Cleaning is necessary for all the parts other than those that only require disinfection.

For cleaning, use a cloth slightly moistened with neutral detergent diluted with cold water or lukewarm water and tightly wrung out. Use a lint-free non-woven or 100 % cotton cloth.

CAUTIONS

- Make sure to use a recommended detergent to clean the equipment. Improper detergent may damage the equipment.
- Make sure not to let detergent get inside the equipment during cleaning.
- Clean the magnification plate under stable conditions. In addition, do not apply load to it while cleaning. The magnification may be broken, causing an injury.

Disinfection

Ethanol for disinfection is recommended.

Parts to be disinfected :

- Compression plate
- Exposure table
- Face guard T

WARNING

Confirm that the respiratory density of disinfectant is under legal regulation. Certain disinfectants may damage health. When using a disinfectant, follow instructions supplied by the manufacturers.

CAUTIONS

- Do not use any of the disinfectants described below as damage to the equipment may result. Quality, performance and safety of the equipment cannot be assured.
- Chloric disinfectant which is strongly corrosive to metals and rubber parts.
- Disinfectant whose uses on metals, plastics, and coating are forbidden according to the instructions supplied with the disinfectant.
- Formalin gas and disinfectant sprays that may get inside the equipment.
- The compression plates and face guard gradually wear out due to disinfectant. Make sure to perform

2.3.3 Flow Chart of Basic Operations

Flow of basic operations is described below.

Preparation before study

Step 1 Start up the FDR MS-3500. ➤ See “2.3.2.1 Starting up the FDR MS-3500” for details.

Performing a study

Step 2 Input patient information. ➤ See “2.3.2.2 Inputting Patient Information” for details.



Step 3 Select exposure menu items. ➤ See “2.3.2.3 Selecting Exposure Menu Items” for details.



Step 4 Attach the compression plate. ➤ See “2.3.2.4 Attaching the Compression Plate” for details.



Step 5 Attach the face guard T. ➤ See “2.3.2.5 Attaching the Face Guard T” for details.



Step 6 Perform exposures. ➤ See “2.3.2.6 Performing Exposures” for details.



Step 7 Display the Tomosynthesis view ➤ See “2.3.2.7 Tomosynthesis View” for details.



Step 8 Check the images ➤ See “2.3.2.8 Checking the Images” for details.



Step 9 Editing the image ➤ See “2.3.2.9 Editing the Images” for details.



Step 10 Close the study ➤ See “2.3.2.11 Closing the Study” for details.

Terminating a study

Step 11 Remove the Compression Plate. ➤ See “2.3.2.12 Remove the Compression Plate” for details.



Step 12 Remove the Face Guard T. ➤ See “2.3.2.13 Remove the Face Guard T” for details.



Step 13 Shut down the FDR MS-3500 ➤ See “2.3.2.14 Shutting down the FDR MS-3500” for details.

2.3.4 Operation Procedures for Stationary Mode

Use stationary mode mainly to make exposures or acquire taken images for the purpose of the tomosynthesis quality management. The mode cannot be used to make exposures of patients.

Normally in tomosynthesis exposure, move the swivel arm tube to acquire projection images from multi-angles, but in stationary mode, you do not move the tube to make exposures. Consequently, unlike normal tomosynthesis images, reconstruction images look similar to the taken images.

Only when the dedicated exposure menus are selected, stationary mode can be used. You cannot use the mode in the other exposure menus.

2.3.4.1 Starting up the FDR MS-3500

1 Start up the FDR MS-3500.

- ▶ For details of how to start up the FDR MS-3500, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2.3.4.2 Inputting Patient Information

There are two methods to enter the patient information. One is inputting newly, and the other is inputting automatically by searching information on the database.

- ▶ For details, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide” or “Workstation FDR-3000AWS Reference Guide”.

1 Input the patient information in the “Patient Information Input window”.

2 Select .



“Patient Information Input window”



- The stationary mode cannot be used to make exposures of patients.
- We recommend using the special IDs including maintenance when making exposures in stationary mode.

2.3.4.3 Selecting Exposure Menu Items



Only when the dedicated exposure menus are selected, stationary mode can be used.

1 Select “Tomosynthesis” from the display group list in the “Exposure Menu Selection window”.

The “Exposure Menu Panel” shows the Tomosynthesis imaging exposure menu items.



- If imaging by the tomosynthesis menu fails, specify the image as the mis-exposed, register it with the tomosynthesis menu again, and then try again.
- To newly create an exposure menu for Tomosynthesis imaging, create it based on the factory-installed Tomosynthesis imaging menus.



Exposure Menu Selection window

2 Select exposure menu items.

- See “Workstation FDR-3000AWS Reference Guide” for details on the “Exposure Menu Selection window”.

The stationary mode imaging menu item is as shown below.

Menu item name	Abbreviated menu item name
Stationary	QC STA

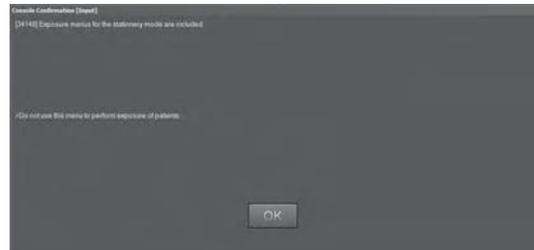
There is no stationary mode imaging set menu or study menu.

3 Select .

The “Study window” is displayed.



A message to pay attention when using stationary mode is shown.



2.3.4.4 Performing Exposures

For the detailed exposure procedures, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

1 Make necessary arrangements according to the purpose of exposure.

(e.g.) attaching the compression plate, placing the measurement device or study phantom

- For details of how to attach the compression plate, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.

2 Perform X-ray exposure.

The beep to indicate radiation sounds several times. Keep pressing the exposure button until Tomosynthesis imaging ends (until the beep is no longer emitted).



-
- Do not release the exposure button until the beep stops. When released, the image is treated as mis-exposed and exposure needs to be done again.
 - When X-ray exposure results are received from the X-ray exposure unit after performing an exposure with a tomo set menu, the actual tomosynthesis values are displayed on the X-ray control panel and the Total icon is displayed in the mAs value display field.
 - Both the decompression button on the exposure stand and the compression foot switch can serve to decompress.
 - To decompress the compression by the compression plate in a case of emergency, use the decompression button on the exposure stand or emergency stop button. For more information of emergency stop, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.
 - If imaging by the tomosynthesis menu fails, specify the image as the mis-exposed, register it with the tomosynthesis menu again, and then try again.
-

2.3.4.5 Image Check

Check taken images in the Tomosynthesis view.



Normally in tomosynthesis exposure, move the swivel arm tube to acquire projection images from multi-angles, but in stationary mode, you do not move the tube to make exposures. Consequently, reconstruction images look similar to the taken images.

- ▶ For basic operations of the tomosynthesis exposure software, see “2.3 Basic Operation”.
- ▶ To save taken image data to the external record medium, use the QC RAW image batch output function. For the operations, see the “Workstation FDR-3000AWS Reference Guide”.

2.3.4.6 Closing the Study

A study including the tomosynthesis exposure menu can only be closed when all the tomosynthesis menu reconstruction processing in a study is completed.

2.3.4.7 Cleanup

Clean up the compression plate, the measuring instruments and the study phantoms.

Clean up and disinfect them before studying a patient.

- ▶ For detailed information, see “2.3 Basic Operation”.

2.3.4.8 Shutting down the FDR MS-3500

1 Shut down the FDR MS-3500.

- ▶ For how to shut down the FDR MS-3500, see “FUJIFILM Digital Mammography System FDR MS-3500 Reference Guide”.



When measuring with a dosimeter, it may be necessary to change settings available for the tomosynthesis exposure. For details, see the dosimeter instructions.

2.4 User Settings

2.4.1 Newly Creating or Editing a Tomosynthesis Set Menu (Tomo Set Menu)

By using the AWS user utility, you can create a new Tomo set menu or edit it.

🔑 For details of how to handle imaging menus see the “Workstation FDR-3000AWS Reference Guide”.

* Additional menus that you create after installation can be deleted. However, the menus registered at the time of installation cannot.

* MPM codes cannot be edited.

2.4.1.1 Newly Creating a Tomo Set Menu

Newly create a tomo set menu.

1 In the “Exposure / Study / Tomo Set Menu column” on the “Menu Setting” screen of user utility, select [Tomosynthesis Set].



2 Select [Create New].

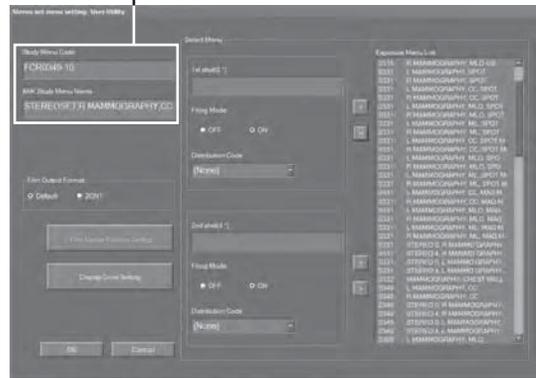
The “Study Menu Setting screen” is displayed.



3 Set the code and menu name.

All items need to be set before proceeding to the next operation.

Code and menu name settings



4 Select an exposure menu to register in the “exposure menu list”, then select .

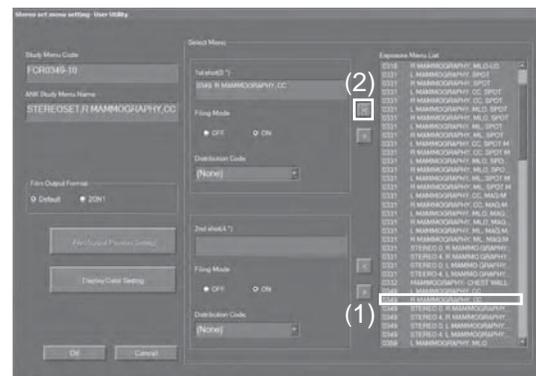
For a tomo set menu, select two exposure menus.



Do not register the MPM codes below for tomo set menus.
• 7355, 7365, 7375



When you perform exposures by using a tomo set menu with which a stereo biopsy exposure menu has been registered, the positioner needs to be removed from the exposure unit. Tomosynthesis imaging is unavailable if it remains attached.



5 Set the film output format.

For details of how to set the film output format, see “Workstation FDR-3000AWS Reference Guide”.

6 Set the display color.

▶ For details of how to set the display color, see “Workstation FDR-3000AWS Reference Guide”.

7 Select [OK].

[Cancel]: Cancels newly creating a tomo set menu.

2.4.1.2 Editing a Tomo Set Menu

Edit tomo set menu information.



- When editing a stationary mode imaging menu, do not change the expansion menu code.
- When editing a menu copied from the stationary mode imaging menu, do not change the expansion menu code prefix from “STATIONARY”.

1 Select “Tomo Set” in the “Exposure / Study / Tomo Set Menu column”.**2 Select [Edit].**

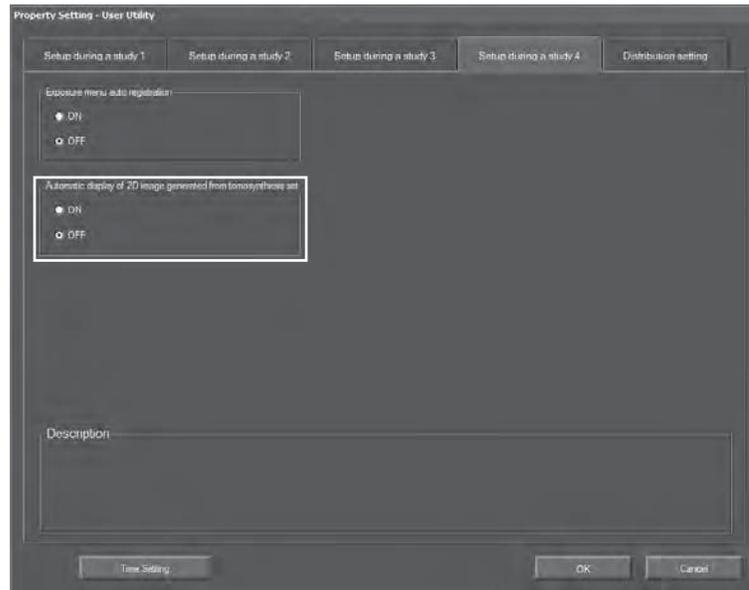
The “Tomo Set Menu Setting screen” is displayed.

**3 Perform various settings.**

To edit a tomo set menu, perform **3** to **7** in “2.4.1.1 Newly Creating a Tomo Set Menu”.

2.4.2 Automatic Display of 2D Images for Tomosynthesis Set Menu (Tomo Set Menu)

When making an exposure with a tomo set menu on “Setup during a study 4” screen of the Property Setting in User Utility for AWS, the ON/OFF function for automatic display of the 2D images (conventional) on the optional monitor is available. (To use this function, settings at installation are necessary.)



When this function is enabled, 2D images of a tomo set menu is displayed after the completion of displaying a tomosynthesis image and switching the optional monitor application to the Precise Enlargement Function*.

*For details, see “FDR-3000AWS Reference Guide (Option)”.

2.4.3 Creating a Study Menu Including a Tomosynthesis Set Menu (Tomo Set Menu)

A study menu including a tomo set menu can be created.

① For details of how to create a study menu, see “Workstation FDR-3000AWS Reference Guide”.



-
- Tomo set menus registered in the [exposure menu list] are displayed. Select a tomo set menu to be registered in the study menu from the list. Exposure menus other than tomo set menus can be also mixed in.
 - 48 exposure menus at most can be registered in a study menu. Registration of one tomo set menu registers two exposure menus.
 - When the film output position setting is set to “default”, the film format set in the tomo set menu is inherited. When the film output position setting is set to “2on1”, the film format set with the tomo set menu is disabled, and 2on1 is set in order from the one registered first in the study menu from the [exposure menu list]. To change the output position setting of 2on1 setting, edit it on the [Film Output Position Setting] screen.
 - Following AWS options are not supported.
 - Portable Data for Imaging (PDI) Software
 - Network Image Search Software
 - Referral Viewing Function Software
 - Free Layout Print Software
 - Patient ID Auto Convert Software
 - Region of Interest (ROI) Measurement Software
 - QA Measurement Software
 - “Confirm Direct X-Ray Field function” cannot be applied to reconstructed images in stationary mode.
-

2.5 When an Error Message Appears

2.5.1 List of Error Messages

Perform coping procedures when the following errors occur on AWS during Tomosynthesis exposure. If the error is not solved even after performing the remedy, contact our official dealer.

Error code	Message	Cause	Remedy
11932	AEC System Error.	Few X-rays may have been transmitted through the subject.	Make an exposure in manual mode referring to the tables below.

ST mode

Compressed breast thickness (mm (in.))	Target/Filter	KV	mAs
10 (0.39)	W/AL	26	36
20 (0.78)	W/AL	26	36
30 (1.18)	W/AL	28	32
40 (1.57)	W/AL	30	30
50 (1.96)	W/AL	31	40
60 (2.36)	W/AL	33	45
70 (2.75)	W/AL	35	50
80 (3.15)	W/AL	37	56
90 (3.57)	W/AL	37	63
100 (3.93)	W/AL	38	71

* The above values are the recommended parameters for exposures in N-mode.

Error code	Message	Cause	Remedy
32040	The combination of compression paddle and exposure menu is invalid.	The compression plate may be not attached.	Make sure that the compression plate is attached correctly.



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